Cost, safety, and environmental impact of reprocessing single-use medical devices

A systematic review and meta-analysis

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Abbreviations

Abbreviation	Explanation
AAMI TIR	Association for the Advancement of Medical Instrumentation – Technical Information Report
CABG	coronary artery bypass graft surgery
CD	corona discharge
CDC	Centers for Disease Control and Prevention
CFU	colony-forming unit
CHEC-list	Consensus Health Economic Criteria list
CI	confidence interval
CiCERO	Criteria for Cost(-Effectiveness) Review Outcomes
COVID-19	coronavirus disease 2019
CRT-D	cardiac resynchronisation therapy defibrillator
CSA	Canadian Standards Association
CSSD	central sterile services department
df	degrees of freedom
DIN	Deutsches Institut für Normung (German Institute for Standardization)
DOH	Department of Health
EDS	energy-dispersive X-ray spectroscopy
EP	electrosurgical pencil
EPPI-Reviewer	Evidence for Policy and Practice Information software programme
ETO	ethylene oxide
EU	European Union
FDA	Food and Drug Administration
FFP2	filtering facepiece level 2
FFR	filtering facepiece respirator
GHz	gigahertz
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
H_2O_2	hydrogen peroxide
HCoV	human coronavirus
HCW	healthcare worker
HPRA	Health Products Regulatory Authority
HRB	Health Research Board
ICD	implantable cardioverter defibrillator
IQR	interquartile range
ISO	International Organization for Standardization
IV	interval variable
Kgray	kilogray
LCA	life cycle assessment
LCCA	life cycle cost analysis
LMIC	low- and middle-income countries
MB(L)	methylene blue (with light)
MD	mean difference
MDA	methylenedioxyamphetamine

MDCG	Medical Device Coordination Group
MDR	Medical Device Regulation
MEDLINE	Medical Literature Analysis and Retrieval System Online
MeSH	Medical Subject Headings
MGS	microwave-generated steam
NaClO	sodium hypochlorite
NIOSH	National Institute for Occupational Safety and Health
OECD	Organisation for Economic Co-operation and Development
OR	odds ratio
OSHA	Occupational Safety and Health Administration
phaco	phacoemulsification
PICO	population, intervention, comparator, and outcome(s)
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PTCA	percutaneous transluminal coronary angioplasty
p-value	probability value
QLFT	qualitative fit test
QNFT	quantitative fit test
RNA	ribonucleic acid
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SD	standard deviation
SEM	scanning electron microscopy
STARR-LCA	standardised technique for assessing and reporting reviews of life cycle assessment
SUD	single-use device
UK	United Kingdom
USA	United States of America
UV	ultraviolet
UVC	ultraviolet-C
UVGI	ultraviolet germicidal irradiation
VHP	vaporised hydrogen peroxide
XRD	X-ray diffraction

Glossary of terms

Term	Explanation
arthroscopic shavers	Arthroscopic shavers are used to remove the tissue from arthroscopic surgery. This type of surgery is a minimally invasive procedure that uses a small incision and special tools to repair or remove damage inside a joint [1].
audit	Audit in healthcare is appraisal of current practice against standards in clinical and non-clinical aspects of healthcare.
bias	Bias is a systematic overestimation or underestimation of an association in research. There are many types of bias, such as selection, recall, interviewer, and observer bias. Bias is minimised through good study design and implementation.
biopsy forceps	Biopsy forceps are surgical instruments used for cutting and dissecting soft tissue during surgical procedures such as a biopsy. They usually have sharp edges, which enable the operator to cut and dissect tissue, or tips that enable them to hold on to or manipulate tissues or to clamp blood vessels [2].
blinding	Blinding is a method used in research to ensure that the people involved in a research study – participants, clinicians, and researchers – do not know which participants are assigned to each study group, or which participants experienced the exposure or outcome of interest. Blinding is used in order to ensure that knowledge of the type of exposure, treatment, or diagnosis does not affect a participant's response to the treatment, a healthcare provider's behaviour, or an interviewer's approach to data collection.
CannulaTome	CannulaTome (CT) are used for cannulation of the ductal system and for sphincterotomy [3].
cardiac ablation catheter	Ablation catheters are used during treatment for atrial fibrillation, a common cardiac rhythm disturbance.
cardiac balloon catheter	Balloon catheters are used to open up blocked arteries and veins during a coronary angioplasty.
cardiac cannula	Cardiac cannulas (which can be either venous or arterial) are used in procedures such as cardiopulmonary bypass or cardiac surgery to manage the flow of blood during these procedures [4].
case-control study	A case-control study is an analytic observational epidemiological study which examines volunteer subjects (cases) with an outcome (disease) back to exposure (cause), and compares their exposures with self-selected controls that do not have the disease (but are otherwise similar) in order to determine the odds that the exposure may have caused the disease. The odds ratio is the measure of choice in a case-control study. This type of study can be used to identify exposures that may cause rare diseases. They contribute low-quality evidence to causality or disease aetiology. The main drawbacks in case-control studies are their potential for recall bias and that they cannot calculate incidence.
case report or series	Case reports or series are descriptive studies that aim to illustrate novel, unusual, or atypical features identified in patients in medical practice, and potentially generate new research questions. They are empirical inquiries or investigations of a patient (case report) or a group of patients (case series) in a natural, real-world clinical setting [5].
causality	Causality is the relation of cause and effect. The Bradford Hill criteria for causality are: strength of association or effect size; consistency of findings across studies (known as reproducibility); biological credibility (plausibility); specificity (other explanations); a temporal relationship (exposure occurred before the outcome) and biological gradient known as a dose–response relationship; coherence (consistent with other lines of evidence); and analogy (similar agents act similarly).
chance	Chance is sampling variability which can give rise to a particular result. It is the 'luck of the draw'. It is an unsystematic over- or underestimation of the cause-and-effect relationship. The probability value (*p*-value) measures the probability or likelihood that an observed result occurred by chance alone.
cohort study	A cohort study is a form of longitudinal (analytic observational) epidemiological study in which a group of subjects (called a cohort) is followed over a period of time, and data

	relating to predetermined exposures and outcomes are collected on two or more occasions over this time period. The incidence (new cases) of the outcome(s) of interest is calculated in the exposed people and compared with the incidence in the non-exposed people. This comparison of incidence is known as relative risk. The data for the cohort can be collected either by following the participants into the future (prospective study) or by asking them about their past (retrospective study). However, retrospective cohort studies are limited by recall bias. One of the indicators of a high-quality cohort study is a loss to follow-up rate of less than 20%. Cohort studies contribute to causality or disease aetiology and provide, at best, moderate-quality evidence.
compression sleeve	Compression sleeves are used to help prevent blood clots in the deep veins of the legs. The devices use cuffs around the legs that fill with air and squeeze the legs. This increases blood flow through the veins of the legs, which helps prevent blood clots [6].
conference abstract	A summary of the main points of a paper presented at a conference.
confidence interval	A confidence interval is the range of values (for example, proportions) in which the true value is likely to be found with a degree of certainty (by convention, a 95% degree); that is, the range of values will include the true value 95% of the time.
confounding	Confounding is when a factor has an association with the exposure and can independently cause the outcome or disease. It can over- or underestimate an effect of interest or association. A confounding variable (also called a confounding factor or confounder) is a variable that has a relationship with both the exposure and the outcome variable. Confounding is controlled for by restricting the study population, matching the study population (for age, sex, geography, and/or socioeconomic factors), randomly selecting the study population, undertaking a stratification in the analysis (for example, by age, sex, geography, and/or socioeconomic factors), and performing regression analysis.
cost(ing) study	Cost(ing) studies are economic studies which use a simple monetary cost-calculator approach and make various assumptions about the inputs in their investigation. These studies do not provide a true analysis of cost-effectiveness or cost benefits.
cost-benefit study	A cost-benefit study is a full economic evaluation which provides a true, comprehensive analysis of costs and benefits. Cost-benefit analysis is a systematic process for calculating and comparing the tangible and intangible benefits with the tangible and intangible costs of an intervention. A cost-benefit analysis identifies, quantifies (in monetary terms), and adds all the positive factors (the benefits or advantages); it then identifies, quantifies (in monetary terms), and subtracts all the negative factors (the costs or disadvantages).
cost-consequence analysis	A cost-consequence analysis is a type of economic evaluation that compares the consequences of the interventions by looking at a wide range of costs and consequences, such as health effects; medication and labour costs; patient out-of-pocket costs; and cost savings. The analysis does not place a value on these various costs and consequences or collate them; rather, it reports them separately and provides a framework for users to compute their own results and judgements [7].
cost-effectiveness study	A cost-effectiveness study is a full economic evaluation which provides a true comprehensive analysis of cost-effectiveness. Cost-effectiveness analysis is a way to examine both the costs and health outcomes of one or more interventions. The analysis compares one intervention with another (or with current practice) by estimating how much it costs to gain a unit of a health outcome, such as a life year gained, or a death prevented.
cost-minimisation analysis (model)	Cost-minimisation analysis is an economic study method of comparing all the monetary costs of alternative, but equally effective, interventions. The costs assessed include the costs of production, delivery, and reprocessing and/or disposal, and of managing any consequences of the intervention.
cost-utility analysis	Cost-utility analysis studies are a type of full economic evaluation used where studies compare interventions which produce different levels of effect in terms of both quantity and quality of life. These effects are known as utilities and they include both length of life as well as subjective levels of well-being, with quality-adjusted life years

	(QALYs) being the best-known example. A cost-utility analysis therefore compares interventions in relation to the cost for each unit of utility (e.g. QALY) gained [8].
ecological or correlational study	An ecological study is a descriptive epidemiological study carried out using aggregated population-based data to describe a disease (outcome) in relation to a factor of interest (exposure) and is used to formulate a theory, not to prove causality. Both the outcome and exposure are correlated to determine their linear association, which is expressed as a proportion of exposure and outcome that correlate with each other. This study type is vulnerable to ecological fallacy, as it is not known whether the individuals who were exposed were the same individuals who experienced the outcome (or disease). These types of studies are not usually included in the hierarchy of evidence and so would only provide very low-quality evidence.
electrophysiology polyurethane catheter	Electrophysiology polyurethane catheters are used for recording and pacing the electrical potentials from within the heart [9,10].
endoscopy	An endoscopy is an investigation inside the body using a camera.
endoscopic and laparoscopic devices	Endoscopic and laparoscopic devices are minimally invasive devices used to look inside the body and are inserted directly into the organ being investigated via a natural orifice or small incision, more commonly known as keyhole surgery [11]. These include probes, pencils, sphincterotomes (which provide a lumen for insertion of a guidewire and an integrated hub for contrast injections [12]), sealers/dividers, scalpels/scissors, scissor tips, and endoscopic trocars (i.e. sharp, three-pointed cannulas [13]).
environmental impact(s)	Outcome capturing environmental and human health impacts. Environmental impacts include carbon emissions for new device production and reprocessing, disposal waste volume, and other environmental impacts. Human health impacts include human health effects of air pollution, human health effects of chemical exposure e.g., cancer, breathing issues.
environmental impact study	An environmental impact assessment is an assessment of the environmental consequences of a plan, policy, programme, or actual project prior to the decision to move forward with the proposed action (e.g. life cycle assessment).
EU MDR approved	Reprocessing standards in the study were reported as compliant with the EU MDR option adopted by the country in which the study was conducted.
experimental study	An experimental study design is the process of carrying out research in an objective and controlled fashion using a standardised procedure so that precision is maximised, and specific conclusions can be drawn regarding a hypothesis statement. Generally, the purpose is to establish the effect that a factor or independent variable has on a dependent variable. The researcher decides where the experiment will take place, at what time, with which participants, and in what circumstances.
external fixator	External fixators are used to treat and stabilise bone fractures and can be used in conjunction with internal fixators if necessary. External fixation is a relatively safe, minimally invasive procedure involving a small incision in soft tissue, drilling, and the placement of pins around the bone fracture, which are then attached to external rods and clamps. The external fixators are left in place for several weeks while the bone heals.
surgical face masks	Surgical face masks are examples of personal protective equipment. While more loose-fitting than respirators, they create a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment [14].
FDA approved	Reprocessing standards in the study were in line with FDA guidance on the reuse of single-use medical devices as provided by the FDA in the USA.
hierarchy of evidence	The hierarchy of evidence for primary epidemiological studies is, from highest to lowest quality: randomised controlled trials, non-randomised trials, longitudinal cohort studies, case-control studies, and cross-sectional studies. Ecological or correlational studies are not usually in the hierarchy of evidence, as their role is to suggest rather than prove causal relationships.
I^2	Index measuring the percentage of inconsistency or heterogeneity
implantable cardioverter defibrillator	Implantable cardioverter defibrillators (ICD) are small, battery-powered devices placed in the chest to detect and stop irregular heartbeats (arrhythmias). These implanted

	devices continuously monitor the heartbeat and deliver electric shocks whenever needed to restore a regular heart rhythm.
incidence	Incidence is a term used to describe the number of new cases of disease or events that develop among a population during a specified time interval.
internal fixators	Internal fixators, such as plates, screws, or staples, are used to unite two or more bone fragments after proper alignment. This process can be referred to as internal fixation or osteosynthesis. The union is mechanically stabilised by the internal fixators, and these fixators remain in place until the fracture has healed [15].
in vitro studies	In this evidence review, in vitro studies are primary research studies on the reprocessing of instruments which are based in a laboratory as part of the preclinical phase of testing, which helps to determine which devices may potentially be safe or unsafe to test on human subjects.
in vivo studies	In this evidence review, in vivo studies are primary research studies on humans, based in a health facility, testing the reprocessing of single-use devices compared with new devices. The comparisons measure one or more of the following outcomes: safety, cost, and environmental impact.
ISPOR	The Professional Society for Health Economics and Outcomes Research
KN95	not resistant to oil, 95% airborne particle filter rate (respirators certified by China)
laparoscopy	Laparoscopy is minimally invasive or keyhole surgery.
life cycle assessment	Life cycle assessment is a framework for assessing the environmental impacts associated with all stages of the life cycle of a commercial product, process, or service. The steps in the assessment are: 1. Goal and scope definition 2. Life cycle inventory analysis 3. Life cycle impact assessment, and 4. Interpretation of the results.
local policy	Reprocessing quality assurance standards were in line with local policy (but were not regulated through legislation) e.g. hospital policy.
logistic regression	Logistic regression is a statistical technique used in research designs that require the analysis of the relationship of an outcome or dependent variable to one or more predictors or independent variables when the dependent variable is either: (a) dichotomous, having only two categories (for example, whether one uses illicit drugs (no or yes)); (b) unordered polytomous, which is a nominal-scale variable with three or more categories (for example, eye colour (blue, brown, grey, or green)); or (c) ordered polytomous, which is an ordinal-scale variable with three or more categories (for example, the highest level of education completed (none or primary school incomplete, primary school, secondary school, third-level diploma, third-level primary degree, third-level master's degree, or third-level doctorate)).
lumen	Inner spaces in narrow tubes that transport liquids, gases, or surgical devices during a medical procedure. Instruments containing lumens are among the most difficult instruments to reprocess.
minor and major medical complications	A minor medical complication or adverse event is defined as a treatment-related adverse event requiring minimal symptomatic relieving therapy or no treatment, with or without overnight hospitalisation for observation. A major medical complication or serious adverse event is defined as a treatment-related adverse event requiring additional therapy with an increase in the level of care and/or prolonged hospitalisation. Such complications or events may result in permanent disability or fatality.
n	total number of individuals or observations in the sample
N	total number of individuals or observations in the population
non-randomised trial	A non-randomised trial is an analytic interventional study in which an intervention is allocated by the researchers. The researchers allocate the participants to the intervention group, the comparator intervention group, or the placebo group. This trial design does not control for confounding variables and will have allocation bias. The

	participants are followed up on over a predefined length of time in order to determine the incidence of the outcome(s) in the intervention group compared with the comparator or control group. The difference in incidence rate in calculated. The interventions may be preventative or therapeutic. Data on confounding variables will need to be collected to control for confounding through stratification or regression.
N95	not resistant to oil, 95% airborne particle filter rate
observational study	An observational study is one in which the researchers observe the effect of a risk factor, diagnostic test, treatment, or other intervention without influencing or changing who is or is not exposed to it. Examples of observational studies include cohort studies and case-control studies.
odds ratio	An odds ratio is a statistic that quantifies the strength of the association between two events, A and B. The odds ratio is defined as the ratio of the odds of A in the presence of B and the odds of A in the absence of B, or equivalently (due to symmetry), the ratio of the odds of B in the presence of A and the odds of B in the absence of A.
pacemaker	Pacemakers are small devices that are placed (or implanted) in the chest to help control the heartbeat. They are used to prevent the heart from beating too slowly. Implantation of a pacemaker in the chest requires a surgical procedure.
phacoemulsification needle	Phacoemulsification needles (also known as phaco needles) are used during a phacoemulsification procedure, which is the extraction of a cataract by breaking down the cataract via a very small incision using an ultrasonic probe and removing the cataract by suctioning it out via the phaco needle [16].
prospective study	A prospective study design follows participants into the future and collects data from the time of recruitment to the study. Examples of prospective studies are randomised controlled trails, cohort studies, and non-randomised trials. These study designs minimise recall bias.
PROSPERO	International Prospective Register of Systematic Reviews
pulse oximeter	Pulse oximeters are used to measure blood oxygen saturation levels by passing small beams of light through the blood in the finger and measuring changes in light absorption in oxygenated or deoxygenated blood [17].
qualitative study	Qualitative studies explore and provide deeper insights into real-world problems. Rather than collecting numerical data points, qualitative research studies help to generate hypotheses as well as further the investigation and understanding of quantitative data [18].
randomised controlled trial	A randomised controlled trial is an analytic interventional study in which an intervention is randomly allocated to 50% of the participants and a comparator intervention or placebo is allocated to the remaining participants. Random allocation is employed to control for confounding variables, and any adaption to the randomisation process reduces a trial's ability to control for confounding and introduces allocation bias. The participants are followed up on over a predefined length of time in order to determine the incidence of the outcome(s) in the intervention group compared with the comparator or control group. The difference in incidence rate in calculated. The interventions may be preventative or therapeutic.
relative risk or risk ratio	The relative risk or risk ratio is the ratio of the probability of an outcome in an exposed (or intervention) group relative to the probability of the outcome in an unexposed (or control) group, and compares the incidence of the outcome in the exposed group with the incidence of the outcome in the unexposed group.
reprocessing	Device cleaning, disinfection, and sterilisation or related procedures, and device function and safety testing.
research team criteria	Reprocessing quality assurance standards were in line with processes determined by the study research team local policy (but were not regulated through legislation).
respirator	Respirators are examples of personal protective equipment. They provide respiratory protection to the wearer and are designed to achieve a very close facial fit and very efficient filtration of airborne particles. Respirators offer a tighter fit than that provided by surgical masks [14].
retrospective study	A retrospective study design asks participants about their past. Examples of retrospective study designs are case-control studies, cross-sectional surveys, and

	cohort studies. All retrospective studies will have recall bias unless there is an existing documentary method to confirm the reported experience.
risk classification	Risk classification is classification broadly based on the potential for a deterioration in the health of the patient when a device is used (I: little risk; IIa: unlikely risk; IIb: potential risk of deterioration; and III: risk of death).
single-use device	A single-use device is designed to be disposed of after one use. Note that this excludes single-person reuse devices, such as dialysers, which, while used on only one patient, are necessarily not designed to be used only once by the same patient.
surveillance system study	Epidemiological surveillance is the ongoing and systematic collection, analysis, and interpretation of health data in the process of describing and monitoring a health event (including exposures, treatments, and outcomes). This information is used for planning, implementing, and evaluating public health interventions and programmes. A surveillance study is the use of data from an epidemiological surveillance system.
studies which do not describe a methodology	Studies where the authors do not include an explicit description of the steps taken; for instance, a non-systematic literature review which does not describe the search strategy used to locate literature or the approach to synthesis taken.

Executive summary

Purpose and review questions

In 2017, European Union (EU) member states, including Ireland, were required to adopt a legislative stance on reprocessing single-use medical devices (SUDs) for reuse under Article 17 of the EU Medical Device Regulation (MDR). Reprocessing, which typically applies to "reusable medical devices", is defined in the legislation as "a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device". Under Article 17, legislative stances on SUD reprocessing could range from prohibiting the reprocessing of SUDs to permitting SUD reprocessing under varying levels of regulation including holding the entity who performs the reprocessing to the same standards as any other manufacturer under the MDR. Following a targeted consultation, Ireland adopted the most heavily regulated available approach permitting reprocessing, whereby any entity reprocessing SUDs is viewed as the device manufacturer and must fulfil the full set of manufacturer requirements and obligations as they apply to all manufacturers of medical devices.

The MDR became fully applicable in May 2021. As part of their evaluation of the policy adopted in Ireland, the Department of Health's (DOH's) Medicines, Controlled Drugs & Pharmacy Legislation Unit asked the Health Research Board (HRB) to complete an evidence review to answer the following research questions:

1. What, if any, SUDs does the available research evidence indicate can be reprocessed where reprocessing involved both device sterilisation and function testing and is in line with the 2017 EU MDR and other related approaches?
2. What are the financial costs, and the safety and environmental consequences, of reusing SUDs which were reprocessed where reprocessing involved both device sterilisation and function testing and is in line with the 2017 EU MDR and other related approaches?
3. How, if at all, do safety outcomes, environmental impacts, and costs associated with reprocessing SUDs where reprocessing involved both device sterilisation and function testing and is in line with the 2017 EU MDR and other related approaches differ by SUD type?

Methods

A standard systematic review design was used to answer the review questions as it was regarded as the most suitable method of evidence synthesis for these research questions. The study protocol was registered on PROSPERO (ID: CRD42022365642), and the review is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria, as well as the Standardized Technique for Assessing and Reporting Reviews of Life Cycle Assessment Data (STARR-LCA) for the life cycle outcomes and recently published guidance on systematic reviews with cost and cost-effectiveness outcomes.

Eligible studies were English- or German-language before-and-after studies, observational studies with a comparison group, and randomised and non-randomised controlled trial studies carried out on humans in a health facility (in vivo) or on devices in a laboratory (in vitro) and published from the year 1994 onwards. Economic and life cycle assessment (LCA) study designs were also eligible. The populations of interest were human subjects (in vivo studies) and clinical or artificial device contamination (in vitro studies). The intervention was SUD reprocessing where reprocessing was defined as including device cleaning, disinfection, and sterilisation or related procedures, and device function and safety testing. The comparator was devices which had not undergone reprocessing. Studies had to examine one or more of

the following outcomes: patient safety, device safety and function, environmental impacts, and/or financial costs (to patients or health facilities/systems).

The review search strategy was based around five broad concepts – single-use medical devices, reprocessing, safety and/or adverse outcomes, cost and cost-effectiveness, and environmental impacts – in order to capture all relevant results. We searched four bibliographic databases (Embase, Medical Literature Analysis and Retrieval System Online (MEDLINE), Dimensions, and Cochrane) and an extensive range of research repositories and grey literature resources. Search results were imported into the Evidence for Policy and Practice Information software programme (EPPI-Reviewer 4), where screening was completed using machine learning technology to improve the efficiency of the process.

We report our findings in the order of the MDR classification rules which is composed of four risk classes: risk class I (little risk); risk class IIa (unlikely risk); risk class IIb (potential risk of deterioration); and risk class III (risk of death). Under the MDCG system, 'risk' refers to the potential for a deterioration in the health of the patient when the device is used. The risk classes are assigned using numerous factors, including the degree of invasiveness, the part of the body affected, duration of use, and whether the device is active.

We separated the included studies into two groups: in vitro (i.e. studies examining SUD reprocessing safety in a laboratory) and in vivo (i.e. studies examining device or patient safety, financial costs of reusing reprocessed SUDs, or the environmental impacts of reusing reprocessed SUDs as part of clinical care). In the context of this review, in vitro studies can be considered part of the preclinical phase of testing the reprocessing of SUDs in order to help determine which devices may be put forward for testing on human patients. Therefore, the findings of in vitro studies on their own cannot determine the safety of reprocessing SUDs, but can add to the knowledge about which SUDs are being considered for reprocessing (and thus partly addresses research question 1). As these studies were not the main focus for this review, we narratively describe these studies' characteristics and report the corresponding study authors' conclusions. We did not extract statistical data, carry out new statistical analyses, undertake quality assessment, or complete a Grading of Recommendations, Assessment, Development and Evaluations (GRADE) assessment of the findings of these studies. Given that in vivo studies can more fully address each of our three research questions, these studies went through all phases of the standard systematic review process. Two reviewers independently extracted data into bespoke extraction sheets which included the study characteristics, outcomes assessed, and related statistical information. Quality assessment of individual studies was completed using a tool appropriate to the individual study design. For each outcome of interest, we undertook an assessment to determine the feasibility of meta-analysis. Where meta-analysis was not possible for an outcome, we reported the findings using narrative synthesis. Finally, we undertook a GRADE assessment on the primary patient safety, device safety, and cost outcomes to determine the certainty of individual review findings.

Findings

In vitro studies

We identified 33 in vitro studies examining 12 SUDs across all MDR risk classes. We did not carry out primary analyses or quality appraisal of the in vitro studies. These studies tested SUDs in relation to reprocessing safety (i.e. device sterility and function) using 14 sterilisation methods. The most common methods of sterilisation were ethylene oxide (n=12) and hydrogen peroxide (n=7). The number of cycles of reprocessing varied between studies. The number of devices sterility and/or function tested in each study ranged from 5 to 650 devices (n=23 studies). One study examined 2050 internal fixator device components and 9 studies did not report the number of devices included. Six studies may have followed

processes in line with Article 17[2] of the EU MDR but none of these provided sufficient information to allow the authors of this report to say this with certainty.

Risk class I devices

Respirators and surgical face masks

The largest group of SUDs in the in vitro studies was respirators and surgical face masks (n=19 studies). In two studies, reprocessing standards were set by international standards (ISO) and the FDA respectively, and therefore these are the only studies in which reprocessing requirements and processes may be aligned with the requirements of Article 17 [2] in the EU MDR. However, the research studies did not provide sufficient detail to allow the authors of this report to conclude this with certainty.

The number of sterilised devices or device samples examined in each study ranged from 2 to 162 and the number of function tested devices or device samples in each study ranged from 2 to 156. These studies reported divergent findings for safety, both between studies assessing the same sterilisation method and between studies assessing different models and brands of these devices. There was consensus among study authors that the reprocessing of respirators and surgical face masks should be restricted to emergency situations only, such as a worldwide shortage during a pandemic.

Risk class IIa and IIb devices

Surgical instruments for cutting and grasping

In two of three identified studies, reprocessing standards were set by the FDA and therefore these are the only studies in which reprocessing requirements and processes may be aligned with the requirements of Article 17 [2] in the EU MDR. However, the research studies did not provide sufficient detail to allow the authors of this report to conclude this with certainty.

Neither biopsy forceps (n=1 study) nor arthroscopic shavers (n=2 studies) were recommended for reuse in humans after one clinical use, as devices did not pass reprocessing tests. The single biopsy foreceps study sterilised 6 devices and function tested 14 devices. Studies of arthroscopic shavers sterilised between 4 – 20 devices and function tested between 4 to 14 devices.

Endoscopic and laparoscopic devices

As all identified studies (n=3) studies followed reprocessing standards aligned with locally agreed requirements without providing sufficient further detail, the authors of this report cannot comment on the extent the requirements followed aligned with those set out in Article 17[2] of the EU MDR.

Two in vitro studies – one assessing sphincterotomes (1 reprocessing cycle using artificial contamination) and one assessing argon plasma coagulation probes (up to 10 reprocessing cycles using artificial contamination) – recommended these devices for in vivo testing in humans. These findings were based on sterilisation and function testing of 11 spincterotomes and sterilisation and function testing of 10 argon plasma coagulation probes. One other in vitro study assessing reprocessing outcomes (sterilisation and function testing) for 24 electrosurgical pencils after clinical use reported that the reprocessed pencils were not safe to reuse in humans using available reprocessing methods.

Internal fixators

Authors of the one identified internal fixator device study did not provide sufficient detail to allow the authors of this report to form conclusions about the extent the reprocessing standards followed aligned with those set out in Article 17[2] of the EU MDR.

The study assessed the safety of reusing 2050 components of internal fixator devices (based on one reprocessing cycle after clinical use) and found that these devices met reprocessing requirements according to a local hospital policy.

Risk class III devices

Cardiac catheters and cannulas

In two studies, reprocessing standards were set by the FDA and therefore these are the only studies in which reprocessing requirements and processes may be aligned with the requirements of Article 17 [2] in the EU MDR. However, the research studies did not provide sufficient detail to allow the authors of this report to conclude this with certainty.

There were conflicting results from four in vitro studies on the safety of reprocessing balloon catheters contaminated via clinical use or artificially. These studies sterilised between 8 and 118 devices and function tested between 8 and 70 devices. One study tested over 650 devices but did not indicate the numbers sterilised or function tested. One study examining reprocessing outcomes of ablation catheters (with 9 devices sterilised and function tested) which were not contaminated and one study of electrophysiology polyurethane catheters (with 16 devices sterilised and function tested) which were contaminated after clinical use, found that these devices did not pass all reprocessing requirements. One study of cardiac cannulas which sterilised 30 and function tested over 189 devices after both clinical use and artificial contamination reported that some device models examined could be reprocessed.

In vivo studies

We identified 19 in vivo studies examining 16 SUDs across all risk classification groups. The outcome types reported were patient safety, device safety, health facility department costs of reprocessing, and health facility reprocessing environmental impacts. The summary findings are presented by outcome, device class, and device type. Five of these studies may have followed processes and obligations in line with Article 17[2] of the EU MDR. However, the study authors did not provide sufficient information for the authors of this report to conclude this with certainly.

Patient and device safety

Risk class I devices

External fixator devices

Reprocessing processes followed by two studies may possibly be considered in line with the requirements of article 17[2] of the EU MDR. However, the study authors did not provide the level of detail required for the authors of this report to say this with certainty.

Two in vivo studies – one poor-quality study and one good-quality study – assessing external fixators used to treat and stabilise bone fractures reported no significant difference for patient and device safety between reprocessed (unclear number of reprocessing cycles) and new devices; pin tract infections [OR = 0.85 (95% CI: 0.24 – 3.03) and OR = 1.13 (95% CI: 0.75– 1.71)]; reoperation rate [OR = 1.69 (95% CI: 0.56–5.04)]; loss of fixation [OR = 1.09 (95% CI: 0.15–8.08)]; loosening of device components [OR = 0.99 (95% CI: 0.26–3.72)]. The certainty of the evidence for reuse of external fixator devices with respect to patient and device safety is very low. Very low certainty of evidence means that the HRB authors have very little confidence in the effect found in these studies.

Deep vein thrombosis compression sleeves

The single available study did not provide sufficient information to determine the extent reprocessing processes and obligations followed aligned with those set out in the EU MDR.

No safety data were available for deep vein thrombosis compression sleeves. In the single available LCA study, deep vein thrombosis compression sleeves had the highest potential for device life cycle-related cost savings and environmental benefits of seven devices examined. Diminishing incremental savings and environmental benefits were reported for each reprocessing cycle, up to five cycles.

Pulse oximeters

The single available study did not provide sufficient information to determine the extent reprocessing processes and obligations followed aligned with those set out in the EU MDR.

No safety data were available for pulse oximeters. In the single available LCA study, diminishing incremental savings and environmental benefits were reported for each reprocessing cycle, up to five cycles. The study authors reported that differences in pulse oximeter environmental benefits between the first use and subsequent reuses were not significant.

Risk class IIa and IIb devices

Ophthalmic devices

The single available study was undertaken prior to the establishment of FDA approval processes for SUD reprocessing and therefore, the processes followed were not comparable to Article 17[2] of the EU MDR.

One in vivo study of poor quality evaluating phacoemulsification (phaco) needles, which are used in cataract operations, found no significant difference (effect size could not be calculated from the data provided) in patient and device safety between first use and reuse for up to five reprocessing cycles. The certainty of the evidence for reuse of phaco needles with respect to patient and device safety is very low. Very low certainty of evidence means that the HRB authors have very little confidence in the effect found in this study.

Surgical instruments for grasping and cutting

The single study did not provide sufficient information to determine the extent reprocessing processes and obligations followed aligned with those set out in the EU MDR.

No safety data were available for the arthroscopic shaver (used in arthroscopic surgery). In the single available LCA study, environmental benefits and device life cycle cost saving were reported for each reprocessing cycle, up to five. Incremental savings were similar with each additional reprocessing cycle. Study authors reported that differences in arthroscopic shaver environmental benefits between first use and subsequent reuses were not significant.

Endoscopic and laparoscopic devices

The endoscopic (investigations inside the body using a camera) and laparoscopic (used for keyhole surgery) devices assessed were: laparoscopic sealers/dividers (n=1 study), ultrasonic scissors/scalpels/shears (n=2 studies) and linear suture machines (n=1 study). In two studies, reprocessing processes were followed by the FDA and by the EU MDR. However, the study authors did not provide sufficient detail to allow the review authors to determine the extent by which these processes aligned with Article 17[2] of the EU MDR. Other studies examined did not follow processes in line with Article 17[2].

The three in vivo studies (two good-quality studies and one excellent-quality study) assessing patient and device safety of endoscopic and laparoscopic devices found no significant difference between first use and reuse (based on one reprocessing cycle only) for; postoperative complications [OR = 0.74 (95% CI: 0.16–3.42), OR = 0.91 (95% CI: 0.59–1.41), OR = 0.47 (95% CI: 0.04–5.36)]; duration of hospital stay [MD = -0.30 (95% CI: -0.48–-0.12) and MD = -0.84 (95% CI: -2.35–0.67)]; or procedure time [MD = -3.00 (95% CI: -17.19–11.19) and MD = -7.20 (95% CI: -20.43–6.03)]. The certainty of the evidence for the reuse of

endoscopic and laparoscopic devices with respect to patient safety is very low. Very low certainty of evidence means that the HRB authors have very little confidence in the effect found in these studies.

Risk class III devices

Implantable cardiac devices

None of the identified studies followed reprocessing processes or obligations aligned with Article 17[2] of the EU MDR. Results of meta-analyses found no significant difference between four in vivo studies (one of fair quality and three of good quality), with respect to patient safety, between first use and one-time reuse (based on one reprocessing cycle), for pacemakers (n=2) and defibrillators (n=2). Specifically, results of meta-analyses for device related infections reported OR = 0.67 (95% CI: 0.37 – 1.20) and for unexpected battery depletion reported OR = 2.29 (95% CI: 0.83 – 6.31). Narrative synthesis indicated similar rates of device related safety outcomes between single used and reused devices; other device malfunction [OR = 3.03 (95% CI: 0.12–75.28) and OR = 2.90 (0.12–71.52)]. The certainty of the evidence for reprocessing pacemakers and defibrillators with respect to patient and device safety is very low. Very low certainty of evidence means that the HRB authors have very little confidence in the effect found in these studies.

Cardiac catheters and cannulas

Two studies, following FDA and EU MDR processes, may possibly have followed reprocessing processes and obligations aligned with article 17[2] of the EU MDR but did not provide enough detail for the authors of this report to say for certain that this is the case. Other studies were not aligned with Article 17[2] of the EU MDR.

Narrative synthesis of results of four studies (one of poor quality, one of fair quality and two of good quality) reporting on patient and device safety for cardiac catheters reported no difference in the rates of major complications between new and reused devices (n=3 studies). However, one old study found higher odds of major complications in persons receiving reused versus new devices [OR = 2.76 (95% CI: 1.41 – 5.40)]. No differences were found between new and reused devices for minor patient complications [OR = 0.91 (95% CI: 0.48 – 1.72) and OR = 3.52 (95% CI: 0.36 - 34.01)]. One study reported average shorter procedure times for reused versus new devices [MD = -16.00 (95% CI: -26.85 – -5.15)] and the other studies reported no difference in average procedure time [MD = 0.80 (95% CI: -0.79 - 2.39), MD = -0.60 (95% CI: -2.48 – 1.28) and MD = -10.60 (95% CI: -25.38 – 4.18)]. One study reported a longer average fluoroscopy time for reused versus new devices [MD = 9.70 (95% CI: 6.43 - 12.97)] and the remainder reported no difference in average fluoroscopy time between new and reused devices [MD = -5.00 (95% CI: -8.40, -1.60), MD = 0.80 (95% CI: -0.79 - 2.39) and MD = -0.20 (95% CI: -0.95 - 0.55)]. One study reported a lower average volume of contrast used during procedures of new versus reused devices [MD = 36.00 (95% CI: 24.73, 47.27) and the remainder of studies reporting on average contrast volume used per procedure reported no differences in this outcome between new and reused devices [MD = -32.00 (95% CI: -69.92 - 5.92) and MD = -4.00 (95% CI -13.77 - 5.77)]. The certainty of the evidence for cardiac catheters and cannulas with respect to patient safety is very low. Very low certainty of evidence means that the HRB authors have very little confidence in the effect found in these studies.

Cost savings

The data in relation to cost savings to healthcare institutions from reprocessing and reusing SUDs were based on eight in vivo studies (three of low quality, one of moderate quality, four of good quality and one reporting 68% of transparency reporting checklist items) assessing this outcome domain. Cost savings were assessed for three class I devices (external fixators, deep vein thrombosis sleeves, and pulse oximeters), six class IIa devices (ultrasonic scissors/scalpel/shears, linear suture machines,

sphincterotomes, endoscopic trocars, ultrasonic scissor tips), one class IIb device (internal fixator devices), and three class III devices (balloon catheters, ablation catheters and electrophysiology catheters).

Cost savings were reported for hospital departments across device groups when direct costs were calculated (i.e. the cost of the reused device compared with the new device). Of two studies capturing indirect costs related to patient safety (i.e. direct costs and costs related to safety outcomes such as patient complications, reoperations, procedure times, and duration of hospital stay), one endoscopic and laparoscopic device study and one cardiac catheter device study each reported that savings were attenuated. We applied the GRADE assessment for indirect safety related costs (primary outcome) and determined that our confidence in indirect cost outcomes was very low. The one study providing life cycle device cost data (i.e. environment-related indirect costs) found that savings decreased with each additional reprocessing cycle (up to five reuses) for all seven devices studied. Taken together, reprocessing-associated savings appeared to differ across individual devices.

Environmental impacts

One study reported environmental impacts of reprocessing seven devices: arthroscopic shavers, deep vein thrombosis compression sleeve pairs, endoscopic trocars, laparoscopic sealers/dividers, pulse oximeters, laparoscopic scissor tips, and ultrasonic scissors/scalpels/shears. Given median/mean reprocessing life cycle inventory inputs (the amount of ethylene oxide, electricity, and water consumed), reprocessing of the seven devices slightly reduced global warming impacts, but concurrently exacerbated human health impacts (i.e. carcinogenic, non-carcinogenic, and respiratory effects). The greatest environmental benefit was seen for deep vein thrombosis compression sleeves due to device materials and cost.

Conclusion

External fixator devices (one of two studies may have followed reprocessing standards aligned with Article 17[2] of the EU MDR) and implanted cardiac devices (pacemakers and defibrillators; reprocessing processes were not aligned with Article 17[2] of the EU MDR) reported no additional adverse events after one reprocessing cycle. However, the certainty in the evidence is very low. Reprocessing results in both direct and indirect cost savings (safety and device life cycle-related), and marginal savings diminish with subsequent reprocessing cycles. The certainty of the evidence for cost outcomes examined is also very low. SUD reprocessing has the potential to reduce global warming impacts, but may exacerbate human health impacts. High-quality randomised controlled trials, cost-effectiveness studies, and environmental studies are needed in order to better understand the safety, costs, and environmental impacts of SUD reprocessing. These future studies should endeavour to compare these outcomes across device models, study device models in isolation or use other appropriate methods to account for potential heterogeneity within device types (e.g., balloon catheters).

1 Introduction

1.1 Policy context

Single-use device (SUD) reprocessing and subsequent reuse is a widespread practice aimed at curbing healthcare costs [19–21]. Regulation of this activity is becoming more common in an effort to ensure patient safety, particularly in the developed world [19]. However, there remains limited documented evidence that reuse following reprocessing does in fact curb costs [22,23]. In 2000, the United States of America (USA) began actively regulating the reprocessing of SUDs and requires SUD reprocessors to seek pre-market Food and Drug Administration (FDA) approval before reprocessed SUDs are placed back on the market [24]. Since 2000, New Zealand, Australia, Canada, and several countries in Europe have adopted legislation requiring reprocessors of SUDs to guarantee quality standards of the devices before they are reused [19,25].

By 2021, European Union (EU) member states, including Ireland, were required to adopt a legislative stance on reprocessing SUDs for reuse under Article 17 of the EU Medical Device Regulation (MDR) [26]. The regulation sets out four policy options, and each option has specific considerations and varying impacts on existing practices in Ireland. These considerations and impacts are: further availability and use of SUDs, the legal status of the person/organisation performing reprocessing, and the health institutions permitted to reuse SUDs [26]. The majority of countries either opted into the most heavily regulated option permitting SUD reprocessing or have opted to prohibit reprocessing of any SUD. Ireland adopted the former approach, where any entity reprocessing SUDs is viewed as the device manufacturer and will have to fulfil the full set of manufacturer requirements and obligations of the MDR as they apply to all manufacturers of medical devices [27]. A principal implication of adopting a heavily regulated approach is that it may not be possible to undertake reprocessing internally in health facilities e.g., within hospital Central Sterile Supply Departments (CSSDs). Rather, reprocessing could be undertaken by external reprocessing entities who assume the risks of reprocessing.

1.2 Background

Reusing medical devices intended for multiple uses by device manufacturers is an accepted practice globally due to the availability and use of clear guidelines for reprocessing and sterilisation [28]. Prior to the reuse of a medical device, it must go through a reprocessing process specified by the device manufacturer [28]. Reprocessing, which typically applies to “reusable medical devices”, is defined in European legislation as “a process carried out on a used device in order to allow its safe reuse, including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device” [26], with a similar definition comprising cleaning, disinfection and sterilisation, and device testing components employed in medical device research [29]. In this way, reprocessing is different from device cleaning, disinfection, or sterilisation only, or from device recycling [30]. Manufacturers of medical devices are required to indicate whether a device is intended for single use or multiple uses.

Between the 1970s and 1980s, there was an increase in the number of medical devices produced, labelled, and marketed ‘for single use only’ [31]. SUDs, also referred to as disposable devices, are defined in European legislation as (medical) devices that are “intended to be used on one individual during a single procedure” [26]. There were two main reasons for the increase in demand for SUDs. First, the introduction of new plastics and other technological advancements enabled the development of instruments with smaller lumens and more intricate, delicate working mechanisms, which were more difficult to clean and sterilise than previous devices. Second, hospital demand for disposables increased due to the desire to cut down on reprocessing costs and the risks of cross-contamination from one patient

to the next. Risks of cross-contamination were a particular concern in relation to human immunodeficiency virus (HIV) and hepatitis transmission [31]. In 2023, reprocessing SUDs is a current practice globally as a strategy to reduce hospital costs, including in Europe [19]. For instance, in Denmark and Germany, an estimated 37–40% of hospitals reprocess SUDs [20,21], while in Madrid, the practice has previously been reported in the media as occurring in up to 80% of hospitals [32]. In developed countries, SUD reprocessing is reported across medical fields, namely:

- Anaesthesiology
- Gastroenterology
- Ophthalmology
- Orthopaedics
- Urology
- Cardiology
- Vascular medicine
- Surgery, and
- Other fields (e.g. in relation to breast pump kits, bone marrow trephine sets, dental appliances, skin staplers) [19].

Reusing reprocessed SUDs is a contentious issue. From the manufacturers' perspective, devices may be marketed as single-use where:

- It is not feasible to make the device with reusable materials and achieve the desired function
- It is not possible to design a device to both achieve the desired function and allow patient-safe reprocessing, or
- Manufacturers wish to control or limit their liability for device failure [31].

Prions are an infective agent of particular concern. Prions are resistant to proteolytic enzymes and remain pathogenic even after long periods of time and exposure to high heat of up to 200° Celsius [33]. Prions account for a large majority of cases of Creutzfeldt Jakob disease globally with much of the transmission attributable to the use of pituitary extracts and dura mater grafts, and from neurosurgical instruments and blood transfusions [34].

In developed countries, proponents of reprocessing SUDs argue that this has economic and environmental benefits [19] without increased adverse patient safety events. According to the reprocessing industry in Europe, cost savings for reprocessing SUDs may be up to 50% for certain devices (e.g. electrophysiology or ablation catheters), and they may be up to 90% when reprocessing is done in-house [31]. In contrast, authors of the only two systematic reviews on the cost of reusing reprocessed SUDs could not establish the cost-effectiveness of reusing single-use medical devices due to an inconclusive evidence base and a paucity of high-quality, appropriately designed studies [22,23]. Hailey *et al.* used data identified in their systematic review to estimate the break-even point for offsetting the indirect costs of the probability of adverse patient events in two common laparoscopic procedures: laparoscopic cholecystectomies and coronary angioplasty. They estimated that a complication rate of 12.6 per 1,000 angioplasty patients and 445 per 1,000 laparoscopic cholecystectomy patients would be needed to break even on SUD reprocessing for each procedure. Therefore, including uncertainty, reuse would generate system-wide savings for laparoscopic cholecystectomies, but would be less likely to do so for

angioplasties, and overall, the authors did not recommend SUD reprocessing in Canada [23]. The European reprocessing industry [31] and available systematic review evidence [22,23] are consistent in reporting that savings could differ by device type. Life cycle assessment studies, which examine the environmental impact of a medical device from its development to disposal, demonstrate that SUDs typically result in higher petrochemical use and global greenhouse gas emissions compared with reusable alternatives [35,36]. It is not yet known whether reprocessing and reusing these SUDs is more environmentally beneficial than their one-time use and subsequent disposal. Regarding safety, proponents of SUD reprocessing argue that regulating the practice reduces the risk of unsafe interventions and resultant infections reported in developing and transitional countries [19]. A health technology assessment undertaken in New Zealand and a 2008 report by the Government Accountability Office in the USA could not draw any definitive conclusions about the safety of reprocessed SUDs from the available published literature, but stated that there are no indications of an elevated health risk resulting from SUD reprocessing in the USA [37]. A health technology assessment undertaken in New Zealand around the same time relied heavily on indirect evidence from studies examining device reprocessing outcomes, rather than patient or device safety outcomes after device reuse, and also concluded that there was insufficient evidence to establish the safety of reusing SUDs at that time [38].

A systematic review of the safety of reprocessing SUDs for laparoscopic cholecystectomy and coronary angioplasty [23], and SUDs generally [38], published around the same time as the 2008 Government Accountability Office report, also concluded that there was insufficient evidence to establish the safety of reusing SUDs at that time. However, in its review of the FDA's audit of FDA SUD reprocessing adverse event data, the Government Accountability Office concluded that there were no indications of an elevated health risk resulting from SUD reprocessing in the USA [37]. This finding suggests that regulating SUD reprocessing could be safe, but research is needed to validate this finding outside of the USA where different regulatory approaches are in place [37].

An up-to-date systematic review of the safety, costs, and environmental impacts of reusing reprocessed SUDs is needed in order to:

1. Collate all the available published research literature on the safety, costs, and environmental impacts of SUD reprocessing where this practice is regulated
2. Determine the quality of the available research evidence on this topic, and
3. Identify the research gaps in order to guide future research in this field.

This systematic review will be the first to report on reprocessing processes and standards applied in individual studies [39]. Although this may have safety implications, to date, the reprocessing method or regulatory requirements were not always clear in available safety [23,38] or cost [22,23] evaluations. Furthermore, where surrogate outcome data were used to inform conclusions about safety, results for these studies were not separated from those providing direct evidence [38]. To our knowledge, ours is the first systematic review able to synthesise the available research evidence on the safety, cost, and environmental impacts of regulated SUD reprocessing practices. This systematic review will provide a clearer and more comprehensive picture of the state of research in this area, which, in turn, may better guide health decision-makers in determining policy approaches to SUD reprocessing and can inform research priorities in each of the topics addressed (i.e. safety, costs, and environmental impacts).

1.3 Research questions

The MDR became fully applicable in May 2021. As part of their evaluation of the policy adopted in Ireland, the Department of Health's (DOH's) Medicines, Controlled Drugs and Pharmacy Legislation Unit asked the Health Research Board (HRB) to complete an evidence review to answer the following research questions:

1. What, if any, SUDs does the available research evidence indicate can be reprocessed where reprocessing involved both device sterilisation and function testing and is in line with the 2017 EU MDR and other related approaches?
2. What are the financial costs, and the safety and environmental consequences, of reusing SUDs which were reprocessed where reprocessing involved both device sterilisation and function testing and is in line with the 2017 EU MDR and other related approaches?
3. How, if at all, do safety outcomes, environmental impacts, and costs associated with reprocessing SUDs where reprocessing involved both device sterilisation and function testing and is in line with the 2017 EU MDR and other related approaches differ by SUD type?

2 Methods

2.1 Review design

A standard systematic review design was used to answer the research questions [40]. Other types of evidence synthesis were considered and ruled out [40]. The study protocol was registered and is available to view on the International Prospective Register of Systematic Reviews (PROSPERO) (ID: CRD42022365642).

This systematic review is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria [41,42], as well as the standardised technique for assessing and reporting reviews of life cycle assessment (STARR-LCA) [43]. It is also consistent with recently published guidance on systematic reviews with cost and cost-effectiveness outcomes [44].

We have separated the included studies into two groups – in vitro (laboratory-based studies) and in vivo (human-based studies) – throughout the review. In the context of this review, in vitro studies are undertaken in a laboratory setting as part of the preclinical phase of testing the reprocessing of SUDs in order to help determine which devices may potentially be safe to test in human subjects. In this setting, the SUDs may be assessed in their complete form or disassembled and assessed in sections. The SUDs may have been artificially contaminated (with viruses, blood, etc.), or contaminated via human exposure to a device after a single clinical use. The findings of the in vitro studies on their own cannot determine the safety of reprocessing SUDs in the clinical setting, but can add to the knowledge about which SUDs are being considered for reprocessing (and thus partly addresses research question 1). As these studies were not the main focus for this review, we narratively describe the study characteristics and report the corresponding study authors' conclusions. We did not extract statistical data, carry out new statistical analyses, undertake quality assessment, or complete a Grading of Recommendations, Assessment, Development and Evaluations (GRADE) assessment of the findings of these studies.

In the context of this review, in vivo studies are those undertaken in clinical settings, with the SUDs being used on human patients or modelled as having been used on human patients; the outcomes of interest in these studies are patient and device safety, cost, and environmental impact. Given that in vivo studies can more fully address each of our three research questions, these studies went through all phases of the standard systematic review process.

2.2 Eligibility criteria

The search strategy was prepared and the studies screened for inclusion considering the eligibility criteria set out in *Table **1***. Where eligibility criteria differed between in vitro (laboratory-based) and in vivo (human-based) studies, this is indicated in *Table **1***.

The setting of interest is any healthcare facility or reprocessing laboratory in an Organisation for Economic Co-operation and Development (OECD) or EU member country where reprocessed SUDs for use in humans are used or tested. These countries were considered for inclusion due to the comparability of their healthcare systems to Ireland's, as well as the need to comply with the EU MDR. Studies must have included at least one type of outcome of interest (cost, safety, or environmental impact) in order to be eligible for inclusion. We did not include systematic review studies because the search terms employed in existing systematic reviews included terms inconsistent with our definition of reprocessing or were not reported, and therefore we could not be certain that studies included in any such systematic reviews would reflect reprocessing as defined in our systematic review [22,23]. Finally, German-language items were the only non-English-language literature given consideration, as Germany has implemented single-use medical device reprocessing since as early as 2001 [45] and is also a leading country in Europe in relation to the application of medical device regulation [46].

For the purposes of this review, we considered devices and components thereof which are purpose-built for individual patients (e.g. fixator devices) as individual medical devices. We identified one device type (cardiac catheters) in the in vitro study group with consistent non-reporting of sterility outcome data [47–51]. We deviated from our exclusion criteria by including these studies based on further reading of device-specific material indicating that the FDA accepted the reprocessing of these SUDs [28]. We considered devices eligible where they fell under legislation as a medical device in any OECD country or region. For instance, in the EU, some dual purpose respirator products may comply with both medical device and personal protective equipment requirements, the governing legislation in the EU is most often the personal protective equipment regulation and in such cases they are not considered low risk products. In recognition that the governing legislation may differ across OECD countries and regions, these items were considered eligible as medical devices.

The systematic review by Jacobs *et al.* was used to set the search date. The cut-off year for publication (1994) was based on the earliest study result included in the Jacobs *et al.*, 2008 systematic review on this topic which otherwise met our systematic review study criteria [22]. Use of the earliest study result included in the Jacobs *et al.*, 2008 systematic review ensured maximum coverage of all potentially relevant items in an under-researched field. It also has the potential to demonstrate changes over time in reprocessing safety, cost and environmental outcomes, particularly with moves toward stringent regulation of this activity [26].

Table 1 Inclusion and exclusion criteria using population, intervention, comparator, and outcome(s) (PICO) and other relevant criteria

Element	Inclusion	Exclusion
In vitro studies		
Population	Single-use medical devices contaminated from clinical use on human patients or artificially using human bacteria, viruses, etc.	Single-use medical devices contaminated from clinical use in non-human patients.
Intervention	A newly developed or established reprocessing method which involved device cleaning, disinfection, sterilisation, or related procedures, and device function and safety testing.	Reprocessing of reusable medical devices. Reprocessing of single-use components of otherwise reusable medical devices. It is unclear whether the reprocessing involved both the cleaning and related

Table 1 Inclusion and exclusion criteria using population, intervention, comparator, and outcome(s) (PICO) and other relevant criteria

Element	Inclusion	Exclusion
	Contaminated devices were exposed to one or more reprocessing cycles.	procedures as well as the function and safety testing aspects. For studies with multiple reuse cycles, devices reused on the same person (i.e. single-person reuse).
Comparator	Unused (i.e. new) SUDs. Manufacturer specifications for device sterilisation, safety, and functioning.	Reusable device alternative of a single-use medical device (e.g. the same device made from different materials). Contaminated devices which have not yet been reprocessed.
Outcome(s)	Device function and safety: Device sterility, device degradation, device failure, device corrosion, or other device-specific reprocessing process-related function and safety outcomes. Environmental impact: Environmental and human health impacts. Environmental impacts include carbon emissions for new device production and reprocessing, disposal waste volume, and other environmental impacts. Human health impacts include human health effects of air pollution, human health effects of chemical exposure e.g., cancer, breathing issues. Cost: First use device purchase cost, SUD reprocessing cost, SUD disposal cost, and costs associated with safety and environmental outcomes.	Does not provide data for all reprocessing components (i.e. device cleaning/sterilisation and device safety and functioning testing).
Study design	In vitro primary studies.	Conference abstracts Qualitative studies Case reports or series Ecological studies Studies which do not describe a methodology (e.g. literature reviews) Systematic reviews
Language	English, German.	Any other language.
In vivo studies		
Population	Human patients exposed to reuse of a medical device classified by	Non-humans exposed to reuse of a medical device classified by

Table 1 Inclusion and exclusion criteria using population, intervention, comparator, and outcome(s) (PICO) and other relevant criteria

Element	Inclusion	Exclusion
	manufacturers as being for single use only.	manufacturers as being for single use only.
Intervention	Second or subsequent use of a reprocessed medical device classified by manufacturers as being for single use only, whereby reprocessing involved: device cleaning, disinfection, sterilisation, or related procedures, and device functioning and safety testing.	It is evident that the reprocessing process did not involve both aspects of the reprocessing definition. It is unclear whether the reprocessing process involved both aspects of the reprocessing definition. Reprocessed reusable medical devices. Reprocessed SUDs reused for a different purpose than their original intended purpose. Reprocessing of single-use components of otherwise reusable medical devices. New, unused SUDs which have been reprocessed. For studies with multiple reuse cycles, devices reused on the same person (i.e. single-person reuse).
Comparator	First use of a medical device classified as being for single use.	Reusable device alternative of a single-use medical device (e.g. the same device made from different materials). Unused SUDs.
Outcome(s)	Safety (patient): Adverse patient events (i.e. infection, burns, procedure-related complications, re-hospitalisation, procedure time, mortality, any other adverse patient outcomes). Device function and safety: Device sterility, device degradation, device failure, device corrosion, or other reprocessing process-related outcomes. Environmental impact: Environmental and human health impacts. Environmental impacts include carbon emissions for new device production and reprocessing, disposal waste volume, and other environmental impacts. Human health impacts include human health effects of air pollution, human health effects of chemical exposure e.g., cancer, breathing issues.	Does not provide data for all reprocessing components (i.e. device cleaning/sterilisation and device safety and functioning testing).

Table 1 Inclusion and exclusion criteria using population, intervention, comparator, and outcome(s) (PICO) and other relevant criteria

Element	Inclusion	Exclusion
	Cost: First use device purchase cost, SUD reprocessing cost, SUD disposal cost, and costs associated with safety and environmental outcomes.	
Study design	Randomised controlled trials Non-randomised controlled trials Economic evaluations (cost-minimisation, cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis, and cost-consequence analysis) Cost studies Environmental studies Observational studies with relevant comparators Surveillance studies	Conference abstracts Qualitative studies Case reports or series Ecological studies Studies which do not describe a methodology In vitro studies Systematic reviews
Language	English, German.	Any other language.

Note: In studies with multiple reprocessing cycles, findings for subsequent reprocessing cycles were not reported if there was no contamination between cycles.

2.3 Identifying research evidence

A comprehensive and systematic search process was developed and carried out for in vivo studies by the information specialist (AF), including database searches, grey literature searches, and supplementary searches. The stages of the literature-gathering process included the comprehensive searches of databases and other information resources, screening of these results, and reference/citation searching of the included items. Given that the primary focus of our review was in vivo studies, we carried out grey literature and supplementary searching for in vivo studies only. We did not carry out grey literature or supplementary searches for in vitro studies.

2.3.1 Search concepts

The search strategy was constructed using a PICO framing of the research question. It was based around the concepts of SUD reprocessing (intervention) within the human population (population), with new devices (in vitro studies) and SUDs (in vivo studies) as the comparators and patient safety, cost, and environmental impacts as the outcomes. The search was therefore based around five concepts: single-use medical devices, reprocessing, environmental impacts, safety and/or adverse outcomes, and cost and cost-effectiveness (Figure 1).

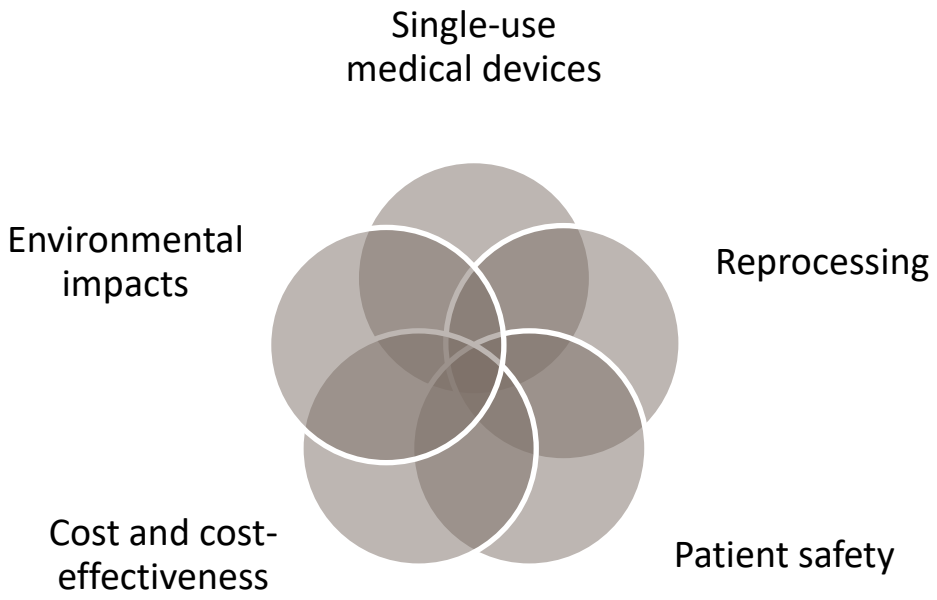

Figure 1 Search concepts

After discussions with the review team, scoping searches were carried out in Embase, Ovid Medical Literature Analysis and Retrieval System Online (MEDLINE), and the Cochrane Library to inform natural language, Medical Subject Headings (MeSH) terms, and appropriate keywords. Relevant reviews and research were followed up on in order to examine the type of material that had been referenced in producing them. From this preliminary work, it was clear that terminology would vary across publications, regions, and search resources. It was evident that SUDs were numerous and varied. Following discussions with the review team, the Health Products Regulatory Authority (HPRA), the DOH, and another information specialist in the HRB (CL), it was decided to keep the search broad in order to capture all relevant results. Therefore, terms such as 'single-use device', 'single-use medical device', 'SUD', 'SUMD', and related terms were used to build the search rather than specific device or instrument names (e.g. 'catheter') or manufacturer/brand names. In this way, the search aimed more for sensitivity (capturing as many relevant items as possible at the cost of including irrelevant material) than specificity (most results in scope at the cost of missing relevant papers). While this approach would return a large number of out-of-scope items, the screening process was estimated to be a more accurate mechanism to distinguish relevant papers from results which contain the correct terminology but are not on the specific topic of the review. On concluding the scoping search, it was apparent that the evidence informing the research questions was situated in a range of sources, including research, government, and statutory body sources.

2.3.2 Search resources and terminology

2.3.2.1 Database searching

A single search strategy was used to answer the three review questions. The search strategy to identify the appropriate published, peer-reviewed research was initially developed for the Embase (Embase.com) database using controlled vocabulary terms, natural language, and keywords with appropriate Boolean operators. Embase was chosen as the primary database because it has an extensive vocabulary of specific medical device terms, and initial searches indicated it had the best coverage for the research topic. The Embase search was then translated for use on the databases MEDLINE (Ovid platform), Dimensions, and the Cochrane Library (John Wiley and Sons Inc.). The translations of the search were reviewed by a senior information specialist in the HRB (LF). Using the same search concepts, a search was also conducted in

grey literature repositories; government websites; national, statutory, and EU bodies; and trial registers. Many of these resources did not support complex structured searching. Search vocabulary for simple searches was developed by reviewing the results of the scoping search and natural language was gleaned through reviewing non-academic results in the Google search engine. Controlled vocabulary was used where the website or repository offered such functionality. Detailed search strategies can be found in Appendix A. The review by Jacobs *et al.* [22] proved very useful during the building of the scoping search and understanding of the literature. As we developed our search strategy and decided on broader language, Embase gave consistently relevant results in test searches and so remained our primary database for this review.

2.3.2.2 Supplementary searching

The following types of resources were searched using subject headings, keywords, natural language, Boolean operators, and specific filters as per the individual website/repository/register:

1. Organisations: The websites of governments, statutory and regulatory bodies, and trial registers were searched. The search engines Google.com and Google Scholar were searched using broad search terms, and the first 200 results (of each) were reviewed by the information specialist (AF) for relevance.
2. Reference checking: The reference section of each included article was screened for relevant references. References were identified by hand and/or using Dimension and citationchaser [52]. References were pre-screened by the information specialist (AF) and screened on title and abstract by two members of the research team (LK, CW).
3. Citation chasing: Articles that cited the included articles were screened for additional relevant references. This was done for each article using the 'cited by' function in Google Scholar and/or using the online web application, citationchaser [52]. Citations were pre-screened by the information specialist. In total, the reference and citation chasing search resulted in (n=1,603) records for screening. After deduplication in EndNote citation management software, the results (n=1,421) were imported into the Evidence for Policy and Practice Information software programme (EPPI-Reviewer 4). The records were further deduplicated against material already screened in EPPI-Reviewer 4, resulting in 1,154 results. These records were screened on title and abstract by two members of the research team (LK, CW) and one item was included in the final study.
4. Systematic reviews: A supplementary search of systematic reviews was also carried out to ensure maximum coverage of eligible primary studies. A total of 126 systematic reviews were identified (from the database search and through Epistemonikos, the PROSPERO systematic review register, and the Cochrane Library) with the aim of carrying out reference and citation chasing to yield more relevant evidence. One member of the research team (NMG) screened these 126 reviews on title and abstract. NMG also screened 26 full texts, which resulted in 2 relevant references for inclusion. Referenced papers and papers citing the reviews were deduplicated and screened by NMG, resulting in the inclusion of one additional paper.
5. German-language grey literature search: Using German-language vocabulary and restricting results to German-language records only in Embase and MEDLINE was not fruitful. Using DeepL Translator software, and referring to German-language papers, NMG and AF compiled relevant keywords and natural language in German. A search was performed in Google Scholar using this vocabulary, which resulted in 12 out of the first 200 search results considered for inclusion. A search was performed within a selection of German government and relevant organisations (n=36) and pre-screened by the

information specialist. NMG screened 48 full texts in the German language, none of which was included in the systematic review.

German-language grey literature and research papers retrieved during the database searches and supplementary searches were translated using DeepL Translator software.

All searches were undertaken between 25 July (databases and trial registers) and 23 September 2022 (supplementary and grey literature). A follow-up database search was not undertaken due to the relatively small number of items published on this topic on an annual basis. The database search parameters are available, and the full search strategy and search filters used in the database search are provided in Appendix A. A complete PRISMA-S checklist [53] for reporting literature searches in systematic reviews is provided in Appendix B.

2.3.3 Screening

A PRISMA flow diagram of the search results is provided in Figure 2. Database search results (n=6,294) were imported into EPPI-Reviewer 4 [54] for deduplication, resulting in 5,041 records to be screened on title and abstract. The review team implemented the EPPI-Reviewer 4 'priority screening' feature during title and abstract screening. Priority screening utilises text mining to improve efficiencies in screening research abstracts for inclusion in systematic reviews by prioritising relevant abstracts for the screener based on their screening decisions. As screening continues, the programme learns which abstracts are more relevant, thus speeding up decision-making in this initial phase [54,55]. Double screening was initially carried out whereby each item was reviewed by two of the four screeners (NMG, LK, AF, and CW) using EPPI-Reviewer's 'multiple: auto-complete (code level)' priority screening setting. At various intervals throughout the priority screening process, individual inclusion/exclusion verdicts were compared where the verdicts did not agree. A consensus verdict was achieved through discussion and further examination of the papers. Once the screeners reached a plateau where 3 of the last 1,000 records were selected for inclusion, the team then switched to the 'single (auto-complete)' priority screening setting. For the remaining 435 records, one screener viewed and made inclusion/exclusion decisions. The plateau is depicted by the EPPI-Reviewer priority screening curve graph, which is available in Appendix C. As the concepts were complex, the team took a cautious approach so as not to exclude relevant studies. During title and abstract screening, items with no abstract were moved forward to the full-text assessment, unless the title or metadata indicated the study was completely out of scope (e.g. a conference report). Duplicate papers were flagged and one of each pair was excluded.

In total, 244 records were put forward for full-text screening, 5 of which we were unable to retrieve and were subsequently excluded. Two of three possible screeners (NMG, LK, CW) screened each item. Given the different approaches we applied to handling in vitro and in vivo studies in this review, items were included separately as 'laboratory' (n=33) and 'human' (n=19) studies. As with title and abstract screening, individual inclusion/exclusion verdicts were compared periodically where the verdicts did not agree, and consensus verdicts were achieved through further examination of the individual records and discussion between all three screeners. Where we were unclear about individual study eligibility due to missing information at full text screening stage, we contacted study authors to seek clarification. If study authors did not respond within two weeks from the initial email and one week after a reminder email, we excluded the study. Reasons for exclusion of items during full-text screening were recorded and are available in Appendix D.

2.4 Data extraction

Data were extracted from included in vivo studies independently by two of four reviewers (NMG, CW, LK, ÁT) into bespoke extraction forms, tailored to the study design. The extracted data were then agreed by

the two reviewers and third party arbitration was used to resolve disagreements. Although an essential part of medical research, in vitro studies of SUDs tell us what SUDs may or may not be put forward for testing in clinical settings and, as such, these studies only partially address the aims of this review. For this reason, we have provided in vitro study-level summary information on the study population, devices examined, and reprocessing outcomes (i.e. sterilisability, device safety, and device functioning) in Appendix E. Included in vitro studies were summarised in a Microsoft Excel spreadsheet. All extraction sheets were developed by NMG and piloted by two other review team members (CW or ÁT). Journal websites for the included articles were checked for supplementary data and errata. The following data were extracted:

- Study author and year of publication
- Study country of publication
- Study aim
- Study design
- Study health care setting
- Study data collection method
- Number of observations (as defined by the study authors)
- Duration of observations/time horizon
- Study device(s) characteristics: device name(s) (manufacturer and brand), device type (e.g. balloon catheter, laparoscopic instrument, tracheal suction tube, etc.), and device classification according to the Medical Device Coordination Group (MDCG) 2021-24 device risk classification system [56] (i.e. class I, class IIa, class IIb, and class III)
- Summary of the reprocessing process (including standards of device function and safety testing)
- Study perspective (if appropriate)
- Safety outcomes evaluated (using process – i.e. reprocessed SUDs – and direct patient outcomes) and their findings
- Environmental outcomes evaluated and their findings
- Cost items and their findings
- Method of determining costs
- Year(s) and currency that costs were based on
- Statistical or sensitivity tests, and
- Confounding and effect modification.

Verbatim extraction was completed where feasible, and care was taken when extracting numeric results. Where multiple time points, measures, or analyses were presented, all results that were compatible with each outcome domain in each study were extracted. Where information was missing, unclear, or conflicting, this was noted and a conservative approach was taken to any interpretations of conflicting information. In relation to the interchangeable units ppm (parts per million) and mg/L (milligrams per litre), we have used the units used by the original study authors in each case. Due to the heterogeneity of outcomes collected by study authors, device-specific outcomes were selected by members of the review team (NMG, CW, LK, JL) for each device group based on their prevalence across device-specific studies

and pertinence to patient or device safety or costs (see 0 for details of outcome selection). Only data for agreed selected outcomes were extracted.

2.5 Quality assessment

To minimise systematic and non-systematic errors, two reviewers independently assessed the quality of in vivo studies included, with any disagreements resolved by consensus. We did not use our assessment of bias results to exclude in vivo studies from the narrative analysis. In line with good practice recommendations, we used the assessment of bias to exclude in vivo studies from the meta-analysis [57]. Given that in vitro studies do not test the safety of reprocessed SUDs in humans, we did not undertake quality appraisal for in vitro studies.

2.5.1 Randomised and comparative studies

The Downs and Black checklist was designed to evaluate the methodological quality of both randomised and non-randomised comparative studies [58]. An adapted version of the checklist was employed in this review to quality appraise trial and before-and-after study designs. The original checklist consists of 27 items across the following methodological components: reporting, external validity, internal validity (bias and confounding), and power. Twenty-six items were rated either as yes (1) or no/unable to determine (0), and one item was rated on a 3-point scale (yes=2, partial=1, and no=0). The checklist has been ranked in the top six quality assessment tools suitable for use in systematic reviews [59] and has adequate internal consistency, test–retest reliability, inter-rater reliability and criterion validity.

We added the question “Was an attempt made to blind SUD user(s) to the intervention they delivered?”, rated either as yes (1) or no/unable to determine (0), to capture performance bias of those implementing SUD reprocessing. We also adapted the scoring for the question “Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?”, rating as yes (2) where the study was powered to detect a difference for at least one-half of the outcomes, including the primary outcome; partially (1) where the study was powered to detect a difference for the primary outcome only; and no/unable to determine (0) where the study was not powered to detect a difference for any outcome, or we could not tell whether power calculations were undertaken. These adaptations resulted in an overall total possible score of 30. We adapted our quality ratings to allow for the score changes as follows: excellent (27–30), good (21–26), fair (16–20), and poor (≤15); these ratings are in line with previously suggested categories [60].

2.5.2 Economic study designs

The quality of the included economic study designs was assessed using an adapted version of the Consensus Health Economic Criteria list (CHEC-list) [61]. The CHEC-list was developed for systematic reviews of full economic evaluations based on effectiveness (as opposed to economic modelling) studies using a consensus procedure between international experts [61]. The checklist contains 19 questions on different aspects of economic evaluations: for example, study design; time horizon; study perspective; type of costs and effectiveness measures that are included; the way these costs are measured and valued; incremental analysis of costs and outcomes; discounting; sensitivity analyses; authors’ conclusions; and generalisability of study results. Each question can be answered ‘yes’ or ‘no’. If the answer is ‘yes’, this means that the study either adequately performed the item of concern or reported the item in an appropriate way.

The economic studies identified in this systematic review were classified as cost studies rather than full economic evaluations, as study authors used a simple cost-calculator approach where they made various assumptions about the inputs to investigate whether these assumptions affected the overall estimates.

Since there are currently no quality appraisal tools specifically designed for these types of studies, adaptations to the CHEC-list were necessary in order to facilitate quality appraisal. Adaptations were made in consultation with two health economists (ÁT and PC) and informed by the Jacobs *et al.* review on this topic which adopted a similar approach to quality appraisal [22]. Specifically, we adapted Question 5 of the CHEC-list to read "Is the chosen time horizon/**duration of study observation period** appropriate to include relevant costs and consequences?" in order to reflect that the time horizon in studies included in this review was derived from the observation period. We removed the questions "Were all outcomes measured appropriately?", "Were all outcomes valued appropriately?", and "Are all future costs and outcomes discounted appropriately?" in line with the Jacobs *et al.* review [22] and given the absence of discounting in these studies. This resulted in a total possible score of 16, with quality ratings of high (>75% of items receiving a score of 1), moderate (between >50% and ≤75% of items receiving a score of 1), and low (≤50% of items receiving a score of 1), which is in keeping with previous research [62–64].

2.5.3 Life cycle assessment study designs

We employed a checklist proposed by Keil *et al.* [65] to critically appraise life cycle assessment (LCA) study designs. This is the first such critical appraisal tool in this area and was developed by study authors carrying out a systematic review on a similar topic, i.e. the environmental impact of switching from single-use to reusable medical devices. The checklist was based on German Institute for Standardization (*Deutsches Institut für Normung*; DIN) and International Organization for Standardization (ISO) standards DIN ISO 14040 and DIN ISO 14044, and oriented towards Lange *et al.*'s [66] checklist for carbon footprint assessments. The proposed checklist explores transparency in the communication of methods, results, and possible biases, and it consists of 22 criteria within 5 groups based on the LCA phases. In keeping with the approach to appraisal adopted by Keil *et al.*, we report the proportion of items individual study authors report information on, rather than using 'cut-off point' systems for classifying high, moderate, and low quality [65].

2.6 Data synthesis

Once extraction was completed, the items were organised by device risk category and then by device type. We report our findings in the order of risk classification of the devices, as described by the Medical Device Coordination Group (MDCG) 2021-24 guidance on the classification of medical device types and as recommended by the HPRA [53, 64]. Factors such as the degree of invasiveness, the part of the body affected, the duration of device use, and whether or not the device is active help to determine the risk classification, which ranges from I to III. Broadly speaking, the classifications are based on the potential for a deterioration in the health of the patient when the device is used (I: little risk; IIa: unlikely risk; IIb: potential risk of deterioration; III: risk of death) [53, 64]. Device type groupings were decided on qualitatively by the members of the research team, with decisions informed by existing published literature on this topic and our knowledge of individual medical fields (NMG, CW, LK, JL).

As set out in Section 2.1, in vitro studies did not go through all steps of the standard systematic review process. An overview of SUDs studied in vitro, and as this relates to in vivo studies, is reported in the main body of this review. Detailed reprocessing intervention information and other study characteristics are reported for each device group in Appendix E. Appendix E also provides a summary of individual study author conclusions and a summary of same by the HRB review authors. Following the overview of in vitro studies in the main body of the report, we provide an overview of vivo studies and report study characteristics by device types. Narrative and meta-analytic syntheses are also reported by device type.

2.6.1 Outcomes

A consensus approach was used to select review outcomes across device groups (0). Primary and secondary safety, cost, and environmental outcomes were selected for each device group. In broad terms across the groups, primary safety outcomes are those which can directly affect patient safety, e.g. complications, infections, reoperations, etc. Secondary safety outcomes were outcomes providing indirect evidence of adverse patient safety outcomes (e.g. procedure time, duration of hospital stay). Primary cost outcomes were those accounting for indirect safety, i.e. direct costs and costs related to safety outcomes such as patient complications, reoperations, procedure times, duration of hospital stay, or device life cycle costs. Secondary cost outcomes were those only providing direct costs, i.e. the cost of the reused device compared with the new device. Primary environmental outcomes were those which contribute to global warming, e.g. greenhouse gas emissions. Secondary environmental outcomes were individual health-related consequences attributable to global warming, e.g. respiratory effects.

2.6.2 Meta-analysis

For each outcome of interest, we completed an assessment of the feasibility of meta-analysis following published guidance [65, 66]. Studies were grouped first by device type and then by outcome. Following this, for each group of studies, comparability on the following variables was assessed in order:

1. Study quality
2. Populations (based on inspection of inclusion criteria and baseline participant characteristics)
3. Intervention (based on the number of reprocessing cycles), and
4. Outcome measures (based on definition and methods of measurement).

The details of the feasibility assessment are reported in Appendix G. The approach to meta-analysis for each individual study outcome was guided by the *Cochrane Handbook for Systematic Reviews of Interventions* [57]. Analyses were performed in Review Manager Software version 5.4. A random-effects model was used due to study-level variability identified across meta-analytic feasibility assessments [57] (Appendix G). The random-effects model meta-analyses take into account both study sample size and the estimate of between-study variation (i.e. study heterogeneity) when weighting study effects. Meta-analytic odds ratios (ORs) and mean differences (MDs) are expressed with 95% confidence intervals (CIs). Odds ratios were calculated for categorical outcomes, and mean differences were calculated for continuous outcomes [57]. Higgins and Thompson's I^2 statistic, defined as the percentage of variability in the effect sizes that is not caused by sampling error [57], was used to quantify between-study heterogeneity.

2.6.3 Narrative synthesis

Narrative synthesis employs a textual approach that provides an analysis of the relationships within and between studies and an overall assessment of the robustness of the evidence [40]. Narrative synthesis of studies was undertaken where results of the meta-analytic feasibility assessment indicated that studies were too diverse (either clinically or methodologically) to combine in a meta-analysis. Where meta-analysis was possible, aspects of narrative synthesis were required in order to fully interpret the collected evidence.

We followed the steps for synthesis approaches where meta-analysis was not possible as set out in the *Cochrane Handbook for Systematic Reviews of Interventions* [57]. We undertook structured reporting of effects, calculating a standardised effect measure for safety outcomes (i.e. odds ratios for categorical outcomes and mean differences for continuous outcomes) including reporting of the number of observed events in the total population (categorical outcomes) and the mean/median with standard deviations (SDs) for continuous events. We then summarised effect estimates after ruling out other possible

narrative synthesis approaches [57]. Due to differences in cost outcome data and reporting, it was not possible to produce standardised effect measures of same, and therefore we only report results reported by the original study authors. It was also not possible to produce standardised effect measures for environmental outcome data, and therefore we also reported these using primary study author data only. Cost outcome data are reported for the original year of study (i.e. were not standardised to account for country or year of study). After discussing this issue with health economists within the HRB (ÁT) and externally at the Health Information and Quality Authority (PC and KW), we did not believe that standardising estimates to 2023 euro would result in costs useful and comparable to these same studies being undertaken in a eurozone country at the time of the current systematic review. This is due to likely technological differences since many of the reviewed studies were undertaken and other unmeasured factors, compounded by the fact that most studies collected direct costs only. Rather, we focused on broader trends of cost differences reported across studies at individual points in time across the regions under review.

2.6.4 Grading of Recommendations, Assessment, Development and Evaluations

The GRADE system [70] was employed in order to grade the quality of evidence and strength of the recommendations. While the quality assessment process described in Section 2.5 rates the quality of individual studies, the GRADE approach is used to rate the quality of evidence for eligible primary outcomes across the included studies. In line with best practice, we only apply GRADE assessments to primary review outcomes [70].

Under the GRADE system, the initial certainty of the evidence is determined based on study design, with well-designed randomised controlled trials providing a high degree of certainty and well-designed observational studies providing a moderate or low degree of certainty depending on the study design (longitudinal cohort, case-control, or cross-sectional survey). The level of certainty is then adjusted upwards or downwards based on a number of factors. Ultimately, a body of evidence related to an outcome receives one of four grades (high, moderate, low, or very low), reflecting the level of certainty we may have that the true effect is similar to, or substantially different from, the estimate of the effect.

Following the GRADE approach, we downgraded the quality of the evidence considering five criteria (risk of bias, inconsistency, indirectness, imprecision, and publication bias), and for outcomes where the five criteria were met, we upgraded the quality of the evidence based on three criteria (large consistent effect, dose response, and confounders reducing effect size). Following the GRADE system, we employed the Revised Cochrane risk-of-bias tool for randomized trials to determine the risk of bias for randomised controlled trials [71] and the Risk Of Bias In Non-randomized Studies – of Interventions assessment tool to determine the risk of bias for non-randomised study designs [72]. For all GRADE domains, NMG carried out the initial assessment and AB validated initial assessments. The reviewers agreed final decisions for each risk of bias and each GRADE domain through a consensus process.

Each study starts at 10 points and can lose 0, 1, or 2 points for each of the five downgrading criteria. However, if all five criteria are met, it can gain an additional 1 or 2 points for large consistent effect, and 1 point for dose response and/or confounders reducing effect size. The reasons for downgrading are:

1. Risk of bias, which takes account of study design considering the hierarchy of evidence and the methodological quality of the study
2. Inconsistency, which considers both clinical and statistical heterogeneity that cannot be controlled for in the analysis
3. Indirectness, which considers the comparator intervention and whether it is the current gold standard or is being used as a proxy, and which also considers the population, intervention, and outcome

4. Imprecision, which takes account of the size of the variance and the optimal effect size and is closely related to sample size and the number of events of interest, and
5. Publication bias, which is a systematic underestimation or overestimation of the underlying beneficial or harmful effect due to the selective publication of studies. In this systematic review, risk of publication bias was evaluated indirectly, since funnel plots are not recommended for meta-analysis containing a small number of studies [73].

The decision to upgrade should only rarely be made if no serious limitations are present in any of these areas and should only be made after full consideration and in the context of reasons to downgrade. The reasons for upgrading are:

1. Large or very large estimates of the magnitude of an intervention or exposure effect
2. The presence of a dose–response gradient, which may increase certainty in the findings of observational studies, and
3. Where all plausible residual confounding from observational studies may be working to increase or decrease the demonstrated effect, if no effect was observed.

3 Findings

3.1 Search results

A total of 6,294 items were retrieved during database searching in Embase (n=2,079), MEDLINE (n=3,617), Dimensions (n=304), the Cochrane Library (n=3), and the Cochrane Trials Register (n=291). Following deduplication in EPPI-Reviewer, 5,041 records remained and were screened on title and abstract. Of the 239 record eligible for retrievals, all records underwent full-text screening as 5 eligible items were unobtainable and therefore excluded. Grey literature, including trial register results (n=119), German-language material (n=48), and results from reference and forward citation chasing of included papers and systematic reviews (n=110) resulted in (n=1,603) records which were also imported into EPPI-Reviewer for title, abstract, and full-text screening. Of the 1,790 supplementary and grey literature records, 189 records underwent full-text screening as 22 eligible items were unobtainable and therefore excluded. Details of the screening process are presented in Figure 2. During full-text screening, it was decided to exclude dialyser studies identified, as the review team determined that their reuse was only for the same patient (i.e. single-patient reuse) rather than for reuse on different patients. Eleven in vitro studies were subsequently excluded on this basis, whereas no in vivo studies were excluded.

A total of 51 studies, reported in 52 papers meeting the review eligibility criteria, were identified for inclusion from all searches (see Figure 2 for PRISMA flow diagram; see Appendix A for an overview of the literature search strategy and results; and see Appendix H for the full list of included papers). As shown in Figure 2, 33 in vitro studies partially addressed reprocessing safety and 19 in vivo studies addressed reprocessing safety, costs, and environmental effects after reuse in humans.

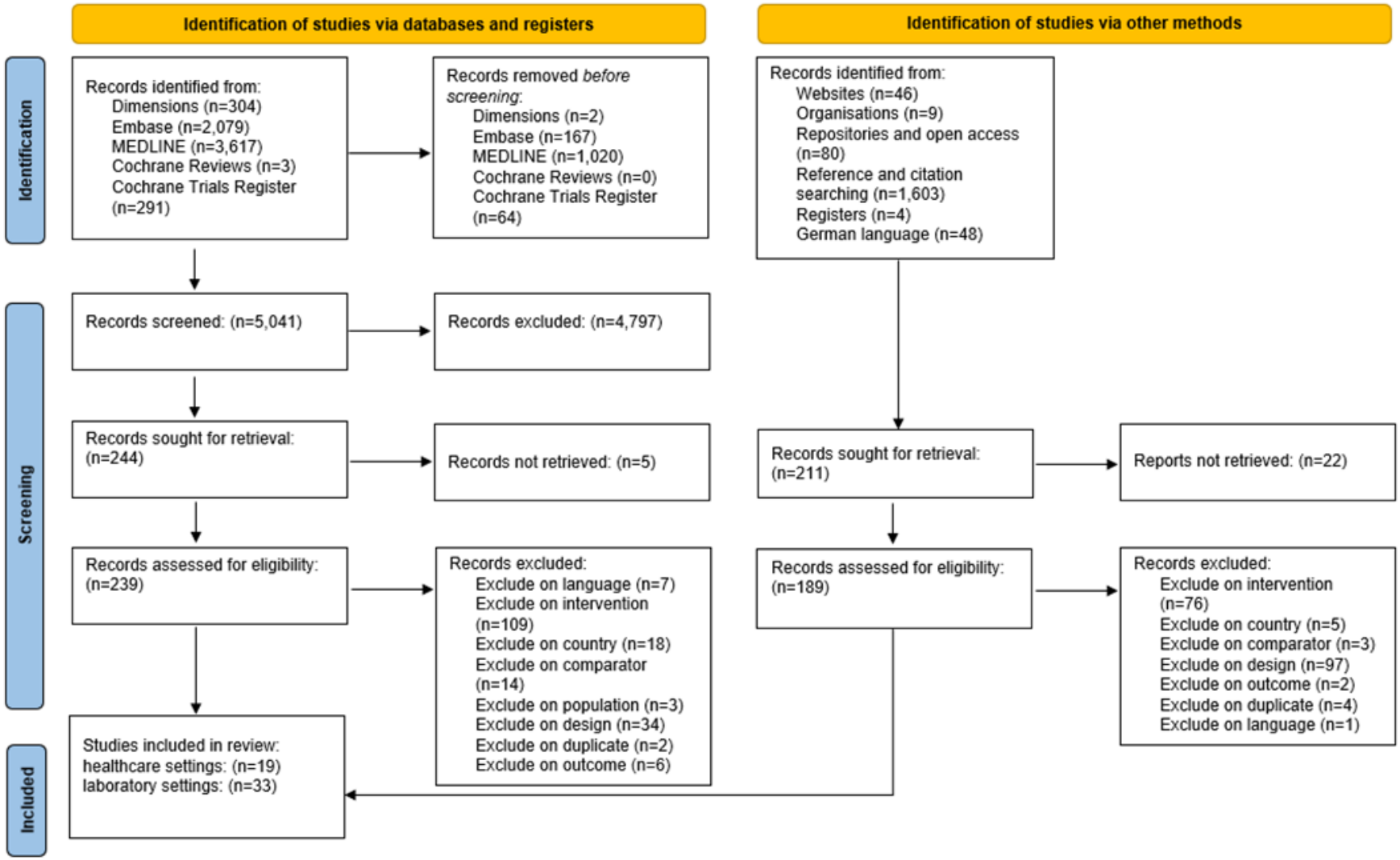

Figure 2 PRISMA flow chart of search results

Source: Page *et al.*, 2021 [42]

3.2 Overview of included studies

In total, 23 SUDs were identified; 12 devices were identified across 33 in vitro studies and 16 devices were identified across 19 in vivo studies spanning all device risk categories. In vitro studies were published between 1995 and 2022, and in vivo studies were published between 1994 and 2021. Descriptions of individual identified devices are available in Appendix I.

For reporting and synthesis, devices were grouped by their purpose. For example, the endoscopic and laparoscopic device group included seven different SUDs. There were 10 different groups of devices across in vitro and in vivo studies. The device groups categorised as risk class I were surgical face masks and respirators (in vitro: n=19 studies); external fixator devices (in vivo: n=3 studies); deep vein thrombosis compression sleeves (in vivo: n=1 study); and pulse oximeters (in vivo: n=1 study). The device groups categorised as risk class IIa were ophthalmic devices (in vivo: n=1 study); surgical instruments for grasping and cutting (in vitro: n=4 studies; in vivo: n=1 study); and endoscopic and laparoscopic devices (in vitro: n=2 studies; in vivo: n=5 studies). There was one type of risk class IIb device: internal fixator devices (in vitro: n=1 study). The device groups categorised as risk class III devices were implantable cardiac devices (in vivo: n=4 studies) and cardiac catheter and cannula devices (in vitro: n=7 studies; in vivo: n=6 studies).

A breakdown of the types of outcomes reported across devices is provided in Table 2, and a visual description of the available outcome types across device groups and individual devices is presented in Figure 3 and Figure 4, respectively.

Table 3 and **Error! Reference source not found.** provide an overview of the individual studies by device type across risk classifications. The countries of origin for the 33 in vitro and 19 in vivo studies had a broadly similar breakdown. Specifically, for both in vitro and in vivo studies, the highest proportion of studies were undertaken in the USA (in vitro: n=16, 49%; in vivo: n=9, 47%), followed by in the EU (in vitro: n=10, 30%; in vivo: n=7, 37%), and finally by other OECD countries (in vitro: n=7, 21%; in vivo: n=3, 16%) (see Table 3 and

Table 4 Overview of in vivo studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)	Outcome			
				Patient safety	Device safety	Costs	Environmental
External fixator devices (n=3): risk class I							
Dirschl and Smith (1998) [102]	USA	Observational case matched (prospective (intervention) and retrospective (comparison))	Name: External fixators Model: Not reported Brands: Synthes, Orthofix, Hoffman, Ace Fisher, EBI, Joint Biomechanics, Richards	✓	✓	X	X
Horwitz *et al.* (2007) [103]	USA	Cost study	Name: External fixation clamps, posts, and rods Model: Not reported	X	X	✓	X

Table 4 Overview of in vivo studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)	Outcome			
				Patient safety	Device safety	Costs	Environmental
			Brand: Stryker Hoffmann				
Sung *et al.* (2008) [104]	USA	Randomised controlled trial	Name: External fixators Model: Not reported Brand: Stryker Hoffmann		✓	✓	✓	X
Compression sleeves (n=1): risk class I							
Unger and Landis (2016) [105]	USA	Hybrid life cycle assessment	Name: Deep vein thrombosis compression sleeve Model: Not reported Brand: Wilson-Cook	X		X	✓	✓
Pulse oximeters (n=1): risk class I							
Unger and Landis (2016) [105]	USA	Hybrid life cycle assessment	Name: Pulse oximeter Model: Not reported Brand: Not reported	X		X	✓	✓
Ophthalmic devices (n=1): risk class IIa							
Perry (1996) [106]	USA	Prospective observational study	Name: Disposable phaco needle tips Model: Not reported Brand: Not reported	✓		✓	X	X
Surgical instruments for grasping and cutting (n=1): risk class IIa							
Unger and Landis (2016) [100]	USA	Hybrid life cycle assessment	Name: Arthroscopic shaver Model: Not reported Brand: Not reported	X		X	✓	✓
Endoscopic and laparoscopic devices (n=5): risk class IIa							
Brady *et al.* (2017) [107]	USA	Observational case matched (prospective (intervention) and retrospective (comparison))	Name: Laparoscopic sealer/divider Model: Blunt tip laparoscopic sealer/divider 5 mm to 37 cm Brand: LigaSure™	✓		✓	✓	X
de Sousa *et al.* (2018) [108]	Portugal	Retrospective observational study	Name: Ultrasonic scissors	✓		X	✓	X

Table 4 Overview of in vivo studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)	Outcome			
				Patient safety	Device safety	Costs	Environmental
			Models: 5 mm/36 cm C/rod Brand: Harmonic ACE® Name: Linear suture machine Models: No. 55/60-3.8, No. 75/80-3.8, and No. 75/80-4.8 Brand: GIA Covidien™				
Kozarek *et al.* (1999) [109]	USA	Cost study	Name: Sphincterotome Models: Braided wise UTS-30 and CT-30 Brand: Wilson-Cook	X	X	✓	X
Mihanović *et al.* (2021) [110]	Croatia	Randomised controlled trial	Name: Ultrasonic scissors/scalpels/shears Model: With adaptive tissue technology and Ethicon Endo-Surgery Brand: Harmonic ACE®	✓	✓	X	X
Unger and Landis (2016) [100]	USA	Hybrid life cycle assessment	Name: Ultrasonic scissors/scalpels/shears Model: Not reported Brand: Harmonic Name: Laparoscopic sealer/divider Model: Not reported Brand: Ligasure™ Name: Endoscopic trocar Model: Not reported Brand: Not reported Name: Ultrasonic scissor tip Model: Not reported Brand: Harmonic	X	X	✓	✓
Implantable cardiac devices (n=4): risk class III							

Table 4 Overview of in vivo studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)	Outcome			
				Patient safety	Device safety	Costs	Environmental
Enache *et al.* (2019) [111]	Romania	Retrospective observational study	Name: Implantable cardioverter defibrillator Models: Single chamber, dual chamber, biventricular/cardiac resynchronisation therapy defibrillator (CRT-D) Brands: Biotronik, St. Jude, Medtronic, Guidant, Ela Medical, Boston Scientific	✓	✓	X	X
Linde *et al.* (1998) [112]	Sweden	Retrospective case matched study	Name: Pacemaker Model: Not reported Brand: Not reported	✓	✓	X	X
Nava *et al.* (2013) [113]	Mexico	Retrospective and prospective observational study (no further details)	Name: Pacemaker Model: Not reported Brand: Not reported	✓	✓	X	X
Şoşdean *et al.* (2015) [114]	Romania	Retrospective observational study	Name: Biventricular cardiac implantable electronic device Model: Not reported Brand: Not reported	✓	✓	X	X
Cardiac catheters/cannulas (n=6): risk class III							
Browne *et al.* (1997) [115]	USA	Observational case matched (prospective (intervention) and retrospective (comparison))	Name: Balloon catheter Model: Not reported Brands: Guidant Corporation and Cordis Corporation	✓	X	X	X
Leung *et al.* (2019) [116]	UK	Observational case matched (prospective	Name: Circular mapping ablation catheter	✓	✓	X	X

Table 4 Overview of in vivo studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)	Outcome			
				Patient safety	Device safety	Costs	Environmental
		(intervention) and retrospective (comparison))	Model: 22-pole Lasso® 2515 eco Variable Catheter with an electro-anatomic system (Carto®, Biosense-Webster®) Brand: Stryker®				
Mak *et al.* (1996) [117]	USA	Cost study	Name: Balloon catheter Model: Not reported Brand: Not reported	X	X	✓	X
Plante *et al.* (1994) [118]	Canada	Prospective observational study	Name: Balloon catheter Model: Not reported Brand: Not reported	✓	✓	X	X
Tessarolo *et al.* (2009) [119]	Italy	Cost minimisation	Name: Coronary angioplasty and electrophysiology catheters Model: Not reported Brand: Not reported	X	X	✓	X
Unverdorben *et al.* (2005) [120]	Germany	Randomised controlled trial	Name: Balloon catheter Model: standard monorail system, featuring a proximal stainless steel hypotube shaft with LEAPTM, a nylon derivative, serving as balloon material Brand: Not reported	✓	✓	X	X

Note: Of the studies that provided cost data, only those of good quality and with meaningful results were included in the table and analysis.

The results of in vitro and in vivo study designs are reported separately throughout the remainder of the findings section. Section 3.3 presents the summary results of in vitro studies, and Section 3.4 presents the synthesis of the in vivo studies.

). Identified in vivo study designs were: randomised controlled trials (n=3); prospective observational studies (n=2); retrospective observational studies (n=4); observational studies using prospective and retrospective data (n=5); costing studies (n=3); cost minimisation studies (n=1), and LCA studies (n=1) (see

Table 4 Overview of in vivo studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)	Outcome			
				Patient safety	Device safety	Costs	Environmental
External fixator devices (n=3): risk class I							
Dirschl and Smith (1998) [102]	USA	Observational case matched (prospective (intervention) and retrospective (comparison))	Name: External fixators Model: Not reported Brands: Synthes, Orthofix, Hoffman, Ace Fisher, EBI, Joint Biomechanics, Richards		✓	✓	X	X
Horwitz *et al.* (2007) [103]	USA	Cost study	Name: External fixation clamps, posts, and rods Model: Not reported Brand: Stryker Hoffmann	X		X	✓	X
Sung *et al.* (2008) [104]	USA	Randomised controlled trial	Name: External fixators Model: Not reported Brand: Stryker Hoffmann		✓	✓	✓	X
Compression sleeves (n=1): risk class I							
Unger and Landis (2016) [105]	USA	Hybrid life cycle assessment	Name: Deep vein thrombosis compression sleeve Model: Not reported Brand: Wilson-Cook	X		X	✓	✓
Pulse oximeters (n=1): risk class I							
Unger and Landis (2016) [105]	USA	Hybrid life cycle assessment	Name: Pulse oximeter Model: Not reported Brand: Not reported	X		X	✓	✓
Ophthalmic devices (n=1): risk class IIa							
Perry (1996) [106]	USA	Prospective observational study	Name: Disposable phaco needle tips Model: Not reported Brand: Not reported	✓		✓	X	X
Surgical instruments for grasping and cutting (n=1): risk class IIa							
Unger and Landis (2016) [100]	USA	Hybrid life cycle assessment	Name: Arthroscopic shaver Model: Not reported Brand: Not reported	X		X	✓	✓
Endoscopic and laparoscopic devices (n=5): risk class IIa							

Table 4 Overview of in vivo studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)	Outcome			
				Patient safety	Device safety	Costs	Environmental
Brady *et al.* (2017) [107]	USA	Observational case matched (prospective (intervention) and retrospective (comparison))	Name: Laparoscopic sealer/divider Model: Blunt tip laparoscopic sealer/divider 5 mm to 37 cm Brand: LigaSure™	✓	✓	✓	X
de Sousa *et al.* (2018) [108]	Portugal	Retrospective observational study	Name: Ultrasonic scissors Models: 5 mm/36 cm C/rod Brand: Harmonic ACE® Name: Linear suture machine Models: No. 55/60-3.8, No. 75/80-3.8, and No. 75/80-4.8 Brand: GIA Covidien™	✓	X	✓	X
Kozarek *et al.* (1999) [109]	USA	Cost study	Name: Sphincterotome Models: Braided wise UTS-30 and CT-30 Brand: Wilson-Cook	X	X	✓	X
Mihanović *et al.* (2021) [110]	Croatia	Randomised controlled trial	Name: Ultrasonic scissors/scalpels/shears Model: With adaptive tissue technology and Ethicon Endo-Surgery Brand: Harmonic ACE®	✓	✓	X	X
Unger and Landis (2016) [100]	USA	Hybrid life cycle assessment	Name: Ultrasonic scissors/scalpels/shears Model: Not reported Brand: Harmonic Name: Laparoscopic sealer/divider Model: Not reported Brand: Ligasure™	X	X	✓	✓

Table 4 Overview of in vivo studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)	Outcome			
				Patient safety	Device safety	Costs	Environmental
			Name: Endoscopic trocar Model: Not reported Brand: Not reported Name: Ultrasonic scissor tip Model: Not reported Brand: Harmonic				
Implantable cardiac devices (n=4): risk class III							
Enache *et al.* (2019) [111]	Romania	Retrospective observational study	Name: Implantable cardioverter defibrillator Models: Single chamber, dual chamber, biventricular/cardiac resynchronisation therapy defibrillator (CRT-D) Brands: Biotronik, St. Jude, Medtronic, Guidant, Ela Medical, Boston Scientific	✓	✓	X	X
Linde *et al.* (1998) [112]	Sweden	Retrospective case matched study	Name: Pacemaker Model: Not reported Brand: Not reported	✓	✓	X	X
Nava *et al.* (2013) [113]	Mexico	Retrospective and prospective observational study (no further details)	Name: Pacemaker Model: Not reported Brand: Not reported	✓	✓	X	X
Şoşdean *et al.* (2015) [114]	Romania	Retrospective observational study	Name: Biventricular cardiac implantable electronic device Model: Not reported Brand: Not reported	✓	✓	X	X

Table 4 Overview of in vivo studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)	Outcome			
				Patient safety	Device safety	Costs	Environmental
Cardiac catheters/cannulas (n=6): risk class III							
Browne *et al.* (1997) [115]	USA	Observational case matched (prospective (intervention) and retrospective (comparison))	Name: Balloon catheter Model: Not reported Brands: Guidant Corporation and Cordis Corporation	✓	X	X	X
Leung *et al.* (2019) [116]	UK	Observational case matched (prospective (intervention) and retrospective (comparison))	Name: Circular mapping ablation catheter Model: 22-pole Lasso® 2515 eco Variable Catheter with an electro-anatomic system (Carto®, Biosense-Webster®) Brand: Stryker®	✓	✓	X	X
Mak *et al.* (1996) [117]	USA	Cost study	Name: Balloon catheter Model: Not reported Brand: Not reported	X	X	✓	X
Plante *et al.* (1994) [118]	Canada	Prospective observational study	Name: Balloon catheter Model: Not reported Brand: Not reported	✓	✓	X	X
Tessarolo *et al.* (2009) [119]	Italy	Cost minimisation	Name: Coronary angioplasty and electrophysiology catheters Model: Not reported Brand: Not reported	X	X	✓	X
Unverdorben *et al.* (2005) [120]	Germany	Randomised controlled trial	Name: Balloon catheter Model: standard monorail system, featuring a proximal stainless steel hypotube shaft with LEAPTM, a nylon derivative, serving as balloon material Brand: Not reported	✓	✓	X	X

Note: Of the studies that provided cost data, only those of good quality and with meaningful results were included in the table and analysis.

The results of in vitro and in vivo study designs are reported separately throughout the remainder of the findings section. Section 3.3 presents the summary results of in vitro studies, and Section 3.4 presents the synthesis of the in vivo studies.

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Table 2 Overview of devices and study outcomes

Device	Image	In vitro safety studies (S)	In vivo safety studies (S+)	Cost studies (C)	Environmental impact studies (E)	Overlap of S, S+, C, and/or E
Risk class I devices						
Surgical face masks		6				S
Respirators		18				S
External fixators			2	2		S+, C
Compression sleeves				1	1	C, E
Pulse oximeters				1	1	C, E
Risk class IIa devices						
Phaco needles			1			S+
Biopsy forceps		1				S
Arthroscopic shavers		2		1	1	S, C, E
Electrosurgical pencils		1				S
Coagulation probes		1				S
Sphincterotomes		1		1		S, C

Table 2 Overview of devices and study outcomes

Device	Image	In vitro safety studies (S)	In vivo safety studies (S+)	Cost studies (C)	Environmental impact studies (E)	Overlap of S, S+, C, and/or E
Laparoscopic sealers/dividers			1	2	1	S+, C, E
Ultrasonic scissors/scalpels/shears			2	2	1	S+, C, E
Linear suture machine			1	1		S+, C
Endoscopic trocars				1	1	C, E
Ultrasonic scissor tips				1	1	C, E
Risk class IIb devices						
Internal fixators		1				S
Risk class III devices						
Pacemakers			2			S+
Implantable cardioverter defibrillators			2			S+
Cardiac cannulas		1				S
Electrophysiology polyurethane catheters		1		1		S, C
Cardiac ablation catheters		1	1			S, S+
Cardiac balloon catheters		4	3	1		S, S+, C

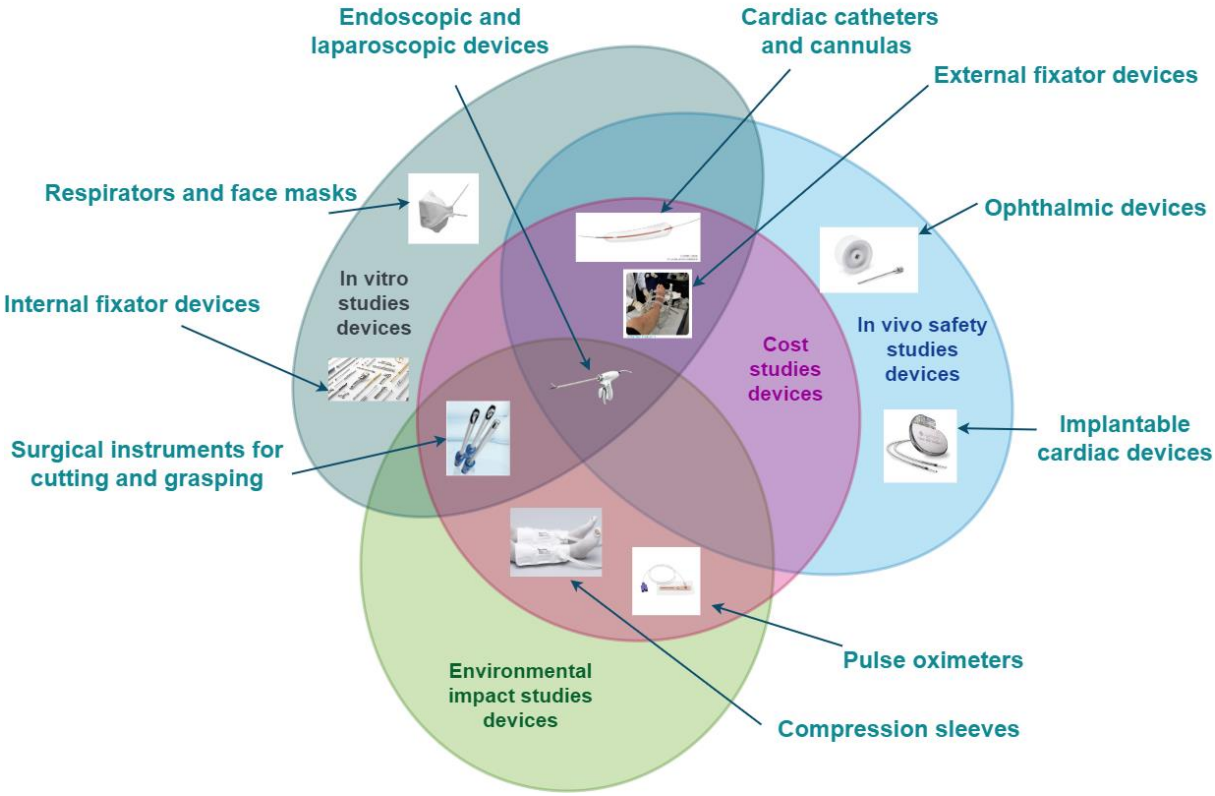

Figure 3 Overview of groups of devices by outcomes

Figure 3 presents the available outcome data types (safety (both in vitro and in vivo), cost, and environmental impact) across the 10 device groups. Of the studies that provided cost data, only those with good-quality and meaningful results were included. Only cost data included in our synthesis are shown. As shown in Figure 3, only studies reporting on the endoscopic and laparoscopic group of devices assess all of these broad outcomes.

Figure 4 presents the available outcome data types across the 23 individual devices. It shows that many of the devices have been tested in vitro only (n=10), that three devices had available data on safety and cost only (external fixators, linear suture machines and cardiac balloon catheters), and that only two devices (ultrasonic scissors/scalpels/shears and laparoscopic sealers/dividers) had available safety, cost, and environmental impact data. Of the studies that provided cost data, only those with good-quality and meaningful results were included.

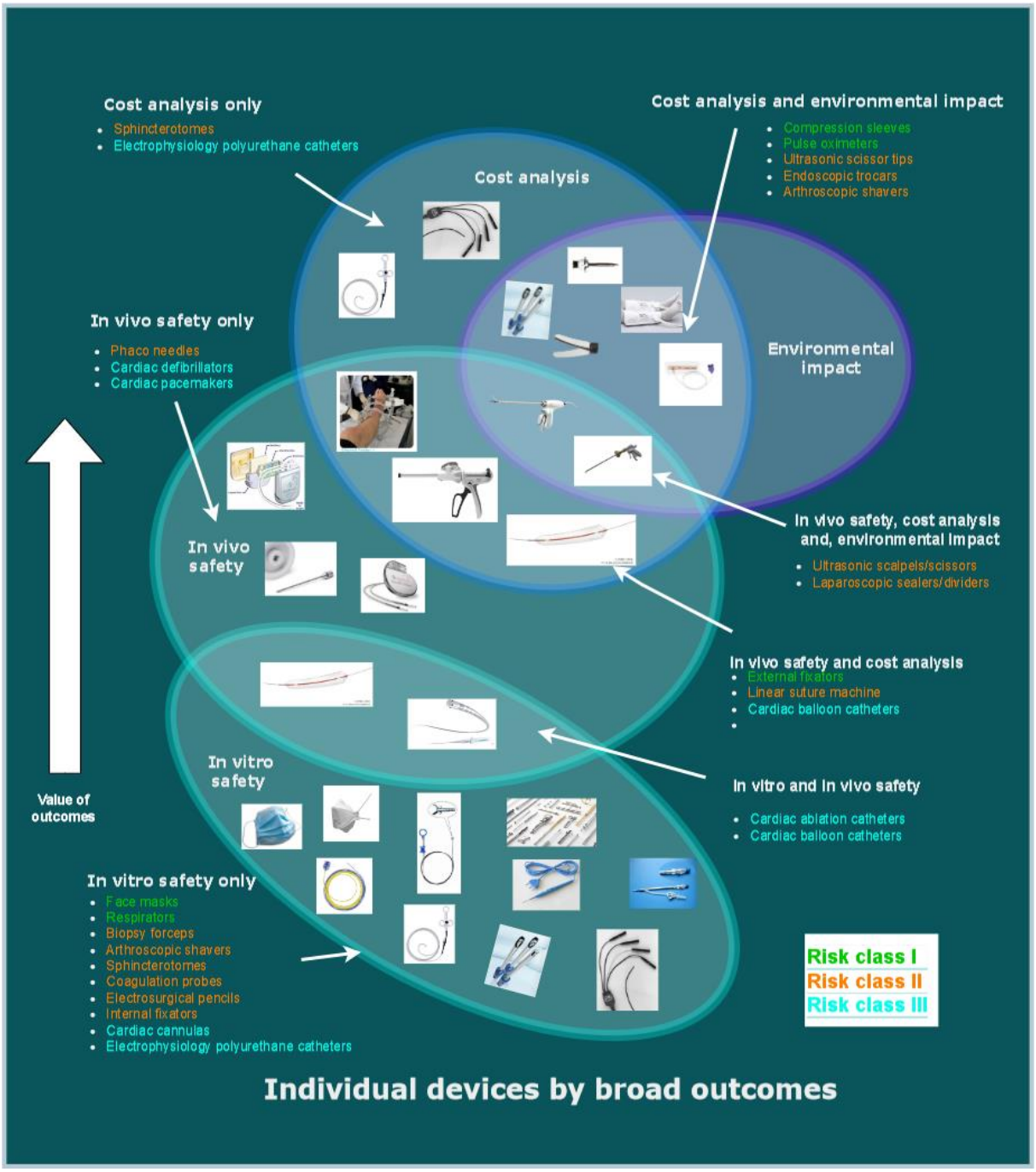

Figure 4 In vitro and in vivo devices by study outcomes

Table 3 Overview of in vitro studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)
Respirators and surgical face masks (n=19): risk class I			
Aljabo *et al.* (2020) [74]	Canada	Non-randomised controlled trial (prospective)	Name(s): Respirators Model(s): 860, 1860s, 1870+, Vflex 910 Brand(s): 3M

Table 3 Overview of in vitro studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)
Christie-Holmes *et al.* (2021) [75]	Canada	Non-randomised controlled trial (prospective)	Name(s): Respirators Model(s): 8210, 9210+ Brand(s): 3M
Harskamp *et al.* (2020) [76]	Netherlands	Non-randomised controlled trial (prospective)	Name(s): Respirators Model(s): Aura 1862+, Aura 9322+ ZZM002, 2920V, Safe Worker 1016 Brand(s): 3M, Maco Pharma, San Huei
Kumar *et al.* (2021) [77]	Canada	Non-randomised controlled trial (prospective)	Name(s): Respirators Model(s): Moulded 1860, 8210, 1510 Pleated Aura 1870, Vfex 1804 Pleats Plus 1054 Brand(s): 3M, Moldex, Aearo
Levine *et al.* (2021) [78]	USA	Non-randomised controlled trial (prospective)	Name(s): Respirators Model(s): Fluidshield 46727, 46827, 1860, 1860S, 1870, 9210, Cardinal Health*, Gerson 2130*, 1730* (*models fit-tested only) Brand(s): Halyard, 3M, Cardinal Health*, Gerson* (*fit-tested only)
Manning *et al.* (2021) [79]	USA	Non-randomised controlled trial (prospective)	Name(s): Respirators Model(s): 1870 Brand(s): 3M
Narayanan *et al.* (2021) [80]	USA	Non-randomised controlled trial (prospective)	Name(s): Respirators and polypropylene fabric Model(s): 8210, non-woven polypropylene fabrics similar to 07048 Brand(s): 3M
Smith *et al.* (2021) [81]	USA	Non-randomised controlled trial (prospective)	Name(s): Respirators Model(s): 1860, 1870+, 8511 Brand(s): Not reported, but all 3M masks
Van der Vossen *et al.* (2022) [82]	Netherlands	Experimental	Name(s): Respirators Model(s): Not reported Brand(s): Not reported
Vernez *et al.* (2020) [83]	Switzerland	Experimental	Name(s): Respirators Model(s): 6923, 1862 Brand(s): 3M
Viscusi *et al.* (2009) [84]	USA	Experimental	Name(s): Respirators Model(s): Random sample of 9 National Institute for Occupational Safety and Health (NIOSH)-approved respirators (3 respirator models, 3 surgical respirator models, and 3 P100 models) Brand(s): Not reported
Yuen *et al.* (2022) [85]	USA	Experimental	Name(s): Respirators Model(s): 1860, Aura™ 1870+, 801, 120B Brand(s): 3M, Bacou Willson, BLS

Table 3 Overview of in vitro studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)
Zulauf *et al.* (2020) [86]	USA	Experimental	Name(s): Respirators Model(s): 1860 Brand(s): 3M
Bernard *et al.* (2020) [87]	France	Experimental	Name(s): Respirators and surgical masks Model(s): Including THF type II R 3 Plis, THF type IIR CA1960, RP2_Mand, NRD type IIR 2192S-WH Brand(s): CA Diffusion, Medicom
Lendvay *et al.* (2022) [88]	USA	Experimental 2 arms	Name(s): Respirators and surgical masks Model(s): Fluidshield-46727, 1860, 1870+, Type II 14683, Type IIR F2100 Level 2 Brand(s): Halyard, 3M, ASTM
Pascoe *et al.* (2020) [89]	United Kingdom (UK)	Experimental	Name(s): Respirators and surgical masks Model(s): cosy cloud, fluidshield Brand(s): Hardshell, Honeywell, Kimberly-Clark, Generic
Yap *et al.* (2022) [90]	USA	Experimental	Name(s): Surgical surgical face masks Model(s): SKU 810484847 Brand(s): Canuxi
Lordelo *et al.* (2022) [91]	Portugal	Experimental	Name(s): Respirators, surgical masks, and cloth masks Model(s): GB2626- 2006 9501+, BV 465-001, Concept 2 B Brand(s): 3M, Bastos Viegas, Borgstena
Schwan *et al.* (2021) [92]	USA	Experimental	Name(s): Respirators, surgical surgical face masks, and cloth face masks Model(s): Not reported Brand(s): Not reported
Surgical instruments for grasping and cutting (n=4): risk class IIa			
Cogdill and Quaglia (1998) [93]	USA	Experimental	Name(s): Biopsy forceps Model(s): Microvasive Brand(s): Boston Scientific
King *et al.* (2006) [94]	USA	Experimental	Name(s): Arthroscopic shavers Model(s): Varied Brand(s): Dyonics Smith and Nephew
Kobayashi *et al.* (2009) [95]	Japan	Experimental	Name(s): Arthroscopic shavers 1. Shaver blades 2. Shaver abraders Model(s): 1. Full radius 5.5 2. 4.0 mm Brand(s): Smith and Nephew
Tessarolo et al. (2017) [96]	Italy	Experimental	Name(s): Electrosurgical pencils

Table 3 Overview of in vitro studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)
Endoscopic and laparoscopic devices (n=2): risk class IIa			
Kozarek *et al.* (1997) [97]	USA	Experimental	Name(s): Sphincterotomes Model(s): Ultra taper sphincterotome UTS-30 single-lumen, CT-30 double-lumen Brand(s): Wilson-Cook Medical, Inc.
Roach *et al.* (1999)† [98]	USA	Experimental	Name(s): Argon plasma coagulation probes Model(s): 2.3 mm, 220 cm Brand(s): ERBE Inc.
Internal fixator devices (n=1): risk class IIb			
Danesi *et al.* (2011)† [99]	Italy	Experimental	Name(s): Internal fixator devices (plates, screws, staples) Model(s): Not reported Brand(s): Not reported
Cardiac catheters/cannulas (n=7): risk class III			
Brown *et al.* (2001) [47]	USA	Experimental	Name(s): Balloon catheters (angioplasty) Model(s): Not reported Brand(s): Not reported
Bloom *et al.* (1997)† [100]	USA	Experimental	Name(s): Venous and arterial cannulas Model(s): Dual- and single-stage venous return cannulas (32F and 36F), Sarns, Soft Flow 8.0 mm Brand(s): Research Medical Incorporated, 3M
Grimandi *et al.* (1996) [101]	France	Experimental	Name(s): Balloon catheters (coaxial, rapid exchange, on-wire) Model(s): Prism, Pronto, Quick, Lightning Brand(s): ACS, Bard, Baxter, Cordis
Mussivand *et al.* (1995) [49]	Canada	Experimental	Name(s): Balloon catheters Model(s): Not reported Brand(s): Not reported
Tessarolo *et al.* (2004)‡ [51]	Italy	Experimental	Name(s): Ablation catheters Model(s): RF Conductr Multi Curve Brand(s): Medtronic
Lerouge *et al.* (2000)‡ [48]	Canada	Experimental	Name(s): Electrophysiology polyurethane catheters Model(s): Not reported Brand(s): Cordis Corp., a division of J&J Medical Products
Unverdorben *et al.* (2003)‡ [50]	Germany	Experimental	Name(s): Balloon catheters (percutaneous transluminal coronary angioplasty catheters) Model(s): Proximal stainless steel hypotube shaft with LEAP™, proximal stainless-steel core covered by a polyimide Brand(s): Not reported

Table 3 Overview of in vitro studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)

* Pre-cleaning processes undertaken before sterilisation varied and are not presented here.

† These studies also included some cost outcomes but were not considered to comply with the criteria for economic studies.

‡ The sterility of these devices was assumed based on existing FDA and EU approval standards.

Table 4 Overview of in vivo studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)	Outcome			
				Patient safety	Device safety	Costs	Environmental
External fixator devices (n=3): risk class I							
Dirschl and Smith (1998) [102]	USA	Observational case matched (prospective (intervention) and retrospective (comparison))	Name: External fixators Model: Not reported Brands: Synthes, Orthofix, Hoffman, Ace Fisher, EBI, Joint Biomechanics, Richards		✓	✓	X	X
Horwitz *et al.* (2007) [103]	USA	Cost study	Name: External fixation clamps, posts, and rods Model: Not reported Brand: Stryker Hoffmann	X		X	✓	X
Sung *et al.* (2008) [104]	USA	Randomised controlled trial	Name: External fixators Model: Not reported Brand: Stryker Hoffmann		✓	✓	✓	X
Compression sleeves (n=1): risk class I								
Unger and Landis (2016) [105]	USA	Hybrid life cycle assessment	Name: Deep vein thrombosis compression sleeve Model: Not reported Brand: Wilson-Cook	X		X	✓	✓
Pulse oximeters (n=1): risk class I								
Unger and Landis (2016) [105]	USA	Hybrid life cycle assessment	Name: Pulse oximeter Model: Not reported Brand: Not reported	X		X	✓	✓
Ophthalmic devices (n=1): risk class IIa								
Perry (1996) [106]	USA	Prospective observational study	Name: Disposable phaco needle tips Model: Not reported Brand: Not reported	✓		✓	X	X

Table 4 Overview of in vivo studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)	Outcome			
				Patient safety	Device safety	Costs	Environmental
Surgical instruments for grasping and cutting (n=1): risk class IIa							
Unger and Landis (2016) [100]	USA	Hybrid life cycle assessment	Name: Arthroscopic shaver Model: Not reported Brand: Not reported	X	X	✓	✓
Endoscopic and laparoscopic devices (n=5): risk class IIa							
Brady *et al.* (2017) [107]	USA	Observational case matched (prospective (intervention) and retrospective (comparison))	Name: Laparoscopic sealer/divider Model: Blunt tip laparoscopic sealer/divider 5 mm to 37 cm Brand: LigaSure™	✓	✓	✓	X
de Sousa *et al.* (2018) [108]	Portugal	Retrospective observational study	Name: Ultrasonic scissors Models: 5 mm/36 cm C/rod Brand: Harmonic ACE® Name: Linear suture machine Models: No. 55/60-3.8, No. 75/80-3.8, and No. 75/80-4.8 Brand: GIA Covidien™	✓	X	✓	X
Kozarek *et al.* (1999) [109]	USA	Cost study	Name: Sphincterotome Models: Braided wise UTS-30 and CT-30 Brand: Wilson-Cook	X	X	✓	X
Mihanović *et al.* (2021) [110]	Croatia	Randomised controlled trial	Name: Ultrasonic scissors/scalpels/shears Model: With adaptive tissue technology and Ethicon Endo-Surgery Brand: Harmonic ACE®	✓	✓	X	X
Unger and Landis (2016) [100]	USA	Hybrid life cycle assessment	Name: Ultrasonic scissors/scalpels/shears Model: Not reported	X	X	✓	✓

Table 4 Overview of in vivo studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)	Outcome			
				Patient safety	Device safety	Costs	Environmental
			Brand: Harmonic Name: Laparoscopic sealer/divider Model: Not reported Brand: Ligasure™ Name: Endoscopic trocar Model: Not reported Brand: Not reported Name: Ultrasonic scissor tip Model: Not reported Brand: Harmonic				
Implantable cardiac devices (n=4): risk class III							
Enache *et al.* (2019) [111]	Romania	Retrospective observational study	Name: Implantable cardioverter defibrillator Models: Single chamber, dual chamber, biventricular/cardiac resynchronisation therapy defibrillator (CRT-D) Brands: Biotronik, St. Jude, Medtronic, Guidant, Ela Medical, Boston Scientific	✓	✓	X	X
Linde *et al.* (1998) [112]	Sweden	Retrospective case matched study	Name: Pacemaker Model: Not reported Brand: Not reported	✓	✓	X	X
Nava *et al.* (2013) [113]	Mexico	Retrospective and prospective observational study (no further details)	Name: Pacemaker Model: Not reported Brand: Not reported	✓	✓	X	X

Table 4 Overview of in vivo studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)	Outcome			
				Patient safety	Device safety	Costs	Environmental
Şoşdean *et al.* (2015) [114]	Romania	Retrospective observational study	Name: Biventricular cardiac implantable electronic device Model: Not reported Brand: Not reported	✓	✓	X	X
Cardiac catheters/cannulas (n=6): risk class III							
Browne *et al.* (1997) [115]	USA	Observational case matched (prospective (intervention) and retrospective (comparison))	Name: Balloon catheter Model: Not reported Brands: Guidant Corporation and Cordis Corporation	✓	X	X	X
Leung *et al.* (2019) [116]	UK	Observational case matched (prospective (intervention) and retrospective (comparison))	Name: Circular mapping ablation catheter Model: 22-pole Lasso® 2515 eco Variable Catheter with an electro-anatomic system (Carto®, Biosense-Webster®) Brand: Stryker®	✓	✓	X	X
Mak *et al.* (1996) [117]	USA	Cost study	Name: Balloon catheter Model: Not reported Brand: Not reported	X	X	✓	X
Plante *et al.* (1994) [118]	Canada	Prospective observational study	Name: Balloon catheter Model: Not reported Brand: Not reported	✓	✓	X	X
Tessarolo *et al.* (2009) [119]	Italy	Cost minimisation	Name: Coronary angioplasty and electrophysiology catheters Model: Not reported Brand: Not reported	X	X	✓	X
Unverdorben *et al.* (2005) [120]	Germany	Randomised controlled trial	Name: Balloon catheter Model: standard monorail system, featuring a proximal stainless steel	✓	✓	X	X

Table 4 Overview of in vivo studies

Author (year)	Country	Study design	Device name(s), model(s), brand(s)	Outcome			
				Patient safety	Device safety	Costs	Environmental
			hypotube shaft with LEAP™, a nylon derivative, serving as balloon material Brand: Not reported				

Note: Of the studies that provided cost data, only those of good quality and with meaningful results were included in the table and analysis.

The results of in vitro and in vivo study designs are reported separately throughout the remainder of the findings section. Section 3.3 presents the summary results of in vitro studies, and Section 3.4 presents the synthesis of the in vivo studies.

3.3 In vitro studies

3.3.1 In vitro study characteristics

Thirty-three studies undertaken in laboratory settings examined five groups of SUDs: respirators and surgical face masks (n=19), surgical instruments for grasping and cutting (n=4), endoscopic and laparoscopic devices (n=2), internal fixator devices (n=1), and cardiac catheters and cannulas (n=7).

Eighteen studies contaminated devices artificially [49,75,77,79–82,84–92,97,98], nine studies reprocessed devices which had been used on humans during clinical care [47,76,78,93–95,99,101], and three studies contaminated devices using a combination of both [74,83,100]. Three studies used new, unused devices to examine function testing after sterilisation only [48,50,51]. The justification for including these new, unused devices is reported in Section 2.2. In one study [47] which contaminated devices using artificial means from animals and after clinical use in humans, we only report on data from contamination after clinical use in humans.

In total, 14 sterilisation methods were tested; the most common methods in the in vitro studies were ethylene oxide (n=12) and hydrogen peroxide (n=7). The method of sterilisation differed across surgical face mask and respirator studies, with 12 methods tested, and across cardiac catheter and cannula studies, with four methods tested. Sterilisation methods were more consistent across other device types, with all studies examining reprocessing of surgical instruments for grasping and cutting [93–95] and of endoscopic and laparoscopic devices [96–98] using ethylene oxide. Most studies (n=24) tested the effects of a single sterilisation method while the remaining nine studies compared device function and safety outcomes across two or more different sterilisation methods [48,77,81,84,85,87–89,91].

Oversight criteria for reprocessing were developed by the research teams in 17 studies [47–49,51,77,78,80–84,87–89,91,92,95], while 7 studies used existing policies in place and regulated locally (e.g. by individual hospitals) [75,76,96–99,101], and 6 were described as being in line with requirements set by national regulatory bodies (e.g. the FDA) [50,79,90,93,94,100]. As such, 6 studies may have followed processes in line with Article 17[2] of the EU MDR but none of these provided sufficient

information to allow the authors of this report to say this with certainty. Two studies followed sterilisation requirements set by the research team and function testing requirements set by recognised standards [85,86] and one study followed recognised standards for both sterilisation and function testing [74].

Devices were exposed and assessed after a number of reprocessing cycles, which differed by the outcome of interest, i.e. sterilisation or function testing. Surgical face mask and respirator studies exposed the devices to between 1 and 10 sterilisation cycles and between 1 and 50 function testing cycles. Surgical instruments for grasping and cutting studies exposed the devices to between one and three cycles for both elements. Endoscopic and laparoscopic devices were exposed to between 1 and 11 reprocessing cycles for both elements. The one internal fixator device study exposed the devices to two sterilisation cycles and one function testing cycle. Cardiac catheters and cannulas were exposed to between 1 and 14 sterilisation cycles and between 1 and 6 function testing cycles.

3.3.2 In vitro study findings

As explained in Section 2.6, we did not carry out quality appraisal or synthesis of in vitro studies. The in vitro study findings are presented in tables summarising the primary study authors' main conclusions about the study in order to answer this evidence review's research questions. The summary tables are located in Appendix E. An overview of findings by device type is reported in Sections 3.3.2.1 to 3.3.2.5.

3.3.2.1 Surgical face masks and respirators

The findings of these studies were device, brand, and model specific, and dependent on the reprocessing protocol used. The reprocessing of respirators and surgical face masks (risk class I) showed diverse findings over 19 studies. Therefore, caution should be applied when drawing any conclusions. Some studies showed that respirators and surgical face masks were safely and effectively reprocessed for at least one cycle in vitro using some (but not all) of the sterilisation methods, and for some (but not all) brands and models of devices. Successful methods identified by more than one study included hydrogen peroxide (n=5) [75,78,81,84,91], moist heat (n=2) [77,87], and ozone (n=2) [79,92].

There were contradictory findings between studies for dry heat [77,85,87,89,90], bleach [84,91], autoclave [76,85], ultra violet light [81–84], and microwave-generated steam [84,86,89,91]. Other successful methods assessed by only one study were ethylene oxide [84], methylene blue with and without light [88], gravity steam [74], and corona discharge [80]. One study assessing microwaves [84] and one study using ethanol [81] found that these methods did not effectively reprocess the tested devices. Many authors stated that reuse should only be considered in emergency scenarios. Further explanation is provided in Appendix E (*Table **44***).

3.3.2.2 Surgical instruments for grasping and cutting

Four studies examining three devices (risk class IIa) – biopsy forceps [93], electrosurgical pencils [96] and arthroscopic shavers [94,95] – determined them not to be reprocessable using ethylene oxide after having been used clinically. Further explanation is provided in Appendix E (*Table **45***).

3.3.2.3 Endoscopic and laparoscopic devices

Two studies examined the reprocessing of two different endoscopic and laparoscopic devices using ethylene oxide, found that the two devices – sphincterotomes [97] and argon plasma coagulation probes [98] – were deemed suitable for 1 and up to 10 reprocessing cycles, respectively, after artificial contamination. Further explanation is provided in Appendix E (*Table **48***).

3.3.2.4 Internal fixator devices

One study of internal fixator devices [99] determined that these devices are reprocessable for one cycle after having been used clinically. Further explanation is provided in Appendix E (Table 50).

3.3.2.5 Cardiac catheters and cannulas

Six studies assessing cardiac catheters found that reprocessing in vitro caused increasing damage to the catheters after each reprocessing cycle and that further research was required to determine acceptable levels of damage [47–51,101]. One study found that two models of cannulas can be effectively and safely reprocessed for at least five cycles in vitro [100] indicating that testing should be carried out on humans. Further explanation is provided in Appendix E (Table 52).

3.4 In vivo studies

As reported in **Error! Reference source not found.**, 19 studies were undertaken in healthcare settings e xamining 8 groups of SUDs. The studies examined three risk class I devices: external fixator devices (n=3), compression sleeves (n=1), and pulse oximeters (n=1); three risk class IIa devices: ophthalmic devices (n=1), arthroscopic shavers (n=1) and endoscopic and laparoscopic devices (n=5); and two risk class III devices: implantable cardiac devices (n=4) and cardiac catheters and cannulas (n=6). Fourteen studies provided data on clinical safety (patient and/or device), 8 studies provided meaningful cost data, and 1 study provided environmental impact data. Seven studies were identified which followed reprocessing standards set by the FDA or the EU MDR. Five of these studies may have followed processes and obligations in line with Article 17[2] of the EU MDR. However, the study authors did not provide sufficient information for the authors of this report to conclude this with certainly.

The results are presented by device type in the order of their risk classification. For each device type, data are reported for the types of outcome(s) available (i.e. safety, cost, and/or environmental impacts). Results are reported using narrative synthesis and, where appropriate and possible, using meta-analysis. The results of the meta-analysis feasibility assessment (Appendix G) indicated that meta-analysis was possible for one safety outcome in the implantable cardiac device group. The main reasons other safety outcomes were deemed unsuitable for meta-analysis were that there were too few studies available measuring an individual outcome, there was low primary study quality with respect to design and implementation, the outcome of interest had a non-normal distribution, or studies contributing data were excluded as they reporting no events in either study arm. Due to the limited available cost and environmental outcome data, these outcomes were not deemed suitable for meta-analysis or a feasibility assessment of same.

3.4.1 Risk class I devices

3.4.1.1 External fixator devices

External fixators are used to treat and stabilise bone fractures and can be used in conjunction with internal fixators if necessary. External fixation is a relatively safe, minimally invasive procedure involving a small incision in soft tissue, drilling, and the placement of pins around the bone fracture, which are then attached to external rods and clamps. The external fixators are left in place for several weeks while the bone heals. The most common complications are pin tract infections and loosening of the pins or fixation frames [121].

3.4.1.1.1 Characteristics of external fixator device studies

As indicated in *Table **5***, 2 studies were available examining the safety of reusing reprocessed external fixator components [102,104] and two studies were available examining the cost of this practice [103,104]. The reprocessing process adopted by Horwitz *et al.* [103] and Sung *et al.* [104] was approved by the FDA, with reprocessing undertaken outside of the hospital setting. The study by Dirschl and Smith

[102] was undertaken prior to the establishment of an FDA SUD reprocessing approval process and reprocessing was undertaken in the hospital's central sterile services department (CSSD). Taken together, the reprocessing processes followed by Horwitz *et al.* [103] and Sung *et al.* [104] may possibly be considered in line with the requirements of article 17[2] of the EU MDR. However, the study authors did not provide the level of detail required for the authors of this report to say this with certainty. Sung *et al.* compared new devices with those put through a single reprocessing cycle [104]. In contrast, both Dirschl and Smith and Horwitz *et al.* put forward devices for testing for up to three reprocessing cycles (i.e. a maximum of four uses).

3.4.1.1.2 Safety outcomes from external fixator device studies

As indicated by the meta-analysis feasibility assessment (Appendix G), external fixator device safety outcome data could not be analysed using meta-analysis, and therefore outcome data are presented narratively here. One safety outcome (pin tract infection rate) was collected by both studies examining safety outcomes, while Dirschl and Smith collected additional patient safety data (reoperation rates) and Sung *et al.* collected additional device safety outcomes (loss of fixation and loosening of components).

Although the absolute rate of infection was higher in the study by Sung *et al.* than in the study by Dirschl and Smith, the overlapping confidence intervals (CIs) across studies indicated similar odds of infection across studies. That the CI 'crossed 1' in both studies examining pin tract infections denotes that neither study found significant differences in the odds of infection between once-reprocessed devices and new SUDs (Table 6). Neither study examining safety outcomes reported significant differences in the additional outcomes collected (Table 6). Sung *et al.* also reported no difference in the rate of loss of device fixation or loosening of device components between reused devices and new SUDs.

Although Dirschl and Smith put devices through up to two reprocessing cycles (i.e. three uses), the study authors did not report outcomes by the number of device reuses/reprocessing cycles, and therefore it is unclear how many reprocessing cycle the reported results pertain to. Also, as reported in Table 6, Dirschl and Smith's study received an overall rating of poor quality with respect to design and conduct, while Sung *et al.*'s study received a rating of good quality. Detailed reporting of the study quality assessments is available in Appendix J.

3.4.1.1.3 Cost outcomes from external fixator device studies

Two studies – Horwitz *et al.* [103] and Sung *et al.* [104] – reported on one cost outcome: savings incurred by the hospital during the study period. Both studies captured US dollar (US$) costs during a similar time frame (between 2001 and 2005) and assumed that a similar proportion (between 75% and 80%) of devices could pass reprocessing requirements and be reused. Horwitz *et al.* reported that reuse of reprocessed devices resulted in savings of 25% on external components of external fixator devices and of 21% when accounting for the cost of internal components of fixation devices. In contrast, Sung *et al.* only reported savings based on device cost differences, without accounting for the actual device reuse rate (*Table **7***).

3.4.1.1.4 Environmental outcomes from external fixator device studies

No studies were identified providing data on the environmental impact of reusing reprocessed external fixator devices.

Table 5 Characteristics of external fixator device studies

Author (year)	Device name(s), model(s), brand(s)	Study location (where devices (re)used	Eligible participants	Intervention (reprocessing) overview			Study data collection period	Outcomes reported
				Reprocessing approval	Internal or external reprocessing	Number of reprocessing cycles		
External fixator devices: risk class I								
Dirschl and Smith (1998) [102]	Name: External fixators Models: Not reported Brands: Synthes, Orthofix, Hoffman, Ace Fisher, EBI, Joint Biomechanics, Richards	Hospital (trauma centre)	All patients, all fracture types	Meets criteria set by research team	Internal	1–2	Intervention: July 1994 to October 1995 Comparison: March 1993 to July 1994	Pin tract infection rate, reoperation rates
Horwitz et al. (2007) [103]	Name: External fixation clamps, posts, and rods Model: Not reported Brand: Stryker Hoffmann	Hospital (trauma centre)	Not reported	FDA approved	External: Original device manufacturer	1–3	Intervention: May to December 2005	Cost savings
Sung et al. (2008) [104]	Name: External fixators Model: Not reported Brand: Stryker Hoffmann	Hospital (trauma centre)	Patients aged 18 years and over, with orthopaedic trauma association type A or C with significant shortening and metaphyseal	FDA approved	External: Independent company	Not reported	Intervention: November 2001 to May 2004 Comparison: November 2001 to May 2004	Pin tract infection rate, loss of fixation, loosening during follow-up, cost savings

Table 5 Characteristics of external fixator device studies

Author (year)	Device name(s), model(s), brand(s)	Study location (where devices (re)used	Eligible participants	Intervention (reprocessing) overview			Study data collection period	Outcomes reported
				Reprocessing approval	Internal or external reprocessing	Number of reprocessing cycles		
			diaphyseal dissociation					

Table 6 Safety outcomes for external fixator device studies

Author (year)	Comparison	Overall study quality appraisal result and rating	Available outcome data							
			n/N, %	Standardised metric (odds ratio (OR) (95% CI))	n/N, %	Standardised metric (OR (95% CI))	n/N, %	Standardised metric (OR (95% CI))	n/N, %	Standardised metric (OR (95% CI))
			Pin tract infection		**Reoperation rate**		**Loss of fixation**		**Loosening of components**	
Dirschl and Smith (1998) [102]	Reprocessed (no more than twice) compared with first use of a new device	13/30 Poor quality	Intervention: 4/65, 6% Comparison: 5/69, 7%	OR=0.85 (0.24–3.03)	Intervention: 9/65, 14% Comparison: 6/69, 9% *p*=0.32	OR=1.69 (0.56–5.04)	Not collected in study		Not collected in study	
Sung *et al.* (2008) [104]	Reprocessed once (i.e. second use of device) compared with first use of a new device	24/30 Good quality	Intervention: 24/46, 52% Comparison: 23/50, 46% *p*=0.320	OR=1.13 (0.75–1.71)	Not collected in study		Intervention: 2/46, 8% Comparison: 2/50, 4% *p*=0.70	OR=1.09 (0.15–8.08)	Intervention: 4/333, 1% Comparison: 5/413, 1% *p*=1.00	OR=0.99 (0.26–3.72)

Note: Where proportions were unavailable, these were calculated by the research team. For binary outcomes, ORs were calculated from the reported summary statistics extracted from the study.

Table 7 Cost outcomes for external fixator device studies

Author (year)	Comparison n/N devices	Costed items per outcome	Currency and year of costs	Overall study quality appraisal score and rating	Available outcome data	
					Cost per device and/or total	Total cost difference during the study period (actual)
					Savings during study period	
Horwitz *et al.* (2007) [103]	N=not reported Reprocessed (n=474) compared with new (n=not reported)	New device Reprocessed device (average 75% reprocessing pass rate, up to three cycles)	US$ Intervention: 2004–2005 Comparison: 2003–2004	6/16 Low quality	Intervention: 50% of new device cost Comparison: Not reported	25% of the cost of the reused components 21% on the total external fixation system (reused and new components)
Sung *et al.* (2008) [104]	N=96 Reprocessed (n=46) compared with new (n=50)	New device Reprocessed device	US$ 2001–2004	24/30 Good quality	Distal radius Intervention: US$982 per device Comparison: US$2,120 per device Pilon Intervention: US$1,225 per device Comparison: US$2,741 per device Plateau	Distal radius (23 reused devices): US$26,174, 46% Pilon (14 reused devices): US$21,224, 45% Plateau (9 reused devices): US$18,054, 45% Total: US$65,452, 45%

Table 7 Cost outcomes for external fixator device studies

Author (year)	Comparison n/N devices	Costed items per outcome	Currency and year of costs	Overall study quality appraisal score and rating	Available outcome data	
					Cost per device and/or total	Total cost difference during the study period (actual)
					Intervention: US$1,608 per device Comparison: US$3,614 per device	

3.4.1.2 Deep vein thrombosis compression sleeves

Deep vein thrombosis compression sleeves are used to help prevent blood clots in the deep veins of the legs. The devices use cuffs around the legs that fill with air and squeeze the legs. This increases blood flow through the veins of the legs and helps prevent blood clots [6].

3.4.1.2.1 Characteristics of deep vein thrombosis compression sleeve study

As indicated in Table 8, one study was available examining the reuse of reprocessed deep vein thrombosis compression sleeves. The reprocessing process described by the study authors [105] was undertaken by an external reprocessing company. The study did not provide sufficient information to determine the extent reprocessing processes and obligations followed aligned with those set out in the EU MDR. The study authors compared new devices with those put through up to five reprocessing cycles in relation to the environmental and financial benefits [105].

3.4.1.2.2 Safety outcomes from deep vein thrombosis compression sleeve study

No studies were identified providing data on the safety of reusing reprocessed deep vein thrombosis compression sleeves.

3.4.1.2.3 Cost outcomes from deep vein thrombosis compression sleeve study

Unger and Landis performed a life cycle cost analysis (LCCA) to model the economic impacts of varying levels of reprocessing at their study hospital. The items costed were: the price of each device (in 2013 US$), quantity of each device used on an annual basis, waste disposal costs at US$0.14 per kilogram of waste generated (SUDs only), and reprocessing markdown for each device at 50% of the original device cost. Compared with first use (n=6,427 device pairs), the cost savings after one reuse (n=3,213 device pairs) was approximately US$72,000; this increased to approximately US$98,000 with two reuses (n=2,142 device pairs), approximately US$110,000 with three reuses (n=1,607 device pairs), approximately US$118,000 with four reuses (n=1,285 device pairs), and approximately US$122,000 with five reuses (n=1,071 device pairs), demonstrating diminishing incremental savings after each reprocessing cycle. Of the seven devices examined in Unger and Landis's study, deep vein thrombosis compression sleeves had the highest potential for cost savings [105].

3.4.1.2.4 Environmental outcomes from deep vein thrombosis compression sleeve study

Normalised global warming (NGW) was lower for one reuse (NGW=approximately 0.28), two reuses (NGW=approximately 0.18), three reuses (NGW=approximately 0.14), four reuses (NGW=approximately 0.11), and five reuses (NGW=approximately 0.08) of deep vein thrombosis compression sleeves compared with SUDs (NGW=approximately 0.55).

The normalised carcinogenic chemical level (NCCL) was lower for one reuse (NCCL=approximately 0.08), two reuses (NCCL=approximately 0.05), three reuses (NCCL=approximately 0.04), four reuses (NCCL=approximately 0.03), and five reuses (NCCL=approximately 0.02) of deep vein thrombosis compression sleeves compared with SUDs (NCCL=approximately 0.17).

The normalised non-carcinogenic chemical level (NNCL) was lower for one reuse (NNCL=approximately 0.28), two reuses (NNCL=approximately 0.18), three reuses (NNCL=approximately 0.12), four reuses (NNCL=approximately 0.11), and five reuses (NNCL=approximately 0.09) of deep vein thrombosis compression sleeves compared with SUDs (NNCL=approximately 0.53).

The normalised respiratory effects (NREs) were lower for one reuse (NRE=approximately 0.39), two reuses (NRE=approximately 0.26), three reuses (NRE=approximately 0.19), four reuses

(NRE=approximately 0.17), and five reuses (NRE=approximately 0.02) of deep vein thrombosis compression sleeves compared with SUDs (NRE=approximately 0.78).

Of the seven devices examined in Unger and Landis's study, deep vein thrombosis compression sleeves had the highest impact on the environment and human health due to the material used to fabricate these devices and the volume of devices used and reprocessed [105].

Table 8 Characteristics of deep vein thrombosis compression sleeve study

Author (year)	Device name(s), model(s), brand(s)	Study location (where devices (re)used	Eligible participants	Intervention (reprocessing) overview			Study data collection period	Outcomes
				Reprocessing approval	Internal or external reprocessing	Number of reprocessing cycles		
Unger and Landis (2016) [105]	Name: Deep vein thrombosis compression sleeves Model: Not reported Brand: Wilson-Cook	Hospital	Patients attending a general medical and surgical hospital	Not reported	External: Independent company	1–5	Intervention: 2013 Comparison: 2013	Cost outcomes and environmental impacts: global warming impacts, human health impacts (carcinogenic, non-carcinogenic, respiratory effects)

3.4.1.3 Pulse oximeters

A pulse oximeter is used to measure the oxygen saturation levels of the blood by passing small beams of light through the blood in the finger and measuring changes in light absorption in oxygenated or deoxygenated blood [17].

3.4.1.3.1 Characteristics of pulse oximeter device study

As reported in Table 9, one study was available examining the reuse of reprocessed pulse oximeter devices. The reprocessing process described by the study authors [105] was undertaken by an external reprocessing company. The study did not provide sufficient information to determine the extent reprocessing processes and obligations followed aligned with those set out in the EU MDR. The study authors compared new devices with those put through up to five reprocessing cycles in relation to the environmental and cost outcomes [105].

3.4.1.3.2 Safety outcomes from pulse oximeter device study

No studies were identified providing data on the safety impact of reusing reprocessed pulse oximeter devices.

3.4.1.3.3 Cost outcomes from pulse oximeter device study

Unger and Landis performed an LCCA in order to model the economic impacts of varying levels of reprocessing at their study hospital. The items costed were: the price of each device (in 2013 US$), quantity of each device used on an annual basis, waste disposal costs at US$0.14 per kilogram of waste generated (SUDs only), and reprocessing markdown for each device at 50% of the original device cost. Compared with first use (n=2,351 devices), the cost savings for pulse oximeter devices after one reuse (n=1,175 devices) was approximately US$27,500; this increased to approximately US$36,000 with two reuses (n=784 devices), to approximately US$41,000 with three reuses (n=588 devices), to approximately US$43,000 with four reuses (n=470 devices), and to approximately US$45,000 with five reuses (n=392 devices), demonstrating diminishing incremental savings after each reprocessing cycle.

3.4.1.3.4 Environmental outcomes from pulse oximeter device study

NGW was approximately <0.01 lower for once-reused pulse oximeter devices, and this reduction decreased for each subsequent reuse (two to five reuses) compared with SUDs (NGW=approximately 0.2). NCCL, NNCL, and NRE were <0.05 lower or showed no change for one reuse and subsequent reuses of reprocessed pulse oximeter devices compared with SUDs (NCCL=approximately 0.01; NNCL=approximately <0.005; NRE=approximately 0.01).

Table 9 Characteristics of pulse oximeter study

Author (year)	Device name(s), model(s), brand(s)	Study location (where devices (re)used	Eligible participants	Intervention (reprocessing) overview			Study data collection period	Outcomes reported
				Reprocessing approval	Internal or external reprocessing	Number of reprocessing cycles		
Unger and Landis (2016) [105]	Name: Pulse oximeter Model: Not reported Brand: Not reported	Hospital	Patients attending a general medical and surgical hospital	Not reported	External: Independent company	1–5	Intervention: 2013 Comparison: 2013	Cost outcomes and environmental impacts: global warming impacts, human health impacts (carcinogenic, non-carcinogenic, respiratory effects)

3.4.2 Risk class IIa devices

3.4.2.1 Ophthalmic devices

One type of ophthalmic device was identified as an SUD in our literature search. Disposable phacoemulsification needles (commonly referred to as 'phaco needles') are used during a phacoemulsification procedure, which is the extraction of a cataract by breaking down the cataract via a very small incision using an ultrasonic probe and removing the cataract by suctioning it out via the phaco needle [16].

3.4.2.1.1 Characteristics of ophthalmic device study

As indicated in Table 10, one study was available examining the reuse of reprocessed phaco needle tips. The study by Perry [106] was undertaken prior to the establishment of FDA approval processes for SUD reprocessing, and the needle tip reprocessing was undertaken at the hospital CSSD. Therefore, the processes followed were not comparable to Article 17[2] of the EU MDR. The study author tested phaco needle tips for up to four reprocessing cycles (i.e. for a maximum of five uses)

Table 10). The number of devices available for reuse reduced with each reprocessing cycle; 86% of all devices were available for reuse after one reprocessing cycle, 50% of all devices were available for reuse after two reprocessing cycles, 23% were available for reuse after three reprocessing cycles, and 3% were available for reuse after four reprocessing cycles.

3.4.2.1.2 Safety outcomes from ophthalmic device study

As only one study is available contributing data on phaco needle tip reprocessing and reuse safety, outcome data are reported as a narrative synthesis by the HRB authors. The study author did not define an outcome of interest as part of the study design and reported no intraoperative problems or complications attributable to phaco needle tips in the single-use or reused device groups. No specific postoperative complications were identified prior to study implementation and no complications associated with the single-use or reused device groups were reported on the day after the surgery, or at 2 weeks, 1 month, and 6 months post-operation. Across all device use groups (one to five uses), phacoemulsification procedure time was most frequently between 1.01 and 2.00 minutes or 2.01 and 3.00 minutes (Table 11) (Figure 5). The study author did not report statistical associations between phacoemulsification time and the number of device reuses, but stated that there was no association [106].

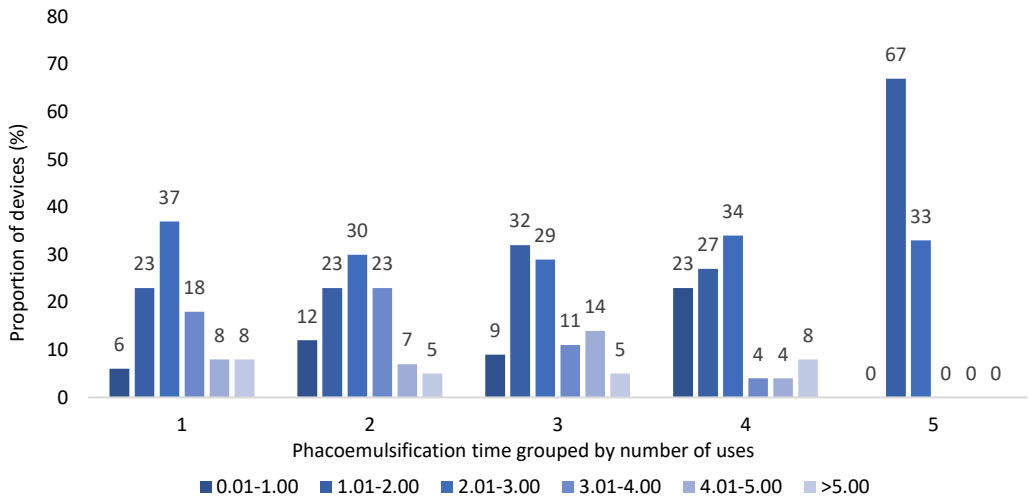

Figure 5 Proportion of devices with different phacoemulsification procedure duration times by number of device uses

3.4.2.1.3 Cost outcomes from ophthalmic device study

No studies were identified providing data on the financial impacts of reusing reprocessed phaco needle tips.

3.4.2.1.4 Environmental outcomes from ophthalmic device study

No studies were identified providing data on the environmental impacts of reusing reprocessed phaco needle tips.

Table 10 Characteristics of ophthalmic device study

Author (year)	Device name(s), model(s), brand(s)	Study location (where devices (re)used	Eligible participants	Intervention (reprocessing) overview			Study data collection period	Outcomes reported
				Reprocessing approval	Internal or external reprocessing	Number of reprocessing cycles		
Perry (1996) [106]	Name: Disposable phaco needle tips Model: Not reported Brand: Not reported	Hospital	Patients with cataracts who underwent extracapsular cataract extraction by phacoemulsification	FDA approved (following FDA guide in place pre-regulation)	Internal	1–4	1 year, dates not reported	Interoperative complications, phacoemulsification procedure time

Table 11 Safety outcomes for ophthalmic devices (by number of reprocessing cycles)

Author (year)	Comparison	Overall study quality appraisal result and rating	Available outcome data						Standardised metric (OR (95% CI))
Phacoemulsification procedure time (intervals) n/N									
Perry (1996) [106]	Reprocessed (1–4 cycles) compared with first use of a new device	14/30 Poor quality	**No. of uses**	**0.00–1.00 minute**	**1.01–2.00 minutes**	**2.01–3.00 minutes**	**3.01–4.00 minutes**	**4.01–5.00 minutes**	**>5.00 minutes**	Not applicable
			Intervention 1 (2nd use)	12/97	22/97	29/97	22/97	7/97	5/97	
			Intervention 2 (3rd use)	5/56	18/56	16/56	6/56	8/56	3/56	
			Intervention 3 (4th use)	6/26	7/26	9/26	1/26	1/26	2/26	
			Intervention 4 (5th use)	0/26	2/26	1/26	0/26	0/26	0/26	
			Comparison (1st use)	7/113	26/113	42/113	20/113	9/113	9/113	

3.4.2.2 Surgical instruments for grasping and cutting

An arthroscopic shaver is a medical device that is used to remove tissue during arthroscopic surgery. This type of surgery is a minimally invasive procedure that uses a small incision and special tools to repair or remove damage inside a joint [1].

3.4.2.2.1 Characteristics of arthroscopic device study

As indicated in Table 12, one study was available examining the reuse of reprocessed arthroscopic shavers. The reprocessing process described by the study authors [105] was undertaken by an external reprocessing company. The study did not provide sufficient information to determine the extent reprocessing processes and obligations followed aligned with those set out in the EU MDR. The study authors compared new devices with those put through up to five reprocessing cycles in relation to the environmental and financial benefits [105].

3.4.2.2.2 Safety outcomes from arthroscopic device study

No studies were identified providing data on the safety of reusing reprocessed arthroscopic shavers.

3.4.2.2.3 Cost outcomes from arthroscopic device study

Unger and Landis performed an LCCA in order to model the economic impacts of varying levels of reprocessing at their study hospital. The items costed were: the price of each device (in 2013 US$), quantity of each device used on an annual basis, waste disposal costs at US$0.14 per kilogram of waste generated (SUDs only), and reprocessing markdown for each device at 50% of the original device cost. Compared with first use (n=47 devices), the cost savings after one reuse (n=24 devices) was approximately US$500; this increased to approximately US$600 with two reuses (n=16 devices), approximately US$650 with three reuses (n=12 devices), approximately US$700 with four reuses (n=9 devices), and approximately US$800 with five reuses (n=8 devices), demonstrating diminishing incremental savings after each reprocessing cycle. Of the seven devices examined in Unger and Landis's study, arthroscopic shavers had the second-lowest potential for cost savings [105].

3.4.2.2.4 Environmental outcomes from arthroscopic device study

NGW was approximately <0.01 lower for once-reused arthroscopic devices, and this reduction decreased for each subsequent reuse (two to five reuses) compared with SUDs (NGW=approximately 0.2).

NCCL, NNCL, and NRE were approximately <0.05 lower or showed no change for one reuse and subsequent reuses of arthroscopic devices compared with SUDs (NCCL=approximately 0.01; NNCL=approximately <0.005; NRE=approximately 0.01).

Table 12 Characteristics of arthroscopic shaver study

Author (year)	Device name(s), model(s), brand(s)	Study location (where devices (re)used	Eligible participants	Intervention (reprocessing) overview			Study data collection period	Outcomes reported
				Reprocessing approval	Internal or external reprocessing	Number of reprocessing cycles		
Unger and Landis (2016) [105]	Name: Arthroscopic shaver Model: Not reported Brand: Not reported	Hospital	Patients attending a general medical and surgical hospital	Not reported	External: Independent company	1–5	Intervention: 2013 Comparison: 2013	Cost outcomes and environmental impacts: global warming impacts, human health impacts (carcinogenic, non-carcinogenic, and respiratory effects)

3.4.2.3 Endoscopic and laparoscopic devices

Disposable endoscopic or laparoscopic devices are minimally invasive devices used to look inside the body and are inserted directly into the organ being investigated via a natural orifice or small incision, commonly known as keyhole surgery [11]. As shown in *Table **13***, we identified studies examining reuse of different laparoscopic devices: laparoscopic sealers/dividers [105,107], ultrasonic scalpel/shears/scissors [105,110] [108], linear suture machine [108], braided wire sphincterotomes [109], and endoscopic trocars and ultrasonic scissor tips [105]. Given that these devices serve a similar function of cutting and/or sealing during endoscopic or laparoscopic procedures, we have grouped these together.

3.4.2.3.1 Characteristics of endoscopic and laparoscopic device studies

As shown in *Table **13***, five studies were identified that examined the safety, costs, and/or environmental impacts of reusing reprocessed laparoscopic and/or endoscopic devices. The reprocessing process adopted by Brady *et al.* [107] was approved by the FDA and reprocessing was undertaken outside of the hospital grounds by an independent reprocessing company. Mihanović *et al.* and de Sousa *et al.* [108] stated that the reprocessing process adopted was in line with national regulations whereby neither Croatia nor Portugal have opted into Article 17[2]. Reprocessing was undertaken at the hospital CSSD in the Mihanović *et al.* study [110] and outside of the hospital grounds by an independent reprocessing company in the de Sousa *et al.* study [108]. Kozarek *et al.* undertook their study prior to the introduction of FDA regulations on reprocessing, and the reprocessing approach and standards were determined by the research team, with reprocessing undertaken at the hospital CSSD [109]. With the exception of Unger and Landis [105] and Kozarek *et al.* [109] who tested the reuse of devices up to five and nine times respectively, the three other studies compared new devices with those put through a single reprocessing cycle [107,108,110].

3.4.2.3.2 Safety outcomes from endoscopic and laparoscopic device studies

Endoscopic and laparoscopic device safety outcomes were not feasible for meta-analysis due to inconsistent statistical outcome reporting (procedure time and duration of hospital stay) and too much heterogeneity in author definitions of complications outcomes (Appendix G). The results of these outcome are therefore assessed narratively. In vivo safety outcome data were available for: laparoscopic sealers/dividers [107], ultrasonic scalpel/shears/scissors [108,110], and linear suture machine [108].

Across studies, there was no significant difference in procedure time between procedures undertaken with new devices and those undertaken with once-reprocessed devices (Table 14). Diverging results were reported for duration of hospital stay, where de Sousa *et al.* found no difference in duration of hospital stay between procedures undertaken with new devices and those undertaken with once-reprocessed devices. The odds of reoperations [107], reoperations and postoperative complications [108], and postoperative complications [110] were consistently reduced in the reused group compared with the SUD group, but differences did not reach significance.

3.4.2.3.3 Cost outcomes from endoscopic and laparoscopic device studies

Three studies – Brady *et al.* [107], Kozarek *et al.* [109], and de Sousa *et al.* [108] – reported on the cost outcome of direct savings incurred by the hospital department during the study period. Two studies each reported on one additional cost outcome: indirect costs [107] and device life cycle costs [105]. Cost outcomes are categorised as:

1. Device/operative cost (direct)
2. Hospitalisation cost (indirect), and
3. Estimated device life cycle cost (indirect).

As reported in Table 15, the cost of a reprocessed device was approximately one-half the cost of a new device, and not all devices were put forward for reuse after reprocessing. Three of the four studies captured costs in US$ [105,107,109], and three studies estimated costs during a similar time frame (2013–2015) [105,107,108].

In relation to device/operative cost, one study reported a significant decrease (US$282) in cost in the reprocessed compared with single-use group (p=0.028) [107]. Two studies reported annual hospital cost savings in the reprocessed group compared with the single-use group: Kozarek *et al.* reported annual cost savings of US$65,961 when 222 devices were reused for an average of 2.4 times [109], and de Sousa *et al.* reported annual cost savings of €14,623.61 based on reuse of 193 linear suture machines compared with purchasing 178 new linear suture machines over the study period. de Sousa *et al.* also reported savings of €75,932.55 based on reuse of 418 ultrasonic scalpel/shears/scissors and purchase of 285 new ultrasonic scalpel/shears/scissors [108].

In relation to indirect hospitalisation costs, one study [107] reported comparable indirect hospitalisation costs for both the reprocessed and single-use groups. Savings were sustained, although the statistically significant difference was reduced (p=0.048). When direct and indirect cost differences were taken together, the study authors reported similar total profits between device reuse (median: US$5,805; interquartile range (IQR): US$855–12,253) and single-use (median: US$5,888; IQR: US$0–11,258; p = 0.34) policies.

In relation to device life cycle costs, one study [105] reported small incremental savings with each reprocessing cycle for each endoscopic and laparoscopic device examined. The authors reported that because of the high original equipment manufacturer costs associated with ultrasonic scalpel/shears/scissors, their reprocessing represented significant reductions in the economic costs of the hospital's supply chain [105]. With the exception of one low-quality study [109], studies contributing cost outcome data were of good and moderate quality. Further information is available in Appendix J.

3.4.2.3.4 Environmental outcomes from endoscopic and laparoscopic device studies

NGW was higher for ultrasonic scalpel/shears/scissors after one reuse (NGW=approximately 0.025), two reuses (NGW=approximately 0.02), three reuses (NGW=approximately 0.015), four reuses (NGW=approximately 0.01), and five reuses (NGW=approximately 0.008) compared with new SUDs (NGW=approximately <0.005). This finding, which is contrary to the lower global warming findings for all other devices in Unger and Landis's study, relates to the high original equipment manufacturer costs referred to in Section 3.4.2.3.3. Similarly, NNCLs and NREs were also higher in the reused devices compared with new SUDs, although the differences were smaller. The NCCLs for ultrasonic scalpel/shears/scissors were lower for the reused devices compared with the new SUDs. It was not possible to quantify the exact differences due to the manner in which the data were presented in the original study report.

NGW was lower for endoscopic trocars after one reuse (NGW=approximately 0.1), two reuses (NGW=approximately 0.08), three reuses (NGW=approximately 0.06), four reuses (NGW=approximately 0.05), and five reuses (NGW=approximately 0.03) compared with new SUDs (NGW=approximately 0.2). NCCLs were lower for endoscopic trocars after one reuse (NCCL=approximately 0.04), two reuses (NCCL=approximately 0.03), three reuses (NCCL=approximately 0.02), four reuses (NCCL=approximately 0.01), and five reuses (NCCL=approximately 0.01) compared with new SUDs (NCCL=approximately 0.08). NNCLs were lower for endoscopic trocars after one reuse (NNCL=approximately 0.06), two reuses (NNCL=approximately 0.05), three reuses (NNCL=approximately 0.04), four reuses (NNCL=approximately 0.03), and five reuses (NNCL=approximately 0.03) compared with new SUDs (NNCL=approximately 0.13). NREs were lower for endoscopic trocars after one reuse (NRE=approximately 0.08), two reuses

(NRE=approximately 0.05), three reuses (NRE=approximately 0.04), four reuses (NRE=approximately 0.03), and five reuses (NRE=approximately 0.02) compared with new SUDs (NRE=approximately 0.15).

Scissor tips and laparoscopic sealers/dividers showed slightly lower NGW, NCCLs, NNCLs, and NREs for the reused cycles compared with the new SUDs. It was not possible to quantify the exact differences due to the manner in which the data were presented in the original study report.

Table 13 Characteristics of endoscopic and laparoscopic device studies

Author (year)	Device name(s), model(s), brand(s)	Study location (where devices (re)used	Eligible participants	Intervention (reprocessing) overview			Study data collection period	Outcomes reported
				Reprocessing approval	Internal or external reprocessing	Number of reprocessing cycles		
Brady *et al.* (2017) [107]	Name: Laparoscopic sealers/dividers Model: Blunt tip laparoscopic sealer/divider 5 mm-37 cm Brand: LigaSure™	Hospital	All patients attending for laparoscopic resections and segmental resections, including right and sigmoid colectomies only	FDA approved	External (independent company)	1	Intervention: January 2014 to October 2015 Comparison: November 2012 to December 2013	Procedure time, duration of hospital stay (days), postoperative complications (complications and/or reoperations), operative/direct costs, total hospitalisation/indirect costs
de Sousa *et al.* (2018) [108]	Name: Ultrasonic scissors/scalpel/shears and linear suture machine Model: 5 mm/36 cm C/rod, No. 55/60-3.8, No. 75/80-3.8, and No. 75/80-4.8 Brand: Harmonic ACE®	Hospital	All patients aged over 17 years attending for surgical interventions in the oesophagus, stomach, and/or duodenum, with or without complications, in which the devices were used	Local policy	External (independent company)	1	Intervention: 2014 Comparison: 2014	Procedure time, duration of hospital stay (days), postoperative complications (complications and/or reoperations), operative/direct costs

Table 13 Characteristics of endoscopic and laparoscopic device studies

Author (year)	Device name(s), model(s), brand(s)	Study location (where devices (re)used	Eligible participants	Intervention (reprocessing) overview			Study data collection period	Outcomes reported
				Reprocessing approval	Internal or external reprocessing	Number of reprocessing cycles		
Kozarek *et al.* (1999) [109]	Name: Sphincterotomes Models: Braided wise UTS-30 and CT-30 Brand: Wilson-Cook	Hospital	Not reported	Meets criteria set by research team	Internal	1–9	Intervention: September 1996 to September 1997 Comparison: September 1995 to September 1996	Operative/direct costs
Mihanović *et al.* (2021) [110]	Name: Ultrasonic scissors/scalpel/shears Model: with adaptive tissue technology and Ethicon Endo-Surgery Brand: Harmonic ACE®	Hospital	All patients aged 5–65 years with acute appendicitis, and without significant comorbidities	Local policy	Internal	1	Intervention: May 2019 to April 2020 Comparison: May 2019 to April 2020	Procedure time, duration of hospital stay (days), postoperative complications (complications and/or reoperations)
Unger and Landis (2016) [105]	Name: Ultrasonic scalpel/shears/scissors Model: Not reported Brand: Harmonic Name: Laparoscopic sealer/divider	Hospital	Patients attending a general medical and surgical hospital	Meets criteria set by research team	External: Independent company	1–5	Intervention: 2013 Comparison: 2013	Cost outcomes and environmental impacts: global warming impacts, human health impacts (carcinogenic, non-

Table 13 Characteristics of endoscopic and laparoscopic device studies

Author (year)	Device name(s), model(s), brand(s)	Study location (where devices (re)used	Eligible participants	Intervention (reprocessing) overview			Study data collection period	Outcomes reported
				Reprocessing approval	Internal or external reprocessing	Number of reprocessing cycles		
	Model: Not reported Brand: Ligasure™ Name: Endoscopic trocar Model: Not reported Brand: Not reported Name: Ultrasonic scalpel/shears/scissors Model: Not reported Brand: Harmonic							carcinogenic, respiratory effects)

Table 14 Statistical summary of safety outcome data for endoscopic and laparoscopic device studies

Author (year)	Comparison	Overall study quality appraisal result and rating	Available outcome data					
			Mean (SD) N/median (IQR) N	Standardised metric (MD (95% CI))	Mean (SD) N/median (IQR) N	Standardised metric (MD (95% CI))	n/N, %	Standardised metric (OR (95% CI))
			Procedure time (minutes)		**Duration of hospital stay (days)**		**Postoperative complications (complications and/or reoperations)**	
Brady *et al.* (2017) [107]	Reprocessed once (i.e. second use of device) compared with first use of a new device	23/30 Good quality	Intervention: 128 (41) 76 Comparison: 131 (48) 76 *p*=0.47	MD: −3.00 (−17.19 to 11.19)	Intervention: 3.50 (0.60) 76 Comparison: 3.80 (0.50) 76 *p*=0.18	MD: −0.30 (−0.48 to−0.12)	Intervention: 3/76, 3.9% Comparison: 4/76, 5.2% *p*=0.12	OR=0.74 (0.16–3.42)
de Sousa *et al.* (2018) [108]	Reprocessed once (i.e. second use of device) compared with first use of a new device	24/30 Good quality	Intervention: 140 (90) 316 Comparison: 147 (91) 417	MD: −7.20 (−20.43 to 6.03)	Intervention: 9.55 (8.92) 316 Comparison: 10.39 (12.00) 417	MD: −0.84 (−2.35-0.67)	Intervention: 39/316, 12.3% Comparison: 56/417, 13.4%	OR=0.91 (0.59–1.41)
Mihanović *et al.* (2021) [110]	Reprocessed once (i.e. second use of device) compared with first use of a new device	28/30 Excellent quality	Intervention: 25 (21–35) 51 Comparison: 22 (20–30) 49	Not applicable	Intervention: 2 (2–3) 51 Comparison: 2 (2–3) 49	Not applicable	Intervention: 1/51, 1.9% Comparison: 2/49, 4.1%	OR=0.47 (0.04–5.36)

Table 15 Cost difference between single-use and reprocessed endoscopic and laparoscopic device (safety) studies

Author (year)	Comparison n/N devices	Costed items per outcome	Year of costs and currency	Overall study quality appraisal result and rating	Available outcome data			
					Cost per device and/or total	Cost difference	Cost per device and/or total	Cost difference
					Device/operative costs (direct)		**Total hospitalisation costs (indirect)**	
Brady *et al.* (2017) [110]	N=152 devices Reprocessed (n=76) compared with new (n=76)	Reprocessed device New device Direct operative expenses (including costs of using new devices for 15 unsatisfactory reprocessed devices) Charges and total costs for overall patient hospitalisation	US dollars ($) 2014–2015	23/30 Good quality	Per device Intervention: US$225 Comparison: US$505 Total (76 devices), median (IQR) Intervention: US$2,674 (US$1,855–4,415) Comparison: US$2,956 (US$1,655–4,740)	Total (76 devices): US$282, *p*=0.027	Total (76 devices), median (IQR) Intervention: US$6,277 (US$1,700–8,750) Comparison: US$6,537 (US$1,565–9,355)	Total (76 devices): US$260, *p*=0.048

Table 15 Cost difference between single-use and reprocessed endoscopic and laparoscopic device (safety) studies

Author (year)	Comparison n/N devices	Costed items per outcome	Year of costs and currency	Overall study quality appraisal result and rating	Available outcome data			
					Cost per device and/or total	Cost difference	Cost per device and/or total	Cost difference
					Device/operative costs (direct)		**Total hospitalisation costs (indirect)**	
Kozarek *et al.* (1999) [109]	N=not reported Reprocessed (mean number of uses) (n=222) compared with new (n=155)	New device Reprocessed device (2.4 reuses on average, up to 9 cycles), including initial cost of new devices	US dollars ($) Intervention: 1996–1997 Comparison: 1995–1996	6/16 Low quality	Per device Intervention: US$5.83 + cost of new device Comparison: US$124.00 Total cost Intervention (222 devices): US$30,634.00 Comparison (775 devices): US$96,595.00	Total difference (222 devices compared with 775 devices): US$65,961.00	Not collected in study	
de Sousa *et al.* (2018) [108]	N=733 Reprocessed (n=316) compared with new (n=417)	Reprocessed suture machine (reprocessing and recharging) Reprocessed scissors	Euros (€) 2014 (12 months)	24/30 Good quality	Per device (suture machine) Intervention: €58.05 per machine + €7.50 per recharge Comparison (average of 3 machines): €127.03 Per device (scissors) Intervention: €246.00	Suture machine (193 reused devices + 386 recharges compared with 178 new devices): €14,623.61 Scissors (285 reused compared	Not collected in study	

Table 15 Cost difference between single-use and reprocessed endoscopic and laparoscopic device (safety) studies

Author (year)	Comparison n/N devices	Costed items per outcome	Year of costs and currency	Overall study quality appraisal result and rating	Available outcome data			
					Cost per device and/or total	Cost difference	Cost per device and/or total	Cost difference
					Device/operative costs (direct)		**Total hospitalisation costs (indirect)**	
		New suture machine (average cost of 3 machines used) New scissors/ scalpel/shears			Comparison: €512.43 Total (suture machine) Intervention (193 devices and 386 recharges): €11,203.65 Comparison (178 devices): €23,819.96 Total (scissors) Intervention (285 devices): €70,110.00 Comparison (418 devices): €214,195.74	with 418 new devices): €75,932.55		

Table 16 Cost difference between single-use and reprocessed endoscopic and laparoscopic devices (estimated device life cycle costs)

Author (year)	Comparison	Costed items per outcome	Year of costs and currency	Overall study quality appraisal result and rating	Cost per device and/or total	Cost difference
Unger and Landis (2016) [105]	Modelled use of devices reprocessed between 1 and 5 times compared with new devices (based on actual quantity of new devices used in 1 year)	Reprocessing device cost at 50% of the original device cost Waste disposal costs: US$0.14 per kilogram of waste generated (SUDs only)	US dollars ($) 2013	15/22 Moderate quality	Ultrasonic scalpel/shears/scissors Per device/total Intervention: Not reported Comparison: Not reported Laparoscopic sealer/divider Per device/total Intervention: Not reported Comparison: Not reported Endoscopic trocar Per device/total Intervention: Not reported Comparison: Not reported	Ultrasonic scalpel/shears/scissors: n uses (n devices) 2 uses compared with new (307 compared with 613): US$39,000 3 uses compared with new (204 compared with 613): US$52,000 4 uses compared with new (204 compared with 613): US$58,000 5 uses compared with new (123 compared with 613): US$63,000 6 uses compared with new (102 compared with 613): US$65,000 Laparoscopic sealer/divider: n uses (n devices) 2 uses compared with new (14 compared with 29): US$4,500 3 uses compared with new (10 compared with 29): US$6,000 4 uses compared with new (7 compared with 29): US$7,000 5 uses compared with new (6 compared with 29): US$7,500 6 uses compared with new (5 compared with 29): US$8,000

Table 16 Cost difference between single-use and reprocessed endoscopic and laparoscopic devices (estimated device life cycle costs)

Author (year)	Comparison	Costed items per outcome	Year of costs and currency	Overall study quality appraisal result and rating	Cost per device and/or total	Cost difference
						Endoscopic trocar: n uses (n devices) 2 uses compared with new (2,079 compared with 5,418): US$23,000 3 uses compared with new (1,806 compared with 5,418): US$31,000 4 uses compared with new (1,355 compared with 5,418): US$36,000 5 uses compared with new (1,084 compared with 5,418): US$38,000 6 uses compared with new (903 compared with 5,418): US$39,500

3.4.3 Risk class III devices

3.4.3.1 Implantable cardiac devices

An implantable cardioverter defibrillator (ICD) is a small, battery-powered device placed in the chest to detect and stop potentially life-threatening abnormal heart rhythms coming from the bottom chamber of the heart i.e., ventricular tachyarrhythmias. An ICD continuously monitors the heart rhythm and delivers electric shocks, when needed, in order to restore or stable heart rhythm. A pacemaker is a small device that is placed (implanted) in the chest to help monitor the heart rate and rhythm and provide pacemaker support when needed, to prevent the heart from beating too slowly. Implantation of both ICDs and pacemakers in the chest requires a cardiac interventional procedure [122,123].

3.4.3.1.1 Characteristics of implantable cardiac device studies

As shown in *Table **17***, four studies were identified examining the safety of reusing reprocessed implantable cardiac devices (i.e. pacemakers and ICDs). The reprocessing process examined by Linde *et al.* [112] and Nava *et al.* [113] was approved by a local hospital, and those examined by Enache *et al.* [111] and Şoşdean *et al.* [114] met criteria set by the research teams. As such, the extent which reprocessing standards and obligations aligned with those set out by Article 17[2] of the EU MDR is unclear. With the exception of the Enache *et al.* study, where the reprocessing location was unclear [111], reprocessing was undertaken within the facility supplying the devices for reuse [112–114]. All studies compared new devices with those put through a single reprocessing cycle [111–114].

3.4.3.1.2 Safety outcomes from implantable cardiac device studies

As indicated by the meta-analysis feasibility assessment, two implantable cardiac device safety outcome (i.e. infections and unexpected battery depletion) were deemed feasible for meta-analysis. One device-related safety outcome, other device malfunction, was not considered suitable for meta-analysis due to too few studies collecting data for this outcome (Appendix G). Summary data reported in Table 18 reported no significant difference in any patient or device safety outcomes between use of once-reprocessed and new implantable cardiac devices across the four studies.

Table 17 Characteristics of implantable cardiac device studies

Author (year)	Device name(s), model(s), brand(s)	Study location (where devices (re)used	Eligible participants	Intervention (reprocessing) overview			Study data collection period	Outcomes reported
				Reprocessing approval	Internal or external reprocessing	Number of reprocessing cycles		
Enache *et al.* (2019) [111]	Name: ICDs Models: Single chamber, dual chamber, biventricular/CRT-D Brands: Biotronik, St. Jude, Medtronic, Guidant, Ela Medical, and Boston Scientific	Hospital	All patients for whom the device was indicated, i.e. those with a history of cardiac arrest or sustained ventricular tachycardia or no history of cardiac arrest or sustained ventricular tachycardia, but at risk for sudden cardiac death	Meets criteria set by research team	Unclear	1	Intervention: January 2001 to December 2011 Comparison: January 2001 to December 2011	Infections, unexpected battery depletion
Linde *et al.* (1998) [112]	Name: Pacemaker Model: Not reported Brand: Not reported	Hospital	All patients requiring a pacemaker and for whom the life expectancy of the patients is estimated to be lower than that of the pacemaker	Local policy	Internal	1	Intervention: January 1992 to January 1994 Comparison: January 1992 to January 1994	Infections, unexpected battery depletion, other device malfunction

Table 17 Characteristics of implantable cardiac device studies

Author (year)	Device name(s), model(s), brand(s)	Study location (where devices (re)used	Eligible participants	Intervention (reprocessing) overview			Study data collection period	Outcomes reported
				Reprocessing approval	Internal or external reprocessing	Number of reprocessing cycles		
Nava *et al.* (2013) [113]	Name: Pacemaker Model: Not reported Brand: Not reported	Hospital	All patients aged 18 years and over with an indication for pacing	Local policy	Internal	1	Intervention: 2000–2010 Comparison: 2000–2010	Infections, unexpected battery depletion, other device malfunction
Şoşdean *et al.* (2015) [114]	Name: Biventricular cardiac implantable electronic device Model: Not reported Brand: Not reported	Hospital	Patients requiring implantation with biventricular devices (pacemakers and/or defibrillators)	Meets criteria set by research team	Internal	1	Intervention: 2000–2014 Comparison: 2000–2014	Infections, unexpected battery depletion

Table 18 Summary of safety outcomes for implantable cardiac device studies

Author (year)	Comparison	Overall study quality appraisal result and rating	Available outcome data					
			n/N, %	Standardised metric (OR (95% CI))	n/N, %	Standardised metric (OR (95% CI))	n/N, %	Standardised metric (OR (95% CI))
			Infections (yes/no)		**Unexpected battery depletion**		**Other device malfunction**	
Enache *et al.* (2019) [111]	Reprocessed once compared with first use of a new device	17/30 Fair quality	Intervention: 3/157, 1.91% Comparison: 5/114, 4.38%	OR=0.42 (0.10–1.81)	Intervention: 0/157, 0.00% Comparison: 0/114, 0.00%	OR=N/A	Not collected in study	
Linde *et al.* (1998) [112]	Reprocessed once compared with first use of a new device	21/30 Good quality	Intervention: 2/100, 2.00% Comparison: 7/100, 7.00%	OR=0.27 (0.05–1.34)	Intervention: 0/100, 0.00% Comparison: 0/100, 0.00%	OR=N/A	Intervention: 1/100, 1.00% Comparison: 0/100, 0.00%	OR=3.03 (0.12–75.28)
Nava *et al.* (2013) [113]	Reprocessed once compared with first use of a new device	24/30 Good quality	Intervention: 10/307, 3.26% Comparison: 11/296, 3.72%	OR=0.87 (0.36–2.09)	Intervention: 11/307, 3.58% Comparison: 5/296, 1.69%	OR=2.16 (0.74–6.30)	Intervention: 1/307, 0.33% Comparison: 0/296, 0.00%	OR=2.90 (0.12–71.52)
Şoşdean *et al.* (2015) [114]	Reprocessed once compared with first use of a new device	22/30 Good quality	Intervention: 5/115, 4.35% Comparison: 7/146, 4.79%	OR=0.90 (0.28–2.92)	Intervention: 1/127, 0.79% Comparison: 0/159, 0.00%	OR=3.78 (0.15–93.65)	Not collected in study	

The results of the meta-analysis were in line with those reported in the narrative summary. Meta-analysis using a random-effects model was performed to address heterogeneity among the included studies. In the four studies included in the meta-analysis for infections [111,113,114,124], there were a total of 1,272 patients, with 650 in the intervention (reuse) and 622 in the control (single use) arms. Meta-analysis found no significant difference in the occurrence of device-associated infections in the reused device (intervention) group compared with the new device (control) group (20 compared with 30 events, *p*=0.180, OR=0.67 [95% CI: 0.37–1.20]; see Figure 6). There was no heterogeneity between individual study effect sizes.

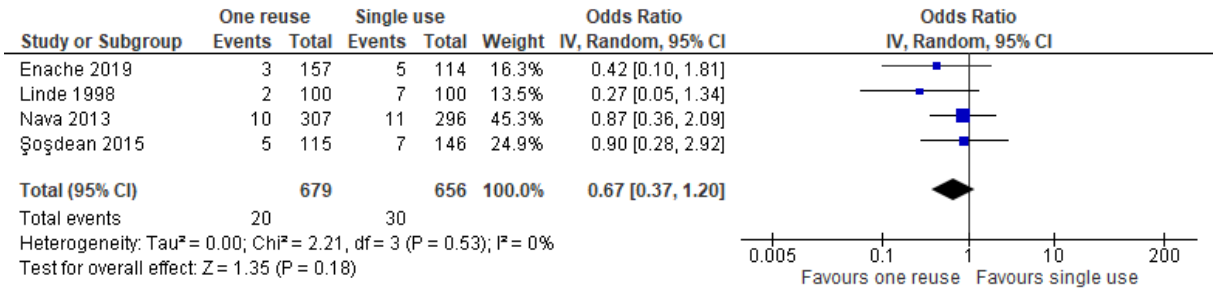

Figure 6 Forest plot of the rate of device-related infections in studies of new devices compared with reused devices

In the four studies included in the meta-analysis for device safety [111,113,114,124], there were a total of 1,360 devices with 691 and 669 in the intervention (reuse) and control (single use) arms respectively. Meta-analysis found no significant difference in the odds of unexpected battery depletion between the reused device (study) group compared with the new device (control) group (12 compared with five events, *p* = 0.110, OR = 2.29 [95% CI: 0.83–6.31]; see Figure 7). There was no heterogeneity between individual study effect sizes.

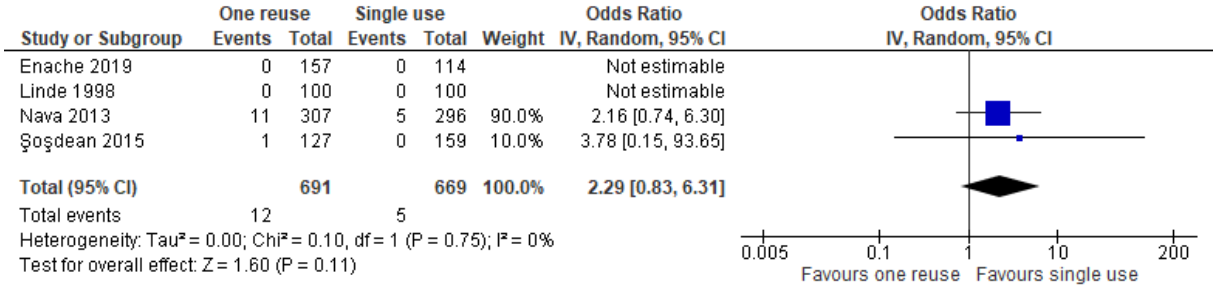

Figure 7 Forest plot of the rate of unexpected battery depletion in studies of new devices compared with reused devices.

3.4.3.1.3 Cost outcomes from implantable cardiac device studies

No studies were identified providing data on the financial impact of reusing reprocessed implantable cardiac devices.

3.4.3.1.4 Environmental outcomes from implantable cardiac device studies

No studies were identified providing data on the environmental impact of reusing reprocessed implantable cardiac devices.

3.4.3.2 Cardiac catheter/cannula devices

Cardiac catheter devices are used for both diagnostic and therapeutic purposes. Balloon catheters are used to open up blocked arteries and veins during a coronary angioplasty; ablation catheters are used during treatment for atrial fibrillation, a common cardiac rhythm disturbance; and electrophysiology polyurethane catheters are used for recording and pacing the electrical potentials from within the heart

[9,10]. Venous and arterial cannulas are used in procedures such as cardiopulmonary bypass or cardiac surgery to manage the flow of blood during the procedures [4].

3.4.3.2.1 Characteristics of cardiac catheter/cannula device studies

As shown in Table Table 19, four studies were identified examining the safety of reusing reprocessed cardiac catheters. The reprocessing process adopted by Unverdorben *et al.* [120] and Leung *et al.* [116] was approved by the FDA and the EU MDR, respectively. As such, these are the only studies which may possibly be aligned with article 17[2] of the EU MDR. The studies by Browne *et al.* [115] and Plante *et al.* [118] were undertaken prior to the implementation of national regulatory standards for SUD reprocessing in the respective countries of study, and therefore criteria were set and met by the research teams. Reprocessing was undertaken by an independent company [116], by the original device manufacturer [115], or internally at the health facility where the devices were reused [118,120]. Three studies compared new devices with those put through multiple (one to six) reprocessing cycles [116,118,120], and one did not report on the number of reprocessing cycles [115].

Two studies were identified examining the cost of reusing reprocessed cardiac catheters. The study by Mak *et al.* was a cost-based study using the same data as the Plante *et al.* study [117], and therefore the reprocessing process, its oversight, and its location were those employed by Plante *et al.* Tessarolo *et al.* confirmed that the reprocessing process they costed [119] was based on the costs of reprocessing by a "third-party professional reprocessor able to implement (and provide evidence) of both cleaning, disinfection, and sterilisation, but also of all essential functionality parameters (e.g. electrical conductivity, steering properties, for [electrophysiology] catheters, physical integrity)" (F Tessarolo, personal communication, 19 November 2022).

3.4.3.2.2 Safety outcomes from cardiac catheter/canula device studies

As indicated by the meta-analysis feasibility assessment (Appendix G), no cardiac catheter device safety outcomes were deemed feasible for meta-analysis. Cardiac catheter safety outcomes (major complications, minor complications, procedure time, fluoroscopy time and quantity of contrast used) were reported narratively due to an insufficient number of available studies of acceptable quality, too few studies after exclusion of studies with zero events in the intervention and comparison study arms, or non-normally distributed (continuous) data (Appendix G). Three studies [115,116,118] provided data on minor complications, defined as pyrogen reactions (fever, temperature, white blood cell count), creatine kinase, and/or author-labelled minor complications, and three studies [115,118,120] reported on contrast volume used (Table 20). Minor complications were recorded in two studies that collected complications data, and there were no clear differences in the occurrence of complications between patients receiving a device for first reuse compared with a new SUD [115,118]. The third study recorded no minor complications [116]. Plante *et al.*'s study was the only study which reported a significantly higher mean volume of contrast used in the reused device group compared with the new device group (see Table 20).

As shown in Table 20, one of four studies [118] collecting major complications data reported higher odds of major complications in the reused compared with new device group, where patients receiving reprocessed devices had 2.76 times higher odds of experiencing a major complication compared with those receiving new devices.

There were no differences in the odds of minor complications between patients receiving reused and new devices. Overlapping CIs in the two studies reporting ORs [115,118] indicates similar odds across both studies. However, the wide CI reported for the findings of Plante *et al.* denotes poor precision (accuracy) of the OR statistic provided (Table 20).

The average procedure time tended to be similar in the reused and new SUD groups, although one study reported a significantly shorter duration in favour of the reused device group [115] and one other study [118] reported a significantly longer procedure duration in the reused device group compared with the new SUD group (Table 20).

The average duration of fluoroscopy tended to be similar between the reused and new SUD groups. One study reported significantly shorter fluoroscopy times during procedures provided with a reused device compared with a new device [115] , whereas Leung *et al.* reported significantly longer fluoroscopy duration during procedures provided with a reused device compared with a new device [116] (Table 20).

Unverdorben *et al.* [120] was the only study to report safety outcomes by each subsequent reprocessing and reuse cycle (up to three reuse cycles). In this study, there was no significant difference in the average procedure time between new devices (9.9, ±6.8) and the first (9.3, ±4.9), second (12.5, ±7.2), and third (11.5, ±1.6) reprocessing cycles (p=0.076). There was also no significant difference in the average fluoroscopy time between new devices (2.6, ±2.8) and the first (2.4, ±1.9), second (3.2, ±2.7), and third (4.2, ±5.4) reprocessing cycles. However, differences here were close to statistical significance (p=0.052). Finally, there was no significant difference in the average volume of contrast used between new devices (44, ±32) and the first (40, ±27), second (47, ±26), and third (49, ±29) reprocessing cycles (p=0.290).

Table 19 Characteristics of cardiac catheter/cannula device studies

Author (year)	Device name(s), model(s), brand(s)	Study location (where devices (re)used	Eligible participants	Intervention (reprocessing) overview			Study data collection period	Outcomes reported
				Reprocessing approval	Internal or external reprocessing	Number of reprocessing cycles		
Browne *et al.* (1997) [115]	Name: Balloon catheter Model: Not reported Brand: Guidant Corporation and Cordis Corporation	Hospital	All patients scheduled for coronary angioplasty	Local policy	External: Original manufacturer	Not reported	Not reported	Major complication, minor complication, procedure time (minutes), fluoroscopy time (minutes), contrast used (millilitres (mL))
Leung *et al.* (2019) [116]	Name: Circular mapping ablation catheter Model: 22-pole Lasso® 2515 eco Variable Catheter with an electro-anatomic system (Carto®, Biosense-Webster®) Brand: Stryker®	Hospital	Patients undergoing a wide mix of atrial fibrillation ablation procedures ranging from pulmonary vein isolation to more complex and lengthy procedures, some lasting more than 4 hours	EU MDR approved	External: Independent company	1–2	Not reported	Major complication, minor complication, procedure time (minutes), fluoroscopy time (minutes)

Table 19 Characteristics of cardiac catheter/cannula device studies

Author (year)	Device name(s), model(s), brand(s)	Study location (where devices (re)used	Eligible participants	Intervention (reprocessing) overview			Study data collection period	Outcomes reported
				Reprocessing approval	Internal or external reprocessing	Number of reprocessing cycles		
Mak *et al.* (1996) [117]	Name: Balloon catheter Model: Not reported Brand: Not reported	Hospital	All patients undergoing coronary angioplasty	Meets criteria set by research team	Internal	2–5	Intervention: June to October 1994 Comparison: Same period	Comparison of best case, likely case, and worst-case reuse cost scenarios with single-use cost scenario
Plante *et al.* (1994) [118]	Name: Balloon catheter Model: Not reported Brand: Not reported	Hospital	All patients undergoing coronary angioplasty	Meets criteria set by research team	Internal	1–6	Not reported	Major complication, minor complication, procedure time (minutes), fluoroscopy time (minutes), contrast used (mL)
Tessarolo *et al.* (2009) [119]	Name: Balloon and electrophysiology catheters Model: Not reported Brand: Not reported	Hospital	Model based on number of patients undergoing interventional cardiology	Not reported	External: Independent company	Balloon catheter: 1–2 Electrophysiology catheter: 1–5	Modelling based on 12 months during the year 2004	Cost savings

Table 19 Characteristics of cardiac catheter/cannula device studies

Author (year)	Device name(s), model(s), brand(s)	Study location (where devices (re)used	Eligible participants	Intervention (reprocessing) overview			Study data collection period	Outcomes reported
				Reprocessing approval	Internal or external reprocessing	Number of reprocessing cycles		
			procedures nationally and presented as a representative cardiology department					
Unverdorben *et al.* (2005) [120]	Name: Balloon catheter Model: Standard monorail system, featuring a proximal stainless steel hypotube shaft with LEAPTM, a nylon derivative, serving as balloon material Brand: Not reported	Hospital	All patients scheduled for angioplasty of a new coronary artery stenosis	FDA approved	Internal	1–3	Not reported	Major complication, procedure time (minutes), fluoroscopy time (minutes), contrast used (mL)

Table 20 Summary of safety outcomes for cardiac catheters/cannula device studies

Author (year)	Comparison	Study quality	Available outcome data									
			n/N, %	Standardised metric (OR (95% CI))	n/N, %	Standardised metric (OR (95% CI))	Mean (SD) N	Standardised metric (MD (95% CI))	Mean (SD) N	Standardised metric (MD (95% CI))	Mean (SD) N	Standardised metric (MD (95% CI))
			Major complication (yes/no)		**Minor complication (yes/no)**		**Procedure time (minutes)**		**Fluoroscopy time (minutes)**		**Contrast used (mL)**	
Browne *et al.* (1997) [115]	Reprocessed once compared with new device	15/30 Poor quality	Intervention: 6/107, 5.6% Comparison: Not reported /108	OR: Could not estimate	Intervention: 24/107, 22.40% Comparison: 26/108, 24.10%	OR=0.91 (0.48–1.72)	Intervention: 67 (30) 107 Comparison: 83 (49) 108	MD: −16.00 (−26.85- −5.15)	Intervention: 13 (10) 107 Comparison: 18 (15) 108	MD: −5.00 (−8.40- −1.60)	Intervention: 275 (125) 107 Comparison: 307 (157) 108	MD: −32.00 (−69.92- 5.92)
Plante *et al.* (1994) [118]	Reprocessed 1–6 times compared with new device	23/30 Good quality	Intervention: 29/320, 9.1% Comparison: 13/373, 3.4%	OR=2.76 (1.41–5.40)	Intervention: 3/320, 0.90% Comparison: 1/373, 0.30%	OR=3.52 (0.36–34.01)	Intervention: 81 (41) 320 Comparison: 68 (32) 373	MD: 13.00 (7.46–18.54)	Intervention: 17.9 (11.2) 320 Comparison: 17.1 (9.9) 373	MD: 0.80 (−0.79- 2.39)	Intervention: 201 (86) 320 Comparison: 165 (61) 373	MD: 36.00 (24.73–47.27)
Unverdorben *et al.* (2005) [120]	Reprocessed 1–3 times compared	23/30 Good quality	Intervention: 0/44, 0.00%	OR: Could not estimate	Not collected in study		Intervention: 9.3 (4.9) 44	MD: −0.60 (−2.48- 1.28)	Intervention: 2.4 (1.9) 44	MD: −0.20 (−0.95- 0.55)	Intervention: 40 (27) 44	MD: −4.00 (−13.77- 5.77)

Table 20 Summary of safety outcomes for cardiac catheters/cannula device studies

			Available outcome data									
Author (year)	**Comparison**	**Study quality**	**n/N, %**	**Standardised metric (OR (95% CI))**	**n/N, %**	**Standardised metric (OR (95% CI))**	**Mean (SD) N**	**Standardised metric (MD (95% CI))**	**Mean (SD) N**	**Standardised metric (MD (95% CI))**	**Mean (SD) N**	**Standardised metric (MD (95% CI))**
	with new device		Comparison: 0/124, 0.00%				Comparison: 9.9 (6.8) 124		Comparison: 2.6 (2.8) 124		Comparison: 44 (32) 124	
Leung *et al.* (2019) [116]	Reprocessed once versus new device	20/30 Fair quality	Intervention: 0/100, 0.00% Comparison: 0/100, 0.00%	OR: Could not estimate	Intervention: 0/100, 0.00% Comparison: 0/100, 0.00%	OR: Could not estimate	Intervention: 178.9 (51.3) 100 Comparison: 189.5 (55.3) 100 *p*=0.160	MD: −10.60 (−25.38-4.18)	Intervention: 21.5 (13.5) 100 Comparison: 11.8 (9.8) 100	MD: 9.70 (6.43–12.97)	Not collected in study	

3.4.3.2.3 Cost outcomes from cardiac catheter/cannula device studies

Two studies provided cost difference data for cardiac catheter devices derived from direct [117,119] and indirect costs [117]. Although Mak *et al.* presented cost models derived from three possible scenarios ('best case', 'likely case', and 'worst case') based on clinical data provided by Plante *et al.,* we only report cost estimates derived from the 'likely case' scenario presented by the study authors. Further detail of the best- and worst-case scenarios are available in the original study report [117]. Tessarolo *et al.* estimated costs based on department activity (number of catheters used per year) across Italian hospital cardiology departments compared with a single study site. Studies estimated costs in CAN$ [117] and euro [119] with costs calculated approximately 10 years apart (5 months during the year 1994 for Mak *et al.* and 1 year during the year 2004 for Tessarolo *et al.* [117,119] (*Table **21***). Studies providing data on cost differences for cardiac catheter devices were of low and moderate quality (Table 21). Further information on study quality is provided in Appendix J.

3.4.3.2.4 Environmental outcomes from cardiac catheter/cannula device studies

No studies were identified providing data on the environmental impact of reusing reprocessed cardiac catheter devices.

Table 21 Cost difference between single-use and reprocessed cardiac catheter/cannulas device studies

Author (year)	Comparison n/N devices	Costed items per outcome	Year of costs and currency	Overall study quality appraisal result and rating	Available outcome data			
					Cost per device and/or total	Cost difference	Cost per device and/or total	Cost difference
					Department-level savings (expressed as a percentage of actual expenditure for SUD purchasing)		**Total cost difference (per patient) (direct and indirect hospital costs)**	
Tessarolo *et al.* (2009) [119]	Balloon catheters (N median = 755): Reprocessed compared with new device (n=not reported, simulated reuse) Electrophysiology catheters (N median ablation=58; N median electrophysiology= 405): Reprocessed compared with first use of a new device (n=not reported, simulated reuse)	Reprocessed device cost New device cost Other fixed costs (waste disposal, collection, and handling costs; assignment of new device contracts)	€ 2004	8/16 Low quality	Balloon catheters Per device/total Intervention: Not reported Comparison: Not reported Electrophysiology diagnostic catheters Per device/total Intervention: Not reported Comparison: Not reported Electrophysiology ablation catheters Per device/total	Balloon catheters: 12.5% (IQR: 11.3–13.4%) Electrophysiology diagnostic catheters: 41.2% (IQR: 36.8–42.7%) Electrophysiology ablation catheters: 32.9% (IQR: 23.8–37.7%)	Not collected in study	

Table 21 Cost difference between single-use and reprocessed cardiac catheter/cannulas device studies

Author (year)	Comparison n/N devices	Costed items per outcome	Year of costs and currency	Overall study quality appraisal result and rating	Available outcome data			
					Cost per device and/or total	Cost difference	Cost per device and/or total	Cost difference
					Intervention: Not reported Comparison: Not reported			
Mak *et al.* (1996) [117]	Mean number of uses with 80% pass rate compared with new device based on N=693 devices; n=373 new and n=320 reprocessed devices)	Cost of balloon catheter per patient Contrast agent per patient Urgent coronary artery bypass graft surgery (CABG) at 2.6% Urgent percutaneous transluminal coronary angioplasty (PTCA) Other costs (human resources, supplies, etc.)	CAN$ 1994	12/16 Moderate quality	Not collected in study		Per procedure Intervention: CAN$279 per device CAN$84 mean contrast use per patient CAN$712 urgent CABG CAN$138 urgent PTCA CAN$7,712 other costs Total: CAN$8,929 Comparison: CAN$618 per device	CAN$129 per patient

Table 21 Cost difference between single-use and reprocessed cardiac catheter/cannulas device studies

Author (year)	Comparison n/N devices	Costed items per outcome	Year of costs and currency	Overall study quality appraisal result and rating	Available outcome data			
					Cost per device and/or total	Cost difference	Cost per device and/or total	Cost difference
							CAN$69 mean contrast use per patient CAN$301 urgent CABG CAN$97 urgent PTCA CAN$7,715 other costs Total: CAN$8,800	

3.4.4 Grading of Recommendations, Assessment, Development and Evaluations rating

The Grading of Recommendations, Assessment, Development and Evaluations (GRADE) approach to rating quality of evidence and strength of recommendations was applied to papers contributing data to the primary review outcomes following the GRADE handbook guidance [70]. Scores for each of the five evaluated safety outcomes across four device groups and the one cost outcome across two device groups are displayed in Table 22. For all outcomes, the a priori rating was 'low', because the majority of evidence for each of the seven primary outcomes was derived from observational studies. All seven primary outcomes received at least one downgrade. When downgrades were applied, all seven primary outcomes received a final rating of very low certainty in the evidence. The rating for each outcome was downgraded due to:

- The high risk of bias judgements based on the risk of bias assessment for randomised trials [71] and the Risk Of Bias In Non-randomised Studies – of Interventions (ROBINS–I) tool [72] (five of seven primary outcomes)
- Inconsistent findings across studies (two of seven primary outcomes)
- Indirectness of study findings (four of seven primary outcomes)
- Imprecision, generally judged by the presence of wide CIs in many or all studies (seven of seven primary outcomes), and
- The detection of publication bias (one of seven primary outcomes).

Table 22 GRADE rating for primary outcomes

Primary outcome	A priori ranking	Downgrade for					Upgrade for			Final grade
		Risk of bias	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Large consistent effect**	**Dose response**	**Confounders only reducing size of effect**	
External fixator devices										
Pin tract infections	Low	Serious limitation	Serious limitation	Very serious limitation	Very serious limitation	No serious limitations	No upgrade	No upgrade	No upgrade	Very low
Reoperations	Low	Serious limitation	Serious limitation	Serious limitation	Very serious limitation	No serious limitations	No upgrade	No upgrade	No upgrade	Very low
Endoscopic and laparoscopic devices										
Postoperative complications (complications and/or reoperations)	Low	Serious limitation	No serious limitations	Serious limitation	Serious limitation	No serious limitations	No upgrade	No upgrade	No upgrade	Very low
Hospitalisation cost	Low	Serious limitation	No serious limitations	No serious limitations	Serious limitation	No serious limitations	No upgrade	No upgrade	No upgrade	Very low
Implantable cardiac devices										
Infections	Low	Serious limitation	No serious limitations	Serious limitation	Serious limitation	Serious limitation	No upgrade	No upgrade	No upgrade	Very low

Table 22 GRADE rating for primary outcomes

		Downgrade for					Upgrade for			
Primary outcome	A priori ranking	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Large consistent effect**	**Dose response**	**Confounders only reducing size of effect**	Final grade
Unexpected battery depletion	Low	No serious limitations	No serious limitations	No serious limitation	Very serious limitation	No serious limitations	No upgrade	No upgrade	No upgrade	Very low
Cardiac catheters/cannulas										
Major complications	Low	Serious limitation	No serious limitations	Serious limitation	Very serious limitation	No serious limitations	No upgrade	No upgrade	No upgrade	Very low
Total cost difference (per patient)	Low	No serious limitations	Serious limitation	No serious limitations	Very serious limitation	No serious limitations	No upgrade	No upgrade	No upgrade	Very low

4 Discussion

4.1 Summary of findings

A total of 51 studies reported in 52 papers were included in this systematic review. Of these, 19 studies addressed reprocessing safety, costs, and environmental effects after reuse in humans in clinical settings (in vivo). The remaining 33 laboratory-based (in vitro) studies partially addressed reprocessing safety. The summary of findings is reported as they relate to individual research questions. Overall, there is still insufficient good-quality evidence to establish the safety, cost-effectiveness, and environmental impacts of reusing SUDs, and the amount of available evidence differs by device type.

4.1.1 Research question 1: What, if any, SUDs does the available research evidence indicate can be reprocessed in line with the 2017 EU MDR and other related approaches?

Most studies did not provide sufficient depth of detail to determine how closely they aligned with the reprocessing regulations set out in the EU MDR. Details regarding the staff undertaking the reprocessing (number of staff, training provided, and their qualifications); the quality and maintenance routine for the equipment being used; the range of devices being reprocessed in the institution; and, importantly, how the institution determined that the SUD was suitable for reprocessing, the number of cycles permitted, and the availability of written documents to support this, would have improved our ability to determine how well they aligned with the EU MDR regulations [39]. The details that were provided in the studies tended to be an outline of the reprocessing cycle only. Of the regulatory approaches identified, we consider devices that underwent reprocessing in line with the FDA approval process or the EU MDR as having undergone regulatory requirements most closely aligned with the EU MDR option adopted by Ireland. For in vivo studies following FDA policies, the EU MDR, national policies, institutional policies, or research team criteria, we assume that devices were previously tested in vitro.

Results of one poor-quality and one good-quality in vivo study indicate that external fixator devices (risk class I) may be reused at least once without causing additional adverse patient- or device-related events. In these studies, reprocessing was undertaken in-house or externally following FDA or research team criteria. Results of four fair-quality and good-quality in vivo studies of implantable cardiac devices (pacemakers and ICDs) (risk class III) indicate no significant differences in the odds of patient complications or device failures between once-reprocessed/reused devices and new devices following local reprocessing policies or research team reprocessing criteria. Very low certainty of evidence, as indicated by the GRADE assessment, means that the HRB authors have very little confidence in the effect found in these studies. It is also worth noting that none of the clinical studies in this review were designed to be able to capture risk of prion infections. However, we estimate this risk to be low given that most studies in this review involved interventions at sites distant from neurological exposure.

4.1.2 Research question 2: What are the financial costs, and the safety and environmental consequences, of reusing SUDs which were reprocessed in line with the 2017 EU MDR and other related approaches?

SUDs reporting no additional adverse safety events are discussed in Section 4.1.1. SUDs which the available published evidence indicated cannot yet be safety reprocessed and which we cannot infer any safety implications are discussed in Sections 4.1.2.1 and 4.1.2.2.

4.1.2.1 SUDs which cannot yet be safely reused following reprocessing

Arthroscopic shavers (surgical instruments; risk class IIa) did not pass in vitro testing undertaken internally as well as by external reprocessing companies and following research team reprocessing standards and FDA reprocessing regulations. We did not identify any in vivo studies examining the safety of reprocessing arthroscopic shavers. As such, the available research evidence indicates that available methods can not yet safety reprocess arthroscopic shavers in vitro and their reuse has not been studied in routine clinical care.

Some respirators and surgical face masks (risk class I) passed reprocessing a limited number of times (up to three reprocessing cycles without device use in between cycles). Findings were specific to the device model and reprocessing method used. Four studies reported following FDA or other stringent reprocessing requirements, with the remainder following local health facility policies or requirements set by the research teams. As all the studies reporting following FDA, ISO or Occupational Safety and Health Administration (OSHA) were undertaken between 2020 and 2022, the reported adherence to these standards for this type of device is most likely following the emergency modification to the list of devices permitted for reprocessing due to worldwide shortages of these devices during the coronavirus disease 2019 (COVID-19) pandemic, which allowed reprocessing of respirators/surgical face masks if original device manufacturer standards could be maintained. These devices have since been removed from the FDA device shortage list and therefore reprocessing is no longer permitted [14]. There was consensus among study authors that the reprocessing of respirators and surgical face masks should be restricted to emergency situations only, such as the worldwide shortage during the pandemic.

4.1.2.2 SUDs requiring additional safety evidence

We identified one in vitro study each examining the safety of reprocessing biopsy forceps (surgical instruments for grasping and cutting; risk class IIa); sphincterotomes, argon plasma coagulation probes, and electrosurgical pencils (endoscopic and laparoscopic devices; risk class IIa); internal fixator devices (risk class IIb); and ablation catheters, electrophysiology polyurethane catheters, and cardiac cannulas (cardiac catheters/cannulas; risk class III). Consequently, there is insufficient published research evidence from which to make statements about the reprocessing safety of these SUDs. Ablation and electrophysiology polyurethane catheters (risk class III) were recommended for further testing by study authors after both internal reprocessing following research team-specified reprocessing requirements. However, no identified in vivo studies examined the safety of reusing reprocessed electrophysiology polyurethane catheters, and one in vivo study was identified examining the safety of ablation catheters.

We identified one in vivo study examining the safety of phacoemulsification needle tips (ophthalmic devices; risk class IIa), indicating insufficient evidence from which to draw any conclusions about safety. We identified one in vivo study each examining the safety of laparoscopic sealers and dividers, ultrasonic scissors/scalpels/shears and linear suture machines. When these four endoscopic and laparoscopic devices (risk class IIa) were analysed together, the odds of patient complications or reoperations were the same between once-reprocessed/reused devices and new devices, following FDA, EU MDR, or country-specific reprocessing requirements. This may indicate that stringent regulation of single-use endoscopic and laparoscopic devices may not cause additional patient safety concerns. However, the certainty in the evidence for this outcome was very low.

There were conflicting results from four in vivo studies of the safety of reprocessing cardiac balloon catheters (risk class III). These conflicting results may be due to differences in the models of balloon catheters studied, the mode of device cleaning and sterilisation, the reprocessing location (in-house compared with an external independent reprocessing company), or individual study quality (Appendix J). It was not possible to synthesise data on major or minor complications across the available in vivo studies,

but narrative synthesis indicated no difference in the odds of major patient complications after one reprocessing and reuse cycle.

4.1.2.3 Cost implications of SUD reprocessing

Cost data were reported for external fixator devices, compression sleeves, pulse oximeters, surgical instruments for grasping and cutting, endoscopic and laparoscopic devices, and cardiac catheter devices. Savings were reported for hospital departments across device groups when direct costs were calculated, i.e. the cost of a reused device compared with a new device. Few studies reported on indirect costs, e.g. both direct costs and costs related to safety outcomes such as patient complications, reoperations, procedure times, or duration of hospital stay. One endoscopic and laparoscopic device and one cardiac catheter device study each reported that savings were reduced but remained significant when indirect costs were accounted for. Furthermore, the very low certainty of evidence for indirect costs, as indicated by the GRADE assessment, means that the HRB authors have very little confidence in the effect found in these studies. Cost savings were also reported by the one study providing life cycle device cost data, i.e. environment-related indirect costs. The amount of savings decreased or remained consistent with each additional reprocessing cycle (up to five reuses) across seven reprocessed SUDs. Taken together, there are too few studies accounting for key indirect costs to make conclusions about the potential for cost savings in clinical practice. It is likely that reprocessing results in environmental related cost savings in clinical practice, with savings remaining consistent or decreasing with subsequent reprocessing cycles.

4.1.2.4 Environmental impact implications of SUD reprocessing

One study reported environmental impacts across seven devices: arthroscopic shavers, compression sleeve pairs, endoscopic trocars, laparoscopic sealers/dividers, pulse oximeters, laparoscopic scissor tips, and ultrasonic scalpel/shears/scissors. Given median/mean reprocessing life cycle inventory inputs (i.e. the amount of ethylene oxide, electricity, and water consumed), reprocessing of the seven devices slightly reduced global warming impacts, but concurrently exacerbated human health impacts (i.e. carcinogenic, non-carcinogenic, and respiratory effects) [105].

4.1.3 Research question 3: How, if at all, do safety outcomes, environmental impacts, and costs associated with reprocessing SUDs in line with the 2017 EU MDR and other related approaches differ by SUD type?

Among devices for which safety data were available, the spectrum of safety outcome data available differed across studies (Appendix F). Three groups of devices collected major complication outcomes, and two groups collected patient infection outcomes, device failure-related outcomes, and procedure time outcomes. Regarding primary patient safety outcomes collected across multiple device types (major complications and infections), the odds of major complications were similar for reused and single-use external fixator devices (risk class I) and endoscopic and laparoscopic devices (risk class IIa), but odds were higher for reused cardiac catheters/cannulas (risk class III). The odds of other device failure-related outcomes were the same in reused and single-use external fixator devices (risk class I) and implantable cardiac devices (risk class III). The odds of secondary patient safety outcomes (i.e. procedure time) were the same in reused and new single-use endoscopic and laparoscopic devices (risk class IIa) and cardiac catheters/cannulas (risk class III).

Cost savings were consistently reported across studies reporting on direct and indirect reprocessing costs. Given heterogeneity across cost studies both within and across device groups (i.e. the year costs were calculated for, currency of costs, device and associated costs costed, and technological advances between the time of original studies and this evidence review), we did not adjust costs to 2023 costs in a single currency. However, Unger and Landis [105] did report differences in device life cycle-related cost savings

across devices examined. The greatest savings were seen for deep vein thrombosis compression sleeves (risk class I), ultrasonic scalpel/shears/scissors (risk class IIa), pulse oximeters (risk class I), and endoscopic trocars (risk class IIa). Savings were lower for laparoscopic sealers/dividers, laparoscopic scissor tips, and arthroscopic shavers (risk class IIa).

In their study, Unger and Landis found that deep vein thrombosis compression sleeves had the highest environmental impacts of all seven devices examined [105]. The significant environmental impacts associated with deep vein thrombosis compression sleeves were driven by high device utilisation on an annual basis at the health facility, as well as the considerable environmental impacts associated with manufacturing the device material (woven cotton). High quantities of plastics in laparoscopic sealers/dividers correlated with significant environmental and human health impacts regardless of whether the devices were reprocessed or only used once.

4.2 Comparison with other research

Ours is one of a few systematic reviews on this topic which seek to collate and synthesise the available evidence across individual and medical discipline groupings of SUDs, thereby setting out the fullest picture of available published research evidence on the topic and also enabling comparison of outcomes across device groups [21, 22, 34, 35]. To date, such systematic reviews have been unable to draw any definitive conclusions about the safety [22, 34, 35] or cost-effectiveness [21, 22] of reprocessing SUDs from the available published literature. Ours is the first systematic review to synthesise the available evidence on the environmental impacts of reprocessing SUDs.

Regarding safety, our findings appear broadly in line with the audit of FDA SUD reprocessing adverse event data by the Government Accountability Office in the USA, which found that there are no indications of an elevated health risk resulting from SUD reprocessing in the USA [37]. Our review captured data on many of the devices included in that audit. Examples of inspected devices are provided in *Table **23*** [37].

Table 23 Comparison of SUDs audited in the Government Accountability Office audit and those identified in this evidence review

Device	Government Accountability Office audit of FDA data	SUDs identified in this evidence review
Arthroscopic accessories	✓	✓
Bite block for endoscope	✓	×
Blood pressure cuff	✓	×
Cardiac stabiliser	✓	×
Compression sleeve	✓	✓
Curette	✓	×
Disposable surgical instrument kit	✓	×
External fixation device	✓	✓
Electrophysiology catheter	✓	✓
Laparoscopic instruments	✓	✓
Non-electric biopsy forceps	✓	×

Table 23 Comparison of SUDs audited in the Government Accountability Office audit and those identified in this evidence review

Device	Government Accountability Office audit of FDA data	SUDs identified in this evidence review
Orthopaedic cutting instrument, bone tap	✓	×
Pneumatic tourniquet	✓	×
Protective restraint	✓	×
Reamer, burr, drill bit	✓	×
Surgical saw blade	✓	×
Tracheal tube stylet	✓	×

In contrast to the USA Government Accountability Office's audit of FDA SUD reprocessing adverse event data [37], our review reported increased odds of major complications for cardiac catheters/cannulas (risk class III) in one of three studies. However, the one study reporting events for this outcome [118] did not undergo as stringent regulation as the other studies collecting data on this outcome did [112, 113]. It is vital to note that the available evidence on which these review findings are based is derived from studies of varying quality (see Appendix J), and our overall certainty in the findings for each primary review outcome was very low (see Section 3.4.4).

Medical field-specific comparable literature is also scarce, with one known health technology assessment published in Canada in 2008 in the field of laparoscopic cholecystectomy and coronary angioplasty [23] and three recent systematic reviews of the safety of implantable cardiac devices [125–127]. We synthesised most of the primary studies included in the review by Hailey *et al.* [23], although some items did not meet our inclusion criteria (see Appendix D). We identified two new cost studies in the field of endoscopic and laparoscopic procedures [107,108] and one new cost study in the field of cardiac catheterisation [119] that were published since the Hailey *et al.* publication in 2008 [23]. The quality of these new studies was better than the older studies (Appendix J). Only one of these studies [107] captured both direct and indirect costs, and, similar to the review by Hailey *et al*., reported that cost savings were reduced after differences in adverse events between participants receiving reused devices and SUDs were accounted for. Therefore, consistent with Hailey *et al.*'s finding, we can say that the indirect costs of reprocessing SUDs reduce the cost savings associated with SUD reprocessing. One known systematic review has examined strategies to reduce greenhouse gas emissions from laparoscopic surgery [128]. In relation to laparoscopic SUD reprocessing as a strategy to reduce greenhouse gas emissions, Rizan *et al.* cited one primary study which estimated that reprocessing of single-use surgical instruments could reduce the greenhouse gas emissions of a laparoscopic operation by 9% [129]. The LCA study included in the current review also estimated reductions in the environmental impacts examined and built on this by demonstrating that the relative environmental impact of reprocessing specific single-use instruments (compared with using new ones) is likely to be determined by the extent of reprocessing required, which in turn depends upon the complexity of the instrument, the extent of damage from use and of decontamination required, the location of the reprocessing unit, and the number of additional uses [105].

To date, the largest amount of systematic review data are available in the field of implantable cardiac devices [125–127]. Given our review criteria that studies from developing countries were not eligible, we did not include all studies synthesised in these previous systematic reviews and did not include any additional primary studies. Not surprisingly, our findings are consistent with those reported in these systematic reviews, particularly the more recent reviews by Sinha *et al.* [126] and Psaltikidis *et al.* [127]. Specifically, modern protocols for reprocessing these devices do not result in additional adverse events [126,127]. In contrast, the systematic review by Baman *et al.* included studies as far back as 1970 and reported no differences in the rates of patient infections or higher odds of device malfunction in the reused pacemaker compared with the new pacemaker device groups [125]. Only Psaltikidis *et al.* [127] undertook a GRADE assessment of their review findings and determined the confidence as moderate for infections and low for premature battery depletion. In the current review, we have determined the confidence as very low for both of these outcomes. This is largely due to differences in the a priori GRADE ranking based on study design [70] and ratings attributed to imprecision (device malfunction outcome). A full justification for our ratings is available in Appendix K. Examining the cost or environmental impacts was beyond the scope of the systematic reviews by Baman *et al.,* Psaltikidis *et al.* and Sinha *et al.* [125–127]. As well as echoing Sinha *et al.*'s calls for high-quality randomised controlled trials on this topic [126], our review demonstrates a requirement for research examining the cost or environmental impacts of this practice.

4.3 Strengths and limitations

The primary strengths of this review are that it is the most comprehensive systematic review to date examining the topic of SUD reprocessing, and that it explicitly incorporated a modern reprocessing definition into its study eligibility criteria and reported individual study reprocessing oversight criteria. The broad scope of our review is a strength because ours is the first systematic review examining the environmental impacts of SUD reprocessing and, by identifying only one eligible study to address this aspect of the review, highlighting a clear research gap in this area. This approach also enables comparison of the volume of available evidence in each of the domains of safety, financial costs and environmental impacts across different device types, which can helpfully guide research priorities on this topic within individual medical disciplines. For instance, endoscopic and laparoscopic devices were the only group of SUDs for which we identified evidence in each of the areas of safety, financial costs and environmental impacts. One of the key arguments in favour of SUD reprocessing is that regulating the practice may reduce the risk of unsafe interventions and resultant infections [19]. By using a modern definition of reprocessing to determine study eligibility for inclusion in this systematic review, and reporting information on SUD reprocessing oversight criteria followed by individual study authors, we were able to eliminate risks of including studies of similar related practices (e.g. sterilisation only, recycling, reprocessing for single-patient reuse) or unsafe reprocessing practices and also distinguish between different 'levels' of reprocessing regulation across studies in order to help contextualise similarities and differences in the findings between studies of similar SUDs. However, we cannot rule out the possibility that excluding studies which did not define 'reprocessing' or report on the reprocessing-related procedures followed could have resulted in missing otherwise eligible items. We believe that failure to report this information adds confusion to this topic and that primary study authors should be encouraged to include these details in their studies. As more developed countries (particularly those in Europe) consider legislative options for SUD reprocessing [39], the regulatory information provided in this review and its implications for where SUD reprocessing can take place may provide decision-makers with better context to inform decisions.

Our review is further strengthened by our use of a validated, commonly used medical device risk classification system [56] for grouping medical devices, which enables readers to consider what SUDs are

being examined in relation to the level of risk to patients of reprocessing. The decision to identify and describe in vitro studies in this review is also regarded as a strength of the review. Although in vitro studies on their own cannot determine the safety of reprocessing SUDs in a clinical setting, when studied alongside available clinical safety studies, they can add to the knowledge about which SUDs are being considered for reprocessing. The search strategy to identify evidence was carefully considered, resulting in many strengths and our confidence in the search results. It was kept intentionally broad in order to capture all relevant results, was peer-reviewed, and was conducted across a range of reputable databases and sources.

Finally, this systematic review and meta-analysis is strengthened by following best research practices. Registering the study protocol on a public repository (PROSPERO; ID: CRD42022365642) in advance of the title and abstract screening ensures transparency [130]. One minor change was subsequently made to the protocol: the inclusion of cardiac catheter/cannula studies where the sterilisation process was not assessed. Justification for this change is reported in Section 2.2. Reporting of the systematic review according to international guidelines for systematic reviews and literature searches in systematic reviews, as well as recent reporting resources for LCA studies and systematic reviews with cost and cost-effectiveness outcomes [40,43,44], promotes the reliability of the systematic review through ensuring transparent and accurate reporting [131]. We undertook study design-specific quality appraisal of in vivo studies and applied the GRADE system to primary safety and cost research outcomes of these studies, which enabled the researchers to draw conclusions by accounting for the quality of data on which review findings are based. A potential limitation is that the tools used to appraise the quality and guide reporting of LCA studies are new and have not yet been validated [43,65]. This is because the study of LCA data in the context of health and healthcare delivery is so new, with the first transparency checklist (used in our review for quality appraisal) published in late 2022 [65]. However, this checklist was developed for a review of a closely related topic (switching from SUDs to reusable alternatives), suggesting that the items covered should be applicable to our review [65]. Still, validating the checklist was beyond the scope of our study, and quality ratings with respect to LCA studies should therefore be interpreted with caution.

Regarding the limitations of our review, the primary limitation is that by taking such a broad approach, we could not involve experts across all fields of medicine included in this systematic review which would have ensured in-depth clinical knowledge of individual SUDs. However, our review team included two members with clinical practice backgrounds in dentistry (CW) and nursing (JL). We also sought advice on our review from the HPRA, Ireland's regulatory body for health products, including medical devices. We also accounted for this in our synthesis by using sensitivity analyses to check if grouping different but similar medical devices within device groups influenced individual outcome findings. Data extraction, synthesis, quality appraisal, and application of the GRADE system were undertaken by NMG. All steps and synthesis decisions were guided by an experienced statistician (CW) and health economists working within the HRB (ÁT) and externally (PC). Relatedly, although standardising cost results to a single currency and for the current year to adjust for inflation is common in systematic reviews of economic studies, due to the quality of the cost studies we identified, the specific cost outcomes identified (mainly direct costs), and the likely advances in technology and regional differences in costs in the available studies, we felt that doing so would not result in comparable costs if these studies were undertaken today in a single country/region. Instead, we focused on the broader trend of the presence or absence of cost savings in individual studies comparing reused and once-used SUDs. Next, SUD reprocessing is a widespread practice Latin America [19,32] and therefore, exclusion of Spanish and Portuguese language studies may have resulted in non-inclusion of relevant items. Additionally, our confidence in the individual review findings are limited by the volume and quality of the studies contributing data to them. We acknowledge the presence of ethical constraints in conducting controlled trials using reprocessed SUDs at least in some

jurisdictions (e.g., in Europe) in the absence of sufficient evidence to support reprocessing. One solution could be more European controlled trials comparing SUDs used a disposable device and SUDS reused after third party professional reprocessors, whereby reprocessors assume the risks related to putting on the market a reprocessed SUDs. Relatedly, details of reprocessing processes followed in the included primary studies varied and were often limited, such that the review authors made assumptions to enable classification. For instance, the rigour of "local policies" may vary across studies and jurisdictions making comparisons of the impact of the reprocessing oversight using our groupings potentially meaningless.

Finally, although not a limitation, the priority screening function of EPPI-Reviewer did not expedite the screening process to the extent anticipated. Due to the reporting of identified studies, it was not always clear from title and abstract review whether studies were clearly not eligible, and therefore we had to err on the side of including studies at the title and abstract stage. This meant that the machine learning function of the EPPI-Reviewer priority screening tool could not easily identify a pattern of likely eligible studies (see Appendix C). This observation may be of interest to researchers considering employing priority screening within EPPI-Reviewer.

4.4 Future research

Since the previous overviews examining this topic across SUD types [22,23] were published, there has been a small number of randomised controlled trials [104,110,120] and one cost minimisation study [119] published on this topic. The call for additional good-quality primary research on this topic has also been stated in previous systematic reviews on this topic [22,23,125,126]. Findings from our systematic review show that the need for good-quality randomised controlled trials examining safety, and for economic evaluations to more appropriately examine the cost and cost-effectiveness of reusing SUDs, still persists. For instance, in the field of implantable cardiac devices where safety is most studied, while the available research from our review and other related systematic reviews [125,126] suggests no additional adverse effects of pacemaker and defibrillator reprocessing, our certainty in the safety outcomes in these studies is very low. Regarding cost and cost-effectiveness, at the very minimum, clinical studies capturing cost data alongside safety trials must include indirect reprocessing costs in their analyses. Economic evaluation research is also needed in order to examine the extent of actual cost savings across devices, as findings from our review are in line with previous research suggesting that the cost savings of SUD reprocessing differ across individual devices and reprocessors [23,31].

Given the move towards regulation of SUD reprocessing, researchers working in this area should endeavour to explicitly report reprocessing protocols and particularly their oversight or any regulatory requirements. This would assist in informing the extent of regulation required in order to ensure safe reprocessing, without trade-offs in terms of cost savings or environmental benefits. New research on this topic should focus on interventions which are not already demonstrated to be cost-effective in a given clinical situation. For instance, if appendicectomy is already demonstrated as being cost-effective, there is no need to explore reprocessed SUDs in this area of general surgery.

When the proposed future primary research is undertaken and reported as recommended, future systematic reviews on this topic should examine the association between "reprocessing oversight" and safety, cost-effectiveness and environmental impacts. This would provide additional important insight into how reprocessing should be implemented. Such comparisons may also be feasible in future primary studies.

Finally, our systematic review highlighted areas for methodological development in the area of LCA research applied to healthcare and health services research. Specifically, research quality assurance tools, such as transparency checklists and reporting resources, should be validated. Formal quality appraisal tools and reporting guidelines are required. In undertaking this methodological development work, LCA

study reporting will be improved and these items will be more amenable to use to inform decision-making. Alongside this, additional LCA studies of this topic across different jurisdictions are required to validate our findings.

4.5 Conclusions

Overall, there is still insufficient evidence to establish the safety, cost-effectiveness, and environmental impacts of reusing SUDs, and the amount of available evidence differs by device type. External fixator devices (one of two studies may have followed reprocessing standards aligned with Article 17[2] of the EU MDR) and implanted cardiac devices (pacemakers and defibrillators; reprocessing processes were not aligned with Article 17[2] of the EU MDR) reported no additional adverse events after one reprocessing cycle. However, the certainty of the evidence is very low. In the absence of high-quality safety data, monitoring of device databases for adverse patient events in jurisdictions allowing at least some SUD reprocessing may provide decision-makers with additional insight into the safety of SUD reprocessing. Reprocessing results in cost savings for both direct and indirect costs (related to safety and device life cycle), but marginal savings diminish with subsequent reprocessing cycles. The certainty of the evidence for cost outcomes examined is also very low. SUD reprocessing has the potential to reduce global warming impacts, but may exacerbate human health impacts. High-quality randomised controlled trials, cost-effectiveness studies, and environmental impact studies are needed in order to better understand the safety, costs, and environmental impacts of SUD reprocessing. These future studies should endeavour to compare these outcomes across device models, study device models in isolation or use other appropriate methods to account for potential heterogeneity within device types (e.g., balloon catheters).

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Appendix A Grey literature table and detailed search strategies

(A) Grey literature table

General scoping searches were carried out on the Google.com search engine to gain an initial idea of terminology and likely key terms. Reviewing literature in the area (retrieved from the Epistemonikos and Cochrane databases) also helped build up our search vocabulary. Initial search terms used included combinations of 'single-use device', 'SUD', 'SUMD', and 'single-use medical device', together with language around reprocessing and reuse. Further searches were carried out using the websites of relevant bodies (see Table 24).

Table 24 Websites included in supplementary grey literature search

Organisation	Website
Bundes Gesundheit Ministerium (Federal Ministry of Health, Germany)	https://www.bundesgesundheitsministerium.de/en/ministry/the-federal-ministry-of-health.html
Center for the Evaluation of Value and Risk in Health (Cost-Effectiveness Analysis (CEA) Registry, Tufts University, Boston, Massachusetts, United States of America (USA))	https://cevr.tuftsmedicalcenter.org/databases/cea-registry
Centre for Reviews and Dissemination (CRD, University of York, United Kingdom (UK))	https://www.york.ac.uk/crd/
Competent Authorities for Medical Devices (CAMD)	https://www.camd-europe.eu/
Department of Health, Ireland	https://www.gov.ie/en/organisation/department-of-health/#
European Commission	https://ec.europa.eu/info/index_en
European Union (EU) Law (Europa)	https://european-union.europa.eu/institutions-law-budget/law_en
European database on medical devices (EUDAMED)	https://ec.europa.eu/tools/eudamed/#/screen/home
Google	https://www.google.ie/
International Health Technology Assessment Database	https://www.inahta.org/
Health Systems Evidence	https://www.healthsystemsevidence.org/
Lenus	https://www.lenus.ie/
Livivo	https://www.livivo.de
MedTech Europe (trade association)	https://www.medtecheurope.org/
OpenGrey repository	http://www.opengrey.eu
PROSPERO registry	https://www.crd.york.ac.uk/prospero/
World Health Organization	https://www.who.int/

(B) Search strategies

Table 25 Overview of database results

Database	Date of search	No. of results
Ovid MEDLINE	25 July 2022	3,617
Embase	25 July 2022	2,079
Cochrane Trial Register	25 July 2022	291
Cochrane Library (John Wiley & Sons Inc.)	25 July 2022	3
Dimensions	25 July 2022	304
Total before deduplication		6,294
Total after deduplication		5,041
Total retained for analysis after screening	Health setting	18
Total retained for analysis after screening	Laboratory setting	33
Total added from reference chasing		1

(a) Embase

Table 26 Embase search strategy 25 July 2022

Query number (#)	Search terms	Results
#46	#45 AND ('article'/it OR 'article in press'/it OR 'chapter'/it OR 'conference abstract'/it OR 'conference paper'/it OR 'preprint'/it OR 'review'/it OR 'short survey'/it)	2,079
#45	#30 AND #34 AND [1994-2022]/py	2,171
#44	#30 AND #34	2,269
#43	#35 NOT #42	2,268
#42	'single-use versus reusable medical devices in spinal fusion surgery':ti	1
#41	#35 NOT #40	2,268
#40	'a cost-effectiveness analysis of exalt model d single-use duodenoscope versus':ti	1
#39	#35 NOT #38	2,268

Table 26 Embase search strategy 25 July 2022

Query number (#)	Search terms	Results
#38	'economic analysis of reprocessing single-use medical devices':ti	1
#37	#35 NOT #36	2,268
#36	'systematic review of reusable versus disposable laparoscopic instruments':ti	1
#35	#30 AND #34	2,269
#34	#31 OR #32 OR #33	11,845,373
#33	#21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29	9,248,690
#32	#14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20	2,212,471
#31	#5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13	1,396,789
#30	#1 OR #2 OR #3 OR #4	2,947
#29	(equipment NEAR/5 (safety OR risk OR infection OR adverse OR malfunction)):ab,ti,kw	4,318
#28	(instrument NEAR/5 (safety OR risk OR infection OR adverse OR malfunction)):ab,ti,kw	2,472
#27	(device* NEAR/5 (safety OR risk OR infection OR adverse OR malfunction)):ab,ti,kw	22,199
#26	'instrument sterilization'/exp OR 'disinfection'/exp OR disinfect*:ab,ti,kw OR sterilz*:ab,ti,kw OR sterilis*:ab,ti,kw OR quarantin*:ab,ti,kw	89,657
#25	'infection'/exp OR 'hygiene'/exp OR 'cross infection'/exp	4,264,422
#24	'risk'/exp	2,850,294
#23	'adverse event'/exp	967,425
#22	'safety procedure'/exp	64,078

Table 26 Embase search strategy 25 July 2022

Query number (#)	Search terms	Results
#21	'safety'/exp OR safety:ab,ti,kw OR incidence:ab,ti,kw OR mortality:ab,ti,kw	3,430,453
#20	'environmental aspects and related phenomena'/exp	2,075,373
#19	('waste' NEAR/5 (dispos* OR management OR cost OR impact)):ab,ti,kw	23,057
#18	(environment* NEAR/5 (dispos* OR management OR cost OR impact)):ab,ti,kw	50,468
#17	(waste OR environment*)	25,727
#16	'environmental sustainability'/exp OR 'environmental impact'/exp	95,197
#15	'waste management'/exp	213,588
#14	'waste disposal'/exp	19,39
#13	(cost NEAR/5 (benefit* OR effectiv* OR comparat* OR analy*)):ab,ti,kw	278,703
#12	'cost benefit':ab,ti,kw OR 'cost-benefit':ab,ti,kw OR 'cost analysis':ab,ti,kw OR 'cost-analysis':ab,ti,kw OR 'cost compar*':ab,ti,kw OR 'cost implication*':ab,ti,kw OR 'cost effectiv*' OR 'cost-effectiv*':ab,ti,kw OR cost:ab,ti,kw	747,969
#11	'cost minimization analysis'/exp	3,797
#10	'hospital cost'/exp	43,215
#9	'health economics'/exp	987,523
#8	'health care financing'/exp	13,727
#7	'health care cost'/exp	323,080
#6	'cost control'/exp	73,496

Table 26 Embase search strategy 25 July 2022

Query number (#)	Search terms	Results
#5	'cost benefit analysis'/exp	90,954
#4	((sud OR sumd) NEAR/20 (instrument* OR device* OR equipment)):ab,ti,kw	146
#3	('certified reprocessing' NEAR/20 (instrument* OR device* OR equipment)):ab,ti,kw	2
#2	((reuse OR 're-use' OR 're use' OR reprocess* OR remanufact*) NEAR/20 (instrument* OR device* OR equipment)):ab,ti,kw	1,807
#1	('single use' NEXT/10 (instrument* OR device* OR equipment)):ab,ti,kw	1,276

(b) MEDLINE

Table 27 MEDLINE search strategy 25 July 2022

Query number (#)	Search terms	Results
#1	((reuse or re-use or reusing or reprocess* or remanufact* or resterili#e*) adj10 (instrument* or device* or equipment)).mp.	3,908
#2	(certified reproc* or sud or SUMD or (single adj use* adj10 (instrument* or device* or equipment))).mp.	7,633
#3	or/1-2	11,259
#4	exp Equipment Reuse/	3,158
#5	exp "Equipment and Supplies"/	1,610,810
#6	((medical or surgical) and (device* or instrument* or equipment)).mp.	293,141
#7	(single adj use* adj10 (instrument* or device* or equipment)).mp.	966
#8	exp Surgical Instruments/	25,809
#9	exp Surgical Equipment/	286,785

Table 27 MEDLINE search strategy 25 July 2022

Query number (#)	Search terms	Results
#10	exp disposable equipment/	5,265
#11	exp "Equipment and Supplies, Hospital"/	27,237
#12	or/4-11	1,775,417
#13	exp Cost-Benefit Analysis/	90,518
#14	exp "Cost Control"/	34,037
#15	health care cost effectiveness.mp.	15
#16	exp Healthcare Financing/	1,202
#17	exp "Health Care Economics and Organizations"/	1,642,271
#18	exp Hospital Costs/	11,865
#19	" cost minimi*ation analysis".mp.	808
#20	('cost benefit' or 'cost-benefit' or 'cost analysis' or 'cost-analysis' or 'cost compar*' or 'cost implication*' or 'cost-effectiv*' or cost).mp.	615,324
#21	(cost adj5 (benefit* or effectiv* or comparat* or analy*)).mp.	280,595
#22	or/13-21	2,004,556
#23	exp Carbon Footprint/	903
#24	(waste adj5 (dispos* or management or cost or impact)).mp.	56,496
#25	(environment* adj5 (dispos* or management or cost or impact)).mp.	42,189
#26	((environment* adj5 sustainab*) or carbon footprint or recycl*).mp.	72,242
#27	or/23-26	158,865
#28	exp Safety Management/ or Safety Management.mp.	22,460
#29	exp Patient Safety/	24,697

Table 27 MEDLINE search strategy 25 July 2022

Query number (#)	Search terms	Results
#30	exp Equipment Safety/	10,437
#31	((device or equipment) adj5 (defect* or failure* or misuse or malfunction*)).mp.	66,479
#32	((contaminat* or complicat* or erosion) adj5 (instrument* or device* or equipment)).mp.	29,419
#33	(safety or incidence or mortality).mp.	2,718,406
#34	(Adverse event or Adverse Event Outcome).mp.	34,945
#35	exp "Risk Evaluation and Mitigation"/	64
#36	exp Risk/	1,350,136
#37	(Infection Control or Infection, Healthcare Associated).mp.	47,963
#38	exp Hygiene/ or exp Cross Infection/	104,935
#39	exp instrument sterilization/ or exp disinfection/ or (disinfect* or sterilz* or sterilis* or quarantin*).mp.	70,970
#40	exp Sterilization/ or (sterili* adj5 (instrument* or device* or equipment)).mp.	34,448
#41	or/28-40	3,867,074
#42	(substance adj5 disorder*).mp.	117,748
#43	22 or 27 or 41	5,675,733
#44	3 and 43	5,423
#45	limit 44 to yr="1994 -Current"	5,203
#46	limit 45 to (comment or editorial or letter or newspaper article)	276
#47	45 not 46	4,927
#48	"substance use".ti,ab,kw.	45,398
#49	47 not 48	3,617

Database(s): **Ovid MEDLINE and Epub Ahead of Print, In-Process, In-Data-Review and Other Non-Indexed Citations, Daily and Versions** 1946 to July 25, 2022

(c) Dimensions database

Table 28 Dimensions database search strategy 25 July 2022

Search term	Results
("reprocessing device"~5) OR ("reuse device" ~5) OR ("resterili?e device"~5) Filter: Title and Abstract search	304

(d) Cochrane Library and Register

Table 29 Cochrane Library (John Wiley & Sons Inc.) search strategy 25 July 2022

Query number (#)	Search terms	Results
#1	(reuse OR re-use or reprocess* or remanufact*) and ((SUD or SUMD* or single-use or "single use") NEAR/5 (device* or instrument* or equipment))	14
#2	MeSH descriptor: [Equipment and Supplies] explode all trees	53,231
#3	MeSH descriptor: [Equipment Reuse] this term only	101
#4	MeSH descriptor: [Equipment and Supplies] this term only	186
#5	[mh "Equipment and Supplies"[mj]]	8,347
#6	#1 or #4 or #3	294

Appendix B Reporting guidelines

(C) Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist

Table 30 Completed PRISMA checklist

Topic	Item	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	(Evidence review) Title page
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Executive summary
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Section 1.2
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Section 1.3
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Section 2.2
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Section 2.3.2
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Appendix A
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Section 2.3.3
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Section 2.4
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Section 2.4

Table 30 Completed PRISMA checklist

Topic	Item	Checklist item	Location where item is reported
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Section 2.4
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Section 2.5, Section 2.6.4
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. odds ratio, mean difference) used in the synthesis or presentation of results.	Tables 6, 7, 11, 14, 15, 18, 20 and 21
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Appendix G
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Section 2.4
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Section 2.6.2 and Section 2.6.3
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Section 2.6.2 and Section 2.6.3
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Appendix G
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Section 2.6.2
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Section 2.6.4
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Section 2.6.4
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Section 3.1

Table 30 Completed PRISMA checklist

Topic	Item	Checklist item	Location where item is reported
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Appendix D
Study characteristics	17	Cite each included study and present its characteristics.	Section 3.2
Risk of bias in studies	18	Present assessments of risk of bias for each included study	Section 3.4.4, Appendix K
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Tables 6, 7, 11, 14, 15, 18, 20 and 21
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Section 3.4.4, Appendix K
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Section 3.4
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	n/a
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Section 3.4
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Appendix K
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Section 3.4.4, Appendix K
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Section 4.2
	23b	Discuss any limitations of the evidence included in the review.	Section 4.3
	23c	Discuss any limitations of the review processes used.	Section 4.3
	23d	Discuss implications of the results for practice, policy, and future research.	Section 4.4
OTHER INFORMATION			

Table 30 Completed PRISMA checklist

Topic	Item	Checklist item	Location where item is reported
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Section 2.1
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Section 2.1
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Section 2.2
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Not reported
Competing interests	26	Declare any competing interests of review authors.	Not reported
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Not reported

(D) PRISMA-S checklist

Table 31Completed PRISMA-S checklist

Section/topic	#	Checklist item	Location(s) reported
INFORMATION SOURCES AND METHODS			
Database name	1	Name each individual database searched, stating the platform for each.	Section 2.2, Section 2.3
Multi-database searching	2	If databases were searched simultaneously on a single platform, state the name of the platform, listing all of the databases searched	Appendix A
Study registries	3	List any study registries searched.	Table 25
Online resources and browsing	4	Describe any online or print source purposefully searched or browsed (e.g. tables of contents, print conference proceedings, web sites), and how this was done.	Appendix A
Citation searching	5	Indicate whether cited references or citing references were examined, and describe any methods used for locating cited/citing references (e.g. browsing reference lists, using a citation index, setting up email alerts for references citing included studies).	Section 2.3.2.2
Contacts	6	Indicate whether additional studies or data were sought by contacting authors, experts, manufacturers, or others.	Section 2.3.3
Other methods	7	Describe any additional information sources or search methods used.	Section 2.3.2.2, Appendix A
SEARCH STRATEGIES			
Full search strategies	8	Include the search strategies for each database and information source, copied and pasted exactly as run.	Section 2.3, Appendix A
Limits and restrictions	9	Specify that no limits were used, or describe any limits or restrictions applied to a search (e.g. date or time period, language, study design) and provide justification for their use.	Section 2.2, Appendix A
Search filters	10	Indicate whether published search filters were used (as originally designed or modified), and if so, cite the filter(s) used.	Section 2.3.3
Prior work	11	Indicate when search strategies from other literature reviews were adapted or reused for a substantive part or all of the search, citing the previous review(s).	Section 2.3
Updates	12	Report the methods used to update the search(es) (e.g. rerunning searches, email alerts).	Section 4.2
Dates of searches	13	For each search strategy, provide the date when the last search occurred.	Section 2.3
PEER REVIEW			

Table 31Completed PRISMA-S checklist

Section/topic	#	Checklist item	Location(s) reported
Peer review	14	Describe any search peer review process.	Section 2.3.3
MANAGING RECORDS			
Total Records	15	Document the total number of records identified from each database and other information sources.	Appendix A
Deduplication	16	Describe the processes and any software used to deduplicate records from multiple database searches and other information sources.	Section 2.3.2.2, Section 2.3.3

Source: Rethlefsen *et al.* (2021) [53]

(E) ISPOR CiCERO checklist

Table 32 ISPOR CiCERO checklist

ISPOR CiCERO Checklist: CrIteria for Cost (-Effectiveness) Review Outcomes. For systematic literature reviews that summarize cost and cost-effectiveness outcomes	Yes/no	Note
Stage 1. Planning and development		
Question 1. Is the review conducted according to the predefined protocol?	Yes	Section 2.1 and 2.2
1.1. Was evidence provided to document that the review methods were established prior to the conduct of the review?	Yes	Section 2.1
1.2. Did the review report whether there were any deviations from the protocol?	Yes	Section 2.2
Question 2. Does the review clearly report targeted population, outcomes, time horizon, study perspective, study design, and, when applicable, intervention(s) and comparator(s)?	Yes	Section 2.2
Stage 2. Search for evidence		
Question 3. Did the review authors provide a detailed search strategy(-ies) for at least one database that includes the search month and year?	Yes	Appendix A
Question 4. Is the search comprehensive and adequate?	Yes	Section 2.3, Appendix A
4.1 Did the search include an argued range of databases/electronic sources for published literature relevant to the aim of the review?	Yes	Section 2.3.2.1, Appendix A
4.2 Was supplementary searching conducted to identify relevant reports for cost or cost-effectiveness outcomes that were not identified in the database search(es)?	Yes	Section 2.3.2.2, Appendix A
4.3 Was a search for the relevant grey literature performed?	Yes	Section 2.3.2.1, Section 2.3.2.2, Appendix A
4.4 Were the terms and structure of the search strategy sufficient to retrieve as many eligible studies as possible?	Yes	Section 2.3.1
Question 5. Were the search dates for the review provided? If “Yes”, was any justification for the search date provided?	Yes	Section 2.3.2.2
Stage 3. Study selection and eligibility		
Question 6. Are the inclusion criteria relevant?	Yes	Section 2.2
6.1. Did the review authors clearly report their inclusion criteria?	Yes	Section 2.2
6.2. Are the inclusion criteria appropriate to answer the research question?	Yes	Section 1.3 and Section 2.2
Question 7. Is the study selection process appropriate?	Yes	Section 2.2 and Section 2.3.3

Table 32 ISPOR CiCERO checklist

ISPOR CiCERO Checklist: CrIteria for Cost (-Effectiveness) Review Outcomes. For systematic literature reviews that summarize cost and cost-effectiveness outcomes	Yes/no	Note
7.1 Did the review authors perform each step of study selection independently in duplicate?	Yes	Section 2.3.3
7.2 If any restrictions to inclusion of evidence were applied (e.g. date, publication format, or language), were they justified by the objectives of the review?	Yes	Section 2.2
Stage 4. Critical appraisal of included studies		
Question 8. Was an assessment of methodological quality of original studies performed?	Yes	Section 2.5 and Appendix J
Stage 5. Data extraction and synthesis		
Question 9. Were the studies' risk of bias considered in the review's synthesis?	Yes	Section 2.6.4 and Appendix K
Question 10. Were appropriate methods used to combine the results?	Yes	Section 2.6.2 and Section 2.6.3
10.1 Was the choice of the method(s) for data synthesis explained?	Yes	Appendix G
10.2 Were the cost data standardized?	No	Section 2.6.3
10.3 Was the data synthesised in a de-aggregated manner, distinguishing individual components of effects, costs, and resource use from incremental results?	Yes	Section 3.4
10.4 Was the synthesis appropriate considering the target audience of the synthesis?	Yes	Section 2.6
10.5 Was the synthesis appropriate, given the nature and similarity in the research questions (participants, interventions and comparators), study designs and outcomes across included studies?	Yes	Section 2.6
10.6. Was relevant between-study variation due to transferability (difference in jurisdiction/setting/context) described and addressed in the synthesis?	Yes	Section 3.4
10.7 If relevant, were the results from empirical cost or cost-effectiveness studies and modelling studies synthesized separately?	Yes	Section 2.6.3, Section 3.4
10.8 Were results from deterministic and probabilistic sensitivity analysis reported separately?	No	Sensitivity analysis not applicable
10.9 For meta-analysis: Was homogeneity of data properly assessed prior to pooling the data together? (For levels of homogeneity assessment, see Stage 5.) • Was the weighting technique justified?	Yes	Appendix G
10.10 For narrative synthesis (including graphical synthesis): Was the data synthesized in a comprehensive, structured narrative way?	Yes	Section 3.4
Stage 6. Presentation and reporting		
Question 11. Were the original studies included in the review described in adequate detail?	Yes	Section 3.4, Tale 4,

Table 32 ISPOR CiCERO checklist

ISPOR CiCERO Checklist: CrIteria for Cost (-Effectiveness) Review Outcomes. For systematic literature reviews that summarize cost and cost-effectiveness outcomes	Yes/no	Note
11.1. Country of studied population	Yes	Table 4
11.2. Description of the population of analysis	Yes	Section 3.4
11.3. Time horizon, perspective	Yes	Section 3.4
11.4. Discount rate	No	Not applicable
11.5. Adjustment for nflation	No	Section 2.6.3 and Section 4.3
11.6. Interventions compared	Yes	Section 3.4
11.7. Method(s) for valuation of economic outcomes	Yes	Section 2.6.3
(a) Cost(s) in the health care sector according to the horizon of interest (direct costs, capital costs)	Yes	Section 2.6.3
(b) Indirect medical costs	Yes	Section 2.6.3
(c) Costs outside the healthcare sector such as productivity loss	Yes	Section 2.6.3
11.8. Method(s) for valuation of effectiveness outcomes, including source, type of source, estimates, duration (when relevant)	No	Not applicable
11.9. Compliance/adherence with treatment	No	Not applicable
11.10. Decision analytic modeling technique or approach for calculation of economic outcomes	No	Not applicable
11.11. Cost outcomes and/or health outcomes (e.g. gained life years, number of deaths avoided, quality adjusted life years, and outcomes of economic value of an intervention	No	Not applicable
11.12. Uncertainty	No	Not applicable
11.13. Conflicts of interest and sources of funding	Yes	Study extraction forms (data not provided in the report)
11.14. Software used (R, STATA, SAS, Excel, SPSS etc.)	Yes	MS Excel, RevMan V 5.4
Question 12. Was any heterogeneity observed in the results of the review explored and discussed?	Yes	Section 3.4
Question 13. Were the biases related to findings of the conducted review, including the conflicts of interest and funding of the reviewers, discussed?	Yes	Section 3.4.4

Source: Mandrik *et al.* (2021) [44]

(F) Standardised technique for assessing and reporting reviews of life cycle assessment (STARR-LCA) checklist

Table 33 STARR-LCA checklist

Item	Checklist item	Location where item is reported
1	Review title, keywords and abstract	Title page and executive summary (abstract and keywords not applicable)
2	Rationale for the review	Section 1.2
3	Review question and objectives	Section 1.3
4	Description of review protocol	Section 2.1
5	Findings and features of the individual studies in the review	Section 3.4
6	Assessment of bias	Section 3.4.4 and Appendix J
7	Synthesis methods (qualitative and quantitative)	Section 2.6
8	Limitations of the review	Section 4.3
9	Summary of findings and conclusions	Section 4.1 and 4.5

Source: Zumsteg *et al.* [43]

Appendix C Priority screening in EPPI-Reviewer

Priority screening in the Evidence for Policy and Practice Information software programme (EPPI-Reviewer) was used to prioritise relevant abstracts and improve efficiency in screening during the title and abstract phase for this systematic review. Figure 8 illustrates the priority screening curve. This curve shows where in the screening process relevant articles were identified. Priority screening ceased at 4,131 out of 5,041 records. Due to the multiple and complex inclusion criteria, while single-screening the remaining 910 records, we included 10 records to retrieve for full-text screening as it was difficult to make an accurate assessment without the full text.

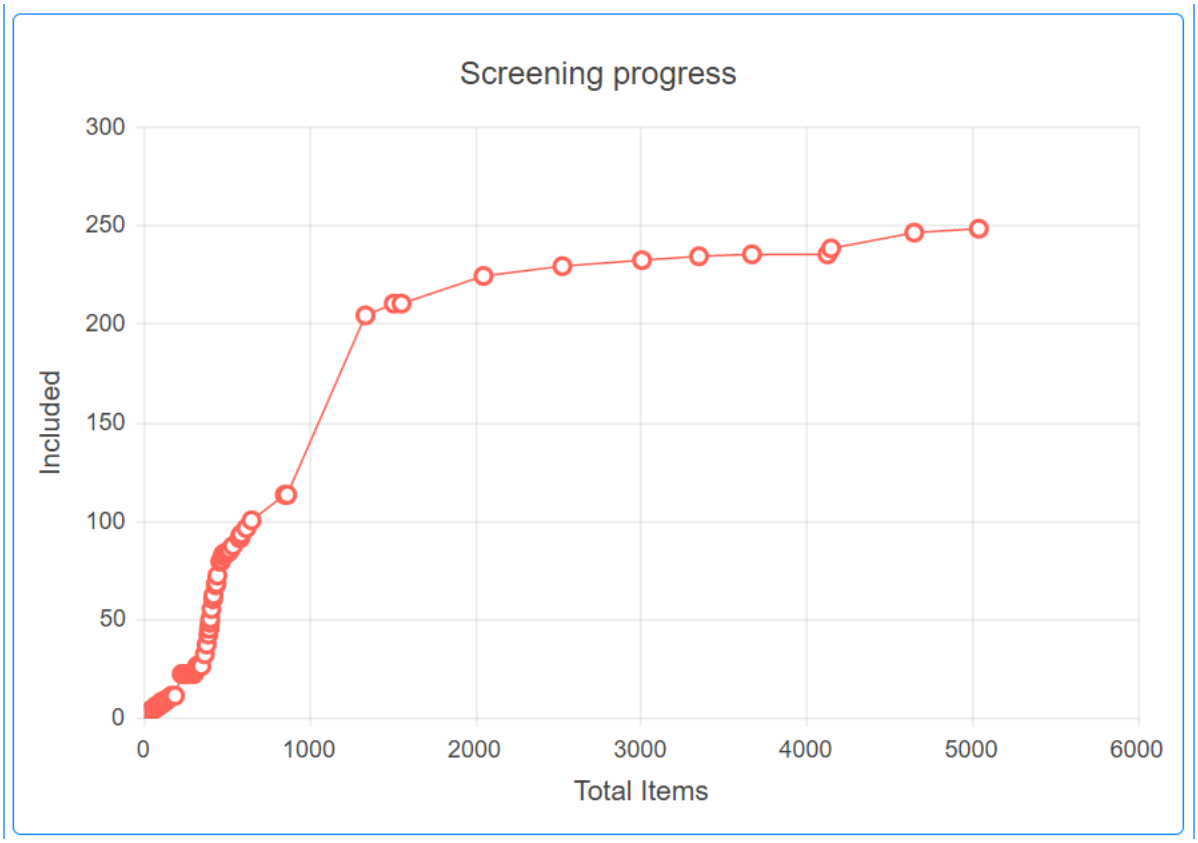

Figure 8 EPPI-Reviewer priority screening curve for the single-use medical device review

Appendix D Reasons for studies excluded at full-text and extraction screening stages

Table 34 Overview of studies excluded at full-text and extraction screening stages

Reason for exclusion	Exclusion criteria
Excluded on intervention (109)	Does not capture reprocessing process (cleaning, testing) Reusable device is used Single-use device (SUD) is reprocessed but reused for a different purpose other than its original intended purpose
Excluded on comparator (14)	Reusable device alternative of a single-use medical device (e.g. same type of device made from different materials) Unused SUDs
Excluded on design (34)	Conference abstracts Qualitative studies Eligible study designs without cost data Case reports or series Ecological studies Studies which do not describe a methodology In vitro studies Editorials, newspaper articles, etc.
Excluded on population (3)	Non-human; animal population
Excluded on duplicate (2)	
Excluded on language (7)	Non-English, Non-German
Excluded on country (18)	Non-Organisation for Economic Co-operation and Development member countries
Excluded on outcome (6)	No measure of patient safety, device safety, or related reprocessing process-related outcomes No measure of environmental or cost outcomes

Table 35 Studies excluded on comparator

Exclude on Comparator (n = 14)
Blomström-Lundqvist C. The safety of reusing ablation catheters with temperature control and the need for a validation protocol and guidelines for reprocessing. Pacing Clin Electrophysiol 1998;21:2563–70. doi:https://doi.org/10.1111/j.1540-8159.1998.tb00032.x
Cakan U, Delilbasi C, Er S, et al. Is it safe to reuse dental implant healing abutments sterilized and serviced by dealers of dental implant manufacturers? An in vitro sterility analysis. Implant Dent 2015;24:174–9. doi:https://doi.org/10.1097/id.0000000000000198
Czubryt M, Stecy T, Popke E, et al. N95 mask reuse in a major urban hospital: COVID-19 response process and procedure. J Hosp Infect 2020;106:277–82. doi:https://doi.org/10.1016/j.jhin.2020.07.035
DesCôteaux J, Poulin E, Lortie M, et al. Reuse of disposable laparoscopic instruments: a study of related surgical complications. Can J Surg 1995;38:497–500. https://pubmed.ncbi.nlm.nih.gov/7497363/

Table 35 Studies excluded on comparator

Exclude on Comparator (n = 14)
Gardeweg S, Bockstahler B, Duprè G. Effect of multiple use and sterilization on sealing performance of bipolar vessel sealing devices. PLoS One 2019;14:e0221488. doi:https://doi.org/10.1371/journal.pone.0221488
Hasan R, Ghanbari H, Feldman D, et al. Safety, efficacy, and performance of implanted recycled cardiac rhythm management (CRM) devices in underprivileged patients. Pacing Clin Electrophysiol 2011;34:653–8. doi:https://doi.org/10.1111/j.1540-8159.2011.03061.x
Heeg P, Roth K, Reichl R, et al. Decontaminated single-use devices: an oxymoron that may be placing patients at risk for cross-contamination. Infect Control Hosp Epidemiol 2001;22:542–9. doi:https://doi.org/10.1086/501949
Kantharia BK, Patel SS, Kulkarni G, et al. Reuse of explanted permanent pacemakers donated by funeral homes. Am J Cardiol 2012;109:238–40. doi:https://doi.org/10.1016/j.amjcard.2011.08.036
Lee RM, Vida F, Kozarek RA, et al. In vitro and in vivo evaluation of a reusable double-channel sphincterotome. Gastrointest Endosc 1999;49:477–82. doi:https://doi.org/10.1016/s0016-5107(99)70046-5
Lopes C de LBC, Graziano KU, Pinto T de JA. Evaluation of single-use reprocessed laparoscopic instrument sterilization. Rev Lat Am Enfermagem 2011;19:370–7. doi:10.1590/s0104-11692011000200020
Pavri BB, Lokhandwala Y, Kulkarni GV, et al. Reuse of explanted, resterilized implantable cardioverter-defibrillators: a cohort study. Ann Intern Med 2012;157:542–8. doi:https://doi.org/10.7326/0003-4819-157-8-201210160-00004
Rotella M, Ercoli C, Funkenbusch P, et al. Performance of single-use and multiuse diamond rotary cutting instruments with turbine and electric handpieces. J Prosthet Dent 2014;111:56–63. doi:https://doi.org/10.1016/j.prosdent.2013.06.003
van Straten B, Robertson P, Oussoren H, et al. Can sterilization of disposable face masks be an alternative for imported face masks? A nationwide field study including 19 sterilization departments and 471 imported brand types during COVID-19 shortages. PLoS One 2021;16:e0257468. doi:https://doi.org/10.1371/journal.pone.0257468
Weinheimer C, Ellsworth M, Ferguson L, et al. Reprocessing N95s with hydrogen peroxide vaporization: A robust system from collection to dispensing. Am J Infect Control 2021;49:508–11. doi:https://doi.org/10.1016/j.ajic.2020.10.011

Table 36 Studies excluded on language

Exclude on Language (n = 7)
Akçay A, Akçay M. Determining the Cost of Reuse of Disposable Devices in Cardiology. Klimik Derg 2019;32:136–45. doi:https://doi.org/10.5152/kd.2019.32
Berto R, Strutz J. Schädigung von mikrochirurgischen Instrumenten durch Aufbereitung in einer Zentralsterilisation. Laryngorhinootologie 2017;96:774–9. doi:https://doi.org/10.1055/s-0043-110857
Cottarelli A, De Giusti M, Solimini A. Microbiological surveillance of endoscopes and implications for current reprocessing procedures adopted by an Italian teaching hospital. Ann Ig Med Prev E Comunità 2020;:166–77. doi:https://doi.org/10.7416/ai.2020.2340
De Casco M, Moraes M, De Souza E, et al. Evaluation of the physical and functional properties of angioplasty insufflation devices undergoing reuse processing. Rev Bras Cardiol Invasiva 2009;17:227–33. doi:https://doi.org/10.1590/S2179-83972009000200016

Table 36 Studies excluded on language

Exclude on Language (n = 7)
Hülse R, Wenzel A, Sommer JU, et al. Umgang und Aufbereitung semikritischer Medizinprodukte in der HNO – eine prospektive Studie. Laryngorhinootologie 2017;21:536–43. doi:https://doi.org/10.1055/s-0043-110858
Paci-bonaventure S, Soreda S, Raspaud S, et al. Cleaning performance on arthroscopic surgical device by protein residues assay. J Pharm Clin 2004;23:169–74.
Silva MV da, Pinto T de JA. Reutilização simulada de produtos médico-hospitalares de uso único, submetidos à esterilização com óxido de etileno. Rev Bras Ciênc Farm 2005;41:181–90. doi:https://doi.org/10.1590/S1516-93322005000200005

Table 37 Studies excluded on design

Exclude on Design (n = 34)
Belotti L, Lambert S, Allaham B, et al. Reuse of a single-use sterile device: Example of prefilled sterile humidifiers [poster]. J Hosp Infect 2010;76:S20. https://www.journalofhospitalinfection.com/article/S0195-6701(10)60065-5/pdf
Boroda K, Lugay M, Sabuda M, et al. The use of atpase monitoring to determine endoscope bioburden and assure satisfactory manual cleaning. Am J Gastroenterol 2016;111:S153. doi: https://doi.org/10.1038/ajg.2016.354
Brady J, Bhakta A, Steele S, et al. Reprocessed bipolar energy for laparoscopic colectomy: Is it worth it? Dis Colon Rectum 2016;59:e55. doi: https://doi.org/10.1097/01.dcr.0000482708.50838.af
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Tessarolo F, Caola I, Fedel M, et al. Different experimental protocols for decontamination affect the cleaning of medical devices. A preliminary electron microscopy analysis. J Hosp Infect 2007;65:326–33. doi:https://doi.org/10.1016/j.jhin.2006.10.015
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Thaker AM, Kim S, Sedarat A, et al. 267 Inspection of Endoscope Instrument Channels After Reprocessing Using a Prototype Video Camera: A Pilot Study. Gastrointest Endosc 2017;85:AB66. doi:10.1016/j.gie.2017.03.078

Table 38 Studies excluded on intervention

Exclude on Intervention (n = 109)
Thaker AM, Kim S, Sedarat A, et al. Inspection of endoscope instrument channels after reprocessing using a prototype borescope. Gastrointest Endosc 2018;88:612–9. doi:https://doi.org/10.1016/j.gie.2018.04.2366
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Vergara ÓA, Domínguez LC, Sierra DO, et al. Comparación de los desenlaces clínicos con cuatro técnicas de apendicetomía laparoscópica tras la implementación de políticas de reúso de dispositivos médicos. Rev Cir 2021;73:132–40. doi:10.35687/s2452-45492021002598
Visrodia KH, Ofstead CL, Yellin HL, et al. The use of rapid indicators for the detection of organic residues on clinically used gastrointestinal endoscopes with and without visually apparent debris. Infect Control Hosp Epidemiol 2014;35:987–94. doi:https://doi.org/10.1086/677148
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Table 39 Studies excluded on country

Exclude on Country (n = 18)
Almehmadi AH, Alghamdi FT. Microbial Culture and Scanning Electron Microscopic Evaluation of Endodontic Hand Files: An In Vitro Study. Cureus 2022;14:e25673. doi:https://doi.org/10.7759/cureus.25673
Briesen S, Schulze Schwering M, Roberts H, et al. Minimal cross-infection risk through Icare rebound tonometer probes: a useful tool for IOP-screenings in developing countries. Eye Lond Engl 2010;24:1279–83. doi:https://doi.org/10.1038/eye.2009.297
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Table 39 Studies excluded on country

Exclude on Country (n = 18)
Côrtes MF, Espinoza EPS, Noguera SLV, et al. Decontamination and re-use of surgical masks and respirators during the COVID-19 pandemic. Int J Infect Dis 2021;104:320–8. doi:https://doi.org/10.1016/j.ijid.2020.12.056
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Da Silva MV, Martinez MB, Andreoli Pinto Tde J. Microbiological evaluation of reused catheter guides in a Brazilian hospital. PDA J Pharm Sci Technol 2006;60:356–65.
da Silva MV, Ribeiro Ade F, Pinto Tde J. Safety evaluation of single-use medical devices after submission to simulated reutilization cycles. J AOAC Int 2005;88:823–9.
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Mallmann F, Murata C, Yamazaki ES, et al. Clinical evaluation of reprocessed blades in LASIK. Arq Bras Oftalmol 2008;71:221–7. doi:https://doi.org/10.1590/s0004-27492008000200016
Poosti M, Rad HP, Kianoush K, et al. Are more nickel ions released from NiTi wires after sterilisation? Aust Orthod J 2009;25:30–3.
Psaltikidis EM, Graziano KU, Frezatti F. [Cost analysis of reprocessing disposable forceps used in video-assisted surgery]. Rev Lat Am Enferm 2006;14:593–600. doi:https://doi.org/10.1590/s0104-11692006000400018
Tan MG, Gui Feng T, Teck Liang L, et al. Effective disinfecting of protective devices used in the course of treating SARS-CoV2-positive patients. J Infect Prev 2022;23:20–4. doi:https://doi.org/10.1177/17571774211033350
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Table 40 Studies excluded on duplicate

Exclude Duplicate (n = 2)
Bloom D, Cornhill J, Malchesky P, et al. Technical and economic feasibility of reusing disposable perfusion cannulae. Biomed Instrum Technol 1997;31:248–9.
Bond T, Nissenso A, Krishnan M, et al. Dialyzer reuse with peracetic acid does not impact patient mortality. Clin J Am Soc Nephrol 2011;6:1368–74. doi: https://doi.org/10.2215/CJN.10391110

Table 41 Studies excluded on population

Exclude on Population (n = 3)
Finck CA, Zur Linden AR, Singh A, et al. Effects of repeated use and resterilization on structural and functional integrity of microwave ablation antennas. Am J Vet Res 2017;78:508–16. doi:https://doi.org/10.2460/ajvr.78.4.508
Lester BR, Miller K, Boers A, et al. Comparison of in vivo clinical performance and shaft temperature and in vitro tissue temperature and transection times between new and reprocessed harmonic scalpels. Surg Laparosc Endosc Percutan Tech 2010;20:e150-159. doi:https://doi.org/10.1097/SLE.0b013e3181eff973
Weld KJ, Dryer S, Hruby G, et al. Comparison of mechanical and in vivo performance of new and reprocessed harmonic scalpels. Urology 2006;67:898–903. doi:https://doi.org/10.1016/j.urology.2005.11.027

Table 42 Studies excluded on outcome

Exclude on Outcome (n = 6)
Lester B R, Boser N P, Miller K, et al. Reprocessing and sterilization of single-use electrophysiological catheters: removal of organic carbon and protein surface residues. J AOAC Int 2009;92:1165–73. https://www.embase.com/search/results?subaction=viewrecord&id=L355304554&from=export
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Yang M, Deng X, Zhang Z, et al. Are intraaortic balloons suitable for reuse? A survey study of 112 used intraaortic balloons. Artif Organs 1997;21:121–30. doi:10.1111/j.1525-1594.1997.tb00348.x

Appendix E In vitro study level summary

An overview of the 33 eligible in vitro studies (including year of publication, country of publication, study design, and device type) is provided in the main text of this report (see Section 3.3). In this appendix, summaries of the characteristics of the studies for each device (year, device type, mode of contamination, sterilisation process used, number of cycles of reprocessing, where devices were reprocessed, regulatory standards, comparator devices, number of devices in intervention and comparison groups, and outcomes assessed) are provided in *Table **43***, *Table **45***, *Table **47*** and *Table **51***, followed by a narrative summary, and finally the authors' conclusions and our conclusions in *Table **44***, *Table **46***, *Table **48***, Table 50, and *Table **52***. We have not extracted the statistical data or undertaken a quality analysis of these studies.

Consistent with the reporting of findings in the main body of this report, we describe the characteristics and conclusions of these studies briefly and in order of device risk classification, as described by the Medical Device Coordination Group (MDCG) *2021-24 Guidance on classification of medical devices* [56]. Factors such as the degree of invasiveness, the part of the body affected, duration of use, and whether or not the device is active help to determine the risk classification, which ranges from I to III. Broadly speaking, the classifications are based on the potential for a deterioration in the health of the patient when the device is used (risk class I: little risk; risk class IIa: unlikely risk; risk class IIb: potential risk of deterioration; and risk class III: risk of death).

Consistent with the reporting of findings in the main body of this report, we describe the characteristics and conclusions of these studies briefly and in order of device risk classification, as described by the Medical Device Coordination Group (MDCG) *2021-24 Guidance on classification of medical devices* [56]. Factors such as the degree of invasiveness, the part of the body affected, duration of use, and whether or not the device is active help to determine the risk classification, which ranges from I to III. Broadly speaking, the classifications are based on the potential for a deterioration in the health of the patient when the device is used (risk class I: little risk; risk class IIa: unlikely risk; risk class IIb: potential risk of deterioration; and risk class III: risk of death).

(G) Respirators and surgical face masks (risk class I)

Respirators and surgical face masks are examples of personal protective equipment (PPE) and are labelled for single use. Respirators provide respiratory protection to the wearer and are designed to achieve a very close facial fit and very efficient filtration of airborne particles. Surgical face masks are more loose-fitting and create a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment [14].

Nineteen studies assessed the potential for reprocessing of respirators and surgical face masks. All but one [84] of these studies was undertaken as a result of the worldwide shortage of PPE during the coronavirus disease 2019 (COVID-19) pandemic, and following the United States of America (USA) Food and Drug Administration's (FDA's) temporary amendment to the guidance in relation to the reuse of respirators and surgical face masks [132].

Thirteen studies assessed the reuse of respirators only [69, 71, 74, 75, 79–81, 83, 84, 88, 91, 93, 95]. Three assessed respirators and surgical face masks [68, 72, 76] and two assessed respirators, surgical face masks, and cloth masks [73, 78]. One study assessed surgical face masks only [90].

Most of the studies were undertaken in the USA (n=10), 3 were undertaken in Canada, 2 in the Netherlands, and 1 each in France, Portugal, Switzerland, and the United Kingdom (UK). There was a large range of brands and models tested.

Respirators and surgical face masks were contaminated artificially with a variety of bacteria or viruses, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), or were used clinically before testing in vitro. For the most part, the reprocessing was undertaken internally, within a hospital laboratory setting. Occasionally some of the function testing was undertaken externally by commercial reprocessing companies. The number of devices tested was generally small, ranging from 12 to 162 devices, with many studies citing the shortage of samples available.

Reprocessing criteria were predominantly set by the researchers or based on local policy, which is not surprising, as the FDA and European Union (EU) currently have no set standards for reprocessing these devices. Other studies met the original manufacturers' standards for these devices as indicated by the FDA. Devices underwent between 1 and 10 reprocessing cycles. Numerous different methods of sterilisation were assessed: hydrogen peroxide (n=5 studies); dry heat (n=5 studies); ultraviolet (UV) light (n=4 studies); autoclave (n=3 studies); microwave-generated steam (n=3 studies); moist heat (n=2 studies); microwave (n=2 studies); bleach (n=2 studies); ozone (n=2 studies); ethylene oxide (n=2 studies); gravity steam processing (n=1 study); corona discharge system (n=1 study); methylene blue (with and without light) (n=1 study); and ethanol (n=1 study), with studies reporting on one method or comparing multiple methods.

Taken together, as the studies by Aljabo *et al.* [74] and Yap *et al.* [90] were the only ones whereby reprocessing standards were set by international standards (ISO) and the FDA respectively, these are the only studies in which reprocessing requirements and processes may be aligned with the requirements of Article 17 [2] in the EU MDR. However, the research studies did not provide sufficient detail to allow the authors of this report to conclude this with certainty.

Table 43 Study characteristics for respirators and surgical face masks

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices (N), intervention (n), comparison (n)	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
Aljabo *et al.* (2020) [74]	Name(s): Respirators Model(s): N95 1860, 1860s, 1870+, Vflex 9105 Brand(s): 3M	Used clinically and artificially contaminated (*Geobacillus stearothermophilus* spore suspension)	Gravity steam reprocessing	Intervention Sterilisation: Up to 3 Function testing: 1 cycle after 3 sterilisation cycles Comparison Sterilisation: 0 cycles Function testing: 0 cycles	Sterilisation: Internal Function testing: External	International Organization for Standardization (ISO) 17665-1:2006 standard	Sterilisation: Used and artificially contaminated but unsterilised Function testing: New, uncontaminated	N=32 Sterilisation: 11 Intervention: 9 Comparison: 2 Function testing: 32 Intervention: 21 Comparison: 11 No breakdown by device models	Sterility Function testing: Filter efficiency, fit evaluation, strap integrity
Christie-Holmes *et al.* (2021) [75]	Name(s): Respirators Model(s): N95 8210, 9210+ Brand(s): 3M	Artificially contaminated (human coronavirus (HCoV)-229E)	Vaporised hydrogen peroxide (VHP)	Intervention Sterilisation: 1 cycle Function testing: 1 cycle Comparison Sterilisation: 1 cycle Function testing: 0 cycles	Internal	Local policy	Sterilisation: a. Tripartite soil suspension alone b. VHP sterilisation, virus laced, washed within 1 hour, unsterilised c. Virus laced; delayed washing, unsterilised	N=15 Sterilisation: Intervention: 7 (7 for each test (3 tests)) Comparison: 6 (6 for each test (3 tests)) Function testing: 2 date expired respirators	Sterility Function testing: Filtration efficiency

Table 43 Study characteristics for respirators and surgical face masks

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices (N), intervention (n), comparison (n)	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
							Function testing: Sterilised, uncontaminated		
Harskamp *et al*. (2020) [76]	Name(s): Respirators Model(s): Aura 1862+, Aura 9322+ ZZM002, 2920V, Safe Worker 1016 Brand(s): 3M, Maco Pharma, San Huei	Used clinically	Autoclave	Intervention Sterilisation: 3 cycles Function testing: 1 cycle after each sterilisation cycle Comparison Sterilisation: 0 cycles Function testing: 0 cycles	Internal: Sterilisation, resistance, shape External: Filter capacity	Local policy	Sterilisation, resistance, shape: New, uncontaminated Filter capacity: New, uncontaminated, benchmark test	N=33 Sterilisation, resistance, shape: Intervention: 28 Comparison: 5 Filter capacity: Intervention: 56 samples (2 each from 28 respirators) Comparison: 10 samples (2 each from 5 respirators)	Sterility Function testing: Shape, filter capacity, flow resistance
Kumar *et al.* (2021) [77]	Name(s): Respirators Model(s): Moulded 1860, 8210, 1510 Pleated Aura 1870, Vfex 1804	Used for fit testing, then artificially contaminated (HCV (SARS-CoV-2), in a standard tripartite	1. Dry heat 2. Moist heat	Intervention Sterilisation: 1 cycle for each of 5 tests (3 hours, 4 hours, 5 hours, 6 hours, 8 hours) Function testing: Up to 5 cycles	Internal	Criteria set by researcher team	Sterilisation: Unsterilised, contaminated and uncontaminated swatches from devices Function testing: Used for fit testing,	N=12 Sterilisation: Intervention: 6 swatches Comparison: 6 swatches Function testing: Intervention: 6 masks Comparison: 6 masks	Sterility Function testing: Structural and functional integrity (fit and filtration)

Table 43 Study characteristics for respirators and surgical face masks

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices (N), intervention (n), comparison (n)	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
	Pleats Plus 1054 Brand(s): 3M, Moldex, Aearo	organic soil load)		Comparison Sterilisation: 0 cycles Function testing: 0 cycles			sterilised and against recognised standards (Canadian Standards Association (CSA) Z94.4-18 protocol, Centers for Disease Control and Prevention (CDC), TSI 8130A Automated filter tester)		
Levine *et al.* (2021) [78]	Name(s): Respirators Model(s): Fluidshield 46727, 46827, 1860, 1860S, 1870, 9210, Cardinal Health, Gerson 2130, 1730 Brand(s):	Used clinically	VHP	Intervention Sterilisation: Up to 8 cycles Function testing: 1–2 cycles after each sterilisation cycle Comparison Sterilisation: N/A Function testing: N/A	Internal	Criteria set by researcher team	Sterilisation: Devices before reprocessing, used clinically Function testing: New, unused devices	N=49 Sterilisation: Intervention: 12 (3 of each model) Comparison: N/A Function testing: Intervention: 49 Comparison: N/A	Sterility Function testing: Functional integrity, fit testing

Table 43 Study characteristics for respirators and surgical face masks

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices (N), intervention (n), comparison (n)	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
	Halyard, 3M, Cardinal Health*, Gerson* (*fit-tested only)								
Manning *et al.* (2021) [79]	Name(s): Respirators Model(s): 1870 Brand(s): 3M	Artificially contaminated (*Pseudomonas aeruginosa*)	Ozone exposure	Intervention Sterilisation: 5 cycles Function testing: 1 cycle (after 5 reprocessing cycles) Comparison Sterilisation: 0 cycles Function testing: 0 cycles	Internal: Filtration efficiency, fit testing, strap integrity External: Ozone exposure, airflow resistance	Criteria set by researcher team	Artificially contaminated, unsterilised	N=28 Sterilisation: 2 devices (disassembled into 4 pieces) Intervention: 4 samples Comparison: 4 samples Function testing: 20 devices Filtration efficiency: 10 devices Intervention: 5 devices Comparison: 5 devices Fit: Intervention: 5 devices Comparison: 5 devices Strap integrity: 6 devices Intervention: 3 devices Comparison: 3 devices	Sterility Function testing: Airflow resistance, filtration efficiency, strap integrity, fit testing

Table 43 Study characteristics for respirators and surgical face masks

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices (N), intervention (n), comparison (n)	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
Narayanan *et al.* (2021) [80]	Name(s): Respirators and polypropylene fabric Model(s): 8210, non-woven polypropylene fabrics similar to 07048 Brand(s): 3M	Artificially contaminated (*Escherichia coli*, *Pichia pastoris*, *Geobacillus stearothermophilus*)	Corona discharge system	Intervention Sterilisation: 3 cycles Filtration efficiency: 15 cycles Surface charge density: 1, 5, and 10 cycles Comparison Sterilisation: 0 cycles Filtration efficiency and surface charge density: 0 cycles	Internal: Sterilisation, recharge effect External: Filtration efficiency	Criteria set by researcher team	Model 07048 Brand 3M, new uncontaminated, unsterilised	N=not reported Intervention: 5 fabric samples and intact devices Comparison: Fabric samples and intact devices (n not reported)	Sterility Function testing: Filtration efficiency
Smith *et al.* (2021) [81]	Name(s): Respirators Model(s): 1860, 1870+, 8511 Brand(s): Not reported	Artificially contaminated (SARS-CoV-2)	1. VHP 2. UV light 3. Ethanol	Intervention Sterilisation: VHP: 2 cycles UV: 1 cycle Ethanol: 2 cycles Function testing: 1 cycle (after sterilisation) Comparison	Internal	Criteria set by researcher team	Sterilisation: a. Artificially contaminated and sterilised b. Uncontaminated and unsterilised Function testing: Uncontaminated, sterilised	N=not reported	Sterility Function testing: Fit testing, mask integrity

Table 43 Study characteristics for respirators and surgical face masks

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices (N), intervention (n), comparison (n)	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
				Sterilisation and function testing: 0 cycles					
Van der Vossen *et al.* (2022) [82]	Name(s): Respirators Model(s): Not reported Brand(s): Not reported	Artificially contaminated (*Geobacillus stearothermophilus*, SARS-CoV-2)	Ultraviolet-C (UVC) light	Intervention Sterilisation: 1 cycle for each of 3 tests (8, 60, and 180 minutes) Function testing: 1 cycle (after sterilisation) Comparison Sterilisation and function testing: 0 cycles	Internal	Criteria set by researcher team	Sterilisation and function testing: New, uncontaminated, unsterilised	N=not reported; devices were disassembled, tests were undertaken in triplicate on 2 models	Sterility Function testing: Filtration properties, respirator fit
Vernez *et al.* (2020) [83]	Name(s): Respirators Model(s): 6923, 1862 Brand(s): 3M	Used clinically and artificially contaminated (*Staphylococcus aureus* (vB_HSa_2002 and P66 phages))	Ultraviolet germicidal irradiation (UVGI)	Intervention Sterilisation: 1 cycle Function testing: Integrity: Up to 50 cycles Structural change: Up to 10 cycles Comparison Sterilisation,	Internal	Criteria set by researcher team	Sterilisation: Contaminated, unsterilised Function testing: New, uncontaminated, unsterilised	N=78 Sterilisation Intervention: 12 Comparison: 8 Function testing Intervention: 40 Comparison: 38	Sterility Function testing: Integrity, structural change

Table 43 Study characteristics for respirators and surgical face masks

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices (N), intervention (n), comparison (n)	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
				function testing: 0 cycles					
Viscusi *et al.* (2009) [84]	Name(s): Respirators Model(s): Random sample of 9 National Institute for Occupational Safety and Health (NIOSH)-approved respirators (3 respirator models, 3 surgical respirator models, and 3 P100 models) Brand(s): Not reported	Artificially contaminated	1. UVGI 2. Ethylene oxide 3. VHP 4. Microwave oven irradiation 5. Bleach	Intervention Sterilisation: UVGI: 1 cycle Ethylene oxide: 2 cycles VHP: 1 cycle Microwave oven irradiation: 1 cycle Bleach: 1 cycle Function testing: Unclear Comparison Sterilisation: 0 cycles Function testing: 0 cycles	Internal	Criteria set by researcher team	Sterilisation and function testing: New, uncontaminated, unsterilised	N=162 Sterilisation Intervention: 135 Comparison: 27 Function testing Intervention: 129 Comparison: 27	Sterility Function testing: Physical appearance, aerosol penetration, airflow resistance

Table 43 Study characteristics for respirators and surgical face masks

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices (N), intervention (n), comparison (n)	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
Yuen *et al.* (2022) [85]	Name(s): Respirators Model(s): 1860, Aura™ 1870+, 801, 120B Brand(s): 3M, Bacou Willson, BLS	Artificially contaminated (SARS-CoV-2)	1. Dry heat 2. Autoclave	Intervention Sterilisation: Dry heat: 4 cycles (for each of 2 temperatures) Autoclave: 1 cycle Function testing: 1 cycle (after each sterilisation test) Comparison Sterilisation: 0 cycles Function testing: 1 cycle	Internal	Sterilisation: Criteria set by researcher team Function testing: Other regulatory body (Occupational Safety and Health Administration (OSHA)) standards	Sterilisation: a. Contaminated, unsterilised b. Uncontaminated, unsterilised Function testing: Uncontaminated, unsterilised	N=not reported; some devices were disassembled Sterilisation Intervention: 6 samples dry heat, 1 sample autoclave Comparison: 1 sample Fit testing Intervention: Dry heat: 2 Autoclave: 1 for each model (4) Comparison: 1 for each model (4) Filtration: Intervention: 10 samples dry heat, 10 samples autoclave Comparison: 10 samples	Sterility Function testing: Fit, filtration
Zulauf *et al.*	Name(s): Respirators	Artificially contaminated (*Escherichia*	Microwave-generated	Intervention Sterilisation: 1 cycle (for each test)	Internal	Sterilisation: Criteria set by	Sterilisation: Contaminated, unsterilised	N=not reported; some devices were disassembled	Sterility

Table 43 Study characteristics for respirators and surgical face masks

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices (N), intervention (n), comparison (n)	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
(2020) [86]	Model(s): 1860 Brand(s): 3M	*coli* MS2 bacteriophage)	steam (MGS)	Fit and function: 1, 5, or 20 cycles Comparison Sterilisation and function testing: 0 cycles		researcher team Function testing: Other regulatory body (OSHA) standards	Function testing: Uncontaminated, unsterilised		Function testing: Fit, filtration
Bernard *et al.* (2020) [87]	Name(s): Respirators and surgical surgical face masks Model(s): iIcluding THF type II R 3 Plis, THF type IIR CA1960, RP2_Mand, NRD type IIR 2192S-WH Brand(s): CA	Artificially contaminated (oropharyngeal bacteria, influenza virus, animal coronaviruses)	1. Dry air heating 2. Moist air heating	Intervention Sterilisation: Up to 5 cycles Structural and chemical integrity: Not reported Filtration efficiency: Not reported Inspiratory resistance: 2 cycles Comparison Sterilisation: 0 cycles Function testing: 0 cycles	Internal	Criteria set by researcher team	Sterilisation: Unused, artificially contaminated, unsterilised Function testing: Unused, uncontaminated, unsterilised, recognised standards	N=6 Intervention and comparison: 1–3 device samples for each test No breakdown by device models	Sterility Function testing: Structural and chemical integrity, filtration efficiency, inspiration resistance

Table 43 Study characteristics for respirators and surgical face masks

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices (N), intervention (n), comparison (n)	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
	Diffusion, Medicom								
Lendvay *et al.* (2022) [88]	Name(s): Respirators and surgical surgical face masks Model(s): Fluidshield-46727, 1860, 1870+, Type II 14683, Type IIR F2100 Level 2 Brand(s): Halyard, 3M, ASTM	Artificially contaminated (HCVs (3): SARS-CoV-2, recombinant Mouse Hepatitis Virus strain rA59-E-FL-M, Porcine Respiratory Coronavirus strain 91V44)	1. Methylene blue (MB) 2. MB with light (MBL)	Sterilisation: MB: 1 cycle MBL: 5 cycles Function testing: 1 cycle (after the 5 cycles of MBL) Comparison Sterilisation: 5 cycles Function testing: 1 cycle	External	Criteria set by researcher team	Sterilisation: New, artificially contaminated, sterilised using FDA-authorised VHP plus ozone Function testing: New, uncontaminated, unsterilised	N=not reported; devices were disassembled for sterility testing and intact for function testing	Sterility Function testing: Filtration efficiency, breathability, fit testing, fluid resistance
Pascoe *et al.* (2020) [89]	Name(s): Respirators and surgical face masks Model(s):	Artificially contaminated membranes placed with folds of devices	1. Dry heat 2. MGS	Intervention Sterilisation: 3 and 5 cycles Filtration efficiency: 1 cycle (after 1 and 3 reprocessing cycles)	Internal	Criteria set by researcher team	Sterilisation: Artificially contaminated membrane samples, unsterilised	N=not reported; some devices were disassembled	Sterility Function testing: Filtration efficiency

Table 43 Study characteristics for respirators and surgical face masks

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices (N), intervention (n), comparison (n)	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
	cosy cloud, fluidshield Brand(s): Hardshell, Honeywell, Kimberly-Clark, Generic	(*Staphylococcus aureus* National Collection of Type Cultures 10788 in fresh tryptone sodium chloride supplemented with 0.3% weight in volume bovine serum albumin)		Comparison Sterilisation and filtration efficiency: 0 cycles			Function testing: Sample material from new, uncontaminated, unsterilised devices		
Yap *et al.* (2022) [90]	Name(s): Surgical masks Model(s): SKU 810484847 Brand(s): Canuxi	Artificially contaminated (SARS-CoV-2)	Dry heat	Intervention Sterilisation: 1 cycle for each of 4 temperatures Physical morphology and chemical composition: 1 cycle for each of 5 tests (varied times and temperatures)	Internal	FDA approved	Sterilisation: Contaminant sample, unsterilised Function testing: Uncontaminated, unsterilised intact device	N=not reported; some devices cut into samples Sterilisation Intervention: 48 samples Comparison: 4 samples Function testing: 1 mask (before and after heat treatment)	Sterility Function testing: Chemical and physical properties

Table 43 Study characteristics for respirators and surgical face masks

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices (N), intervention (n), comparison (n)	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
				Comparison Sterilisation and chemical and physical properties: 0 cycles					
Lordelo *et al.* (2022) [91]	Name(s): Respirators, surgical face masks, and cloth masks Model(s): GB2626- 2006 9501+, BV 465-001, Concept 2 B Brand(s): 3M, Bastos Viegas, Borgstena	Artificially contaminated (*Geobacillus stearothermophilus* DSM22 (for methods 1 and 3), *Bacillus atrophaeus* DSM675 (for method 2)	1. Nebulised hydrogen peroxide 2. Commercial bleach 3. Microwave steam-sanitising bags	Intervention Sterilisation: 1, 5, and 10 cycles Function testing: 5 or 10 cycles Comparison Sterilisation: 0 cycles Function testing: 0 cycles	Internal	Criteria set by researcher team	Artificially contaminated, unsterilised	N=not reported Sterilisation: Intervention: 1 device for each of 1–3 tests on 3 models Comparison: 9 (1 device for each of 3 tests on 3 models) Function testing: As above, except for physicochemical properties; devices were disassembled for testing	Sterility Function testing: Filtration efficiency, air permeability, physicochemical properties, structure
Schwan *et al.* (2021) [92]	Name(s): Respirators, surgical face masks, and cloth face masks	Artificially contaminated (*Escherichia coli* or *Vesicular*	Ozone generated from a dielectric barrier discharge	Intervention Sterilisation: 1 cycle Function testing: 1 cycle Comparison	Internal: Sterilisation and function testing External:	Criteria set by researcher team	Sterilisation: Artificially contaminated, unsterilised	N=not reported; some devices were disassembled	Sterility Function testing: Mask structure,

Table 43 Study characteristics for respirators and surgical face masks

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices (N), intervention (n), comparison (n)	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
	Model(s): Not reported Brand(s): Not reported	*stomatitis virus*)		Sterilisation and function testing: 0 cycles	Function testing		Function testing: Uncontaminated, unsterilised		filtration efficiency

*Pre-cleaning processes undertaken before sterilisation varied and are not presented here.

A summary of the study authors' and Health Research Board (HRB) review authors' conclusions about individual in vitro respirator and surgical face mask studies is provided in *Table **44***. The study authors' conclusions are direct quotations with some minor edits for conciseness and clarity.

Taken together, available study conclusions indicate that respirators and surgical face masks were safely and effectively reprocessed for at least one cycle in vitro using some (but not all) of the sterilisation methods and for some (but not all) brands and models. Successful methods identified by more than one study included hydrogen peroxide (n=5), moist heat (n=2), and ozone (n=2). There were contradictory findings between studies for dry heat, UV light, bleach, autoclave, and MGS. Results of two studies assessing microwaves reported that these could not effectively reprocess the devices.

Some issues highlighted by the study authors in relation to the reprocessing of respirators and surgical face masks which may explain the diverse findings were:

- The impact of the design of the respirators and surgical face masks on reprocessing
- The variety of temperatures and duration of the sterilising processes
- The importance of accurately assessing sterilisability, function, and fit when reprocessing
- The suitability of the contaminants used to contaminate the respirators and surgical face masks to mimic SARS-CoV-2, and
- The fact that the level of contamination in vitro may be higher than what would be expected in vivo.

Concerns about reprocessing respirators and surgical face masks were in relation to healthcare workers' acceptance of reused respirators and surgical face masks and concerns that reprocessing of respirators and surgical face masks could become normal practice. There was consensus that the reprocessing of respirators and surgical face masks should be restricted to emergency situations only, such as a worldwide shortage during a pandemic.

Table 44 Summary of findings for respirators and surgical face masks

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
Aljabo *et al.* (2020) [74]	Canada	Name(s): Respirators Model(s): 860, 1860s, 1870+, Vflex 9105 Brand(s): 3M	Gravity steam reprocessing	Gravity steam reprocessing enables the safe and effective reprocessing of N95 respirators over multiple reuse cycles. In particular, the 1870+ model shows high bacterial deactivation while maintaining high filtration capacity, good fit, and consistent strap integrity over at least three cycles of gravity steam reprocessing, with further optimization of the method to better promote steam penetration into the folds of the 9105 model likely also to overcome the occasional failure of this model in the microbiology test protocol. However, the fit quality of	This study found that gravity steam reprocessing effectively reprocessed some respirators (1870+, 9105), but not others (1860, 1860s), for up to three reuse cycles in vitro, due to differences in respirator model characteristics.

Table 44 Summary of findings for respirators and surgical face masks

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
				the more rigid 1860 model appears to be significantly affected by the gravity steam process and, as such, this protocol is not recommended for this respirator model.	
Christie-Holmes *et al.* (2021) [75]	Canada	Name(s): Respirators Model(s): 8210, 9210+ Brand(s): 3M	VHP	A single cycle of standardized VHP reprocessing will inactivate SARS-CoV-2 without compromising the filtration efficiency of unexpired N95 FFRs [filtering facepiece respirators]; however, future work should include comparative testing data with untreated FFRs to determine if there is an impact of these treatments on filtration efficiency.	This study found that VHP effectively reprocessed respirators (8210, 9210+), for one cycle, in vitro.
Harskamp *et al.* (2020) [76]	Netherlands	Name(s): Respirators Model(s): Aura 1862+, Aura 9322+ ZZM002, 2920V, Safe Worker 1016 Brand(s): 3M, Maco Pharma, San Huei	Autoclave	Selected FFP2 [filtering facepiece level 2] respirators may be reprocessed for use in primary care, as the respirators retain their shape, ability to retain particles and breathing comfort after decontamination using a medical autoclave. However, future studies are warranted to confirm our findings.	This study found that some respirators (Aura 1862+, Aura 9322+ ZZM002, 2920V), but not others (Safe Worker 1016), could be reprocessed for up to three cycles using an autoclave in vitro. No fit test was undertaken.
Kumar *et al.* (2021) [77]	Canada	Name(s): Respirators Model(s): Moulded 1860, 8210, 1510 Pleated Aura 1870, Vfex 1804 Pleats Plus 1054 Brand(s): 3M, Moldex, Aearo	1. Dry heat 2. Moist heat	Our data demonstrate that exposure of SARS-CoV-2-contaminated N95 [FFRs] to a temperature of 70 °C in the presence of passive humidity for 6 [hours] is highly effective for thermal inactivation of the virus. For a viable, simple, scalable but local solution to the problem of N95 respirator decontamination, it is necessary to consider the aversion of HCWs [healthcare workers] to re-use of respirators previously utilized by others. Our study suggests SARS-CoV-2 decontamination of respirators requires more time at 70 °C than might be expected based on other studies that did not use any organic soil load.	This study found that the respirator models tested (Moulded 1860, 8210, 1510 Pleated Aura 1870, Vfex 1804 Pleats Plus 1054) could be reprocessed in vitro using moist heat for 6 hours for up to five cycles, but not using dry heat.

Table 44 Summary of findings for respirators and surgical face masks

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
Levine *et al.* (2021) [78]	USA	Name(s): Respirators Model(s): Fluidshield 46727, 46827, 1860, 1860S, 1870, 9210, Cardinal Health*, Gerson 2130*, 1730* (*models fit-tested only) Brand(s): Halyard, 3M, Cardinal Health*, Gerson* (*fit-tested only)	VHP	In conclusion, decontamination and re-use of 3M 1860/3M 1860S, 3M 1870 and 3M 9210 N95 respirators is a potential solution to N95 respirator supply shortages. Further studies must address the downward trends observed in the functional integrity of Halyard Fluidshield 46727 N95 respirators after decontamination with VHP. Caution should be taken when returning 3M 1870 respirators to a second user following VHP decontamination. Finally, the lack of consistency between QLFT [qualitative fit test] and QNFT [quantitative fit test] results may have far-reaching consequences on the type of fit test administered by institutions when determining which respirator is best for protection against aerosolized pathogens.	This study found that some lightly used N95 respirators (Fluidshield 46727, 46827, 1860, 1860S, 1870, 9210) could be reprocessed using VHP for up to two cycles in vitro. There was a significant downward trend in the functional integrity of one of the respirators assessed (Fluidshield 46727) and caution should be taken with the 1870 model. The models Cardinal Health, Gerson 2130, 1730 were available for fit testing only.
Manning *et al.* (2021) [79]	USA	Name(s): Respirators Model(s): 1870 Brand(s): 3M	Ozone exposure	Ozone exposure disinfected 3M 1870 N95 respirators heavily inoculated with *P.* [*Pseudomonas*] *aeruginosa*. Ozone exposure did not negatively affect the airflow resistance, filtration efficiency, strap strength or fit of the 3M 1870 N95 respirator. The necessary conditions were 400 ppm [parts per million] ozone for 2 hours with relative humidity 80%. Future directions will focus on repeating these experiments using additional gram-negative and gram-positive bacteria, phages which are frequently used surrogates for COVID-19, and an airborne non-pathogenic virus. However, further studies are required to directly assess the effects of ozone on SARS-CoV-2.	This study found that the respirator model tested (1870) could be reprocessed using ozone exposure under specified conditions, for up to five cycles, in vitro.
Narayanan *et al.*	USA	Name(s): Respirators and polypropylene	Corona discharge system	The results indicate that even subjected to 15 cycles of CD [corona discharge] treatment, the filtration	This study found that non-woven polypropylene fabric,

Table 44 Summary of findings for respirators and surgical face masks

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
(2021) [80]		fabric Model(s): 8210, non-woven polypropylene fabrics similar to 07048 Brand(s): 3M		efficiencies of N95s were kept almost the same with the unused ones without deterioration. Ideally, safe reusable times for N95s can easily be extended to over 10 times by CD treatment, which is much more than most other disinfection solutions. Further understanding of CD disinfection mechanism will allow the development of more efficient and safe disinfection solutions.	similar to respirator model 07048 and model 8210, could be reprocessed for more than 10 cycles using corona discharge in vitro. No fit test was undertaken.
Smith *et al.* (2021) [81]	USA	Name(s): Respirators Model(s): 1860, 1870+, 8511 Brand(s): Not reported	1. VHP 2. UV light 3. Ethanol	Both ethanol and UV decontamination showed functional degradation to different degrees while VHP treatment showed no significant change after two treatments. We also report a single SARS-CoV-2 virucidal experiment using Vero E6 cell infection in which only ethanol treatment eliminated detectable SARS-CoV-2 RNA [ribonucleic acid]. Conclusions: We hope our data will guide further research for evidence-based decisions for disposable N95 mask reuse and help protect caregivers from SARS-CoV-2 and other pathogens. Samples from the 6 highest titer patients in our healthcare system to date were pooled, and 100 uL [microlitres] of this concentrated SARS-CoV-2 containing media was directly infiltrated into the N95 masks with the attempt to expose the middle layer. It is hard to imagine a realistic scenario where healthcare workers would face this degree of mask inoculum. Methods that appear less effective in decontaminating SARS-CoV-2 in our experiment, such as UV, would almost certainly be more effective if masks were challenged in a more realistic exposure scenario.	This study found that the respirator models tested (1860, 1870+, 851) could be reprocessed for up to two cycles using VHP in vitro. Reprocessing with either 70% ethanol or UV light was shown to significantly impair respirator function in vitro. No fit test was undertaken for any reprocessing method.

Table 44 Summary of findings for respirators and surgical face masks

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
Van der Vossen *et al.* (2022) [82]	Netherlands	Name(s): Respirators Model(s): Not reported Brand(s): Not reported	UVC light	UVC was shown to be a mild and effective way of respirator disinfection allowing for reuse of the UVC-treated respirators. Special attention should be paid to the construction of the respirators. A few respirators are on the market that have their strap passed through a folded part of the mask which forms a crevice that is probably less accessible for UVC. These types of respirator may not be a logical choice for UVC disinfection.	This study found that respirators could be reprocessed for one cycle using UVC light in vitro.
Vernez *et al.* (2020) [83]	Switzerland	Name(s): Respirators Model(s): 6923, 1862 Brand(s): 3M	UVGI	Our results demonstrated that after a single decontamination cycle, no viable phage particles were recovered from any of the 24 phage-contaminated FFR tested. The developed decontamination procedure successfully inactivated the phage particles and represents therefore a valuable strategy to decontaminate FFR contaminated with SARS-CoV-2. The germicidal efficiency observed for the overall decontamination process is due to both UVGI and heat drying treatments. By combining the two methods, we propose additional safety by overcoming some of the limitations of each treatment alone and bring convincing arguments for healthcare facilities, which are familiar UVGI treatment.	This study found that the respirator models tested (6923, 1862) could be reprocessed using UVGI for one cycle, in vitro.
Viscusi *et al.* (2009) [84]	USA	Name(s): Respirators Model(s): Random sample of 9 NIOSH-approved respirators (3 respirator models, 3 surgical	1. UVGI 2. Ethylene oxide 3. VHP 4. Microwave oven irradiation 5. Bleach	In light of these results, the microwave oven irradiation and bleach decontamination methods investigated in this study were determined to be the least desirable among the five methods tested for consideration in future studies. UVGI, EtO [ethylene oxide], and VHP were found to be the most promising decontamination methods; however, concerns remain about the	This study found that of five reprocessing methods assessed for the reprocessing of respirators (nine different unidentified models), three methods were determined to have promise in relation to device function after

Table 44 Summary of findings for respirators and surgical face masks

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
		respirator models, and 3 P100 models) Brand(s): Not reported		throughput capabilities for EtO and VHP. Further research is needed before any specific decontamination methods can be recommended.	one cycle (UVGI, EtO, and VHP) and two were less promising (microwave oven irradiation and bleach) in vitro. The effectiveness of the sterilisation processes was not assessed.
Yuen *et al.* (2022) [85]	USA	Name(s): Respirators Model(s): 1860, Aura™ 1870+, 801, 120B Brand(s): 3M, Bacou Willson, BLS	1. Dry heat 2. Autoclave	In the current study, we demonstrate the complete inactivation of SARS-CoV-2 and preservation of fit test performance of N95 respirators following treatment with dry heat. We apply scanning electron microscopy with energy dispersive X-ray spectroscopy (SEM/EDS), X-ray diffraction (XRD) measurements, Raman spectroscopy, and contact angle measurements to analyze filter material changes as a consequence of different decontamination treatments. We further compared the integrity of the respirator after autoclaving versus dry heat treatment via quantitative fit testing and found that autoclaving, but not dry heat, causes the fit of the respirator onto the user's face to fail, thereby rendering the decontaminated respirator unusable. Our findings highlight the importance to account for both efficacy of disinfection and mask fit when reprocessing respirators for clinical redeployment.	This study found that the respirator models tested (1860, 1870+, 801, 120B) could be reprocessed using dry heat, but not using an autoclave, in vitro.
Zulauf *et al.* (2020) [86]	USA	Name(s): Respirators Model(s): 1860 Brand(s): 3M	MGS	Using widely available glass containers, mesh from commercial produce bags, a rubber band, and a 1,100-W [watt] commercially available microwave, we constructed an effective, standardized, and reproducible means of decontaminating N95 respirators [a	This study found that a respirator model (1860) could be reprocessed for up to 20 cycles using microwave-generated steam, in vitro.

Table 44 Summary of findings for respirators and surgical face masks

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
				single 3-minute microwave treatment]. Notably, quantified respirator fit and function were preserved, even after 20 sequential cycles of microwave steam decontamination. This method provides a valuable means of effective decontamination and reuse of N95 respirators by frontline providers facing urgent need.	
Bernard *et al.* (2020) [87]	France	Name(s): Respirators and surgical face masks Model(s): Including THF type II R 3 Plis, THF type IIR CA1960, RP2_Mand, NRD type IIR 2192S-WH Brand(s): CA Diffusion, Medicom	1. Dry air heating 2. Moist air heating	We found that treatment in a climate chamber at 70 °C during 1 h [for 1 hour] with 75% humidity rate was adequate for enabling substantial decontamination of both respiratory viruses, oropharyngeal bacteria, and model animal coronaviruses, while maintaining a satisfying filtering capacity. Further studies are now required to confirm the feasibility of the whole process during routine practice.	This study found that the respirators and surgical masks tested (THF type II R 3 Plis, THF type IIR CA1960, RP2_Mand, NRD type IIR 2192S-WH) could be reprocessed using moist heat (at 70 °C and 75% humidity for 1 hour), but not with dry heat (at 70 °C for 15 or 60 minutes) in vitro.
Lendvay *et al.* (2022) [88]	USA	Name(s): Respirators and surgical masks Model(s): Fluidshield-46727, 1860, 1870+, Type II 14683, Type IIR F2100 Level 2 Brand(s): Halyard, 3M, ASTM	1. MB 2. MBL	MBL treatment decontaminated respirators and masks by inactivating 3 tested coronaviruses without compromising integrity through 5 cycles of decontamination. MBL decontamination is effective, is low cost, and does not require specialized equipment, making it applicable in low- to high-resource settings. Residual MB on the mask surface could potentially provide a novel means of continual inactivation of viral particles to decontaminate a mask while donned because MB inactivated SARS-CoV-2 on mask surfaces even under ambient light conditions.	This study found that the respirators and surgical masks tested (Fluidshield-46727, 1860, 1870+, Type II 14683, Type IIR F2100 Level 2) could be reprocessed for up to five cycles using MB with or without light in vitro; the time required varied depending on the intensity and colour of the light used.

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Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
Pascoe *et al.* (2020) [89]	UK	Name(s): Respirators and surgical masks Model(s): cosy cloud, fluidshield Brand(s): Hardshell, Honeywell, Kimberly-Clark, Generic	1. Dry heat 2. MGS	In conclusion, we found that MGS (industrial-grade 2.45 GHz [gigahertz] microwave oven; 1800 W, 90 s [seconds], 100 or 200 mL [millilitres] water in a 'sterilizer') was potentially effective in decontaminating some types of FFP-2/N95-type respirators, while dry heat (70C for 90 min) was potentially effective for the reprocessing of either N95-type respirators or Type-II surgical face masks, providing possible safe reprocessing methods should the procurement of unused PPE fail. While dry heat was not found to negatively impact function of PPE or surgical face masks, MGS was incompatible with surgical masks and some models of respirator. In this study, we only tested some aspects of the performance of surgical masks and respirators, and other tests might be needed to ensure that there was no degradation of other aspects such as the fit to the face.	This study found that the respirator tested (Fluidshield) was reprocessable using both dry heat and MGS for up to three cycles in vitro. The surgical mask tested (Cosy Cloud) was reprocessable using dry heat for up to three cycles, but not using MGS in vitro. No fit test was undertaken.
Yap *et al.* (2022) [90]	USA	Name(s): Surgical masks Model(s): SKU 810484847 Brand(s): Canuxi	Dry heat	Our results show that heating surgical masks to 70 °C for 5 min inactivates over 99.9% of SARS-CoV-2. We also characterized the chemical and physical properties of disposable masks after heat treatment and did not observe degradation.	The study found that a model of surgical mask (SKU 810484847) could be reprocessed for one cycle using dry heat (at 70 °C for up to 30 minutes) without degrading the physical properties in vitro. No fit test was undertaken.
Lordelo *et al.* (2022) [91]	Portugal	Name(s): Respirators, surgical masks, and cloth masks Model(s): GB2626- 2006 9501+, BV 465-	1. Nebulised hydrogen peroxide 2. Commercial bleach 3. Microwave	Results demonstrated that the H_2O_2 [hydrogen peroxide] protocol sterilized KN95 and surgical masks (reduction of >6 $\log_{10}$ CFUs [colony-forming units]) and disinfected cloth masks (reduction of >3 $\log_{10}$ CFUs). The NaClO [sodium hypochlorite] protocol sterilized surgical masks,	This study found that for up to 10 cycles in vitro, nebulised hydrogen peroxide could be used to reprocess one model of respirator (GB2626- 2006

Table 44 Summary of findings for respirators and surgical face masks

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
		001, Concept 2 B Brand(s): 3M, Bastos Viegas, Borgstena	steam-sanitising bags	and disinfected KN95 and cloth masks. Steam bags sterilized KN95 and disinfected surgical and cloth masks. Cycles of treatments, using any of the three decontamination methods under analysis, did not have a statistically significant impact on filtration efficiency, with the exception of the use of steam bags on KN95 and surgical masks, where the differences were found, even though statistically significant, did not have a major practical impact since the final efficiency was always higher than 97%. Even though the results obtained confirm the potential of the methods, additional studies are required, such as off-gassing experiments to ensure that residual chemicals are not present at potentially harmful levels.	9501+) and one model of surgical mask (BV 465-00); microwave steam-sanitising bags could be used to reprocess one type of respirator; and commercial bleach could be used to reprocess surgical masks. None of these methods effectively sterilised cloth masks but did disinfect them. No fit test was undertaken.
Schwan *et al.* (2021) [92]	USA	Name(s): Respirators, surgical masks, and cloth face masks Model(s): Not reported Brand(s): Not reported	Ozone generated from a dielectric barrier discharge	We have demonstrated that the efficiency of an ozone decontamination system for facepiece respirators can be dramatically increased by careful design of the reactor configurations. Specifically, a flow-through configuration where the ozone is passed directly through the porous fiber structure of the mask demonstrated superior decontamination kinetics with respect to the standard approach of an ozone chamber. This method has proven effective against both viral and bacterial pathogens causing a reduction of active pathogens by a minimum of two orders of magnitude within the first hour of processing. Treatment has also proven to be non-destructive to the mask's physical structure and does not reduce filtration efficiency over time.	This study found that respirators, surgical masks, and cloth masks (unidentified models) could be reprocessed once using ozone generated from a dielectric barrier discharge, in vitro. No fit test was undertaken.

Table 44 Summary of findings for respirators and surgical face masks

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions

*Pre-cleaning processes undertaken before sterilisation varied and are not presented here.

(H) Surgical instruments for grasping and cutting (risk class IIa)

Three studies assessed the potential for reprocessing disposable surgical instruments, namely biopsy forceps and arthroscopic shavers [93–95]. These surgical instruments are used for cutting and dissecting soft tissue during surgical procedures and usually have sharp edges which enable the operator to cut and dissect tissue, or tips that enable them to hold on to or manipulate tissues or to clamp blood vessels [2].

Two of the studies were undertaken in the USA and one in Japan. In all three studies, the devices were contaminated via clinical use in humans and were sterilised using ethylene oxide. Two studies assessed the sterility after each of three cycles and function tested them after the third cycle [93,95], and the third study did not report on the number of sterilisation cycles. The two studies undertaken in the USA followed FDA standards and the study undertaken in Japan followed criteria set by the researchers themselves. The devices were reprocessed by external reprocessing companies for two studies, and internally but by technicians from an external reprocessing company in the third.

Taken together, as the studies by Cogdill and Quaglia [93] and King *et al.* [94] were the only ones whereby reprocessing standards were set by the FDA, these are the only studies in which reprocessing requirements and processes may be aligned with the requirements of Article 17 [2] in the EU MDR. However, the research studies did not provide sufficient detail to allow the authors of this report to conclude this with certainty.

A summary of the study authors' and HRB review authors' conclusions about individual in vitro studies of surgical instruments for grasping and cutting is provided in *Table **46***. The study authors' conclusions are direct quotations with some minor edits for conciseness and clarity. The outcomes reported were sterility and function, which included blade sharpness and damage. All three studies found that the devices could not be safely or effectively reprocessed: "The reprocessing of [surgical instruments for grasping and cutting] presents an increased health risk to the patient and a loss of device effectiveness" [93 p434].

Table 45 Study characteristics for surgical instruments for grasping and cutting

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
Cogdill and Quaglia (1998) [93]	Name(s): Biopsy forceps Model(s): Microvasive Brand(s): Boston Scientific	Used clinically	Ethylene oxide	Intervention Sterilisation: 1–3 cycles Function testing: 1–3 cycles (after each sterilisation cycle) Comparison Intervention: 0 cycles Function testing: 1 cycle	External	FDA approved	New, unused devices, original manufacturers' standards	N=19 Intervention Sterilisation: 5 Function testing: 13 Comparison: 1	Sterility Function testing: Performance (8 tests)
King *et al.* (2006) [94]	Name(s): Arthroscopic shavers Model(s): Varied Brand(s): Dyonics Smith & Nephew	Used clinically	Ethylene oxide	Not reported	External	FDA approved	New, unused used, unsterilised	N=34 Sterilisation Intervention: 16 Comparison: 4 Function testing Intervention: 11 Comparison: 3	Sterility Function testing: Blade damage, sharpness
Kobayashi *et al.* (2009) [95]	Name(s): Arthroscopic shavers	Used clinically	Ethylene oxide	Intervention	Internal (by technicians from an	Criteria set by researcher team	New, unused	N=10 1. Blades Intervention: 4	Sterility Function

Table 45 Study characteristics for surgical instruments for grasping and cutting

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
	1. Shaver blades 2. Shaver abraders Model(s): 1. Full radius 5.5 2. 4.0 mm Brand(s): Smith & Nephew			Sterilisation and function testing: 1 and 3 cycles Comparison Sterilisation 0 cycles Function testing: 1 cycle	external reprocessing setting)			Comparison: 2 2. Abraders Intervention: 3 Comparison: 1	testing: Damage

*Pre-cleaning processes undertaken before sterilisation varied and are not presented here.

Table 46 Summary of findings for surgical instruments for grasping and cutting

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
Cogdill and Quaglia (1998) [93]	USA	Name(s): Biopsy forceps Model(s): Microvasive Brand(s): Boston Scientific	Ethylene oxide	Nine devices were tested for performance and quality assurance criteria, which included a visual, microscopic, and one pathological examination, and these examinations demonstrated that all had been unsatisfactorily cleaned, with remains of tissue, blood and/or chemical residues. Using the AAMI TIR 12 [Association for the Advancement of Medical Instrumentation – Technical Information Report] as a foundation for the acceptance criteria to evaluate the effectiveness of reprocessing, we found that all the devices did not meet the acceptance criteria. The reprocessing of single-use only devices presents an increased health risk to the patient and a loss of device effectiveness.	This study found that biopsy forceps reprocessed one to three times by external commercial companies using ethylene oxide were not effectively reprocessed when assessed by a contracted laboratory.
King et al. (2006) [94]	USA	Name(s): Arthroscopic shavers Model(s): Varied Brand(s): Dyonics Smith & Nephew	Ethylene oxide	The results of this study question the effectiveness of reprocessing techniques for arthroscopic shaver blades, from both the viewpoint of contamination and the viewpoint of blade damage. The level of contamination found on the reprocessed blades may signify a risk of iatrogenic disease transmission. However, it is not known what levels of contamination act as a threshold to infection. Contamination of resterilised single-use shaver blades may expose patients to an avoidable risk of iatrogenic disease transmission. Of the reprocessed shaver blades, 48% had detectable levels of protein and 63% had detectable levels of nucleic acid. All of the reprocessed blades visually evaluated showed some level of	This study found that arthroscopic shavers were not effectively reprocessed using ethylene oxide in vitro. The number of reprocessing cycles was not reported.

Table 46 Summary of findings for surgical instruments for grasping and cutting

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
				damage or wear, whereas no new blade had such damage. In addition, menisci cut with reprocessed shavers showed rougher edges than did menisci cut with new shavers. Clinical Relevance: To make an informed decision regarding the use of reprocessed shaver blades, surgeons will want to know the level of contamination on, and the quality of, reprocessed shaver blades.	
Kobayashi et al. (2009) [95]	Japan	Name(s): Arthroscopic shavers 1. Shaver blades 2. Shaver abraders Model(s): 1. Full radius 5.5 2. 4.0 mm Brand(s): Smith & Nephew	Ethylene oxide	This is the first study to analyse elements and chemicals of contaminants on reprocessed shaver blades used for arthroscopic surgery. It was confirmed that residual contaminants contain collagen, hydroxyapatite, some types of salts including calcium carbonate, and polycarbonate even after 1 reprocessing. These contaminations may signify a risk for disease transmission. Clinical Relevance: Surgeons should keep in mind that mechanical damage and chemical contamination are found on reprocessed arthroscopic blades.	This study found that arthroscopic shavers reprocessed using ethylene oxide had increasing amounts of residual debris and damage after one to three cycles in vitro. The reprocessed shavers were contaminated with organic proteins and inorganic salts and chemical compounds. The authors concluded that these contaminations may signify a risk for disease transmission.

*Pre-cleaning processes undertaken before sterilisation varied and are not presented here.

(I) Endoscopic and laparoscopic devices (risk class IIa)

Three studies assessed the potential for reprocessing disposable endoscopic or laparoscopic devices, which are minimally invasive devices used to look inside the body and are inserted directly into the organ being investigated via a natural orifice or small incision, more commonly known as keyhole surgery [11]. The devices assessed were sphincterotomes (single and double lumen), argon plasma coagulation probes, and electrosurgical pencils, respectively [96–98].

Two studies were undertaken in the USA and one in Italy. In two studies, devices were artificially contaminated, and in the third study, devices were contaminated via their first clinical use. All three studies assessed ethylene oxide as the method of sterilisation, with one also comparing this method with

soaking the devices in glutaraldehyde before sterilising with ethylene oxide [97]. The devices were sterilised in the study setting following local policy standards (i.e. standards set by the hospital or organisation) for up to11 cycles, with each study function testing the devices after each cycle of sterilisation. The outcomes reported were sterility (which included levels of biologics and debris) and function (which included device malfunction, damage or surface modifications, electrical output, and coagulation depth).

As all studies followed reprocessing standards aligned with locally agreed requirements without providing sufficient further detail, the authors of this report cannot comment on the extent the requirements followed aligned with those set out in Article 17[2] of the EU MDR.

A summary of the study authors' and HRB review authors' conclusions about individual in vitro endoscopic and laparoscopic device studies is provided in Table 48. The study authors' conclusions are direct quotations with some minor edits for conciseness and clarity. The outcomes reported were sterility (which included levels of biologics and debris) and function (which included device malfunction, damage or surface modifications, electrical output, and coagulation depth). Kozarek *et al.* (1997), reporting on the reprocessing of sphincterotomes, concluded that sphincterotomes have the potential for safe reuse for one cycle using ethylene oxide with or without glutaraldehyde, but that further studies are required. Roach *et al.* (1999), reporting on the reprocessing of argon plasma coagulation probes, concluded that they were safely and effectively reprocessed using ethylene oxide for 10 cycles without significant loss of form or function in vitro and had planned a follow-up in vivo study. Tessarolo *et al.* (2017), reporting on the use of electrosurgical pencils, concluded that overall, the reprocessing protocol used was not sufficient for safe reuse. Some components of the device fared better than others over five cycles of reprocessing.

Table 47 Study characteristics of endoscopic and laparoscopic devices

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
Kozarek *et al.* (1997) [97]	Name(s): Sphincterotomes Model(s): UTS30 single-lumen, CT-30 double-lumen Brand(s): Wilson-Cook Medical, Inc.	Artificially contaminated (*Mycobacteroides chelonei* (various strains), *Mycobacteroides abscessus*, or a patient isolate)	1. Glutaraldehyde and ethylene oxide 2. Ethylene oxide only	Intervention Sterilisation and function testing: 11 cycles Comparison Sterilisation: 0 cycles Function testing: 1 cycle	Internal	Local policy	New, unused	N=11 Intervention 1: 10 Intervention 2: 1 Comparison: New, unused	Sterility: Cultures Function testing: Device malfunction, electrical output
Roach *et al.* (1999) [98]†	Name(s): Argon plasma coagulation probes Model(s): 2.3 mm, 220 cm Brand(s): ERBE Inc.	Artificially contaminated (*Bacillus subtilis*)	Ethylene oxide	Intervention Sterilisation and function testing: 10 cycles Comparison Sterilisation: 0 cycles Function testing: 1 cycle	Internal	Local policy	New, unused	N=10 Intervention: 10 Comparison: New, unused	Sterility Function testing: Damage, coagulation depth
Tessarolo *et al.* (2017) [96]	Name(s): Electrosurgical pencils Model(s): HT-1	Used clinically	Ethylene oxide	Intervention Sterilisation: 1–5 cycles Function testing: 1–5 cycles (after each sterilisation cycle)	Internal	Local policy	New, unused	N=24 Intervention: 20 Comparison: 4	Sterility: Debris, biologics Function testing:

Table 47 Study characteristics of endoscopic and laparoscopic devices

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
	Brand(s): Huatong Medical Appliance Co.			Comparison Sterilisation: 0 cycles Function testing: 1 cycle					Surface modifications

* Pre-cleaning processes undertaken before sterilisation varied and are not presented here.

† This study also included some cost outcomes but was not considered to comply with the criteria for economic studies.

Table 48 Summary of findings for endoscopic and laparoscopic devices

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
Kozarek *et al.* (1997) [97]	USA	Name(s): Sphincterotomes Model(s): UTS30 single-lumen, CT-30 double-lumen Brand(s): Wilson-Cook Medical, Inc.	1. Glutaraldehyde and ethylene oxide 2. Ethylene oxide only	Seven of the 10 sphincterotomes withstood the rigors of reuse; three 6F sphincterotomes developed wire fracture between four and eight uses. Electrical integrity, as measured by an electrosurgical analyzer, remained intact up to time of breakage in all sphincterotomes. Manual cleaning followed by glutaraldehyde soak resulted in residual mycobacterial colonies in five 6F sphincterotomes and a single 5F sphincterotome. No instrument had residual organisms cultured following manual cleaning and ethylene oxide sterilization. Despite the persistence of a variable number of mycobacteria after manual processing and glutaraldehyde alone, our study documents that ethylene oxide treatment renders both types of sphincterotomes sterile of mycobacteria even without pre-treatment with glutaraldehyde. The authors conclude that one-time-use sphincterotomes have the potential for safe reuse. Additional studies are advised before widespread and indefinite reuse of sphincterotomes can be recommended.	This study found that two models of sphincterotomes (UTS30 single-lumen, CT-30 double-lumen) could be reprocessed using ethylene oxide with or without glutaraldehyde for one cycle, in vitro. The authors concluded that sphincterotomes reprocessed once have potential for safe reuse.
Roach *et al.* (1999) [98]	USA	Name(s): Argon plasma coagulation probes Model(s): 2.3 mm, 220 cm Brand(s): ERBE Inc.	Ethylene oxide	This current study has demonstrated that the combination of a manual clean and ETO [ethylene oxide] gas will safely and effectively sterilize ERBE argon plasma probes without significant loss of form or function. Ten of 10 probes completed 10 testing sessions. One probe split at the proximal end but remained functionally intact. Electrical integrity remained intact for all 10 sessions. All probes grew too numerous to	This study found that a model plasma coagulation probe (2.3 mm, 220 cm) could be reprocessed using ethylene oxide for up to 10 cycles in vitro. An in vivo study regarding the reuse of argon plasma coagulation probes

Table 48 Summary of findings for endoscopic and laparoscopic devices

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
				count colonies of *B.* [*Bacillus*] *subtilis* after inoculation and no *B. subtilis* was detected after ETO sterilization. An in vivo study regarding reuse of APC [argon plasma coagulation] probes is currently under way in our institution.	was under way in the authors' institution.
Tessarolo *et al.* (2017) [96]	Italy	Name(s): Electrosurgical pencils Model(s): HT-1 Brand(s): Huatong Medical Appliance Co.	Ethylene oxide	The complexity of EP [electrosurgical pencil] design and materials requires carefully developing and validating the reprocessing protocol in order to maintain device safety and performance. The application of the tested in-hospital reprocessing protocol showed a suboptimal cleaning of the tested EP. The analysis of surface and thermal properties of the device components reported significant differences between new and reprocessed devices. Considering that the silicon-coated EP tip underwent substantial variation due to clinical use and reprocessing, a single-use policy for this device component should be considered. Conversely, the handle and the cable cord showed minor and no alterations, respectively, up to five clinical uses and reprocessing cycles. EP tip could undergo major surface modifications that can affect functionality. The efficacy of the reprocessing protocol in removing debris from the EP handle should be carefully assessed.	This study found that one electrosurgical pencil (HT-1) model had increasing levels of debris and surface modifications following one to five reprocessing cycles using ethylene oxide in vitro. The authors concluded that the development of a validated reprocessing protocol to maintain device safety and performance was required.

* Pre-cleaning processes undertaken before sterilisation varied and are not presented here.

(J) Internal fixator devices (risk class IIb)

One study assessed the potential for reprocessing internal fixator devices, which included plates, screws, and staples [99]. Osteosynthesis or internal fixation is the union of two or more bone fragments after

proper alignment. The union is mechanically stabilised by the devices, which remain in place until the fracture has healed [15].

In the one included study, which was undertaken in Italy, the devices were used clinically and sterilised using an autoclave with and without ultrasonic cleaning in-house following local reprocessing standards, for one or two reprocessing cycles, and were then compared with new, unused devices. The outcomes reported were sterility and function, which was assessed by inspecting the devices for damage against set criteria. The study did not provide sufficient detail to allow the authors of this report to form conclusions about the extent the reprocessing standards followed aligned with those set out in Article 17[2] of the EU MDR.

A summary of the study authors' and HRB review authors' conclusions about individual internal fixator devices is provided in Table 50. The study authors' conclusion is a direct quotation with some minor edits for conciseness and clarity. The study authors concluded that reprocessing of internal fixation devices was safe and effective for one reuse cycle when a rigorous decontamination and inspection protocol was in place. This protocol included use of both autoclave and ultrasonic cleaning for decontamination.

Table 49 Study characteristics of internal fixator devices

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices	Outcomes
		Mode and type of contamination	Sterilisation process*	Number of reprocessing cycles	Where reprocessed				
Danesi *et al.* (2011) [99]†	Name(s): Internal fixator devices (plates, screws, staples) Model(s): Not reported Brand(s): Not reported	Used clinically	1. Autoclave 2. Autoclave and ultrasonic cleaning	Intervention Sterilisation: 1–2 cycles Function testing: 1 cycle Comparison Sterilisation and function testing: 0 cycles	Internal	Local policy	New, unused	N=2,050	Sterility: Visual inspection for organic residues Function testing: Damage

* Pre-cleaning processes undertaken before sterilisation varied and are not presented here.

† This study also included some cost outcomes but was not considered to comply with the criteria for economic studies.

Table 50 Summary of findings for internal fixator devices

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
Danesi *et al.* (2011) [99]	Italy	Name(s): Internal fixator devices (plates, screws, staples) Model(s): Not reported Brand(s): Not reported	1. Autoclave 2. Autoclave and ultrasonic cleaning	The rigorous decontamination protocol and generalized inspection criteria proved useful for efficiently screening a large volume of devices. Given that re-used osteosynthesis devices can yield satisfactory results, this study addresses potential complications of re-used devices and valid concerns that relate to patient safety. Implementing this defined reprocessing protocol into existing re-use practices in LMIC [low- and middle-income countries] helps to limit the risks of inadequate sterilization and structural failure without adding additional risks to patients receiving re-used devices.	This study found that a variety of stainless steel and titanium alloy internal fixator plates, screws, and staples could be reprocessed using a combination of steam sterilisation and ultrasonic cleaning for one cycle in vitro. The authors concluded that implementing a defined reprocessing protocol may help to limit risks to patients receiving reprocessed devices.

* Pre-cleaning processes undertaken before sterilisation varied and are not presented here.

(K) Cardiac catheters and cannulas (risk class III)

Seven studies assessed the reprocessing of a variety of cardiac catheters (balloon catheters, ablation catheters, and electrophysiology polyurethane catheters (including coaxial, rapid exchange, on-wire catheters)) and venous and arterial cannulas. These devices are used for both diagnostic and therapeutic purposes. Balloon catheters are used to open up blocked arteries and veins during a coronary angioplasty, ablation catheters are used during treatment for atrial fibrillation (a common cardiac rhythm disturbance), and electrophysiology polyurethane catheters are used for recording and pacing the electrical potentials from within the heart [9,10]. Venous and arterial cannulas are used in procedures such as cardiopulmonary bypass or cardiac surgery to manage the flow of blood during the procedures [4].

Six studies assessed catheters [47,47–51,101] and one study assessed cannulas [100]. The studies were undertaken in Canada (n=2), France (n=1), Germany (n=1), Italy (n=1), and the USA (n=2).

Five of the catheter studies undertook between 1 and 14 cycles of sterilisation but only reported on the functional aspects of reprocessing, as the sterilisation processes used in these studies were comparable to either FDA [133] or EU MDR [39] regulations, the sterility of these devices was assumed. The studies were only included if they clearly reported the sterilisation process used and this met either the FDA or EU standards for these devices. The methods of sterilisation used were ethylene oxide, (four studies) hydrogen peroxide (two studies), and liquid chemical sterilisation (using STERIS 20 Sterilant Concentrate®, a broad-spectrum liquid sporicide effective against bacteria, fungi, viruses, and bacterial spores) (one study). The remaining catheter study assessed both the sterilisation process and functional aspects, and

used gamma ray irradiation as the method of sterilisation [101]. The devices were function tested for between one and six cycles depending on the device, and after a varied number of cycles of sterilisation. The function tests varied between devices but included simulated reuse, compliance (diameter compared with applied pressure), bending, shear, slip testing, surface roughness, stability, bursting pressure, breakage, hydrolytic stability, and crossing profile. The reprocessing took place internally for five studies and externally for two studies, and met criteria set by the researchers or FDA standards. The number of devices tested varied considerably, ranging from 8 to more than 650 devices.

Taken together, as the studies by Bloom *et al.* [100] and Unverdorben *et al.* [50] were the only ones whereby reprocessing standards were set by the FDA, these are the only studies in which reprocessing requirements and processes may be aligned with the requirements of Article 17 [2] in the EU MDR (ref). However, the research studies did not provide sufficient detail to allow the authors of this report to conclude this with certainty.

Table 51 Study characteristics of cardiac catheters and cannulas

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
Brown *et al.* (2001) [47]	Name(s): Balloon catheters (angioplasty) Model(s): Not reported Brand(s): Not reported	Used clinically and artificially contaminated	Ethylene oxide	Intervention Sterilisation: 2 cycles Function testing: 1 or 2 cycles for each of 6 tests Comparison Sterilisation: 0 cycles Function testing: 0 cycles	External	Criteria set by researcher team	Function testing: Manufacturers' specifications	N=650+ (30 different models) Sterilisation: Unclear Function testing: Unclear	Sterility: Undertaken but not assessed Function testing: Compliance (diameter versus applied pressure), simulated reuse, slip testing
Bloom *et al.* (1997) [100]†	Name(s): Venous and arterial cannulas Model(s): Dual- and single-stage venous return cannulas (32F and 36F), Sarns, Soft Flow 8.0 mm	Used clinically and artificially contaminated (human plasma, human bacteria, a *Bacillus subtilis* (American Type Culture	Liquid chemical sterilisation (STERIS 20 Sterilant Concentrate)	Intervention Sterilisation: 1–10 cycles Function testing: 1 cycle (after 1, 5, and 10 reprocessing cycles) Comparison Sterilisation: 1 cycle	Internal	FDA approved	Sterilisation: New, unused, sterilised with sterilant's active ingredient omitted Function testing: New, unused	N=unclear Sterilisation: 30 (clinical use: 15, simulated use: 15) Function testing: 189+ over 4	Sterility Function testing: Materials, bending, tensile properties, shear

Table 51 Study characteristics of cardiac catheters and cannulas

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
	Brand(s): Research Medical Incorporated, 3M	Collection No. 19659))		Function testing: 0 cycles				tests and 3 models	
Grimandi *et al.* (1996) [101]	Name(s): Balloon catheters (coaxial, rapid exchange, on-wire) Model(s): Prism, Pronto, Quick, Lightning Brand(s): ACS, Bard, Baxter, Cordis	Clinically used	Gamma ray irradiation	Intervention Sterilisation: 1 cycle for each of 2 doses (25 or 35 Kgray) Function testing: 1 cycle (after sterilisation at 35 kgray) Comparison Sterilisation: 0 cycles Function testing: 0 cycles	Internal	Local policy	Unused, uncontaminated, unsterilised	N=118 Sterilisation: 118 Function testing: 70 (over 4 tests)	Sterility Function testing: Surface condition, balloon diameters, bursting pressure, resistance/breakage
Mussivand *et al.* (1995) [49]	Name(s): Balloon catheters Model(s): Not reported Brand(s): Not reported	Artificially contaminated (*Bacillus subtilis* spores)	Ethylene oxide with glutaraldehyde as part of pre-cleaning	Intervention Sterilisation: Not reported Burst testing: 6 cycles Surface changes: 1 cycle Comparison Sterilisation: Not reported	Internal	Criteria set by researcher team	Sterilisation: N/A Burst testing and surface changes: Unused, uncontaminated, unsterilised	N=8 Sterilisation: Unclear Function testing: Intervention: 7 Comparison: 1	Sterility: Undertaken but not assessed Function testing: Burst test, surface changes

Table 51 Study characteristics of cardiac catheters and cannulas

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
				Burst testing: 0 cycles Surface changes: 0 cycles					
Tessarolo *et al.* (2004) [51]‡	Name(s): Ablation catheters Model(s): RF Conductr Multi Curve Brand(s): Medtronic	New, uncontaminated	Hydrogen peroxide	Intervention Sterilisation: Up to 14 cycles Function testing: 1 cycle for each of 2 tests (after up to 14 sterilisation cycles) Comparison Sterilisation: 0 cycles Function testing: 0 cycles	Internal	Criteria set by research team	Unused, uncontaminated, unprocessed	N=9 Sterilisation: Intervention: Not reported Comparison: Not reported Function testing: 9 Intervention: 7 Comparison: 2	Sterility: Undertaken but not assessed Function testing: Roughness, stability
Lerouge *et al.* (2000) [48]‡	Name(s): Electrophysiology polyurethane catheters Model(s): Not reported Brand(s): Cordis	New, uncontaminated	1. Hydrogen peroxide (two machine models: Plazlyte and Sterrad-100S)	Intervention Sterilisation: 1, 5, 10 cycles Function testing: 1 cycle for each of 2 tests (after up to 10 cycles of sterilisation) Comparison	Internal	Criteria set by research team	New devices before testing	N=16 Sterilisation: Intervention: Not reported Comparison: Not reported	Sterility: Undertaken but not assessed Function testing: Surface and bulk

Table 51 Study characteristics of cardiac catheters and cannulas

Author (year)	Device name(s), model(s), brand(s)	Reprocessing intervention description				Reprocessing approval	Comparison devices	Number of devices	Outcomes
		Mode and type of contamination	**Sterilisation process***	**Number of reprocessing cycles**	**Where reprocessed**				
	Corp., a division of J&J Medical Products		2. Ethylene oxide	Sterilisation: 0 cycles Function testing: 0 cycles				Function testing: 16 over 3 tests	modifications, hydrolytic stability
Unverdorben *et al.* (2003) [50]‡	Name(s): Balloon catheters (percutaneous transluminal coronary angioplasty catheters) Model(s): Proximal stainless steel hypotube shaft with LEAP™, proximal stainless-steel core covered by a polyimide Brand(s): Not reported	New, uncontaminated	Ethylene oxide	Intervention Sterilisation: 1–3 cycles Function testing: 1 cycle (after 3 cycles of reprocessing) Comparison Sterilisation: 0 cycles Function testing: 0 cycles	External	FDA approved	New, unused	N =40 Sterilisation: Intervention: Not reported Comparison: Not reported Mechanical testing: Intervention: 20 Comparison: 20	Sterility: Undertaken but not assessed Function testing: Burst pressure, nominal diameter, crossing profile, balloon surface

* Pre-cleaning processes undertaken before sterilisation varied and are not presented here.

† This study also included some cost outcomes but was not considered to comply with the criteria for economic studies.

‡ The sterility of these devices was assumed based on existing FDA and EU approval standards.

A summary of the study authors' and HRB review authors' conclusions about individual in vitro cardiac catheter and cannula studies is provided in *Table **52***. The study authors' conclusions are direct quotations with some minor edits for conciseness and clarity. Taken together, the studies found that reprocessing balloon, ablation, or electrophysiology polyurethane cardiac catheters using any of the tested forms of reprocessing in vitro was model specific and caused damage to the devices, and that the negative effects of reprocessing increased with each reprocessing cycle. There was consensus that further in vitro and in vivo studies were required in order to determine what levels of damage are safe for reuse. The single study that assessed two models of cannulas concluded that they can be effectively and safely reprocessed for at least five cycles using liquid chemical sterilisation (STERIS 20 Sterilant Concentrate) in vitro. The FDA reprocessing standard applied during this study has since been updated and so the findings may no longer be valid [133].

Table 52 Summary of findings for cardiac catheters and cannulas

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
Brown *et al.* (2001) [47]	USA	Name(s): Balloon catheters (angioplasty) Model(s): Not reported Brand(s): Not reported	Ethylene oxide	The results demonstrated that the effects of use and EO-resterilization [ethylene oxide resterilisation] is model specific. Furthermore some balloons demonstrated a time-dependent behaviour while others recovered from the effects of simulated reuse by compliance testing at high pressure. Testing for the slipperiness of the catheters after repeated EO-resterilization also demonstrated that changes were model specific. One cannot generalize regarding the effects of reprocessing and reuse on PTCAs [percutaneous transluminal coronary angioplasty catheters] as a class.	This study found that the success of reprocessing balloon catheters using ethylene oxide in vitro was model specific, and for some models the negative effects of reprocessing increased with each reprocessing cycle. The authors made no conclusions regarding reprocessing in general.
Bloom *et al.* (1997) [100]†	USA	Name(s): Venous and arterial cannulas Model(s): Dual- and single-stage venous return cannulas (32F and 36F), Sarns, Soft Flow 8.0 mm	Liquid chemical sterilisation (STERIS 20 Sterilant Concentrate)	Preliminary data suggest that the perfusion cannulas tested can be safely and efficaciously used five times. The cannulas showed no physical or mechanical changes that would appear to affect their use or function. Where defects were noted, or where scoring occurred, visual inspection by trained staff would be sufficient to eliminate these cannulas from further use. The results of this testing suggest that a clinical trial	This study found that some models of venous and arterial cannulas (dual- and single-stage venous return cannulas (32F and 36F), Sarns, Soft Flow 8.0 mm) could be reprocessed for at least five cycles using liquid chemical sterilisation (STERIS 20

Table 52 Summary of findings for cardiac catheters and cannulas

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
		Brand(s): Research Medical Incorporated, 3M		be designed and carried out to assess the clinical utility and overall economic impact of reuse of perfusion cannulas.	Sterilant Concentrate) in vitro.
Grimandi *et al.* (1996) [101]	France	Name(s): Balloon catheters (coaxial, rapid exchange, on-wire) Model(s): Prism, Pronto, Quick, Lightning Brand(s): ACS, Bard, Baxter, Cordis	Gamma ray irradiation	The results presented here show that our protocol does not offer enough guarantee of safety for the reutilization of angioplasty catheters, in our institution. Adequate decontamination was not achieved since cellular elements were still present after this procedure. High irradiation doses were thus required to render the catheters sterile, or apparently sterile if we take into consideration the inhibitory effects induced by the material. The presence of pyrogens capable of producing shock was an additional negative factor. Moreover, our observations and results are not necessarily valid for all resterilization protocols that have been proposed. Nonetheless, they indicate that teams wishing to reuse angioplasty material should validate their decontamination-resterilization procedures through experimental testing in order to avoid any additional risk for their patients.	This study found that the safety of reprocessing a selection of balloon catheters (coaxial, rapid exchange, and on-wire models (Prism, Pronto, Quick, Lightning)) using gamma ray irradiation for one cycle could not be guaranteed in vitro.
Mussivand *et al.* (1995) [49]	Canada	Name(s): Balloon catheters Model(s): Not reported Brand(s): Not reported	Ethylene oxide with glutaraldehyde as part of pre-cleaning	Unused catheters and single use catheters appear to have similar mechanical bursting properties. Significant differences were observed between unused and used catheter surfaces. Used catheters exhibited scratches, gouging, roughness, and pits on the balloon surface, and cracking	This study found that balloon catheters showed damage and residual debris following reprocessing using ethylene oxide and glutaraldehyde in vitro after an unreported number of

Table 52 Summary of findings for cardiac catheters and cannulas

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
				was detected on the tip of a Rotablator. Particulate debris, most likely protein adhesion, was identified on used catheters and the Rotablator. Discoloration and some debris were observed on a vasculatar stent at certain locations. A quantitative measure must now be developed to properly characterize changes in surface morphology.	sterilisation cycles and one to six function testing cycles.
Tessaro lo *et al.* (2004) [51]‡	Italy	Name(s): Ablation catheters Model(s): RF Conductr Multi Curve Brand(s): Medtronic	Hydrogen peroxide	Reprocessing of single-use medical devices represents a great challenge between the need of absolute sterility and maintaining physical and chemical properties peculiar of a new device. The comparison of new and reprocessed samples allowed us to find alterations and to correlate the phenomena to reprocessing modality and to number of regeneration cycles. The presented approach constitutes the necessary propaedeutic checklist for reprocessing feasibility assessment that should be pursued on each market product before reusing single-use devices. Moreover the individuation of the specific modifications and their causes allows optimising the regeneration protocol.	This study found that ablation catheters showed increasing levels of roughness and absorbency after reprocessing for up to 14 cycles in vitro. The authors concluded that further studies are required to determine what levels of roughness and absorbency are safe for reuse.
Leroug e *et al.* (2000) [48]‡	Canada	Name(s): Electrophysiol ogy polyurethane catheters Model(s): Not reported Brand(s):	1. Hydrogen peroxide (two machine models: Plazlyte and Sterrad-100S) 2. Ethylene oxide	This study was carried out to compare plasma based and EO sterilizations in terms of material damage for electrophysiology catheters. Plasma-based [hydrogen peroxide] sterilization by Sterrad and Plazlyte allows for a much quicker reuse of catheters as compared with pure EO, because no aeration is	This study found that electrophysiology polyurethane catheters sterilised up to 10 times and function tested once using hydrogen peroxide (two machine models: Plazlyte and Sterrad-100S) or

Table 52 Summary of findings for cardiac catheters and cannulas

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions
		Cordis Corp., a division of J&J Medical Products		required. Material modifications were found to be limited to oxidation of the near surface layer, whereas EO induced slight but deeper alkylation. No carcinogenic MDA [methylenedioxyamphetamine] was detected with either plasma-based sterilizers or EO sterilization. However, because modification of the oligomer profile and surface oxidation was found to be induced by plasma-based sterilization, the biocompatibility of sterilized catheters must be assessed. Before concluding that the reuse of catheters is safe, a future study should include the effect of cleaning and reuse, because these two steps can induce severe material alterations.	ethylene oxide had some surface layer material modifications. The authors concluded that the biocompatibility of catheters reprocessed using hydrogen peroxide must be assessed and that future studies to assess the effect of cleaning and reuse must be undertaken before the safety of reprocessing them can be confirmed.
Unverdorben *et al.* (2003) [50]‡	Germany	Name(s): Balloon catheters (percutaneous transluminal coronary angioplasty catheters) Model(s): Proximal stainless steel hypotube shaft with LEAP™, proximal stainless-steel core covered by a polyimide Brand(s): Not reported	Ethylene oxide	Deterioration of the mechanical properties after sterilization up to three times was observed in the two types of balloon catheters tested. Nevertheless, with the diminished burst pressure taken into consideration, a prospective randomized clinical trial is recommended to assess the short- and long-term outcome to interpret the results in view of the mechanical data.	This study found that balloon catheters reprocessed using ethylene oxide for up to three cycles in vitro did show some deterioration of the devices' mechanical properties. The authors concluded that this deterioration may not impact patient safety but may impact the operator and procedure flow. In vivo studies were recommended.

Table 52 Summary of findings for cardiac catheters and cannulas

Author (year)	Country	Device name(s), model(s), brand(s)	Sterilisation process*	Study authors' conclusions	High-level HRB review authors' conclusions

*Pre-cleaning processes undertaken before sterilisation varied and are not presented here.

†The sterility of these devices was assumed based on existing FDA and EU approval standards.

Appendix F Selection of outcomes

Table 53 shows the full spectrum of outcomes collected in eligible studies. Items in red font denote studies or individual outcomes excluded at this stage. We excluded studies which did not report on patient safety or only provided patient or device safety outcomes via subjective measurement methods (e.g. surgeon opinion). For many outcomes, we provided a note (highlighted in yellow) indicating a possible strategy of combining and grouping outcomes. This is not indicative of finalised outcome grouping decisions. As a result of this process, two studies were excluded from the review due to our outcome selection approach.

Table 54 Safety outcome selection and preliminary groupings

Author	Safety outcome name	Outcome type	Definition and note on preliminary grouping
Cardiac catheters/cannulas			
Browne *et al.* (1997) [115]	Crossing success	Device function (direct)	Opposite to crossing failure in Plante *et al.* (1994)
	Pyrogen reactions	Patient safety (direct)	Temperature and white blood cell (WBC) count MINOR COMPLICATION
	Evidence of subsequent myocardial infarction (MI) or requirement for emergent percutaneous or surgical revascularisation of the target vessel	Patient safety (direct)	All patients were followed until hospital discharge for evidence of subsequent MI or requirement for emergent percutaneous or surgical revascularisation of the target vessel. MAJOR COMPLICATION
	Procedure time	Patient safety (indirect)	As name
	Fluoroscopy time	Patient safety (indirect)	As name
	Dye volume	Patient safety (indirect)	As name
	Number of balloons used per lesion	Device function (indirect)	Before and after crossing
	Death	Patient safety (direct)	As name MAJOR COMPLICATION
Hoffman *et al.* (2000) [134]	Pushability	Device function (direct)	Pushability of Intravascular ultrasound catheter (IVUS) (subjective measure)
	Trackability	Device function (direct)	Trackability of IVUS catheter (subjective measure)

Table 54 Safety outcome selection and preliminary groupings

Author	Safety outcome name	Outcome type	Definition and note on preliminary grouping
	Ease of moving the IVUS catheter on the guide wire	Device function (direct)	Ease of moving on guide wire (subjective measure)
	Imaging failure	Device function (direct)	Lesion could be reached (early failure) and imaged
	Near-field image quality	Device function (direct)	Characteristic of image quality
	Far-field image quality	Device function (direct)	Characteristic of image quality
	Ring-down artefact	Device function (direct)	Characteristic of image quality
	Image homogeneity	Device function (direct)	Characteristic of image quality
	4. Procedure duration (Paroxysmal atrial fibrillation, Persistent atrial fibrillation, re-do cases)	Patient safety (indirect)	As name
	5. Fluoroscopy duration by pulmonary vein isolation only, or pulmonary vein isolation + other	Patient safety (indirect)	As name
Leung *et al.* (2019) [116]	3. Patient major complication	Patient safety (direct)	Complications that did not have any likely relationship to the catheter were also recorded up until the point of discharge from hospital, including any major adverse cardiovascular/cerebrovascular events (MACCEs), vascular injury, or cardiac tamponade. Medical records were reviewed for evidence of complications of the procedure occurring in the period within 3 months after ablation, and for any pyrexial or infective illness reported in this period. MAJOR COMPLICATION
	2. Patient minor complication	Patient safety (direct)	Medical records were reviewed for evidence of complications of the procedure occurring in the period within 3 months after ablation, and for any pyrexial or infective illness reported in this period. MINOR COMPLICATION

Table 54 Safety outcome selection and preliminary groupings

Author	Safety outcome name	Outcome type	Definition and note on preliminary grouping
Plante *et al.* (1994) [118]	Mapping catheter failure	Device function (direct)	Failure of communication with the electro-anatomic mapping system
	Other catheter failure	Device function (indirect)	Physical defect or deformation of the catheter on inspection after use (subjective measure)
	Angiography success	Device function (indirect)	A lesional residual stenosis <50%, as determined by visual assessment
	Clinical success	Patient safety and device function	Angiographically successful angioplasty of all attempted lesions without in-hospital adverse clinical event, defined as death, MI, stroke, emergency angioplasty, or bypass surgery. COMBINE WITH MAJOR COMPLICATION IF POSSIBLE
	Clinical failure	Device function (direct)	If all attempted lesions could not be dilated successfully CROSSING FAILURE
	4. Procedure duration	Patient safety (indirect)	As name
	5. Fluoroscopy time	Patient safety (indirect)	As name
	6. Volume of contrast medium used	Patient safety (indirect)	As name
	7. The number of catheters required per lesion	Device function (indirect)	As name
	2. Fever: temperatures, creatine kinase (CK) levels	Patient safety (direct)	Temperature was >38 °C buccal or >38.5 °C rectal MINOR COMPLICATION
	Length of hospital stay	Patient safety (indirect)	As name
Unverdorben *et al.* (2005) [120]	Device (balloon catheter) success	Device function (direct)	Crossing of the lesion with balloon and inflation of the balloon within the lesion
	19. Procedure success	Device function (indirect)	A residual stenosis of <30%, achieved either by stand-alone balloon angioplasty, stenting, or by another means Angiographic success in Plante *et al.* (1994)

Table 54 Safety outcome selection and preliminary groupings

Author	Safety outcome name	Outcome type	Definition and note on preliminary grouping
	3.Complications (thrombus; acute and subacute MI)	Patient safety (direct)	A thrombus was defined as a non-calcified filling defect within the vascular lumen, which was visible in several views and which could migrate to the peripheral artery. An acute thrombosis was defined by a total occlusion (Transient myocardial ischemia grade O) occurring within 24 hours of stent deployment whereas subacute thrombosis was the one that occurred >24 hours after stenting and <1 month after stenting. Q-wave MI was diagnosed with the occurrence of new Q-waves (>0.04 seconds) and rise of CK twice the upper limit of normal with significant increase in creatine phosphokinase-isoenzyme levels (CK-MB), whereas in non-Q-wave MIs, pathological Q-waves were absent. MAJOR COMPLICATION
	Target lesion revascularisation rate	Device function (indirect)	Not reported
	Restenosis rate	Device function (indirect)	Not reported
	Late loss index	Device function (indirect)	The ratio between late loss and acute gain
	7. The number of balloons used per procedure	Device function (indirect)	As name
	6. Consumption of contrast	Patient safety (indirect)	As name – as dye volume in Browne *et al.* (1997)
	Time taken for procedure	Patient safety (indirect)	As name
	Exposure time to radiation	Patient safety (indirect)	As fluoroscopy time in Plante *et al.* (1994), Browne *et al.* (1997) and Leung *et al.* (2019)
Endoscopic and laparoscopic devices			
Brady *et al.* (2017) [107]	Estimated blood loss	Patient safety (direct)	As name

Table 54 Safety outcome selection and preliminary groupings

Author	Safety outcome name	Outcome type	Definition and note on preliminary grouping
	Additional interventions required for vascular pedicle ligation	Patient safety (direct)	Additional interventions were defined as any application of additional monopolar or bipolar energy after the initial ligation, the application of clips, or a stapling device. COMPLICATIONS (during procedure)
	Efficiency: by comparing operative time between groups	Patient safety (indirect)	As name (procedure time)
	Length of hospital stay	Patient safety (indirect)	As name
	Reoperations	Patient safety (direct)	As name COMPLICATIONS
de Sousa *et al.* (2018) [108]	3. Clinical efficiency: duration of surgical intervention	Patient safety (indirect)	As name (procedure time)
	6. Postoperative infection incidence	Patient safety (direct)	Postoperative infection incidence up to 30 days after surgery COMPLICATIONS
	7. Antibiotic consumption	Patient safety (indirect)	Antibiotic consumption (using the daily dose defined) up to 30 days after surgery COMPLICATIONS
	5. Reoperations	Patient safety (direct)	No patients requiring reoperation up to 30 days after surgery COMPLICATIONS
	4. Length of hospital stay	Patient safety (indirect)	Up to 30 days after surgery
	8. In-hospital mortality	Patient safety (direct)	Up to 30 days after surgery COMPLICATION
	9. Re-hospitalisation rate	Patient safety (direct)	Up to 30 days after surgery COMPLICATION
Mihanović *et al.* (2021) [110]	10. Speed of transection of the appendiceal base	Device function (direct)	As name
	5. Complications (intraoperative, postoperative, reoperations)	Patient safety (direct)	As name COMPLICATIONS – COMBINE ALL FOR INTRAOPERATIVE, POSTOPERATIVE, REOPERATIONS

Table 54 Safety outcome selection and preliminary groupings

Author	Safety outcome name	Outcome type	Definition and note on preliminary grouping
	Subjective assessment of the surgeon about the instrument	Device function (direct)	Hemostasis, coagulation efficiency, cutting efficiency, force applied for dissection, error messages/disturbing notes (subjective assessment)
	Duration of surgery	Patient safety (indirect)	As name (procedure time)
	Duration of hospital stay	Patient safety (indirect)	As name (until discharge)
External fixator devices			
Dirschl and Smith (1998) [102]	Pin tract infection rate	Patient safety (direct)	As name
	Reoperation after external fixation	Patient safety (direct)	As name
	Device failure rate	Device failure (direct)	As name (unclear – no further details)
Sung *et al.* (2008) [104]	Pin tract infections	Patient safety (direct)	Any site of purulence, erythema, or drainage. If any pin site in a patient showed these signs, it was considered a positive finding – as Dirschl and Smith
	Loosening during follow-up	Device function (direct)	Loosening was determined clinically by gross motion at the pin site.
	Loss of fixation	Device failure (direct)	Loss of fixation (as determined by the attending surgeon) was defined by a change in the radiographic alignment of the fracture (greater than 5 degrees or any shortening were the criteria so as to account for varying radiographic views)
Implantable cardiac device			
Enache *et al.* (2019) [111]	Complications: infections	Patient safety (direct)	Complications were defined as infections that required reintervention. COMPLICATIONS – combine
	2. + 3. Complications: device malfunction and replacements	Device function (direct)	Device malfunction and replacements due to untimely or unexpected battery depletion COMPLICATIONS (DEVICE) – combine
Linde *et al.* (1998) [112]	Complications rate: infections	Patient safety (direct)	Infections that required antibiotics and/or reoperations COMPLICATIONS – combine

Table 54 Safety outcome selection and preliminary groupings

Author	Safety outcome name	Outcome type	Definition and note on preliminary grouping
	Complications: malfunction	Device function (direct)	Suspicion of pacemaker malfunction described in the file or causing replacement COMPLICATIONS (DEVICE) – combine
	Complications: replacements	Device function (direct)	Replacements due to battery depletion COMPLICATIONS (DEVICE) – combine
Nava *et al.* (2013) [113]	Unexpected battery depletion	Device function (direct)	For new pacemakers, early battery depletion was defined as depletion before the 6th year after implantation without relation to high pacing outputs or abnormal electrode impedances that would void the device warranty. Premature battery depletion was considered to have occurred when the elective replacement indication was reached between the 6th and 8th years after the initial implantation. The expected battery depletion in reused devices would occur after the 4th year, early battery depletion would occur before the 2nd year, and premature battery depletion would occur between the 2nd and 4th years. BATTERY DEPLETION (DEVICE) – combine
	Infection	Patient safety (direct)	Four types of infection: 1) right endocarditis with electrode involvement; 2) sepsis without evidence of involvement of the circuit or pocket; 3) infection of the pacemaker pocket; and 4) extrusion of wires or generator. COMPLICATIONS – combine
	Malfunction	Device function (direct)	Device or electrode malfunction (software or hardware malfunction) COMPLICATIONS (DEVICE) – combine
Şoşdean *et al.* (2015) [114]	Device-related infection	Patient safety (direct)	As name COMPLICATIONS – combine
	4. Early battery depletion	Device function (direct)	As name BATTERY DEPLETION (DEVICE) – combine
	3. Device malfunction requiring reintervention	Device function (direct)	As name COMPLICATIONS (DEVICE) – combine
	5. Infection-related burden in ‘elderly’ and ‘young’ patients	Patient safety (direct)	As name
Ophthalmic devices			

Table 54 Safety outcome selection and preliminary groupings

Author	Safety outcome name	Outcome type	Definition and note on preliminary grouping
Perry (1996) [106]	Number of phacoemulsification (phaco) tip uses	Device function (indirect)	Never used more than five times. Assessed before use under the operative microscope and for integrity.
	Phacoemulsification time	Device function (direct)	As name
	Nuclear sclerosis	Patient safety (direct)	Of the cataract with each use
	Problems related to needle tip	Patient safety (direct)	Intraoperative problems during the procedure
Diathermy devices			
Loftus (2015) [135]	Reported defects	Device function (direct)	Any time a member of the surgical team (surgeon, scrub technician, first assistant, or circulating nurse) determined that the bipolar and ultrasound diathermy device was not functioning in a manner consistent with the devices' intended purpose (subjective measure).

We also reviewed studies contributing cost data to determine the eligibility of available outcome data for this review. In *Table **55***, the criteria used by Health Research Board (HRB) reviewers (ÁT and NMG) to determine the eligibility of cost outcomes, and our final decisions on same, are reported.

Table 55 Selection of cost outcomes

Author (Year)	Transparent methods	Actual costs used	Costing source	Other comments	Findings	HRB inclusion decision
Brady *et al.* (2017) [107]	No – lack of information on costing sources	Yes Operative (device cost; time) Postoperative (length of stay; reoperation)	Hospital Chief Financial Officer	In 19.7% of cases, surgeon was dissatisfied with reprocessed device.	No significant increase in hospital profit margin	Keep
Browne *et al.* (1997) [115]	No	No	Invoices	Cost savings are speculation	It is expected that the restoration process used in this study would permit institutions to save	Reject

Table 55 Selection of cost outcomes

Author (Year)	Transparent methods	Actual costs used	Costing source	Other comments	Findings	HRB inclusion decision
					40% of the original invoice cost of the product to the hospital.	
de Sousa *et al.* (2018) [108]	Yes	Yes Device cost only	Actual cost of reprocessed versus new device	Postoperative factors (surgery duration, hospital stay, re-hospitalisation) all insignificant between reprocessed and new device groups	A total of 193 linear suturing machines (GIA Covidien™) were reprocessed, saving €14,623.61. Of the ultrasonic scalpel/shears/scissors (Harmonic ACE®), 285 were reprocessed, corresponding to savings of €75,932.55.	Keep
Dirschl and Smith (1998) [102]	No	Yes Pre-operative: Nurse training cost Operative: Device cost	Not reported		The overall mean hospital charge for an external fixation device decreased 32% as a result of the reuse programme, from US$4,067 (US dollars) before reuse (range: US$2,009–10,002) to US$2,791 after reuse (range: US$1,106–10,415).	Inclined to reject – lack of clarity on methods
Leung *et al.* (2019) [116]	No	Cannot tell	List prices	Cannot tell what has actually been included in costing	Based on list prices, we have calculated the cost savings to our department arising from these 100 cases at GB£30,444 (Great British pounds).	Reject
Linde *et al.* (1998) [112]	No	No	Estimated cost – no further detail		The corresponding cost for the 317 reused units was US$31,700. This amounts to an estimated national savings of US$919,300.	Reject

Table 55 Selection of cost outcomes

Author (Year)	Transparent methods	Actual costs used	Costing source	Other comments	Findings	HRB inclusion decision
Plante *et al.* (1994) [118]	No	Yes Device cost only	Estimated reuse cost New device cost source not reported	The additional costs associated with in-hospital adverse events (e.g. increased rates of bypass surgery and myocardial infarction, and prolonged procedure time and hospital stay) may be offsetting.	This study demonstrated important catheter cost differences between the reuse and single use centres. There was an estimated savings of CAN$110,000 over the 10-month course of the study in the reuse centres, which had an average of 5.2 balloon catheter reuses.	Inclined to reject – estimated reuse cost, estimated hospital savings
Sung *et al.* (2008) [104]	No	Yes – device cost only	Hospital purchasing department	It would take 1,600 patients per arm to truly demonstrate equivalence with 80% power based on our pilot study.	Actual savings of US$65,452	Keep

Appendix G Feasibility assessment for meta-analysis

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
External fixator devices								
Pin tract infections	2 studies: Dirschl and Smith (1998) [102] and Sung *et al.* (2008) [104]	Different Dirschl and Smith (1998): 13/30 Sung *et al.* (2008): 24/30	Similar eligibility Sung *et al.* (2008): Aged 18 years and over, could consent, functioned independently, lived locally, sustained a fracture of the humerus, distal radius, wrist, femur, tibia, or ankle for which external fixation was the chosen initial treatment Dirschl and Smith (1998): All patients with external fixation devices applied at the study centre within the study period Demographics similarity unclear	Similar device(s) Both: Stryker Hoffman (+6 more in Dirschl and Smith (1998)) Different locations Dirschl and Smith (1998): Internal Sung *et al.* (2008): External Different number of reprocessing cycles Dirschl and Smith (1998): 1–2 Sung *et al.* (2008): 1	Definition similarity unclear Dirschl and Smith (1998): Not reported Sung *et al.* (2008): Any site of purulence, erythema, or drainage Similar measurement Dirschl and Smith (1998): N, derive % (not reported by reprocessing cycle) Sung *et al.* (2008): N, %	Different Sung *et al.* (2008): Randomised controlled trial (RCT) Dirschl and Smith (1998): Non-randomised controlled trial (NRCT)	Unclear similarity Sung *et al.* (2008): 1–20 weeks Dirschl and Smith (1998): Not reported	Does not meet criteria – too few studies

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
			Age: Dirschl and Smith (1998): Not reported Sung *et al.* (2008): 45 years % female: Dirschl and Smith (1998): Not reported Sung *et al.* (2008): 26%					
Device failure rate	2 studies: Dirschl and Smith (1998) [102] and Sung *et al.* (2008) [104]	Different Dirschl and Smith (1998): 13/30 Sung *et al.* (2008): 24/30	Similar eligibility Sung *et al.* (2008): Aged 18 years and over, could consent, functioned independently, lived locally, sustained a fracture of the humerus, distal radius, wrist, femur, tibia, or ankle for which external fixation was the chosen initial treatment Dirschl and Smith (1998): All patients with external fixation devices applied at	Similar device(s) Both: Stryker Hoffman (+6 more in Dirschl and Smith (1998)) Different locations Dirschl and Smith (1998): Internal Sung *et al.* (2008): External Different number of reprocessing cycles	Definition unclear: Dirschl and Smith (1998): Mechanical or other failure Sung *et al.* (2008): Loss of fixation and loosening during follow up Similar measurement Dirschl and Smith (1998): n, derive % (not reported by reprocessing cycle)	Different Sung *et al.* (2008): RCT Dirschl and Smith (1998): NRCT	Unclear time frame Sung *et al.* (2008): 1–20 weeks Dirschl and Smith (1998): Not reported	Does not meet criteria – too few studies

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
			the study centre within the study period Demographics similarity unclear Age: Dirschl and Smith (1998): Not reported Sung *et al.* (2008): 45 years % female: Dirschl and Smith (1998): Not reported Sung *et al.* (2008): 26%	Dirschl and Smith (1998): 1–2 Sung *et al.* (2008): 1	Sung *et al.* (2008): n, %			
Reoperations	1 study: Dirschl and Smith (1998) [102]	N/A	N/A	N/A	N/A	N/A	N/A	Does not meet criteria – too few studies
Ophthalmic devices								
Needle tip issues	1 study: Perry (1996) [106]	N/A	N/A	N/A	N/A	N/A	N/A	Does not meet criteria –

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
								too few studies
Phacoemulsification time	1 study: Perry (1996) [106]	N/A	N/A	N/A	N/A	N/A	N/A	Does not meet criteria – too few studies
Endoscopic and laparoscopic devices								
Procedure time	3 studies: Brady *et al.* (2017) [107] Mihanović *et al.* (2021) [110] de Sousa *et al.* (2018) [108]	Similar Brady *et al.* (2017): 23/30 Mihanović *et al.* (2021): 28/30 de Sousa *et al.* (2018): 24/30	Similar eligibility Brady *et al.* (2017): Patients attending for laparoscopic resections of right and sigmoid colectomies Mihanović *et al.* (2021): All patients with acute appendicitis de Sousa *et al.* (2018): All surgical interventions using ultrasonic scalpel/shears/scissors (Harmonic ACE®) and the linear suture machine (GIA	Broadly similar devices/procedures Brady *et al.* (2017): LigaSure Sealer/Divider 5 mm–37 cm for laparoscopic colorectal surgery Mihanović *et al.* (2021): Ultrasonic scalpel/shears/scissors for laparoscopic appendectomy de Sousa *et al.* (2018): Ultrasonic s	Same definition Different measurements (minutes) Brady *et al.* (2017): μ, standard deviation (SD) (unadjusted) de Sousa *et al.* (2018): μ, SD (unadjusted) Mihanović *et al.* (2021): (Adjusted) median,	Different Brady *et al.* (2017): NRCT Mihanović *et al.* (2021): RCT de Sousa *et al.* (2018): NRCT	Similar Brady *et al.* (2017): Procedure duration Mihanović *et al.* (2021): Procedure duration de Sousa *et al.* (2018): Procedure duration	Does not meet criteria – different measurements, non-normal outcome distribution

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
			Covidien™) with cut and anastomosis (various regions of body) Different demographics Age: Brady *et al.* (2017): 66 years Mihanović *et al.* (2021): 15 years de Sousa *et al.* (2018): 57 years % female: Brady *et al.* (2017): 50% Mihanović *et al.* (2021): 20% de Sousa *et al.* (2018): 60% Health status: Brady *et al.* (2017): Body mass index (BMI) 30 Mihanović *et al.* (2021): BMI 20	scalpel/shears/scissors (Harmonic ACE®) for digestive or thoracic surgery (intestines, stomach, oesophagus) Different locations Brady *et al.* (2017): External Mihanović *et al.* (2021): Internal de Sousa *et al.* (2018): External Same number of reprocessing cycles: Brady *et al.* (2017): 1 Mihanović *et al.* (2021): 1 de Sousa *et al.* (2018): 1	interquartile range (IQR) de Sousa *et al.* (2018) report overall and by diagnosis-related group			

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
			de Sousa *et al.* (2018): Not reported					
Duration of hospital stay	3 studies: Brady *et al.* (2017) [107] Mihanović *et al.* (2021) [110] de Sousa *et al.* (2018) [108]	Similar Brady *et al.* (2017): 23/30 Mihanović *et al.* (2021): 28/30 de Sousa *et al.* (2018): 24/30	Similar eligibility Brady *et al.* (2017): Patients attending for laparoscopic resections of right and sigmoid colectomies Mihanović *et al.* (2021): All patients with acute appendicitis de Sousa *et al.* (2018): All surgical interventions performed in 2014 in which ultrasonic scalpel/shears/scissors (Harmonic ACE® -5 mm/36 cm C/rod) and the linear suture machine GIA Covidien™ with cut and anastomosis (No. 55/60-3.8, No. 75/80-3.8, and	Broadly similar devices/procedures Brady *et al.* (2017): LigaSure Sealer/Divider 5 mm–37 cm for laparoscopic colorectal surgery Mihanović *et al.* (2021): Ultrasonic scalpel/shears/scissors for laparoscopic appendectomy de Sousa *et al.* (2018): Ultrasonic scalpel/shears/scissors (Harmonic ACE®) for digestive or thoracic surgery (intestines, stomach, oesophagus)	Same definition Different measurements (days) Brady *et al.* (2017): μ, SD (unadjusted) de Sousa *et al.* (2018): μ, SD (unadjusted) Mihanović *et al.* (2021): Median, IQR	Different Brady *et al.* (2017): NRCT Mihanović *et al.* (2021): RCT de Sousa *et al.* (2018): NRCT	Similar Brady *et al.* (2017): Length of stay Mihanović *et al.* (2021): Length of stay de Sousa *et al.* (2018): Length of stay	Does not meet criteria – different measurements, non-normal outcome distribution

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
			No. 75/80-4.8) were used (various regions of body) Different demographics Age: Brady *et al.* (2017): 66 years Mihanović *et al.* (2021): 15 years de Sousa *et al.* (2018): 57 years % female: Brady *et al.* (2017): 50% Mihanović *et al.* (2021): 20% de Sousa *et al.* (2018): 60% Health status: Brady *et al.* (2017): BMI 30 Mihanović *et al.* (2021): BMI 20 de Sousa *et al.* (2018): Not reported	Different locations Brady *et al.* (2017): External Mihanović *et al.* (2021): Internal de Sousa *et al.* (2018): External Same number of reprocessing cycles: Brady *et al.* (2017): 1 Mihanović *et al.* (2021): 1 de Sousa *et al.* (2018): 1				

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
Complications (infections, additional interventions, reoperations)	3 studies: Brady *et al.* (2017) [107] Mihanović *et al.* (2021) [110] de Sousa *et al.* (2018) [108]	Similar Brady *et al.* (2017): 23/30 Mihanović *et al.* (2021): 28/30 de Sousa *et al.* (2018): 24/30	Similar eligibility Brady *et al.* (2017): Patients attending for laparoscopic resections of right and sigmoid colectomies Mihanović *et al.* (2021): All patients with acute appendicitis de Sousa *et al.* (2018): All surgical interventions performed in 2014 in which ultrasonic scalpel/shears/scissors (Harmonic ACE® (5 mm/36 cm C/rod) and the linear suture machine GIA Covidien™ with cut and anastomosis (No. 55/60-3.8, No. 75/80-3.8, and No. 75/80-4.8) were used (various regions of body)	Broadly similar devices/procedures Brady *et al.* (2017): LigaSure Sealer/Divider 5 mm–37 cm for laparoscopic colorectal surgery Mihanović *et al.* (2021): Ultrasonic scalpel/shears/scissors for laparoscopic appendectomy de Sousa *et al.* (2018): Ultrasonic scalpel/shears/scissors (ACE®) for digestive or thoracic surgery (intestines, stomach, oesophagus) Different locations	Different definitions de Sousa *et al.* (2018): Infections, reoperations, re-hospitalisations Mihanović *et al.* (2021): Complications (intraoperative, postoperative, reoperations) Brady *et al.* (2017): Additional interventions required, reoperations Similar reporting de Sousa *et al.* (2018): % Mihanović *et al.* (2021): n, %	Different Brady *et al.* (2017): NRCT Mihanović *et al.* (2021): RCT de Sousa *et al.* (2018): NRCT	Different time periods de Sousa *et al.* (2018): 30 days Mihanović *et al.* (2021): 30 days Brady *et al.* (2017): Surgery to discharge	Does not meet criteria for meta-analysis – different devices

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
			Different demographics Age: Brady *et al.* (2017): 66 years Mihanović *et al.* (2021): 15 years de Sousa *et al.* (2018): 57 years % female: Brady *et al.* (2017): 50% Mihanović *et al.* (2021): 20% de Sousa *et al.* (2018): 60% Health status: Brady *et al.* (2017): BMI 30 Mihanović *et al.* (2021): BMI 20 de Sousa *et al.* (2018): Not reported	Brady *et al.* (2017): External Mihanović *et al.* (2021): Internal de Sousa *et al.* (2018): External Same number of reprocessing cycles: Brady *et al.* (2017): 1 Mihanović *et al.* (2021): 1 de Sousa *et al.* (2018): 1	Brady *et al.* (2017): n, %			
Implantable cardiac devices								
Infections	4 studies: Enache *et al.* (2019) [111]	Similar Enache *et al.* (2019): 17/30	Similar eligibility	Similar devices/procedures	Similar definitions (except Şoşdean *et al.* (2015))	Similar designs	Similar (except Nava *et al.* (2013))	Meets criteria for

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
	Nava *et al.* (2013) [113] Linde *et al.* (1998) [112] Şoşdean *et al.* (2015) [114]	Linde *et al.* (1998): 21/30 Nava *et al.* (2013): 24/30 Şoşdean *et al.* (2015): 22/30	Enache *et al.* (2019): All patients for whom the device was indicated Linde *et al.* (1998): As above, and only patients for whom life expectancy was estimated to be lower than that of the pacemaker received a reprocessed device Nava *et al.* (2013): All patients aged 18 years and over with an indication for pacing Şoşdean *et al.* (2015): Patients requiring implantation with biventricular devices Different demographics (Gender only – Enache) Age: Enache *et al.* (2019): 52 years	Enache *et al.* (2019): Implantable cardioverter defibrillators Nava *et al.* (2013): Pacemaker Linde *et al.* (1998): Pacemaker Şoşdean *et al.* (2015): Biventricular devices (pacemakers or defibrillators) Location similar Enache *et al.* (2019): Unclear, likely internal Linde *et al.* (1998): Internal Nava *et al.* (2013): Internal Şoşdean *et al.* (2015): Likely internal	Enache *et al.* (2019): Infections that required reintervention Linde *et al.* (1998): Infections that required antibiotics and/or reoperations Nava *et al.* (2013): I: Right endocarditis with electrode involvement; II: Sepsis without evidence of involvement of the circuit or pocket; III: Infection of the pacemaker pocket; and IV: Extrusion of wires or generator Şoşdean *et al.* (2015): Device-	Enache *et al.* (2019): Retrospective cohort Linde *et al.* (1998): Retrospective case-matched Nava *et al.* (2013): case matched prospective and retrospective Şoşdean *et al.* (2015): Retrospective case-matched	Enache *et al.* (2019): 1–108 months (1 month, 3 months, every 6 months), average 33 months Linde *et al.* (1998): 32 months (±11 months) Nava *et al.* (2013): Not reported Şoşdean *et al.* (2015): Up to 94 months, median 35 months	meta-analysis

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
			Linde *et al.* (1998): 79 years Nava *et al.* (2013): 60 years Şoşdean *et al.* (2015): 62 years % female: Enache *et al.* (2019): 25% Linde *et al.* (1998): 55% Nava *et al.* (2013): 46% Şoşdean *et al.* (2015): 85%	Same number of reprocessing cycles Enache *et al.* (2019): 1 Linde *et al.* (1998): 1 Nava *et al.* (2013): 1 Şoşdean *et al.* (2015): 1	related (not defined) Similar reporting Enache *et al.* (2019): n, %, odds ratio (OR), confidence interval (CI) Linde *et al.* (1998): n, % Nava *et al.* (2013): n, %, risk ratio (RR) (adjusted), CI Şoşdean *et al.* (2015): n, OR (adjusted), CI			
Unexpected battery depletion	4 studies: Enache *et al.* (2019) [111] Nava *et al.* (2013) [113]	Similar Enache *et al.* (2019): 17/30 Linde *et al.* (1998): 21/30	Similar eligibility Enache *et al.* (2019): All patients for whom the device was indicated Linde *et al.* (1998): As above, and only patients	Similar devices/procedures Enache *et al.* (2019): Implantable cardioverter defibrillators	Broadly similar definitions Enache *et al.* (2019): Replacement due to untimely or	Similar designs Enache *et al.* (2019): Retrospective cohort	Similar Enache *et al.* (2019): 1–108 months (1 month, 3 months,	Meets criteria for meta-analysis

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
	Linde *et al.* (1998) [112] Şoşdean *et al.* (2015) [114]	Nava *et al.* (2013): 24/30 Şoşdean *et al.* (2015): 22/30	for whom life expectancy was estimated to be lower than that of the pacemaker received a reprocessed device Nava *et al.* (2013): All patients aged 18 years and over with an indication for pacing Şoşdean *et al.* (2015): Patients requiring implantation with biventricular devices Different demographics Age: Enache *et al.* (2019): 52 years Linde *et al.* (1998): 79 years Nava *et al.* (2013): 60 years Şoşdean *et al.* (2015): 62 years	Nava *et al.* (2013): Pacemaker Linde *et al.* (1998): Pacemaker Şoşdean *et al.* (2015): Biventricular devices (pacemakers or defibrillators) Location Enache *et al.* (2019): Unclear, likely internal Linde *et al.* (1998): Internal Nava *et al.* (2013): Internal Şoşdean *et al.* (2015): Likely internal Same number of reprocessing cycles	unexpected battery depletion Linde *et al.* (1998): Replacement due to battery depletion Nava *et al.* (2013): The need to remove or change the device because of unexpected battery depletion. Unexpected battery depletion was defined by study group. For new pacemakers, it was defined as depletion before the 6th year after implantation without relation to high pacing output	Linde *et al.* (1998): Retrospective case-matched Nava *et al.* (2013): case matched prospective and retrospective Şoşdean *et al.* (2015): Retrospective case-matched	every 6 months), average 33 months Linde *et al.* (1998): 32 months (±11 months) Nava *et al.* (2013): Not reported Şoşdean *et al.* (2015): Up to 94 months, median 35 months	

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
			% female: Enache *et al.* (2019): 25% Linde *et al.* (1998): 55% Nava *et al.* (2013): 46% Şoşdean *et al.* (2015): 85%	Enache *et al.* (2019): 1 Linde *et al.* (1998): 1 Nava *et al.* (2013): 1 Şoşdean *et al.* (2015): 1	or abnormal electrode impedances. In reused devices, early battery depletion was defined as occurring before the 4th year. Şoşdean *et al.* (2015): Early battery depletion – considered as after less than 2 years (24 months) Similar reporting Enache *et al.* (2019): N, OR, 95% CI Linde *et al.* (1998): n			

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
					Nava *et al.* (2013): n, %, RR, 95% CI Şoşdean *et al.* (2015): n, IQR			
Other device malfunction	2 studies: Nava *et al.* (2013) [113] Linde *et al.* (1998) [112]	Similar Linde *et al.* (1998): 21/30 Nava *et al.* (2013): 24/30	Similar eligibility Linde *et al.* (1998): All patients for whom the device was indicated, and only patients for whom life expectancy was estimated to be lower than that of the pacemaker received a reprocessed device Nava *et al.* (2013): All patients aged 18 years and over with an indication for pacing Different demographics Age: Linde *et al.* (1998): 79 years	Similar devices/procedures Linde *et al.* (1998): Pacemaker Nava *et al.* (2013): Pacemaker Same location Linde *et al.* (1998): Internal Nava *et al.* (2013): Internal Same number of reprocessing cycles Linde *et al.* (1998): 1 Nava *et al.* (2013): 1	Similar definition Nava *et al.* (2013): Suspicion of pacemaker malfunction described in the file or causing replacement Linde *et al.* (1998): Suspicion of pacemaker malfunction described in the file or causing replacement Similar reporting Nava *et al.* (2013): n, % (unadjusted)	Similar designs Linde *et al.* (1998): Retrospective case-matched Nava *et al.* (2013): NRCT (prospective and retrospective, matched)	Unclear similarity Nava *et al.* (2013): Not reported	Does not meet criteria – too few studies

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
			Nava *et al.* (2013): 60 years % female: Linde *et al.* (1998): 55% Nava *et al.* (2013): 46%		Linde *et al.* (1998): n, % (unadjusted)			
Cardiac catheter devices								
Minor complications (pyrogen reactions (fever, temperature, white blood cell count), creatine kinase, author-labelled minor	3 studies: Plante *et al.* (1994) [118] Browne *et al.* (1997) [115] Leung *et al.* (2019) [116]	2/3 similar Leung *et al.* (2019): 20/30 Browne *et al.* (1997): 15/30 Plante *et al.* (1994): 23/30	Similar eligibility Plante *et al.* (1994): All patients undergoing coronary angioplasty Browne *et al.* (1997): All patients undergoing coronary angioplasty Leung *et al.* (2019): All patients undergoing elective atrial fibrillation ablation Similar demographics Age: Browne *et al.* (1997): 64 years	Broadly similar devices/procedures Plante *et al.* (1994): Balloon, no brand/coronary angioplasty Browne *et al.* (1997): Angioplasty balloon catheters Leung *et al.* (2019): Circular mapping catheter/elective AF ablation Different locations	Similar definition Plante *et al.* (1994): Temperature (>38 °C buccal or 38.5 °C rectal), creatine kinase levels Browne *et al.* (1997): Temperature and white blood cell count, obtained before and 24 hours after the procedure (screen	Similar designs Plante *et al.* (1994): Observational Browne *et al.* (1997): NRCT, case-matched Leung *et al.* (2019): NRCT, case-matched	Different follow-up times Plante *et al.* (1994): Admission to discharge Browne *et al.* (1997): Admission to discharge Leung *et al.* (2019): 3 months	Does not meet criteria – too few studies

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
complications)			Plante *et al*. (1994): 60 years Leung *et al*. (2019): 66 years % female: Plante *et al*. (1994): 28% Browne *et al*. (1997): 44% Leung *et al*. (2019): 32%	Plante *et al*. (1994): Internal Browne *et al*. (1997): External Leung *et al*. (2019): External Unclear similarity for number of reprocessing cycles Plante *et al*. (1994): 1–6 (not reported by cycle) Browne *et al*. (1997): Not reported Leung *et al*. (2019): 1–2	for pyrogen reactions) Leung *et al*. (2019): Any pyrexial or infective illness Similar reporting Plante *et al*. (1994): n, % Browne *et al*. (1997): n, % Leung *et al*. (2019): n, %			
Major complications (evidence of	4 studies: Plante *et al*. (1994) [118] Leung *et al*. (2019): 20/30	Similar (except Browne *et al*. (1997))	Similar eligibility Plante *et al*. (1994): All patients undergoing coronary angioplasty	Broadly similar devices/procedures Plante *et al*. (1994): Balloon, no	Broadly similar definitions Plante *et al*. (1994): Angiographically successful	Similar designs Plante *et al*. (1994): Observational	Different follow-up times Plante *et al*. (1994):	Does not meet criteria for meta-analysis –

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
subsequent myocardial infarction (MI) or requirement for emergent percutaneous or surgical revascularisation of the target vessel, death, other complications (thrombus; acute and subacute MI))	Browne *et al*. (1997) [115] Leung *et al*. (2019) [116] Unverdorben *et al.* [120]	Unverdorben *et al*. (2005): 23/30 Browne *et al*. (1997): 15/30 Plante *et al*. (1994): 23/30	Browne *et al*. (1997): All patients undergoing coronary angioplasty Unverdorben *et al*. (2005): Coronary angioplasty patients with coronary artery stenosis of ≥70% and <100%, and a visually estimated maximum lesion length of <20 mm in association with angina pectoris Leung *et al*. (2019): All patients undergoing elective AF ablation Similar demographics Age: Browne *et al*. (1997): 64 years Plante *et al*. (1994): 60 years Unverdorben *et al*. (2005): 66 years	brand/coronary angioplasty Unverdorben *et al*. (2005): No brand/coronary angioplasty Browne *et al*. (1997): Angioplasty balloon catheters Leung *et al*. (2019): Circular mapping catheter/elective AF ablation Different locations Plante *et al*. (1994): Internal Browne *et al*. (1997): External Unverdorben *et al*. (2005): Internal Leung *et al*. (2019): External	angioplasty of all attempted lesions without in-hospital adverse clinical event (defined as death, MI, stroke, emergency angioplasty, or bypass surgery) Browne *et al*. (1997): Evidence of subsequent MI or requirement for emergent percutaneous or surgical revascularisation of the target vessel, and death Unverdorben *et al*. (2005): Q-wave MI was diagnosed with the occurrence of	Browne *et al*. (1997): NRCT, case-matched Unverdorben *et al*. (2005): RCT Leung *et al*. (2019): NRCT, case-matched	Admission to discharge Browne *et al*. (1997): Admission to discharge Unverdorben *et al*. (2005): 3 months Leung *et al*. (2019): 3 months	too few studies after removal of Browne *et al*. (1997) (poor-quality study) and double zero event studies

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
			Leung *et al*. (2019): 66 years % female: Plante *et al*. (1994): 28% Browne *et al*. (1997): 44% Unverdorben *et al*. (2005): 23% Leung *et al*. (2019): 32%	Unclear similarity for number of reprocessing cycles Plante *et al*. (1994): 1–6 (not reported by cycle) Browne *et al*. (1997): Not reported Unverdorben *et al*. (2005): 1–3 Leung *et al*. (2019): 1–2	new Q-waves (>0.04 seconds) and rise of creatine kinase twice the upper limit of normal with significant increase in creatine kinase whereas in non-Q-wave MIs, pathological Q-waves were absent Leung *et al*. (2019): Evidence of complications of the procedure Similar reporting Plante *et al*. (1994): n, % Browne *et al*. (1997): n, %			

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
					Unverdorben *et al*. (2005): n, % Leung *et al*. (2019): n, %			
Procedure time	4 studies: Plante *et al*. (1994) [118] Browne *et al*. (1997) [115] Leung *et al*. (2019) [116] Unverdorben *et al.* [120]	Similar (except Browne *et al*. (1997)) Leung *et al*. (2019): 20/30 Unverdorben *et al*. (2005): 23/30 Browne *et al*. (1997): 15/30 Plante *et al*. (1994): 23/30	Similar eligibility Plante *et al*. (1994): All patients undergoing coronary angioplasty Browne *et al*. (1997): All patients undergoing coronary angioplasty Unverdorben *et al*. (2005): Coronary angioplasty patients with coronary artery stenosis of ≥70% and <100%, and a visually estimated maximum lesion length of <20 mm in association with angina pectoris Leung *et al*. (2019): All patients undergoing elective AF ablation	Broadly similar devices/procedures Plante *et al*. (1994): Balloon, no brand/coronary angioplasty Unverdorben *et al*. (2005): No brand/coronary angioplasty Browne *et al*. (1997): Angioplasty balloon catheters Leung *et al*. (2019): Circular mapping catheter/elective AF ablation Different locations	Same definition Similar reporting (minutes) Plante *et al*. (1994): μ, SD Browne *et al*. (1997): μ, SD Unverdorben *et al*. (2005): μ, SD Leung *et al*. (2019): μ, SD	Similar designs Plante *et al*. (1994): Observational Browne *et al*. (1997): NRCT, case-matched Unverdorben *et al*. (2005): RCT Leung *et al*. (2019): NRCT, case-matched	Same time frame (procedure duration)	Does not meet criteria for meta-analysis – non-normally distributed data

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
			Similar demographics Age: Browne *et al*. (1997): 64 years Plante *et al*. (1994): 60 years Unverdorben *et al*. (2005): 66 years Leung *et al*. (2019): 66 years % female: Plante *et al*. (1994): 28% Browne *et al*. (1997): 44% Unverdorben *et al*. (2005): 23% Leung *et al*. (2019): 32%	Plante *et al*. (1994): Internal Browne *et al*. (1997): External Unverdorben *et al*. (2005): Internal Leung *et al*. (2019): External Unclear similarity for number of reprocessing cycles Plante *et al*. (1994): 1–6 (not reported by cycle) Browne *et al*. (1997): Not reported Unverdorben *et al*. (2005): 1–3 Leung *et al*. (2019): 1–2				

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
Fluoroscopy time	4 studies: Plante *et al*. (1994) [118] Browne *et al*. (1997) [115] Leung *et al*. (2019) [116] Unverdorben *et al.* [120]	Similar (except Browne *et al*. (1997)) Leung *et al*. (2019): 20/30 Unverdorben *et al*. (2005): 23/30 Browne *et al*. (1997): 15/30 Plante *et al*. (1994): 23/30	Similar eligibility Plante *et al*. (1994): All patients undergoing coronary angioplasty Browne *et al*. (1997): All patients undergoing coronary angioplasty Unverdorben *et al*. (2005): Coronary angioplasty patients with coronary artery stenosis of ≥70% and <100%, and a visually estimated maximum lesion length of <20 mm in association with angina pectoris Leung *et al*. (2019): All patients undergoing elective AF ablation Similar demographics Age: Browne *et al*. (1997): 64 years	Broadly similar devices/procedures Plante *et al*. (1994): Balloon, no brand/coronary angioplasty Unverdorben *et al*. (2005): No brand/coronary angioplasty Browne *et al*. (1997): Angioplasty balloon catheters Leung *et al*. (2019): Circular mapping catheter/elective AF ablation Different locations Plante *et al*. (1994): Internal Browne *et al*. (1997): External	Same definition (fluoroscopy time) Same reporting (minutes) Browne *et al*. (1997): μ, SD Plante *et al*. (1994): μ, SD Unverdorben *et al*. (2005): μ, SD Leung *et al*. (2019): μ, SD	Similar designs Plante *et al*. (1994): Observational Browne *et al*. (1997): NRCT, case-matched Unverdorben *et al*. (2005): RCT Leung *et al*. (2019): NRCT, case-matched	Same time frame (during procedure)	Does not meet criteria for meta-analysis – non-normally distributed data

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
			Plante *et al*. (1994): 60 years Unverdorben *et al*. (2005): 66 years Leung *et al*. (2019): 66 years % female: Plante *et al*. (1994): 28% Browne *et al*. (1997): 44% Unverdorben *et al*. (2005): 23% Leung *et al*. (2019): 32%	Unverdorben *et al*. (2005): Internal Leung *et al*. (2019): External Unclear similarity for number of reprocessing cycles Plante *et al*. (1994): 1–6 (not reported by cycle) Browne *et al*. (1997): Not reported Unverdorben *et al*. (2005): 1–3 Leung *et al*. (2019): 1–2				
Contrast used	3 studies: Plante *et al*. (1994) [118] Browne *et al*. (1997) [115]	2/3 similar Unverdorben *et al*. (2005): 23/30 Browne *et al*. (1997): 15/30	Similar eligibility Plante *et al*. (1994): All patients undergoing coronary angioplasty	Broadly similar devices/procedures Plante *et al*. (1994): Balloon, no brand/coronary angioplasty	Definition Unverdorben *et al*. (2005): Not reported	Similar designs Plante *et al*. (1994): Observational	Same time frame (during procedure)	Does not meet criteria – too few studies, as Browne *et*

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
	Unverdorben *et al.* [120]	Plante *et al*. (1994): 23/30	Browne *et al*. (1997): All patients undergoing coronary angioplasty Unverdorben *et al*. (2005): Coronary angioplasty patients with coronary artery stenosis of ≥70% and <100%, and a visually estimated maximum lesion length of <20 mm in association with angina pectoris Similar demographics Age: Browne *et al*. (1997): 64 years Plante *et al*. (1994): 60 years Unverdorben *et al*. (2005): 66 years % female: Plante *et al*. (1994): 28% Browne *et al*. (1997): 44%	Unverdorben *et al*. (2005): No brand/coronary angioplasty Browne *et al*. (1997): Angioplasty balloon catheters Different locations Plante *et al*. (1994): Internal Browne *et al*. (1997): External Unverdorben *et al*. (2005): Internal Unclear similarity for number of reprocessing cycles Plante *et al*. (1994): 1–6 (not reported by cycle)	Plante *et al*. (1994): Volume of contrast medium used Browne *et al*. (1997): Dye volume Similar reporting (mL) Unverdorben *et al*. (2005): μ, SD Plante *et al*. (1994): μ, SD Browne *et al*. (1997): μ, SD	Browne *et al*. (1997): NRCT, case-matched Unverdorben *et al*. (2005): RCT		*al*. (1997) is excluded due to poor study quality

Table 56 Feasibility assessment for meta-analysis of individual outcomes across device groups

Outcome	Number of studies (>3)	Low assessment of quality or of risk of bias (bias in blinding, randomisation, missing outcome data, outcome assessment)	Population, intervention, comparator, outcome(s), time frame, and study design (PICOTS) assessment (clinical and methodological diversity)					Meta-analysis feasibility decision
			Population (eligibility, key demographics)	Intervention and comparator	Outcome (definition and means of reporting)	Study design	Time frame	
			Unverdorben *et al*. (2005): 23%	Browne *et al*. (1997): Not reported Unverdorben *et al*. (2005): 1–3				

Appendix H Full list of included papers

Table 57 List of included in vivo studies

Included in-vivo studies (19)
Brady J, Bhakta A, Steele A, et al. Reprocessed bipolar energy for laparoscopic colectomy: Is it worth it? Am J Surg 2017;214:59–62. doi:https://doi.org/10.1016/j.amjsurg.2017.02.012
Browne K, Maldonado R, Telatnik M, et al. Initial experience with reuse of coronary angioplasty catheters in the United States. J Am Coll Cardiol 1997;30:1735–40. doi:https://doi.org/10.1016/S0735-1097(97)00362-8
de Sousa Martins B, Queiroz e Melo J, Logarinho Monteiro J, et al. Reprocessing of Single-Use Medical Devices: Clinical and Financial Results. Port J Public Health 2018;36:150–6. doi:https://doi.org/10.1159/000496299
Dirschl DR, Smith IJ. Reuse of external skeletal fixator components: effects on costs and complications. J Trauma Acute Care Surg 1998;44:855–8. doi:https://doi.org/10.1097/00005373-199805000-00018
Enache B, Șoșdean R, Macarie R, et al. Assessing the safety of implantable cardioverter-defibrillator reuse—A retrospective case-control study. PACE - Pacing Clin Electrophysiol Published Online First: 2019. doi:https://doi.org/10.1111/pace.13742
Horwitz D, Schabel K, Higgins T. The economic impact of reprocessing external fixation components. J Bone Jt Surg 2007;89:2132–6. doi:https://doi.org/10.2106/JBJS.F.01409
Kozarek R, Raltz S, Ball T, et al. Reuse of disposable sphincterotomes for diagnostic and therapeutic ERCP: A one-year prospective study. Gastrointest Endosc 1999;49:39–42. doi:https://doi.org/10.1016/S0016-5107(99)70443-8
Leung L, Evranos B, Grimster A, et al. Remanufactured circular mapping catheters: safety, effectiveness and cost. J Interv Card Electrophysiol 2019;56:205–11. doi:https://doi.org/10.1007/s10840-018-0497-x
Linde C, Bocray A, Jonsson H. Re-used pacemakers: as safe as new? A retrospective case-control study. Eur Heart J 1998;19:154–7. doi:https://doi.org/10.1053/euhj.1997.0728
Mak K-H, Eisenberg MJ, Eccleston DS, et al. Cost-efficacy modeling of catheter reuse for percutaneous transluminal coronary angioplasty. J Am Coll Cardiol 1996;28:106–11. doi:https://doi.org/10.1016/0735-1097(96)00097-6
Mihanović J, Šikić N, Mrklić I, et al. Comparison of new versus reused Harmonic scalpel performance in laparoscopic appendectomy in patients with acute appendicitis—a randomized clinical trial. Langenbecks Arch Surg 2021;406:153–62. doi:https://doi.org/10.1007/s00423-020-02039-y
Nava S, Morales J, Márquez M, et al. Reuse of pacemakers: comparison of short and long-term performance. Circulation 2013;127:1177-1183. doi:https://doi.org/10.1161/CIRCULATIONAHA.113.001584
Perry E. To reuse or not reuse: reuse of phacoemulsification needle tips, their efficacy, and patient response. Insight Am Soc Ophthalmic Regist Nurses 1996;21:45–8. doi:https://doi.org/10.1016/s1060-135x(96)90057-3

Table 57 List of included in vivo studies

Included in-vivo studies (19)
Plante S, Strauss BH, Goulet G, et al. Reuse of balloon catheters for coronary angioplasty: A potential cost-saving strategy? J Am Coll Cardiol 1994;24:1475–81. doi:https://doi.org/10.1016/0735-1097(94)90142-2
Şoşdean R, Mornoş C, Enache B, et al. Safety and feasibility of biventricular devices reuse in general and elderly population – A single-center retrospective cohort study. Clin Interv Aging 2015;10:1311–8. doi:https://doi.org/10.2147/CIA.S88805
Sung J, Levin R, Siegel J, et al. Reuse of external fixation components: A randomized trial. J Orthop Trauma 2008;22:126–30. doi:https://doi.org/10.1097/BOT.0b013e318162e55c
Tessarolo F, Disertori M, Guarrera GM, et al. Reprocessing single-use cardiac catheters for interventional cardiology. A cost-minimization model for estimating potential saving at departmental scale and national level. Ital J Public Health 2009;6:140–9.
Unger S, Landis A. Assessing the environmental, human health, and economic impacts of reprocessed medical devices in a Phoenix hospital's supply chain. J Clean Prod 2016;112:1995–2003. doi:https://doi.org/10.1016/j.jclepro.2015.07.144
Unverdorben M, Degenhardt R, Erny D, et al. Clinical and angiographic procedural and mid-term outcome with new versus reused balloon catheters in percutaneous coronary interventions. Indian Heart J 2005;57:114–20. doi:https://doi.org/

Table 58 List of included in vitro studies

Included in-vitro studies (n=33)
Aljabo A, Mueller E, Abdul-Azeez D, et al. Gravity steam reprocessing in healthcare facilities for the reuse of N95 respirators. J Hosp Infect 2020;106:698–708. doi:https://doi.org/10.1016/j.jhin.2020.09.032
Bernard L, Desoubeaux G, Bodier-Montagutelli E, et al. Controlled Heat and Humidity-Based Treatment for the Reuse of Personal Protective Equipment: A Pragmatic Proof-of-Concept to Address the Mass Shortage of Surgical Masks and N95/FFP2 Respirators and to Prevent the SARS-CoV2 Transmission. Front Med 2020;7. doi:https://doi.org/10.3389/fmed.2020.584036
Bloom D, Cornhill J, Malchesky P, et al. Technical and economic feasibility of reusing disposable perfusion cannulas. J Thorac Cardiovasc Surg 1997;114:448–60. doi:https://doi.org/10.1016/S0022-5223(97)70193-4
Brown S, Merritt K, Woods T, et al. The effects of use and simulated reuse on percutaneous transluminal coronary angioplasty balloons and catheters. Biomed Instrum Technol 2001;35:312–22.
Christie-Holmes N, Tyli R, Budylowski P, et al. Vapourized hydrogen peroxide decontamination in a hospital setting inactivates SARS-CoV-2 and HCoV-229E without compromising filtration efficiency of unexpired N95 respirators. Am J Infect Control 2021;49:1227–31. doi:https://doi.org/10.1016/j.ajic.2021.07.012
Cogdill C, Quaglia L. How safe and effective is reuse of 'single-use only' medical devices? Biomed Instrum Technol 1998;32:434–5.

Table 58 List of included in vitro studies

Included in-vitro studies (n=33)
Danesi V, Cristofolini L, Stea S, et al. Re-use of explanted osteosynthesis devices: A reliable and inexpensive reprocessing protocol. Injury 2011;42:1101–6. doi:https://doi.org/10.1016/j.injury.2011.02.006
Grimandi G, Sellal O, Grimandi F, et al. Risks of reusing coronary angioplasty catheters: results of an experimental study. Cathet Cardiovasc Diagn 1996;38:123–32.
King JS, Pink MM, Jobe CM. Assessment of reprocessed arthroscopic shaver blades. Arthrosc J Arthrosc Relat Surg 2006;22:1046–52.
Kobayashi M, Nakagawa Y, Okamoto Y, et al. Structural damage and chemical contaminants on reprocessed arthroscopic shaver blades. Am J Sports Med 2009;37:266–73. doi:https://doi.org/10.1177/0363546508325668
Kozarek R A, Sumida S E, Raltz S L, et al. In vitro evaluation of wire integrity and ability to reprocess single-use sphincterotomes. Gastrointest Endosc 1997;45:117–21.
Kumar A, Kasloff SB, Cutts T, et al. Standard hospital blanket warming cabinets can be utilized for complete moist heat SARS-CoV2 inactivation of contaminated N95 masks for re-use. Sci Rep 2021;11:18316. doi:https://doi.org/10.1038/s41598-021-97345-w
Lendvay TS, Chen J, Harcourt BH, et al. Addressing personal protective equipment (PPE) decontamination: Methylene blue and light inactivates severe acute respiratory coronavirus virus 2 (SARS-CoV-2) on N95 respirators and medical masks with maintenance of integrity and fit. Infect Control Hosp Epidemiol 2022;43:876–85. doi:https://doi.org/10.1017/ice.2021.230
Lerouge S, Guignot C, Tabrizian M, et al. Plasma-based sterilization: effect on surface and bulk properties and hydrolytic stability of reprocessed polyurethane electrophysiology catheters. J Biomed Mater Res 2000;52:774–82.
Levine C, Grady, Block T, et al. Use, re-use or discard? Quantitatively defined variance in the functional integrity of N95 respirators following vaporized hydrogen peroxide decontamination during the COVID-19 pandemic. J Hosp Infect 2021;107:50–6. doi:https://doi.org/10.1016/j.jhin.2020.10.007
Lordelo R, Botelho J, Morais P, et al. Evaluation of the Microbiological Effectiveness of Three Accessible Mask Decontamination Methods and Their Impact on Filtration, Air Permeability and Physicochemical Properties. Int J Environ Res Public Health 2022;19:6567. doi:https://doi.org/10.3390/ijerph19116567
Manning E, Stephens M, Dufresne S, et al. Disinfection of Pseudomonas aeruginosa from N95 respirators with ozone: a pilot study. BMJ Open Respir Res 2021;8. doi:https://doi.org/10.1136/bmjresp-2020-000781
Mussivand T, Duguay D, Valadares M, et al. Assessment of reused catheters. ASAIO J 1995;41:M611–6. doi:https://doi.org/10.1097/00002480-199507000-00084
Narayanan S, Wang X, Paul J, et al. Disinfection and Electrostatic Recovery of N95 Respirators by Corona Discharge for Safe Reuse. Environ Sci Technol 2021;55:15351–60. doi:https://doi.org/10.1021/acs.est.1c02649

Table 58 List of included in vitro studies

Included in-vitro studies (n=33)
Pascoe M, Robertson A, Crayford A, et al. Dry heat and microwave-generated steam protocols for the rapid decontamination of respiratory personal protective equipment in response to COVID-19-related shortages. J Hosp Infect 2020;106:10–9. doi:https://doi.org/10.1016/j.jhin.2020.07.008
Roach SK, Kozarek RA, Raltz SL, et al. In vitro evaluation of integrity and sterilization of single-use argon beam plasma coagulation probes. Am J Gastroenterol 1999;94:139–43. doi:https://doi.org/10.1111/j.1572-0241.1999.00784.x
Schwan J, Alva T, Nava G, et al. Efficient facemask decontamination via forced ozone convection. Sci Rep 2021;11:12263. doi:https://doi.org/10.1038/s41598-021-91735-w
Smith JS, Hanseler H, Welle J, et al. Effect of various decontamination procedures on disposable N95 mask integrity and SARS-CoV-2 infectivity. J Clin Transl Sci 2021;5:e10. doi:https://doi.org/10.1017/cts.2020.494
Tessarolo F, Ferrari P, Silvia B, et al. Evaluation and quantification of reprocessing modification in single-use devices in interventional cardiology. Appl Surf Sci 2004;238:341–6. doi:https://doi.org/10.1016/j.apsusc.2004.05.223
Tessarolo F, Torres S, Ballesteros LM, et al. Surface and Thermal Characteristics of Single-Use Electrosurgical Pencils After Clinical Reuse and In-Hospital Reprocessing. J Med Devices 2017;11. doi:https://doi.org/10.1115/1.4038145
Unverdorben M, Quaden R, Werner C, et al. Change of the mechanical properties of two different balloon catheters with increasing numbers of cycles of resterilization. Catheter Cardiovasc Interv 2003;58:29–33. doi:https://doi.org/10.1002/ccd.10391
van der Vossen J, Fawzy A, Ouwens A, et al. Effective ultraviolet C light disinfection of respirators demonstrated in challenges with Geobacillus stearothermophilus spores and SARS-CoV-2 virus. J Hosp Infect 2022;122:168–72. doi:https://doi.org/10.1016/j.jhin.2022.01.021
Vernez D, Save J, Oppliger A, et al. Reusability of filtering facepiece respirators after decontamination through drying and germicidal UV irradiation. BMJ Glob Health 2020;5. doi:https://doi.org/10.1136/bmjgh-2020-003110
Viscusi DJ, Bergman MS, Eimer BC, et al. Evaluation of five decontamination methods for filtering facepiece respirators. Ann Occup Hyg 2009;53:815–27. doi:https://doi.org/10.1093/annhyg/mep070
Yap T, Hsu J, Liu Z, et al. Efficacy and self-similarity of SARS-CoV-2 thermal decontamination. J Hazard Mater 2022;429. doi:https://doi.org/10.1016/j.jhazmat.2021.127709
Yuen JG, Marshilok AC, Benziger PT, et al. Dry heat sterilization as a method to recycle N95 respirator masks: The importance of fit. PLoS ONE 2022;17:e0257963. doi:https://doi.org/10.1371/journal.pone.0257963
Zulauf KE, Green AB, Nguyen B, et al. Microwave-Generated Steam Decontamination of N95 Respirators Utilizing Universally Accessible Materials. Mbio 2020;11. doi:https://doi.org/10.1128/mBio.00997-20

Appendix IDescription of individual devices

(L) Risk class I

(a) Respirators and surgical face masks

Respirators (Figure 9) and surgical face masks (Figure 10) are examples of personal protective equipment and are labelled for single use. Respirators provide respiratory protection to the wearer and are designed to achieve a very close facial fit and very efficient filtration of airborne particles; surgical masks are more loose-fitting and create a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment [14].

Figure 9 Respirator

Figure 10 Surgical face mask

(b) External fixator devices

External fixators (Figure 11) are used to treat and stabilise bone fractures and can be used in conjunction with internal fixators if necessary. External fixation is a relatively safe, minimally invasive procedure involving a small incision in soft tissue, drilling, and the placement of pins around the bone fracture which are then attached to external rods and clamps. The external fixators are left in place for several weeks while the bone heals. The most common complications are pin tract infections and loosening of the pins or fixation frames [121].

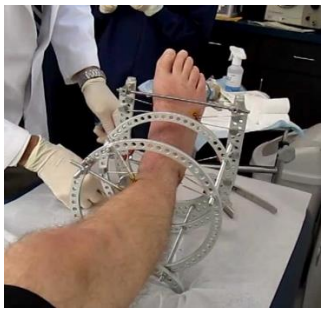

Figure 11 External fixators

(c) Deep vein thrombosis compression sleeves

Deep vein thrombosis compression sleeves (Figure 12) are used to help prevent blood clots in the deep veins of the legs. The devices use cuffs around the legs that fill with air and squeeze the legs. This increases blood flow through the veins of the legs and helps prevent blood clots [6].

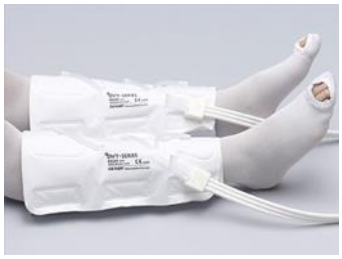

Figure 12 Deep vein thrombosis compression sleeves

(d) Pulse oximeters

A pulse oximeter (Figure 13) is used to measure blood oxygen saturation levels by passing small beams of light through the blood in the finger and measuring changes in light absorption in oxygenated or deoxygenated blood [17].

Figure 13 Disposable pulse oximeter

(M) Risk class IIa

(a) Ophthalmic devices

Disposable phacoemulsification needles (also known as phaco needles) (Figure 14) are used during a phacoemulsification procedure, which is the extraction of a cataract by breaking down the cataract via a very small incision using an ultrasonic probe and removing the cataract by suctioning it out via the phaco needle [16].

Figure 14 Disposable phaco needle

(b) Endoscopic and laparoscopic devices

Disposable endoscopic or laparoscopic devices (Figure 15,Figure 16,Figure 17,Figure 18,Figure 19,Figure 20,Figure 21) are minimally invasive devices used to look inside the body and are inserted directly into the organ being investigated via a natural orifice or small incision, more commonly known as keyhole surgery [11].

Figure 15 Laparoscopic sealer/divider (ligasure)

Figure 16 Ultrasonic scalpel/scissors/shears

Figure 17 Linear suture machine

Figure 18 Disposable endoscopic trocar

Figure 19 Ultrasonic scissor tip

Figure 20 Sphincterotome

Figure 21 Argon plasma coagulation probe

(c) Surgical instruments for grasping and cutting

These surgical instruments are used for cutting, dissecting or cauterising soft tissue during surgical procedures (Figure 23,Figure 23). They usually have sharp edges which enable the operator to cut and dissect tissue, or tips that enable them to hold on to or manipulate tissues or to clamp blood vessels [2]. An arthroscopic shaver (Figure 24) is a medical device that is used to remove the tissue from arthroscopic surgery. This type of surgery is a minimally invasive procedure that uses a small incision and special tools to repair or remove damage inside a joint [1].

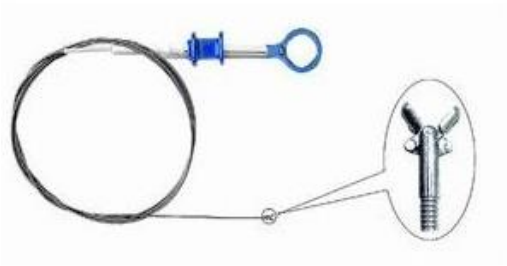

Figure 22 Biopsy Figure 22forceps

Figure 23 Electrosurgical pencil

Figure 24 Arthroscopic shavers

(N) Risk class IIb

(a) Internal fixator devices

Osteosynthesis or internal fixation is the union of two or more bone fragments after proper alignment. The union is mechanically stabilised using internal fixators (Figure 25), which remain in place until the fracture has healed [15].

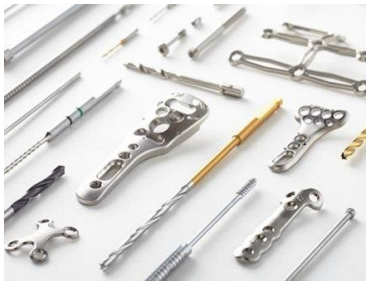

Figure 25 Internal fixators

(O) Risk class III

(a) Implantable cardiac devices

An implantable cardioverter defibrillator (ICD) is a small, battery-powered device placed in the chest to detect and stop potentially life-threatening abnormal heart rhythms coming from the bottom chamber of the heart i.e., ventricular tachyarrhythmias. An ICD continuously monitors the heart rhythm and delivers electric shocks, when needed, in order to restore or stable heart rhythm. A pacemaker is a small device that is placed (implanted) in the chest to help monitor the heart rate and rhythm and provide pacemaker support when needed, to prevent the heart from beating too slowly. Implantation of both ICDs and pacemakers in the chest requires a cardiac interventional procedure [122,123].

A pacemaker (Figure 27) is a small device that is placed (implanted) in the chest to help control the heartbeat. It is used to prevent the heart from beating too slowly. Implantation of both ICDs and pacemakers in the chest requires a surgical procedure [123].

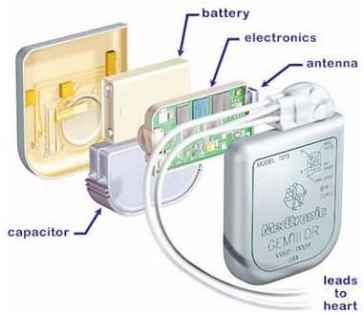

Figure 26 Defibrillator

Figure 27 Pacemaker

(b) Cardiac catheters and cannulas

These cardiac devices are used for both diagnostic and therapeutic purposes. Balloon catheters (Figure 28) are used to open up blocked arteries and veins during a coronary angioplasty, ablation catheters (Figure 29) are used during treatment for atrial fibrillation (a common cardiac rhythm disturbance), and electrophysiology polyurethane catheters (Figure 30Figure 30) are used for recording and pacing the electrical potentials from within the heart [9,10]. Venous and arterial cannulas (Figure 31) are used in procedures such as cardiopulmonary bypass or cardiac surgery to manage the flow of blood during these procedures [4].

Figure 28 Balloon catheter

Figure 29 Ablation catheter

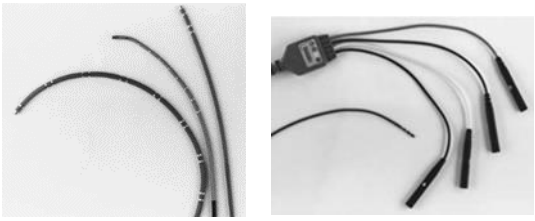

Figure 30 Electrophysiology polyurethane catheters

Figure 31 Cannulas

Appendix J Quality assessment

Table 59 Quality assessment ratings for trials and comparative observational studies

	Cardiac catheters/cannulas				External fixator devices		Endoscopic and laparoscopic devices			Implantable cardiac devices				Ophthalmic devices
Item	Browne *et al.* (1997) [115]	Leung *et al.* (2019) [116]	Plante *et al.* (1994) [118]	Unverdorben *et al.* (2005) [120]	Dirschl and Smith (1998) [102]	Sung *et al.* (2008) [104]	Brady *et al.* (2017) [107]	de Sousa *et al.* (2018) [108]	Mihanović *et al.* (2021) [110]	Enache *et al.* (2019) [111]	Linde *et al.* (1998) [112]	Nava *et al.* (2013) [113]	Şoşdean *et al.* (2015) [114]	Perry (1996) [106]
1. Aim/objectives stated	1	1	1	0	1	1	1	1	1	1	1	1	1	0
2. Main outcomes stated before results	0	1	1	1	0	1	1	1	1	1	1	1	1	1
3. Observation characteristics clearly described	0	1	1	1	0	1	1	1	1	1	1	1	1	0
4. Interventions clearly described	1	1	1	1	1	1	1	1	1	1	1	1	1	1
5. Distribution	1	2	2	2	0	2	1	1	2	2	1	2	2	0

Table 59 Quality assessment ratings for trials and comparative observational studies

	Cardiac catheters/cannulas				External fixator devices		Endoscopic and laparoscopic devices			Implantable cardiac devices				Ophthalmic devices
s of confounders clearly described														
6. Main findings clearly described	0	0	1	1	0	1	1	1	1	0	1	1	1	1
7. Estimates of random variability	1	1	1	1	1	1	1	1	1	1	1	1	1	1
8. Adverse events reported	1	1	1	1	1	1	1	1	1	0	0	1	1	0
9. Patients lost to follow-up described	1	0	1	1	1	1	1	1	1	0	1	0	0	0
10. Exact probability values reported	0	1	0	1	0	1	1	1	1	1	1	1	1	1
11. Subjects representative of the	1	1	1	1	1	1	1	1	0	1	1	1	1	1

Table 59 Quality assessment ratings for trials and comparative observational studies

	Cardiac catheters/cannulas				External fixator devices		Endoscopic and laparoscopic devices			Implantable cardiac devices				Ophthalmic devices
entire population														
12. Subjects representative of population recruited	0	1	1	0	1	0	1	1	1	1	1	1	1	1
13. Treatment representative of what the majority of patients receive	1	1	1	1	1	1	1	1	1	1	1	1	1	1
14. Attempt made to blind subjects	1	1	1	1	0	1	1	1	1	0	0	0	0	0
15. Attempt made to blind single-use device user(s)	0	0	0	0	0	0	0	0	1	0	0	0	0	0
16. Attempt made to blind those	1	1	1	0	1	0	1	1	1	0	1	1	1	0

Table 59 Quality assessment ratings for trials and comparative observational studies

	Cardiac catheters/cannulas				External fixator devices		Endoscopic and laparoscopic devices			Implantable cardiac devices				Ophthalmic devices
measuring outcomes														
17. 'Data dredging' made clear	0	0	0	1	1	1	1	1	1	1	1	1	1	1
18. Analyses adjusted for follow-up	1	1	1	1	0	0	1	1	1	0	1	1	1	1
19. Statistical tests appropriate	0	1	1	1	0	1	1	1	1	1	1	1	1	0
20. Compliance reliable	1	1	1	1	1	1	0	1	1	1	1	1	1	1
21. Outcome measures accurate	1	1	1	1	0	1	1	1	1	1	1	1	1	0
22. Patients recruited from the same population	1	1	1	1	1	1	1	1	1	1	1	1	1	1

Table 59 Quality assessment ratings for trials and comparative observational studies

	Cardiac catheters/cannulas				External fixator devices		Endoscopic and laparoscopic devices			Implantable cardiac devices				Ophthalmic devices
23. Subject recruited over the same period	0	0	1	0	0	1	1	1	1	1	1	1	1	1
24. Randomised	0	0	0	1	0	1	0	0	1	0	0	0	0	0
25. Assignment concealed	0	0	0	0	0	1	0	0	1	0	0	0	0	0
26. Adjustment for confounding	0	1	1	1	0	1	1	1	1	0	0	1	1	0
27. Losses to follow-up considered	1	0	1	0	1	1	1	1	1	0	1	1	0	1
28. Power to detect effect	0	0	0	2	0	0	0	0	1	0	0	1	0	0
Total score out of 30	**15**	**20**	**23**	**23**	**13**	**24**	**23**	**24**	**28**	**17**	**21**	**24**	**22**	**14**

Table 60 Quality assessment ratings for cost studies

Cost quality assessment	Cardiac catheters/cannulas		External fixator devices	Endoscopic and laparoscopic devices
	Tessarolo *et al.* (2009) [119]	Mak *et al.* (1996) [117]	Horwitz *et al.* (2007) [103]	Kozarek *et al.* (1999) [109]
1. Is the study population clearly described?	0	1	0	0
2. Are competing alternatives clearly described?	1	1	1	1
3. Is a well-defined research question posed in answerable form?	1	1	0	1
4. Is the economic study design appropriate to the stated objective?	1	1	0	0
5. Is the chosen time horizon/duration of study observation period appropriate to include relevant costs and consequences?	0	1	0	0
6. Is the actual perspective chosen appropriate?	0	1	1	1
7. Are all important and relevant costs for each alternative identified?	0	1	0	0
8. Are all costs measured appropriately in physical units?	1	0	1	1
9. Are costs valued appropriately?	1	1	1	0
10. Are all important and relevant safety outcomes for each alternative identified?	0	1	0	0
11. Is an incremental analysis of costs and outcomes of alternatives performed?	0	1	1	0
12. Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis?	1	1	0	0
13. Do the conclusions follow from the data reported?	1	1	0	1
14. Does the study discuss the generalisability of the results to other settings and patient/client groups?	0	0	0	1
15. Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)?	1	0	1	0
16. Are ethical and distributional issues discussed appropriately?	0	0	0	0
Total score out of 16	**8**	**12**	**6**	**6**

Table 61 Quality assessment ratings for life cycle assessment studies

Checklist item	Score (0, 0.5, 1.0)
	Unger and Landis (2016) [105]
Does the study specify its goal?	0.5
What kind of product(s) is examined?	0.5
Is the functional unit described?	1.0
What scope is used in this study?	1.0
Does the study describe the process modules with qualitative and quantitative data?	1.0
Does the study specify excluded processes?	1.0
Does the study specify data quality requirements?	0.0
Which region is used as the reference region?	1.0
What year is used as the reference year?	1.0
Does the study specify the data sources for primary data?	1.0
Does the study specify the data sources for secondary data?	1.0
What allocation method(s) was (were) used?	1.0
Was the final life cycle inventory model made available?	0.0
What midpoint impact categories are used?	0.5
Does the study report the used impact category or classification and characterisation?	1.0
Does the study report the total results of the examined products?	1.0
Does the study report the results for each life cycle phase?	0.0
Does the study report an uncertainty analysis?	0.0
Does the study report a sensitivity analysis?	1.0
Does the study discuss its limitations?	0.0
Does the study state a funding source and its role?	0.5
Does the study state that an external critical review was performed?	1.0
Total score out of 22	**15.0**

Note: Devices included in the study were: deep vein thrombosis compression sleeves, pulse oximeters, endoscopic trocars, laparoscopic scissor tips, arthroscopic shavers, laparoscopic sealers/dividers, and ultrasonic scalpel/shears/scissors

(c) Summary of study quality by device type

(i) External fixator devices

Overall, the quality of evidence in relation to external fixators was mixed in studies of safety outcomes and low in cost studies. The randomised controlled trial by Sung *et al.* (2008) [104] received an overall rating of good quality based on the Downs and Black checklist, while the observational study by Dirschl and Smith (1998) [102] was deemed to be of poor quality (see Table 59). The only study of external fixator devices to assess cost received an overall rating of low quality when assessed using an adapted version of the CHEC-list, with less than 50% of total quality criteria met (see Table 60). No studies on environmental outcomes were available for external fixator devices. Common areas where study performed poorly on the Downs and Black checklist were: failure to perform adequate blinding, and failure to report having adequate power to detect significant results. Common areas where these studies performed well were:

clear reporting of study aims, clear description of the intervention, appropriate reporting of statistics, inclusion of important adverse events, inclusion of a representative study sample and treatment, good compliance with the intervention and appropriate participant recruitment. There were no losses-to-follow-up in either study. The strengths and limitations of the single external fixator device quality appraised using the adapted CHEC-list is available in Table 53.

(ii) Ophthalmic devices

The one available study providing evidence on reusing ophthalmic devices – in this case, phacoemulsification needle tips – following reprocessing was a prospective observational study by Perry (1996) and was rated as being of poor quality based on the Downs and Black checklist (see Table 59). No studies were available relating to cost or environmental outcomes for ophthalmic devices.

(iii) Endoscopic and laparoscopic devices

Overall, the quality of evidence in relation to safety outcomes for endoscopic and laparoscopic devices was good to excellent, with a randomised controlled trial on ultrasonic scalpel/shears/scissors [110] scoring particularly high on the Downs and Black checklist (see Table 59). There were no domains where all quality appraised studies performed poorly. These studies consistently performed well across all Downs and Black checklist with the exception of: inclusion of subjects representative of the population, appropriate blinding, ensuring compliant with intervention protocols, random and concealed assignment, and, failure to report having adequate power to detect significant results. In relation to cost, just one study on endoscopic and laparoscopic devices was available [109], and it received an overall rating of low quality when assessed using an adapted version of the CHEC-list, with less than 50% of total quality criteria met (see Table 60). The strengths and limitations of the single external fixator device quality appraised using the adapted CHEC-list is available in Table 53. Finally, in relation to environmental outcomes, just one study [105] of endoscopic and laparoscopic devices (including endoscopic trocars, ultrasonic scissor tips, laparoscopic sealers/dividers, and ultrasonic scalpel/shears/scissors) was available, and it received an overall rating of 15/22 for transparency reporting based on the life cycle assessment transparency reporting checklist developed by Keil *et al.* [65] (see
).

(iv) Implantable cardiac devices

Overall, the quality of evidence in relation to safety outcomes for implantable cardiac devices was fair to good, with three studies rated as good based on the Downs and Black checklist and the remaining study rated as fair (see Table 59). Common areas where studies performed poorly on the Downs and Black checklist were: failure to perform adequate blinding, and failure to perform randomisation. Common areas where these studies performed well were: clear reporting of study aims, clear description of the participants, intervention, confounders and outcomes, appropriate reporting of statistics and appropriate analyses, sampling and recruitment of a sample representative of the population, compliance with the intervention, and employment of a representative interventions. No studies were available relating to cost or environmental outcomes for implantable cardiac devices.

(v) Cardiac catheters and cannulas

Overall, the quality of evidence in relation to safety outcomes for balloon catheters was poor to good, with two studies [118,120] rated as good based on the Downs and Black checklist and the remaining study, by Browne *et al*. [115], rated as poor (see Table 59). The quality of evidence for balloon catheters in relation to cost outcomes was assessed using the CHEC list, and two studies [117,119] received scores of

12 and 8, indicating moderate and low quality, respectively (see Table 60). No studies on environmental outcomes were available for balloon catheters.

The one available study providing evidence on ablation catheters following reprocessing was an observational prospective (intervention) and retrospective (comparison) study by Leung *et al.* [116], and was rated as being of fair quality based on the Downs and Black checklist (see Table 59). No studies were available relating to cost or environmental outcomes for ablation catheters.

The one available study providing evidence on electrophysiology catheters following reprocessing was a cost minimisation study by Tessarolo *et al.* [119] and was rated as being of low quality based on the CHEC list (see Table 59). No studies were available relating to cost or environmental outcomes for ablation catheters.

One common area where studies performed poorly on the Downs and Black checklist was failure to perform adequate blinding. Common areas where these studies performed well on were: clear description of the intervention, compliance with the intervention, appropriate reporting of statistics, selection of appropriate outcomes for analysis, and inclusion of representative subjects and treatment. Common areas where cardiac catheter and cannula cost-studies performed poorly on the CHEC-list were: discussion of the generalisability of the results to other settings and patient/client groups and appropriate discussion of ethical and distributional issues. Common areas where these studies performed well on the CHEC-list were: provision of a clearly written research question and competing alternatives, employment of an appropriate design, appropriate cost valuations and presentation of conclusions grounded in the data provided.

(vi) Other devices (arthroscopic shavers, deep vein thrombosis compression sleeves, pulse oximeters)

There were environmental health and environmental cost related outcomes available in relation to other devices from Unger and Landis's life cycle assessment study [105]; namely arthroscopic shavers, deep vein thrombosis compression sleeves, and pulse oximeters. As previously discussed, this study was rated as 15/22 items i.e. 68% of transparency checklist items were reported on in the Unger and Landis study using the transparency reporting checklist developed by Keil *et al.* [65] (see
). No studies were available relating to safety or cost outcomes for these devices.

Appendix K table Extended Grading of Recommendations, Assessment, Development and Evaluations

Table 62 Grading of Recommendations, Assessment, Development and Evaluations (GRADE) table with explanations of ratings for individual domains

Outcome	A priori ranking	Downgrade for					Upgrade for			Final grade
		Risk of bias	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Large consistent effect**	**Dose response**	**Confounders only reducing size of effect**	
External fixator devices										
Pin tract infections	Low: One RCT and one observational study.	Serious limitation – downgrade by one: Results based on studies of high and critical risk of bias (each in one domain).	Serious limitation – downgrade by one: Varied point estimates and overlapping confidence intervals. Can't explain differences e.g., whether differences are due to population, intervention, or outcomes and/or to non-reporting of same in the Dirschl and Smith study	Very serious limitation – downgrade by two: No details of the study population reported in the study by Dirschl and Smith (50% of all studies contributing data). The intervention context differed between studies - Dirschl and Smith compared several device brands whereas Sung *et al.* examined a single brand, reprocessing	Very serious limitation – downgrade by two: Wide confidence intervals the study by Dirschl and Smith (50% of all studies contributing data), both with appreciable benefit and harm. Both studies were likely underpowered based on Sung *et al.* assessment "Power analysis	No serious limitations – no downgrade: Our search is comprehensive. Our findings are largely positive and unadjusted.	No upgrade: Inconsistent findings.	No upgrade: Dose-response not applicable.	No upgrade: No adjustment for confounders.	Very low

Table 62 Grading of Recommendations, Assessment, Development and Evaluations (GRADE) table with explanations of ratings for individual domains

Outcome	A priori ranking	Downgrade for					Upgrade for			Final grade
		Risk of bias	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Large consistent effect**	**Dose response**	**Confounders only reducing size of effect**	
				was undertaken in different reprocessing locations and Dirschl and Smith did not report findings by the number of reprocessing cycles (i.e. one and tow). Outcome reporting time was not reported in the study by Dirschl and Smith.	indicates that minimum of 1,600 patients would be necessary to demonstrate equivalence in the most common complication which was pin tract infections."					
Reoperations	Low: One observational study.	Serious limitation - downgrade by one: Results based on study of critical risk of bias (in	Serious limitation - downgrade by one: Result based on one study	Serious limitation - downgrade by one: No details of the study population, several device brands, and indirect comparison (no. reprocessing cycles not disaggregated i.e. between 1 and 2).	Very serious limitation - downgrade by two: Wide confidence interval with appreciable benefit and harm, likely underpowered	No serious limitations - no downgrade: Our search is comprehensive; findings largely positive and unadjusted	No upgrade: One study	No upgrade: Dose response N/A	No upgrade: No adjustment for confounding	Very low

Table 62 Grading of Recommendations, Assessment, Development and Evaluations (GRADE) table with explanations of ratings for individual domains

Outcome	A priori ranking	Downgrade for					Upgrade for			Final grade
		Risk of bias	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Large consistent effect**	**Dose response**	**Confounders only reducing size of effect**	
		one domain)								
Endoscopic and laparoscopic devices										
Postoperative complications (complications and/or reoperations)	Low: Two of threee studies are observational.	Serious limitation – downgrade by one: Results based on studies receiving risk of bias scores of some concerns, moderate concerns and serious concerns	No serious limitations – no downgrade: Similar point estimates and overlapping (sometimes wide confidence intervals). Meta-analysis not undertaken due to differences in outcome definition.	Serious limitation – downgrade by one: Differences in study population, study procedures and reprocessing location in the Mihanovic *et al.* study compared to others, device brands were not reported in two studies	Serious limitation – downgrade by one: Wide confidence interval in 2/3 studies, confidence intervals in all studies reported appreciable benefit and harm. No power calculation undertaken in any study. Small sample sizes in 2/3 studies	No serious limitations – no downgrade: Our search is comprehensive. Our findings are unadjusted.	No upgrade: Consistent findings, potential for confounders.	No upgrade: Dose-response not applicable.	No upgrade: No adjustment for confounders.	Very low

Table 62 Grading of Recommendations, Assessment, Development and Evaluations (GRADE) table with explanations of ratings for individual domains

Outcome	A priori ranking	Downgrade for					Upgrade for			Final grade
		Risk of bias	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Large consistent effect**	**Dose response**	**Confounders only reducing size of effect**	
		in one or more domains.								
Hospitalisation costs (indirect)	Low: One observational study	Serious limitation – downgrade by one: Result based on study of serious risk of bias concerns	No serious limitations – no downgrade: Relatively narrow interquartile range	No serious limitations – no downgrade: Comparable population for intervention and comparison groups	Serious limitation – downgrade by one: Wide confidence interval and small sample	No serious limitations – no downgrade: Our search is comprehensive. Our findings are unadjusted.	No upgrade: One study	No upgrade: Dose-response not applicable	No upgrade: No adjustment for confounders	Very low
Implantable cardiac devices										
Infections	Low: Observational studies.	Serious limitation – downgrade by one: Result based on studies of	No serious limitations – no downgrade: Similar point estimates and overlapping (relatively narrow) confidence intervals.	Serious limitation – downgrade by one: Some differences in intervention eligibility (reused devices provided when new devices were unavailable,	Serious limitation – downgrade by one: Reasonably narrow confidence intervals across all 4 studies (all with	No serious limitation – no downgrade: Our search is comprehensive. Our findings were unadjusted.	No upgrade: Consistent findings, potential for confounders.	No upgrade: Dose-response not applicable.	No upgrade: No adjustment for confounders.	Very low

Table 62 Grading of Recommendations, Assessment, Development and Evaluations (GRADE) table with explanations of ratings for individual domains

Outcome	A priori ranking	Downgrade for					Upgrade for			Final grade
		Risk of bias	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Large consistent effect**	**Dose response**	**Confounders only reducing size of effect**	
		serious risk of bias concerns.	Results of meta-analysis Cochran's Q test ($p > 0.10$) and Higgins's I^2 (<40%) indicated low heterogeneity.	reused devices provided to patients with low life expectancy, reused devices given to patients who could not afford new devices). Patients were older in the Linde *et al.* study compared with others. The gender breakdown varied across studies ranging from 25% - 85% female. 3/4 studies did not report device brands.	appreciable benefit and harm). One of 4 studies (Nava *et al.*) undertook a power calculation (and was adequately powered). Consequently, it was unclear whether other studies were adequately powered.					
Unexpected battery depletion	Low: Two observational studies.	No serious limitations – no downgrade: Result based on	No serious limitations – no downgrade: Similar point estimates and overlapping	No serious limitations – no downgrade: Some differences in study population (eligibility, age, gender) and	Very serious limitation – downgrade by two: Wide confidence interval across 2 studies with	No serious limitations – no downgrade: Our search is comprehensive. Our findings were unadjusted.	No upgrade: Inconsistent findings.	No upgrade: Dose-response not applicable.	No upgrade: No adjustment for confounders.	Very low

Table 62 Grading of Recommendations, Assessment, Development and Evaluations (GRADE) table with explanations of ratings for individual domains

Outcome	A priori ranking	Downgrade for					Upgrade for			Final grade
		Risk of bias	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Large consistent effect**	**Dose response**	**Confounders only reducing size of effect**	
		low risk of bias for all studies for this outcome.	(relatively narrow) confidence intervals.	intervention (device brands and reprocessing location) unlikely to seriously influence this outcome.	events. One of 2 studies (Nava *et al*.) undertook a power calculation (and was adequately powered). Consequently, it was unclear whether other studies were adequately powered.					
Cardiac catheters/cannulas										
Major complications	Low: Three of four studies are observational.	Serious limitation – downgrade by one: Result based on serious concerns with respect to	No serious limitations – no downgrade:	Serious limitation – downgrade by one: Some differences in procedures (coronary angioplasty vs elective atrial fibrillation ablation). Three of four studies didn't report device brands.	Very serious limitation – downgrade by two: Wide confidence interval across studies with events. One study (Unverdorben *et al.*) undertook a power calculation	No serious limitations – no downgrade: Our search is comprehensive. Our findings were unadjusted.	No upgrade: Inconsistent findings.	No upgrade: Dose-response not applicable.	No upgrade: No adjustment for confounders	Very low

Table 62 Grading of Recommendations, Assessment, Development and Evaluations (GRADE) table with explanations of ratings for individual domains

Outcome	A priori ranking	Downgrade for					Upgrade for			Final grade
		Risk of bias	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Large consistent effect**	**Dose response**	**Confounders only reducing size of effect**	
		risk of bias in three of four studies in relation to this outcome.		Devices were reprocessed externally in three of four studies.	(and was underpowered for procedure success). Other studies were likely adequately powered but did not undertake a power calculation.					
Total cost difference (per patient)	Low: Observational study	No serious limitation – no downgrade: Moderate risk of bias in two domains.	Serious limitation – downgrade by one: One study.	No serious limitations – no downgrade: Comparable population for intervention and comparison	Very serious limitation – downgrade by two: Not reported.	No serious limitations – no downgrade: Our search is comprehensive. Our findings were unadjusted.	No upgrade: One study.	No upgrade: Dose-response not applicable.	No upgrade: No adjustment for confounders	Very low