Safety, cost and environmental impact of reprocessing single use medical devices (SUDs)

An evidence review

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Research. Evidence. Action.

Single use medical devices (SUDs)

- Intended to be used on **one individual,** during a **single procedure**
- No manufacturer instructions on how to reprocess

Reprocessing

"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"

Typically, of "reusable medical devices"

- SUDs also reprocessed

- SUD reprocessing undertaken with varying levels of quality and safety assurances
  - Developed countries moving toward regulation

EU Medical Device Regulation 2017 (MDR)

Prohibit all SUD reprocessing activities

Opt-in to Article 17(2) - Any entity reprocessing SUDs is viewed as the device manufacturer and must fulfil the full set of manufacturer requirements and obligations of the MDR as they apply to all manufacturers of medical devices.

Opt-in to Article 17(3) - Health institutions reprocessing SUDs for reuse in-house are exempt from certain manufacturer obligations with the exception of a limited set of specific obligations known as “common specifications.”

Opt-in to Article 17(4)- an extension to 17(3), whereby any external reprocessor reprocessing SUDs on behalf of a health institution can benefit from the 17(3) derogation if the device is returned to the same health institution for reuse there.

Mixed opinions on SUD reprocessing

Safety

- Belief that the device could not achieve a desired function and maintain patient safety standards
- No increased health risks (in regulated settings)

Economic advantages

- Cost-effectiveness is unknown
- Regulation has had mixed impacts

Environmental benefits

- Environmental impacts are unknown

Research questions

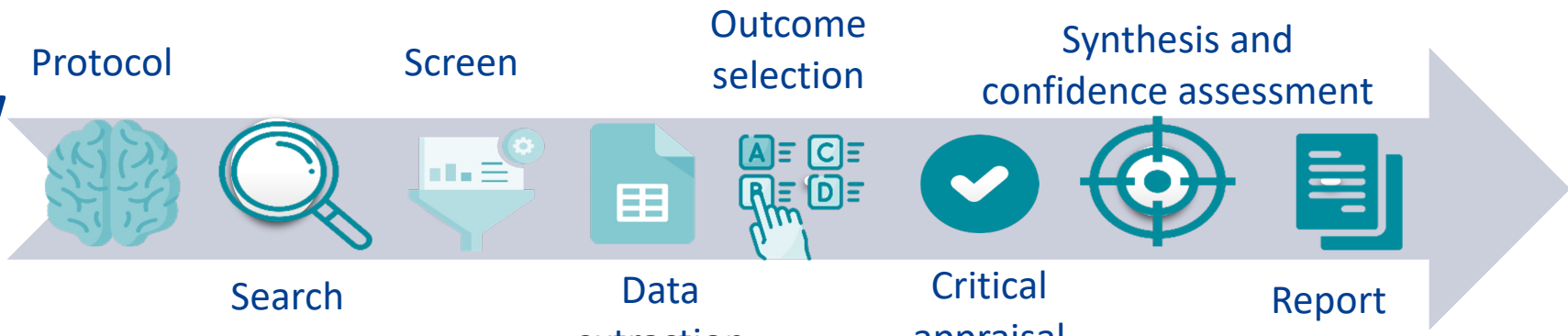
1. **What, if any, SUDs** does the research evidence indicate **can be reprocessed in line with** the 2017 EU medical device regulation and other related approaches?

2. What are the **financial costs, safety and environmental consequences** of reusing SUDs which were reprocessed **in line with** the 2017 EU medical device regulation and other related approaches?

3. **How, if at all, do safety outcomes, environmental impacts, and costs** associated with reprocessing SUDs **in line with** the 2017 EU medical device regulation and other related approaches **differ by SUD type**?

Methods

Review design



Protocol

Table 1. Summary of review inclusion criteria

Element	Criteria
Population	Human patients
Intervention	Reprocessed SUD studies using EU MDR reprocessing definition
Comparison	First device use
Outcomes	Safety (patient or device) and device function, environmental impact and costs to patients or facilities
Study designs	RCTs, NRCTs, observational studies, economic evaluations, LCAs
Study year	From 1994
Languages	English or German

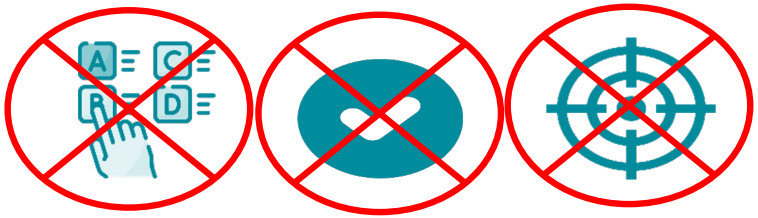
PROSPERO (International Prospective Register of Systematic Reviews) ID CRD42022365642

Splitting studies by study setting

In vitro studies

Studies examining SUD reprocessing safety in a laboratory

- Limited value
- Limited analysis



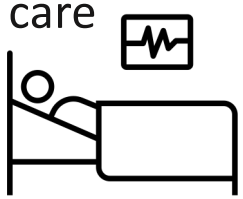
Outcome selection

Critical appraisal

Synthesis and confidence assessment

In vivo studies

Studies examining device or patient safety, financial costs, or environmental impacts of reprocessing SUDs, during clinical care



- More valuable
- Full analysis

Outcome selection

Critical appraisal

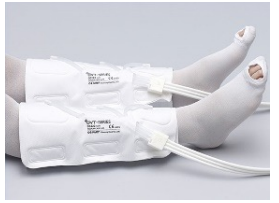
Synthesis and confidence assessment

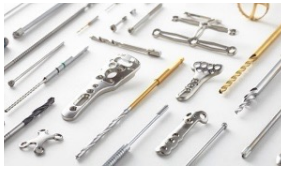
Medical Device Coordination Group 2021-24 (MDCG) Risk classifications

Risk: the potential for deterioration in the health of the patient when a device is used

Four “risk” categories

- Risk classification I (little risk)
- Risk classification IIa (unlikely risk)
- Risk classification IIb (potential risk of deterioration)
- Risk classification III (risk of death)





Literature searching, screening and data extraction

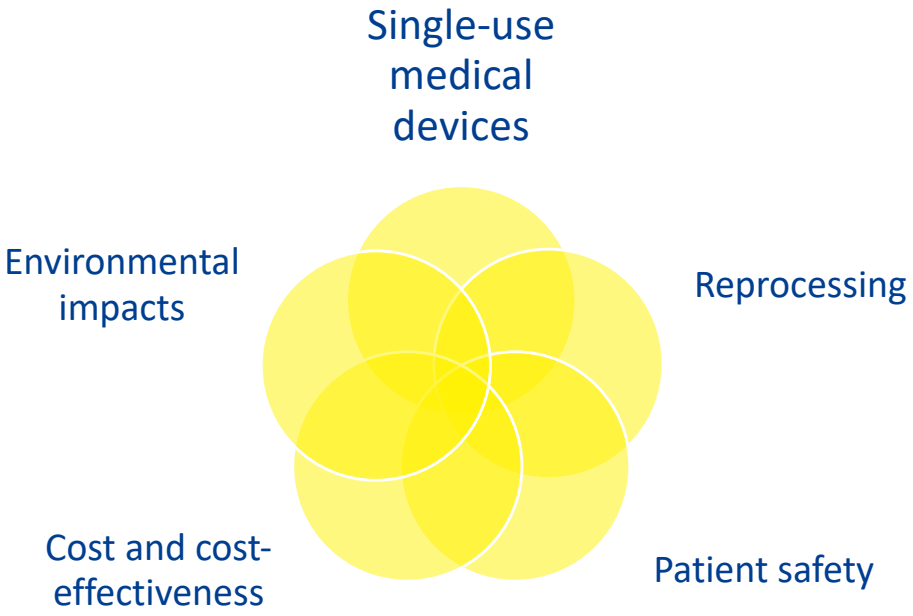


Figure 1 Search concepts

Search resources

- Four databases (Medline, Embase, Cochrane, Dimensions)
- Supplementary search to identify published, peer reviewed and grey literature items

Screening

- By two independent reviewers (all stages)
- In Eppi-reviewer (using priority screening)

Data extraction

- By two independent reviewers
- Into bespoke extraction forms

Synthesis and confidence assessment

Selection of review outcomes

- Primary: directly impact/account for patient safety (safety and cost), or contribute to global warming
- Secondary: may indirectly impact patient safety (safety), didn't account indirect costs (costs), global warming health consequences

Eligible study quality assessment

- The Downs and Black checklist
- Consensus Health Economic Criteria list
- Life cycle assessment checklist

Data synthesis

- Meta-analysis including feasibility assessment
- Narrative synthesis

Certainty in the evidence assessment

- GRADE tool
  - Primary review outcomes

Results

Overview of identified SUDs

Search results

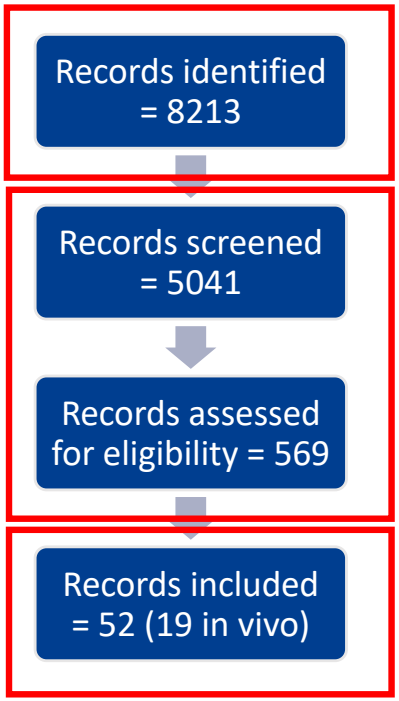


Figure 2. Adapted PRISMA flow diagram showing review search results

Device grouping

Respirators and facemasks

Compression sleeves

Pulse oximeters

External fixator devices

Ophthalmic devices

Internal fixator devices

Surgical instruments (4 devices)

Endoscopic and laparoscopic devices (7 devices)

Implantable cardiac devices (2 devices)

Cardiac catheters and cannulas (4 devices)

All three outcome types were available for 2 SUDs **(ultrasonic scalpel and laparoscopic sealer)**

Device outcome categories

Safety

In-vitro: 12 SUDs

In-vivo: 9 SUDs

Cost

In-vivo: 12 SUDs

Environmental

In-vivo: 7 SUDs

Summary of in vitro studies

Risk class I
Risk class II
Risk class III

Risk class I

- Respirators and facemasks (n=19)

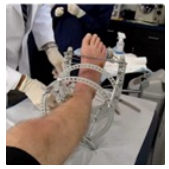
Risk class IIa and IIb

- Surgical instruments for cutting/grasping (n = 4)
- Endoscopic/laparoscopic devices (n=2)
- Internal fixators (n=1)

Risk class III

- Cardiac catheters and cannulas (n=7)

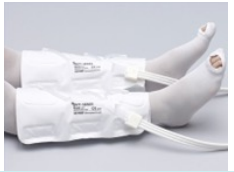
risk class I



1. External fixator devices

Domain	Review finding
Overview of studies	n = 3 (1998 – 2008), USA
Reprocessing oversight	FDA regulations (n = 2 studies) Research team quality criteria (n = 1 study)
Outcome(s) assessed	Safety (n = 2 studies), costs (n = 2 studies)
Safety outcome results summary	• Similar odds of pin tract infections, reoperations, loss of fixation and loosening of device components
Costs outcome results summary	• Direct savings ranged from 21%-45% (for all devices, during study periods)
GRADE/study quality	• Very low certainty evidence (pin tract infections, reoperations) • 1 low quality and 1 good quality study (direct costs)

risk class I



2. Deep vein thrombosis compression sleeves

Domain	Review finding
Overview of studies	n = 1 (2016), USA
Reprocessing oversight	FDA regulations
Outcome(s) assessed	Environmental impacts, device life cycle costs (up to 5 reprocessing cycles)
Env. outcome results summary	• Environmental and human health outcomes reduced with each additional reprocessing cycle
Cost outcome results summary	• Device lifecycle related savings reported • Incremental savings decreased with each additional cycle
GRADE/study quality	68% of items on a transparency reporting checklist

risk class I

3. Pulse oximeters

Domain	Review finding
Overview of studies	n = 1 (2016), USA
Reprocessing oversight	FDA regulations
Outcome(s) assessed	Environmental impacts, device life cycle costs (up to 5 reprocessing cycles)
Env. outcome results summary	• Adverse environmental and human health outcomes reduced or remained the same with each additional reprocessing cycle
Cost outcome results summary	• Device lifecycle related savings reported • Incremental savings decreased with each additional cycle
GRADE/study quality	• 68% of items on a transparency reporting checklist

risk class IIa

1. Ophthalmic devices

Domain	Review finding
Overview of studies	n = 1 (1996), USA
Reprocessing oversight	FDA Compliance Policy Guide
Outcome(s) assessed	Safety, up to 4 reprocessing cycles
Safety outcome results summary	• No intraoperative or postoperative problems or complications • No association between no. device uses and procedure time • Devices available reduced with each reprocessing cycle (86% after the 1st cycle, to 50%, then 23%, then 3%)
GRADE/study quality	• Very low certainty evidence • (interoperative and postoperative complications)

Risk class IIb

2. Surgical instruments for grasping/cutting

Domain	Review finding
Overview of studies	n = 1 (2016), USA
Reprocessing oversight	FDA regulations
Outcome(s) assessed	Environmental impacts, device life cycle costs (up to 5 reprocessing cycles)
Env. outcome results summary	• Adverse environmental and human health outcomes reduced or remained the same with each additional reprocessing cycle
Cost outcome results summary	• Device lifecycle related savings reported • Incremental savings were consistent with each additional reprocessing cycle ($100 approx.)
GRADE/study quality	68% of items on a transparency reporting checklist

Risk class IIb

3. Endoscopic and laparoscopic devices

Domain	Review finding		
Overview of studies	n = 5 (1999 - 2021), 3 in USA, 2 in Europe		
Reprocessing oversight	FDA/EU MDR regulations (n = 3 studies) National regulations (n = 1 study) Research team criteria (n = 1 study)		
Devices	• laparoscopic sealer • ultrasonic scalpel	• linear suture machines • sphincterotomes	• endoscopic trocars • ultrasonic scissor tips
Outcome(s) assessed	Safety (n = 3 studies) Costs (n = 4 studies) Environmental impacts (n = 1 study)		
Safety outcome results summary	• Similar odds of reoperations and postoperative complications • Similar average procedure time and length of hospital stay		

3. Endoscopic and laparoscopic devices

Risk class IIb

Domain	Review finding
Cost outcome results summary	• Direct savings from $282 (laparoscopic sealer/divider) to $65961 (sphincterotomes) and €14623.61 (suture machine) to €75932.55 (ultrasonic scalpel), total devices/patients included during the study • Savings reduced after accounting for indirect costs • Incremental cost savings diminished (ultrasonic scalpel and endoscopic trocar) or remained consistent (laparoscopic sealer) with each subsequent reprocessing cycle
Env. outcome results summary	• Adverse environmental outcomes increased for ultrasonic scalpel and reduced for endoscopic trocars and laparoscopic sealers
GRADE/study quality	• Very low certainty evidence (complications, indirect costs) • Safety study quality: good or excellent (n = 3 studies) • Cost study quality: low (n = 1 study) or good (n = 2 studies) • 68% of items on a transparency reporting checklist

risk class III

1. Cardiac catheter devices

Domain	Review finding
Overview of studies	N = 6 (1994 – 2019), 2 in the USA and in Europe, 1 in the UK and in Canada
Reprocessing oversight	FDA/EU MDR regulations (n = 2 studies) Research team criteria (n = 2 studies) Local hospital policy (n = 1 study) Did not say (n = 1 study)
Outcome(s) assessed	Safety (n= 4 studies), costs (n = 2 studies)
Safety outcome results summary	• No difference in the odds of major complications in 2 of 3 studies or minor complications in 2 studies. • No difference in procedure time in 3 of 4 studies or fluoroscopy times in 3 of 4 studies. • Similar volume of contrast dye used in 2 of 3 studies.

risk class III

1. Cardiac catheter devices

Domain	Review finding
Cost outcome results summary	• Direct cost savings ranged from 12.5% (balloon catheters) to 33% (ablation catheters) to 42% (EP catheters) **across devices/patients** (n = 1 study) • Indirect cost savings estimated at $129 **per patient** (n = 1 study)
GRADE/study quality	• Very low certainty evidence (complications, indirect costs) • Safety study quality: poor (n = 1 study), fair or good quality (n = 3 studies) • Cost study quality: low quality (n = 1 study), moderate quality (n = 1 study)

2. Implantable cardiac devices

Domain	Review finding
Overview of studies	N = 4 (1998 – 2019), 3 in Europe and 1 in Mexico
Reprocessing oversight	Local hospital policy (n = 2 studies) Research team criteria (n = 2 studies)
Outcome(s) assessed	Safety (n= 4 studies)
Safety outcome results summary	• Similar odds of new and reused device malfunction • Meta-analysis for two safety outcomes: infections and unexpected battery depletion

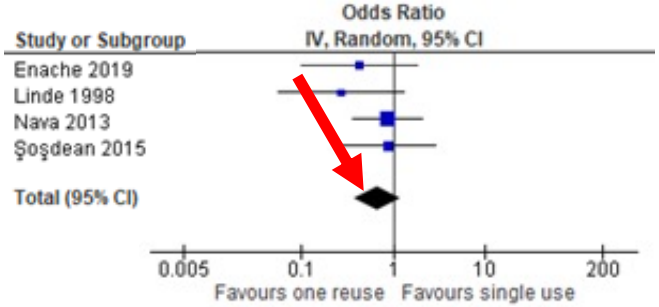


Figure 3. Forest plot of the rate of device related infections in studies of new compared with reused implantable catheter devices

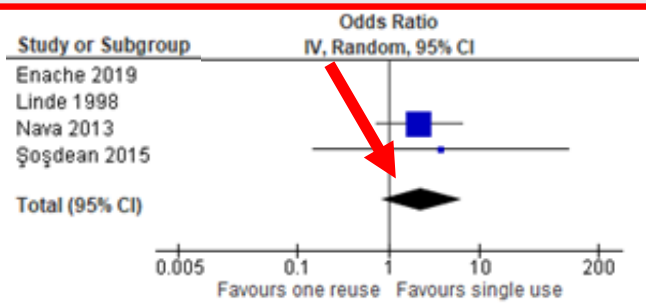


Figure 4. Forest plot of the odds of unexpected battery depletion in studies of new compared with reused implantable catheter devices

2. Implantable cardiac devices (contd.)

Domain	Review finding
GRADE/study quality	• Very low certainty evidence (device associated infection, unexpected battery depletion) • Fair or good study quality (n = 4 studies)

Discussion

Conclusions

RQ 1: What SUDs can be reprocessed?

- Too few in-vitro studies for any one SUD
- Some SUDs were reused (once) without additional adverse patient safety impacts but certainty in the evidence is very low
    - External fixator devices (n = 2) and implantable cardiac devices (n = 4)

RQ 2: Safety, cost and environmental impacts

No difference in adverse patient safety outcomes (in-vitro)

- Few studies and very low certainty in the evidence

Cost-effectiveness still unknown
Device life cycle savings reported

Environmental benefit reported
Emerging area of research

Conclusions

RQ 3: Differences by devices

Safety outcomes

- Extent safety studied differed (e.g., patient versus device outcomes)
- Volume of evidence differed by device

Cost outcomes

- Direct cost savings differed by device
- Device life cycle cost savings differed by device

Environmental outcomes

- Environmental benefits differed by devices

Strengths, limitations and future directions

- ✓ Broad review focus
- ✓ Reprocessing definition
- ✓ Inclusion of in-vitro studies
- ✓ Information specialist
- ✓ Followed best research practices

- x Review team lacked clinical expertise
- x Language restriction
- x Limited study by device types,
- x Limited study of the impact of regulation on review outcomes

Future research

- Call for good-quality RCTs of patient safety persists
- Call for economic evaluations examining cost-effectiveness persists
- Primary research on environmental effects is needed
- Identified areas for methodological development in LCA research applied to healthcare and health services research
- Researchers should endeavour to report on regulatory or related requirements
    - examine the association between “reprocessing oversight” and safety, cost-effectiveness and environmental impacts

Questions?