Prerequisites for reprocessing and reusing disposable medical devices in Sweden

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Preface

In December 2019, the National Board of Health and Welfare was commissioned by the Government (S2019 / 05187 / FS) to, in consultation with the Swedish Health and Care Inspectorate (IVO) and the Medical Products Agency, investigate whether - from a patient safety perspective - there are conditions to allow disposable medical devices to be reprocessed. and reused in Sweden. The assignment must be reported no later than 31 December 2020 to the Government Offices. This report constitutes the account of the assignment.

Reprocessing and reuse of disposable medical devices mainly concerns product liability issues and the issue of patient safety, but also finances, accessibility and environmental aspects. The report analyzes available evidence, the existence of, and conditions for, reprocessing and reuse of disposable medical devices in Sweden.

The project has been led by investigator Patrik Hidefjäll. The project group has included lawyers Louise Follin Johannesson and Lena Koepke Holmvall and investigators Axana Haggar and Birgitta Svensson. Anders Bengtsson has been responsible for the unit manager. Employees from IVO and the Medical Products Agency have participated in the work. The National Board of Health and Welfare would like to extend a special thank you to all external actors who participated in the implementation of the assignment.

Olivia Wigzell
General
Manager

Content

Summary

The National Board of Health and Welfare assesses that there are conditions for reprocessing and reusing disposable medical devices in Sweden in a patient-safe manner.

Based on a government assignment (S2019 / 05187 / FS), we have investigated whether, from a patient safety perspective, there are conditions for reprocessing and reusing disposable medical devices in Sweden. The report shows that re-processing and reuse of disposable medical devices that take place according to a validated protocol, according to current law in the field, can be considered patient-safe. We have not found in the literature any decisive difference in patient safety between products that have been reprocessed in hospitals in Sweden and new medical devices that are used for the first time. In addition, re-processing means that health care becomes more resilient in everyday life and is better prepared to cope with a crisis situation.

Article 17 (3) and (4) imply higher requirements

The report builds i.a. on a questionnaire study in Swedish somatic hospital care, and according to the answers, 40 percent of the participants reuse disposable products. In order for this to be permitted in the future, care providers must apply Articles 17 (3) and 17 (4) of the MDR Medical Technology Regulation (EU) 2017/745. Article 17 (3) and the common specifications to be complied with impose higher requirements than today, but reprocessing and re-use of disposable products should be possible to some extent and for certain products.

No ban on external reprocessing in other EU countries

Some of the care providers who currently reprocess and reuse disposable products will probably not have sufficient resources or capacity to go through the process required by the new regulations. Therefore, it should also be possible to apply 17.4 in the MDR so that a care provider can hire an external reprocessor to reprocess disposable medical devices on their behalf.

The National Board of Health and Welfare does not propose any prohibitions or restrictions regarding external reprocessing (according to Article 17 (4)) of medical devices to any other Member State within the EU, but that it will be prohibited for the time being to transfer disposable products for reprocessing to third countries. The National Board of Health and Welfare does not propose any prohibitions or restrictions regarding the provision or reuse of certain reprocessed product types, in accordance with Article 17 (9) of the MDR.

The mission

A number of disposable medical devices have been reprocessed and reused clinically in several hospitals for a long time [1]. Reprocessing is defined in Article 2.39 of Regulation (EU) 2017/745 on Medical Device Products, MDR (Medical Device Regulation), hereinafter abbreviated MDR[1], such as the measures taken to ensure that a used product is safe to reuse, e.g. cleaning, disinfection, sterilization and related measures as well as testing and restoration of the technical and functional safety of the used product. According to MDR, which on 26 May 2021 will replace previous EU legislation in this area (Medical Devices Directives 90/385 / EEC and 93/42 / EEC), there will no longer be any possibility to reprocess and reuse disposable medical devices unless there is a national exception.

The Government assignment (S2019 / 05187 / FS) on conditions for reprocessing and reusing disposable medical devices in Sweden states that the National Board of Health and Welfare, in consultation with IVO and the Medical Products Agency, shall investigate
- from a patient safety perspective - there are conditions for allowing disposable medical devices to be reprocessed and reused in Sweden.

If such conditions are deemed to exist, the National Board of Health and Welfare shall investigate whether the exemptions pursuant to Articles 17.3 and 17.4 of the MDR should be applicable. Article 17 (3) becomes applicable when a health care institution reprocesses and reuses disposable medical devices itself, and Article 17 (4) of the MDR applies if the health care system hires an external reprocessor to process the products on their behalf. Furthermore, proposals for restrictions or prohibitions of such activities in accordance with Article 17 (9) of the MDR shall be submitted. A Member State which allows the reprocessing of disposable products may, according to Article
17.9 of the MDR, introduce national provisions restricting or prohibiting the reprocessing of disposable products and the transfer of disposable products to another country for reprocessing, or the provision or reuse of reprocessed disposable products within its territory. Restriction or prohibition of supply means that only certain disposable products are allowed to be reprocessed by an external reprocessor (and then provided to a Swedish healthcare provider), or that only certain reprocessed disposable products may be reused by the health service in Sweden (Article 17 (9) (b) MDR).

In the assignment, the National Board of Health and Welfare shall take into account aspects relating to packaging, storage and storage time when reusing disposable products. The authority must also report the advantages and disadvantages of the business. The National Board of Health and Welfare shall make an estimate of the consequences and costs that this may entail for healthcare if reprocessing and reuse of disposable products are permitted or not permitted in Sweden.

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,

amending Directive 2001/83 / EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385 / EEC and 93/42 / EEC, MDR (Medical Devices Regulation).

Within the framework of the assignment, the National Board of Health and Welfare shall obtain views from other relevant actors such as the Swedish Public Health Agency, Sweden's Municipalities and Regions (SKR), Swedish Medtech, the Swedish Association for Care Hygiene (SFVH) and the Sterile Technology Association.

Purpose

The overall purpose is to investigate on behalf of the Government whether, from a patient safety perspective, there are conditions for allowing disposable medical devices to be reprocessed and reused in Sweden. In addition:

- it is being investigated whether articles 17.3 and 17.4 of the MDR should be applicable.
- proposals are made for restrictions or prohibitions on: (a) the transfer of disposable products to another Member State or to a third country for reprocessing; or (b) the provision or reuse of disposable reprocessed products (Article 17.9, MDR).
- Advantages and disadvantages of reprocessing of disposable medical devices are reported, as well as an economic impact assessment of whether reprocessing and reuse of disposable products is permitted or not permitted in Sweden. In addition to economic aspects, the impact assessment must take into account logistics (packaging, transport and storage) and environmental, sustainability and crisis preparedness aspects.

Issues

A number of questions must be able to be answered in order to complete the assignment. The following questions primarily concern the overall purpose of the assignment, but also the other parts:

- Which disposable medical technology products are currently reused in Swedish healthcare and internationally.
- What are the main reasons for reusing disposable products.
- How patient safety risks and financial value vary among the products that are reprocessed.
- How well are the requirements expressed in the current constitution met (eg the National Board of Health and Welfare's regulations [SOSFS 2008: 1] on the use of medical devices in health care and the National Board of Health and Welfare's regulations and general guidelines [SOSFS 2011: 9] on management system for systematic quality work) for reprocessing and reuse of disposable medical devices in Swedish healthcare.
- What does the preparedness look like to be able to meet MDR's future requirements in health care.
- Implement an external company reprocessing of the health care medical technology products.
- What patient safety risks are associated with reprocessing and reuse of disposable medical devices.

In order to fulfill the task of investigating whether Articles 17 (3) and 17 (4) of the MDR should be applicable, the following questions need to be answered:

- How do the provisions in MDR on reprocessing and reuse of disposable products differ from the current national regulation in the area (SOSFS 2008: 1 and SOSFS 2011: 9 mm).
- What arguments are there from a patient safety perspective for and against the application of Articles 17.3 and 17.4 MDR, based on experiences of reprocessing in Swedish healthcare and through external reprocessing companies.
- What are the conditions financially and in terms of competence and resources for Swedish healthcare to be able to meet the requirements for reprocessing and reuse specified in the MDR within a reasonable time frame.

In order to fulfill the task concerning proposals for restrictions or prohibitions, the following questions need to be answered:

- Are there any obstacles or reasons against:
    - reprocessing of disposable products and transfer of disposable products to another Member State or third country for reprocessing.
    - supply or reuse of reprocessed disposable products.

In order to fulfill the assignment concerning the reporting of advantages and disadvantages of re-processing of disposable medical devices, the following questions need to be answered:

- What are the advantages and disadvantages of internal healthcare and external reprocessing and reuse of disposable medical devices?
- What are the financial consequences of in-hospital or external reprocessing and reuse of disposable products being allowed and not allowed in Sweden?
- How are logistics (packaging, transport and storage), environment and sustainability and the emergency preparedness capability in health care affected by in-hospital and external reprocessing and reuse of disposable products being allowed and not allowed in Sweden?

Scope and boundaries

The report does not concern comparisons between disposable products and reusable products for the same purpose, but only reprocessing and reuse of CE-marked disposable medical devices.

The report focuses mainly on invasive activities in specialized somatic care in institutions (hospitals[2]) which has access to cleaning, disinfection and sterilization of medical devices, ie. sterile technical units. Thus, no comprehensive survey in health care has been carried out.

The report does not address the reprocessing and reuse of disposable medical devices such as needles and syringes where evidence is unambiguous

[2] The term hospital is not unambiguously defined, but is used in various contexts for an organizational unit with qualified and specialized resources where invasive measures, e.g. endoscopy, surgery and endovascular procedures are performed and a sterile center is available.

that this should not happen. Environmental aspects of reprocessing have only been analyzed to a limited extent, due to limited data and difficulties in carrying out a methodologically reliable analysis within the framework of this assignment.

The assignment does not state that the authority must investigate whether in Sweden there are conditions for allowing reprocessing of actors whose purpose is to reprocess disposable products so that the product can be CE-marked again and placed on the common market (reprocessing according to Article 17.2) and MDR). Our assessment is that it is not part of the assignment to investigate this issue.

Definitions of terms used in the report[3]

Medical device: article which, according to the manufacturer, is intended to be used, either separately or in combination, in humans for one or more of the following medical purposes:

- diagnosis, prophylaxis, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation or compensation for an injury or disability,
- examination, replacement or modification of the anatomy or of a physiological or pathological process or a physiological or pathological condition;
- providing information through in vitro examination of samples from the human body, including donations of organs, blood and tissues,

and which do not achieve their main intended effect in or on the human body by means of pharmacological, immunological or metabolic agents, but which can be supported in their function by such agents.

Disposable medical device: product intended for use by one person in a single procedure.

Reprocessing: the measures taken to ensure that a used product is safe to reuse, e.g. cleaning, disinfection, sterilization and related measures as well as testing and restoration of the technical and functional safety of the used product.

Recycling: use of the same product more than once, on the same patient or other patients.

Agenda 2030

This assignment on the conditions for reprocessing and reusing disposable medical technology products in Sweden is linked to goals 3 and 12 in Agenda 2030 for sustainable development.

- Goal 3 is about ensuring healthy lives and promoting well-being for everyone of all ages.
- Goal 12 is to promote sustainable consumption and production patterns

[3] The definitions for all terms except for "Reuse" are taken from the definitions in MDR. The definition of reuse has been discussed within the project and with representatives of the Medical Products Agency.

Method and implementation

In order to be able to fulfill the various parts and issues of the assignment, a large number of data sources have been collected and analyzed. The project has been conducted in a reflexive, iterative manner with many external contacts, with the intention of quickly generating an overview and then during the execution of the assignment be prepared to be able to change direction.

Preliminary study, workshop and ongoing contacts

In order to be able to generate various alternative hypotheses about the patient safety issue at an early stage, the project began with an initial stakeholder analysis, in which all stakeholders in Sweden were identified. A number of websites, various policy documents and documentation from conferences were collected and analyzed (see Figure 1).

Opinions of the European Commission on MDR and Commission Implementing Regulation (EU) 2020/1207, hereinafter referred to as the common specifications, were also examined.[4] All identified Swedish parties involved were invited to a workshop (participants, see Appendix 1).

Contacts with several of the participants in this workshop have been made continuously during the project to shed light on various issues. The issues have, for example, concerned routines for reprocessing at sterile technical units and data for financial calculations for reprocessing of electrophysiological catheters.

Figure 1: Overview of the medical technology sector and its stakeholders

[4] COMMISSION IMPLEMENTING REGULATION (EU) 2020/1207 of 19 August 2020 laying down detailed rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of disposable products.

Site visits and ongoing contacts

Early in the project, a number of sterile technical units were contacted with a request to carry out site visits. At each visit, the project group had a first theoretical review of the activities, which was then followed by a tour and final discussion. The project group visited St. Göran Hospital, Örebro University Hospital, Karolinska University Hospital Huddinge and Danderyd Hospital. Several visits and contacts took place at Huddinge Hospital to obtain financial data for financial impact assessments. Contacts in Region Stockholm's procurement unit and clinical experts in orthopedics at Karolinska University Hospital and Södersjukhuset were also consulted.

Compilation of evidence

Based on the initially identified literature and stakeholder analysis, the project took part in various hypotheses about how patient-safe reprocessing of disposable medical devices is. Arguments for the various hypotheses were also presented during the workshop conducted with invited interested parties. Based on the initial understanding of the issue, an overview of evidence was initiated, mainly from published studies in the medical database PubMed, of reprocessing and reuse of disposable medical devices. A search strategy with different search terms was developed together with one of the agency's information experts and led to 335 articles that were reviewed in full text or abstract (Appendix 7). A total of 200 articles were selected as relevant to this assignment and examined on the basis of a predefined protocol (study design; method and material; results and conclusions; medical field; comments) by an external medical expert (see Appendix 7). The reference lists of these articles were used according to the snowball methodology to identify additional literature, which formed the basis for the literature review presented in the results section of this report, based on medical areas in which reprocessing and reuse of disposable medical devices occur. In addition to evidence from scientific publications, various databases for incident reporting and relevant quality registers have also been analyzed.

Legal investigation work

The legal investigation work of comparing the current and proposed constitution for reprocessing and reuse of disposable products has been used to assess what new requirements are placed on the health care operations. Knowledge of the legal requirements for reprocessing has been a prerequisite for dialogues with various stakeholders during the project, and a starting point for the design of the web survey.

Online survey and follow-up contacts

In parallel with the literature review that began, an online survey was planned to get a better idea of which activities and disposable medical technology products in Sweden are covered by reprocessing and reuse. The first approach was to cover all clinical activities, hygienists, business development, medical technology, chief physicians and sterile technical units at the largest hospitals, where a sterile technical unit is located. This first broad approach had to be revised so as not to disrupt clinical practice,

especially in view of the development of the covid-19 pandemic. Based on the literature review, five areas were identified, in addition to the sterile technology units, where re-processing and reuse of disposable products took place. It was about cardiology, orthopedics, surgery, IVA / anesthesia and gastroenterology. Gastroenterology, which can be considered a sub-area of surgery but in many hospitals is organized under the medical clinic, was selected to target the activity called ERCP (endoscopic retrograde cholangiopancreatography) where disposable products are used together with endoscopic examination. . Several drafts of the questionnaire were extensively tested by various activities in the health care system, e.g. sterile technology, medical technology, hygienists and chief physicians, but also regulatory consultants and the agency's own survey designers as well as the project's internal group and external consultation group. Recipients of the web survey were identified by means of inquiries to the regions' registrars, patient guides and in some cases switchboard operators.

Economic impact assessments

At the end of the project, an economic impact assessment has been carried out to be able to determine what costs and other resource and environmental impact may arise depending on whether reprocessing and reuse are to be permitted or not permitted. Data for these financial analyzes have been collected on an ongoing basis from procurement databases and contacts with controllers, primarily within the Stockholm Region.

Consultation with relevant actors

The original plans for participation in the Swedish Association for Care Hygiene (SFVH) and the Sterile Technology Association's annual meetings were canceled due to. covid- 19-pandemic. E-mail contact with information about referral statements from SFVH has taken place. Ongoing contact with SKR's responsible person for medical technology issues has taken place during the project and a consultation took place with the Medical Technology Product Council (MTP Council) on 14 May. The Swedish Public Health Agency was consulted in particular on the issue of the handling of prion risk and medical devices. Contact with representatives of Swedish Medtech took place mainly initially and also at a specific meeting on 1 October 2020 in which the Director General of the National Board of Health and Welfare participated.

Project members also participated in the Management Network for Medical Technology (LfMT)'s annual meeting on 9 September 2020 and informed about the project's work. The increased demands that MDR entails were discussed with the chairman of LfMT, who convened medical technology representatives for some regions, in order to further shed light on the role that medical technology units in the regions can play in the work with regulatory compliance regarding reprocessing of disposable medical technology products.

On 16 September 2020, a digital meeting was arranged with a number of representatives from different regions with the aim of documenting experiences of the material shortage management that prevailed during the beginning of the covid-19 pandemic.

Collaboration with IVO and the Medical Products Agency

During the work on the report, an ongoing reconciliation has taken place with representatives of the Medical Products Agency and the Swedish Health and Care Inspectorate (IVO).

Historical background to reprocessing of disposable medical devices

Reprocessing of disposable medical devices is defined in Article 2.39 of the MDR as the measures taken to ensure that a used product is safe to reuse, e.g. cleaning, disinfection, sterilization and related measures as well as testing and restoration of the technical and functional safety of the used product.

The process used in the reprocessing of reusable products and disposable products is equivalent, with the exception of the requirement for special risk management of disposable products which, according to the manufacturer, has only been approved for single use. When reprocessing a disposable product, the care provider thus takes over product responsibility. The next chapter on the meaning of MDR describes the requirements that a care provider must meet. In this chapter, a brief account will be given of the historical background to the reprocessing of disposable products. How reprocessing of disposable products takes place is described in Appendix 2 on processes and routines for reprocessing.

Introduction of disposable products in healthcare

As can be seen from the forthcoming review of the various medical areas, the reuse of disposable medical devices was something that took place relatively soon after disposable products were gradually introduced from the 1950s onwards, in both the USA and Western Europe. In many medical fields, the disposable medical technology products were completely new products and involved new ways of diagnosing and treating patients. In some other cases, disposable products offered an alternative to established reusable medical devices. In the first case, the products were a prerequisite for diagnosing and treating the patients and therefore a crucial resource that they were prepared to clean, disinfect and sterilize in some cases to be able to use later [2]. With the introduction of new plastic materials in disposable products from the 1950s onwards, which replaced reusable products and could not withstand steam sterilization, many hospitals could not reprocess these. Relatively soon, many hospitals in the United States and in Western Europe created the capacity to use other methods, e.g. ethylene oxide sterilization, also reprocessing some products with plastic components because it was perceived as a "waste" to throw them away [3, 4].

Important events affecting the reuse of disposable medical devices were the introduction of legal requirements for medical devices in the United States in 1976, regulated by the Food and Drug Administration (FDA), and in Europe the introduction of the Medical Devices Directive and the requirement for

CE marking in the early 1990s. The introduction of regulatory requirements for medical technology companies to demonstrate that their products were safe and suitable for their defined purpose forced manufacturers to choose how to classify and label their products. In many cases, this meant that products that had been regularly reused by clinical users were now only approved for single use. Not all clinical professions and staff agreed with this, but chose to reprocess and reuse disposable medical devices at their own risk [5]. This, of course, posed challenges for healthcare regulators in how to safely and consistently address the issue of reprocessing of disposable products [4, 6].

Another significant change in health care was the introduction of prospective reimbursement systems based on diagnosis-related groups (DRG) from the financier to the clinic. These systems calculated the compensation for a particular examination or treatment on what the costs for these previously looked like. With the introduction of new, expensive and innovative disposable medical devices, it was common for the stated reimbursement levels not to cover the higher costs of the new products, which in some cases provided an incentive for clinicians to start reusing these products in order to be able to offer patients care [7]. Under the general cost control in the health care systems and hospitals, reuse could thus also be a way of protecting its clinical area from criticism from a financial point of view.

The emergence of new viral infections such as HIV in the 1980s, and prions in the form of variant Creutzfeldt-Jacob's disease (vCJD) in the latter part of the 1990s, influenced in particular in the UK the view of reuse of disposable products by health care politicians . In 1996, a number of cases of a new prion disease were detected in humans in the United Kingdom, and the cases could be correlated with the consumption of meat products from cows with bovine spongiform encephalopathy (BSE). The disease led to great media attention under the name "crazy cow disease". This so-called variant CJD (vCJD) has mainly affected the United Kingdom with a total of 178 identified cases until 2016. It was previously known that sporadic CJD (sCJD) can be transmitted in connection with a surgical procedure (transplantation of the hard brain or cornea) or via growth hormone from another human being. This prompted authorities in several countries to also investigate and increase preparedness for iatrogenic transmission of vCJD from human to human via healthcare. Of all Swedish CJD cases since 1985, no case of iatrogenic CJD has been identified [8]. Guidelines for how medical devices should be handled in connection with established cases of CJD were quickly introduced in European countries, and they entailed quarantine and destruction of materials that may have been exposed to infection [9].

Reprocessing development in the USA

Apart from the discussions about the risks of reusing disposable medical devices in connection with HIV or prion disease, reprocessing and reuse increased in the USA and many European countries during the 1980s and 1990s. In connection with the introduction of the FDA's Medical Devices Act in the USA in 1976, the FDA informed American hospitals in 1977 that reprocessing and reuse of disposable medical devices meant that they would take over the legal responsibility as manufacturers. However, the FDA did not conduct any hospital inspections [12]. Discussions about the risks of reusing disposable products and the difficulty for OEMs (Original Equipment Manufacturers) to ensure that their products were properly reprocessed prompted the FDA in 1997 to send a warning letter to hospitals and manufacturers.

When GAO's report was published in June 2000, it showed widespread re-use, and that many of the cases mentioned in the media with patient injuries as a result of re-used disposable products on closer inspection proved to be incorrect. Furthermore, GAO's report stated that most disposable products were reprocessed and reused in a safe manner and that substantial financial savings could be realized. GAO's report meant that the prevalence of reused disposable medical devices could be considered justified, but would need to be better regulated by the FDA [14]. In August 2000, the FDA presented a final strategy to introduce the same requirements for healthcare and external companies that reprocess disposable medical devices as those that apply to companies that manufacture medical devices.

The introduction of the same requirements for reprocessing as for the original manufacture of disposable medical devices had extensive consequences. Before the FDA regulation was introduced in 2000, it was estimated that 20 to 30 percent of American hospitals were involved in reprocessing for reuse of disposable medical devices. Following the introduction of the FDA's regulation of the reprocessing of disposable medical devices, GAO was given a new mandate to evaluate the consequences of the FDA's regulation and supervision. According to the FDA, after the implementation of the regulation in 2007, only a single hospital organization was involved in the reprocessing of disposable products. The reprocessing continued, but now took place through companies that reprocessed disposable medical technology products for the hospitals. GAO:

Reprocessing development in Europe

The regulation of reprocessing of disposable medical devices in the United States was expected to affect how the issue would be handled within the European Medical Devices Directive. Although the organization and execution of health care is a national responsibility within the EU, medical devices are covered by the EU's requirements for the free movement of goods and services. The situation in Europe was relatively fragmented as the issue was subject to national self-determination. The UK's competent authority in medical technology, MHRA (Medicines & Healthcare Products Regulatory Agency), issued a recommendation in 2000 not to reuse disposable medical devices. France already had legislation in 1994 that prevented the reprocessing and reuse of disposable medical devices,

The European Commission proposed in 2005 an update of the Medical Technology Directive, to strengthen patient safety and competition within the EU, which was adopted in 2007. This update 2007/47 / EC contained an article (Article 12) to present a report to the Council of Europe by 5 September and European Parliament on the reprocessing of disposable medical devices [16].

As part of the basis for that report, a workshop was organized in December 2008 with various stakeholders as well as a scientific review (Scientific Committee on Emerging and Newly Identified Health Risks, SCENIHR) of risks and dangers involved in reprocessing and recycling. use of disposable medical devices. The Committee's recommendation was that some disposable products are not suitable for reprocessing and reuse, while other products can be reprocessed and reused if known hazards are reduced by managing risks in a systematic way [17]. The report to the European Parliament and the Council was largely based on the expert report from SCENIHR and concluded that in the absence of quantitative data it is not possible to quantify the risk associated with the re-use of single-use medical devices and that only a few - accidents have been reported. The report concluded with the following wording [18]:

'Against this background, and in view of the potential risks identified by SCENIHR in terms of residual contamination, residual residues of chemicals and altered functionality, the Commission will, in the context of a recast of the Medical Devices Directive, assess the measures to be taken for: to guarantee a high level of patient protection with regard to the reconditioning of disposable medical devices. The assessment must also take into account the economic, social and environmental consequences that any measures may have. ”

The step taken by the Commission was to revise and transfer the Medical Devices Directive to MDR, the consequences of which for the reprocessing and reuse of disposable medical devices are described in the following chapters of this report.

MDR - reprocessing and reuse of disposable medical devices

This chapter describes, among other things, the purpose of the MDR and the parts of the MDR that will be applied if the Member State allows the reprocessing and reuse of disposable medical devices. For a background on applicable law in the field of health care with a focus on medical devices, in-house production of medical devices and reprocessing and reuse of disposable medical devices, see Appendix 3.

MDR, Regulation (EU) 2017/745 of the European Parliament and of the Council

The MDR entered into force on 25 May 2017 and, according to its original wording, would begin to be applied three years after the entry into force.[5] Certain parts of the regulation, which concern e.g. notified bodies and the authority responsible for notified bodies, had a different date of application and became applicable already six months after its entry into force.[6] Due to the proliferation of covid-19, the European Parliament and the European Council decided to adopt a proposal, presented by the Commission in early April 2020, to postpone the application of the MDR by one year. Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices describes the provisions of the MDR that have been amended as regards the date of application. Among other things, it appears from Article 1 that Article 17 on reprocessing will come into force on 26 May 2021, instead of 26 May 2020, which was the intention from the beginning.

Recital (2) in the preamble to the MDR states that the purpose of the Regulation is to ensure the smooth functioning of the internal market for medical devices, based on a high level of health protection for patients and users and taking into account small and medium-sized enterprises operating in this sector. In order to eliminate common concerns regarding the safety of medical devices, the Regulation also sets high quality and safety requirements for such products. Both of these goals are pursued at the same time and are inseparable and equally important.

According to EU regulations, a health care institution refers to an organization whose primary purpose is to provide care or treatment to patients or

[5] MDR entered into force 20 days after publication in the Official Journal of the European Union, OJ, ie 25 May 2017.
[6] Cf. Ds 2019: 32 pp. 111.

to promote public health. Recital (30) in the preamble to the MDR states that the concept of health care institution does not include institutions whose primary purpose is to promote health issues or a healthy lifestyle, such as gyms, spas, wellness and fitness facilities. Caregivers are examples of an organization in Sweden that provides care and treats patients.[7]

Reprocessing (Articles 2.39 and 17 of the MDR)

Reprocessing refers to the measures pursuant to Article 2.39 of the MDR that are taken to ensure that a used product is safe to reuse, e.g. cleaning, disinfection, sterilization, and related measures as well as testing and restoration of the technical and functional safety of the used product.[8]

Member States may choose to allow reprocessing. If Member States choose to allow reprocessing, this may be done only in accordance with national law and Article 17 of the MDR. Article 17 (2) of the MDR states that a natural or legal person who reprocesses a disposable product in order to be fit for reuse within the Union shall be deemed to be the manufacturer of the reprocessed product and to assume the manufacturer's obligations under the MDR, which include traceability obligations. for the reprocessed product in accordance with Chapter III of the MDR. The person reprocessing the product shall furthermore be considered a manufacturer for the purposes of Article 3 (1) of Directive 85/37 / EEC.[9]

Under Article 17 (3) of the MDR, Member States may choose to introduce exemptions for disposable products that are reprocessed and reused within a healthcare institution.[10]

This possibility means that Member States can decide that healthcare institutions that reprocess and reuse disposable products do not have to apply all the provisions of the MDR on the obligations of the manufacturer. In these cases, according to Article 17 (3) (a), the safety and performance of the reprocessed product shall correspond to the safety and performance of the original product, and some of the requirements for self-manufactured products referred to in Article 5 (5) (a), (b), fulfilled.[11]

It further follows from Article 17 (5) of the MDR that, pursuant to Article 17 (5) by 26 May 2020, as amended by 26 May 2021, the Commission[12], shall adopt common specifications on reprocessing.

Member States shall encourage, and may require, healthcare institutions to provide information to patients on the use of reprocessed products within the healthcare facility and, where appropriate, other relevant information on the reprocessed product being treated by patients. with.

Under Article 17 (4), Member States may also choose to apply the provisions referred to in point (3) to disposable products reprocessed by a

[7] See Ds 2019: 32 pp. 123.
[8] See Ds 2019: 32 pp. 123.
[9] See Article 17.2 of the MDR.
[10] See Ds 2019: 32 p. 131.
[11] See Article 17 (3) and (3) (a) of the MDR.
[12] See Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices as regards the date of application of certain provisions.

external reprocessor at the request of a health care institution, provided that the reprocessed disposable product is returned in its entirety to that health care institution and the external reprocessor meets the requirements referred to in 17.3 a and b.[13]

Finally, under Article 17 (9), Member States which allow the reprocessing of single-use products may maintain or introduce national provisions which are stricter than those laid down in the Regulation and which restrict or prohibit the following within their territory:

a) Reprocessing of disposable products and transfer of disposable products to another Member State or to a third country for reprocessing.
b) Provision or reuse of reprocessed disposable products.

Member States shall also notify such national provisions to the Commission and to the other Member States. The Commission shall make this information publicly available.[14]

In-house production Article 5.5

There are exceptions in the regulation regarding self-manufactured products. Article 5.5 sets out the requirements that apply to products that are only manufactured and used in healthcare establishments established in the Union. There are certain conditions that they are required to meet and which also apply to disposable medical devices that are reprocessed and reused within a health care institution, see Article 17 (3) (a) which refers to the conditions in 5.5 a, b, d, e, f, g and h.
The following conditions are assumed to be met both in the in-house production of medical devices and in the reprocessing and reuse of disposable medical devices in accordance with Article 17 (3) (a):

a) The products are not transferred to another legal entity.
b) The products are manufactured and used within the framework of appropriate quality management systems.
c) The Department of Health Care justifies in its documentation that the special needs of the intended patient group cannot be met or cannot be met at a corresponding level of performance through an equivalent product that is already on the market (applies only to in-house production).
d) The health care institution shall, upon request, inform its competent authority of the use of such products, and the information shall include a justification for the manufacture, modification and use of the products.
e) The health care institution publishes a declaration, which contains the name and address of the manufacturing health care institution, the information required to identify the product, a declaration that the products meet the general requirements for safety and performance in Annex 1 to the MDR and, where applicable, information on which requirements are not fully met and a justification for this.

[13] See Article 17.4 of the MDR.
[14] See Article 17.9 of the MDR.

f) The healthcare institution shall draw up documentation which makes it possible to understand the manufacturing plant, the manufacturing process and the design and performance of the products, including the intended purpose, and which is sufficiently detailed to enable the competent authority to determine the general safety and performance in Appendix 1 to the MDR are met.
g) The health care institution takes all necessary measures to ensure that all products are manufactured in accordance with the documentation referred to in point f.
h) The Department of Health Care reviews experiences from the clinical use of the products and takes all necessary corrective measures.

Member States may require those healthcare institutions to provide additional relevant information on products manufactured and used in their territory to the competent authority. Member States shall retain the right to restrict the manufacture and use of specific such product types and shall have access to inspections of the activities of the healthcare institution. Article 5 (5) does not apply to products manufactured on an industrial scale.

Common specifications

Commission Implementing Regulation (EU) 2020/1207 of 19 August 2020, laying down detailed rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of disposable products, shall apply from 26 May 2021.

Consequences of MDR for reprocessing and reuse of disposable medical devices

The regulations in MDR entail a lot of news in comparison with previous provisions in the National Board of Health and Welfare's regulations SOSFS 2008: 1 for the health and medical care institutions (care providers) that reprocess and reuse disposable products. If external reprocessing is permitted, a health and medical care institution may, via agreement, use companies that reprocess used disposable products for reuse in their own operations. An external reprocessor that reprocesses disposable products that are then resold to the health care institutions or other users has the same responsibility for the products as a manufacturer of medical devices.[15] In this report, it is mainly Article 17 (3) and 17 (4) of the MDR that become applicable.

Similar to SOSFS 2008: 1, e.g. the provisions of the MDR for self-manufactured products when it is a healthcare institution that reprocesses and reuses disposable products, unlike external companies which have a manufacturer's responsibility when they reprocess and CE mark disposable products.

[15] See Article 17.2 of the MDR.

products for sale on the open market. There are exceptions, if the Member State allows, which means that Article 17 (3) (a) and (b), the rules for in-house production, also apply to external reprocessors when a health care institution transfers used medical devices to an external reprocessor that reprocesses the products and then returns them to the same health care institution. The rules for in-house production in MDR, however, place higher demands on e.g. that the health care institutions, at the request of the competent authority, inform about the use and justification of such products, ie. draw up a declaration, which it must publish, which contains the name and address of the manufacturing (reprocessing) health care institution, the information required for the identification of the product; a statement that the products meet the general requirements for safety and performance in Annex 1 to the MDR, and, where applicable, information on the requirements that are not fully met and a justification for this. Requirements for documentation have also existed in the past, but in general these requirements will be expanded with the new regulations. One of the major changes for a healthcare institution relating to the reprocessing of disposable medical devices is the requirement in Article 17 (5) that compliance with the common specifications mentioned in Article 17 (3) be certified by a notified body. Requirements for documentation have also existed in the past, but in general these requirements will be expanded with the new regulations. One of the biggest changes for a healthcare institution that deals with reprocessing disposable medical devices is the requirement in Article 17 (5) that compliance with the common specifications mentioned in Article 17 (3) be certified by a notified body. Requirements for documentation have also existed in the past, but in general these requirements will be expanded with the new regulations. One of the biggest changes for a healthcare institution that deals with reprocessing disposable medical devices is the requirement in Article 17 (5) that compliance with the common specifications mentioned in Article 17 (3) be certified by a notified body.

The common specifications

The application of Article 17 of the MDR, 'Reprocessing of disposable products', also requires compliance with the common specifications (EU) 2020/1207, in accordance with Article 17 (5) of the MDR. The common specifications provide for more detailed implementing rules for the reprocessing and reuse of disposable products in accordance with Article 17 (3) and (4) of the MDR. According to recital (2) of the preamble to the common specifications, in order to ensure the quality of reprocessing, the common risk management specifications should include minimum requirements for personnel, premises and equipment. Reason (4) in the preamble states that, in order to ensure the safety and performance of the reprocessed disposable product, e.g.

Recital (6) states that the health care institution must also have a system that makes it possible to collect information on incidents involving such products. Serious incidents must, as before, be reported to the competent authority. According to recital (7) in the preamble, the health care institution and external reprocessors should have a system in place to ensure the traceability of the reprocessed disposable product, in particular as regards the reprocessing cycles of a disposable product.

According to Article 4 (2) of the Common Specifications, the reprocessers shall designate one or more persons responsible for the reprocessing. The requirements for these people are that they must have sufficient experience and sufficient qualifications in reprocessing. Article 4 (7) of the common specifications states that the reprocessors shall publish a list of the products which they are capable of reprocessing. Article 5 requires that health

and the health care institution shall make a preliminary assessment of the suitability of a disposable product for reprocessing. Among other things, an analysis must be made of the properties of the disposable product, taking into account all available documentation and information about the disposable product, to ensure sufficient understanding and expertise of design, manufacturing properties, material properties, functional properties and other risk factors, including its previous use.

According to Article 7 (1) to (4) of the Common Specifications, healthcare institutions shall, inter alia: determine in writing the reprocessing cycle to be used in reprocessing. Where applicable, the technical assessment shall include physical, electrical, chemical, biological and microbiological tests as well as reverse engineering. The validation shall ensure that the performance and safety of the disposable product, after each reprocessing cycle and up to the maximum number of reprocessing cycles allowed, correspond to the performance and safety of the original disposable product.

A reprocessed disposable product must be labeled and contain instructions for use. Article 20 of the common specifications states, inter alia: that the labeling of disposable reproduced products must include the word "reprocessed" and the status of the disposable product, the word "disinfected" or "sterilized", followed by the sterilization method or disinfection method and shelf life. The name and address must be stated, and the maximum number of permitted reprocessing cycles and the number of reprocessing cycles performed must be clearly stated.

Quality management system

According to Article 21 of the common specifications, the quality management system must cover all stages of reprocessing and, inter alia: include reporting incidents and handling corrective and preventive measures, and checking their effectiveness. Furthermore, the quality management system shall include risk management, traceability systems including procedures for disposal or return to the external reprocessor of such disposable products that do not belong to the health care institution. Furthermore, internal and external audits and the terms for agreements with the external units that participate in the reprocessing must be stated. According to Article 22, the reprocessors must carry out at least one independent external audit of the reprocessing each year. The audit report shall be made available to the notified body responsible for issuing the certificate to the processor referred to in Article 17 (5) of the MDR. According to Article 23 (8) of the common specifications, the healthcare institution shall, inter alia: record and compile information on all incidents involving reprocessed products, and make a critical analysis of these incidents at least once a year.

Traceability system

Article 24 (1) to (2) of the common specifications provides that the reprocessors shall establish a tracking system which makes it possible to identify the single product throughout the reprocessing cycle and throughout the life of the reprocessed disposable product. This tracking system must record how many reprocessing cycles the disposable product has undergone and ensure that the health care institution checks that the disposable product reprocessed by an external reprocessor and returned to the health care

institution is the same disposable product used in the

the health care institution concerned and sent to the external reprocessor for reprocessing. The tracking system shall ensure that the reprocessed products can be linked to the correct batch number for taking a corrective precautionary measure in accordance with Article 89 of the MDR.

Another novelty is that compliance with the common specifications, or in the absence of such specific harmonized standards and national provisions, must be certified by a notified body.[16]

International outlook

Reprocessing of disposable products has not been the subject of EU legal regulation before, but it has been up to each Member State to regulate the issue itself. The Ministry's memorandum Adaptations to EU regulations on medical technology - part 2 (Ds. 2019: 32) states that Germany, the Netherlands, Portugal and Latvia have stated that they intend to allow the reprocessing of disposable products.

Within the framework of the government assignment, the National Board of Health and Welfare has sent out a questionnaire to the responsible authorities of the above countries[17] with questions about the respective countries' regulation of reprocessing of disposable products. The authority has also sent the questionnaire to Norway, Denmark, Finland andBelgium.[18] The countries that responded to the form are Norway, Denmark, Belgium, the Netherlands and Latvia. Information about Germany's regulation has been obtained via internet searches.[19]

Belgium states that reprocessing is currently not permitted but will be permitted in future legislation. The Federal Agency for Medicines and Health Products (FAMHP) has consulted Belgian hospitals and conducted an investigation of their activities and views on reprocessing. In the national regulations, they intend to introduce a national requirement for notification. They also intend to introduce a list of products that are not allowed to be reprocessed.

In Germany, national rules on reprocessing of disposable products have existed since 2002. The regulations are applied together with national guidelines that establish a minimum standard for reprocessing and also set requirements for certification. Germany will continue to allow reprocessing according to the MDR and the common specifications.

In the Netherlands, reprocessing of disposable products is allowed, under certain conditions. Among other things, they requirement that the manufacturer of the original product must consent to the product being reprocessed and reused. The person who reprocesses must also be able to certify that the requirements set out in Appendix 1 to the MDR are met and that cleaning and sterilization of the products is done in accordance with a validated process. Companies that sterilize medical technology

[16] See Article 17.5 of the MDR.

[17] Germany: Federal Institute for Drugs and Medical Devicesc, Bfarm
Netherlands: Health and Youth Care Inspectorate, IGZ
Portugal: National Authority of Medicines and Health Products, INFARMED
Latvia: Health Inspectorate

[18] Norway: The Norwegian
Medicines Agency Denmark:
The Danish Medicines Agency

Finland: Valvira
Belgium: Federal Agency for Medicines and Health Products, FAMHP
[19] file: /// C: / Users / lefn01 / Downloads / mielke_3191_en% 20 (3) .pdf

products on behalf of third parties are covered by national regulations. The Netherlands intends to continue to allow the reprocessing and reuse of disposable products when the MDR enters into force and will introduce national legislation complementing the MDR and the common specifications.

Denmark states that at present there is no ban on caregivers reprocessing. In cases where a healthcare provider reprocesses a disposable product for the purpose of reusing it, they take over the manufacturer's responsibility from the original manufacturer. Denmark is currently reviewing national legislation and it has not yet been decided whether Article 17 (1) of the MDR will be implemented.

Anyone who reprocesses and reuses a disposable product in Norway is to be regarded as a manufacturer and must meet the same requirements as a manufacturer of medical devices. There is no special regulation concerning external reprocessors.

Latvia has stated that reprocessing is not allowed today and will not be allowed when MDR comes into force.

Evidence overview - reuse of disposable products in various medical areas

This chapter summarizes the more detailed literature review based on the first 200 articles identified in the original literature search (Appendix 7). Based on these 200 originating articles, additional articles arranged by medical field were identified via the reference lists of the articles (Appendix 4). This more comprehensive literature review shows that reprocessing and reuse of disposable medical devices, if done with validated methods and for a defined number of cycles, for the majority of the disposable products analyzed is patient-safe. This conclusion applies regardless of the invasiveness of the products, according to Earle H. Spaulding's classification depending on whether the product: 1) penetrates the skin, mucous membranes and is applied to sterile areas (bloodstream, central nervous system, etc.),

Experiences of medical methods where reuse has taken place

The literature review concentrates on the products that have been of interest for reuse for primarily economic reasons in the following medical areas:

- Cardiology (radiology) - catheters and implants
- Nephrology (dialysis)
- Orthopedics
- Surgery (laparoscopy)
- Gastroenterology (endoscopy / ERCP)
- Urology and gynecology
- IVA / anesthesia

Cardiology

In angiography since the 1950s and later in interventional cardiology during the 1980s and 1990s, catheters were reprocessed and reused. Several articles describe that this can be done without increased patient risk, despite the fact that these are products with long lumens that are now considered unsuitable to reuse. Some articles mentioned that the performance of reusable PTCA catheters in small sizes deteriorated [22]. In electrophysiology, there are a large number of published studies, all of which show that reprocessing and reuse is possible between 5-10 times, without risk to patient safety. Active, electrical implants such as pacemakers and implantable defibrillators have been regularly reused without any demonstrated increased patient risk. On

Due to the sharp price reduction of these products since the 2000s, the incidence of reprocessing of these products has decreased. In cardiology, single-use imaging ultrasound probes are still reprocessed and reused, although there is a lack of documentation of this [23].[20] In summary, in cardiology, it is mainly electrophysiological catheters that are reprocessed and reused in a systematic way.

Nephrology (Dialysis)

Dialysis filters have been reused since the introduction of the product for the treatment of patients with renal failure. Since they were labeled as disposable products during the 1980s, there was an increase in reuse until the end of the 1990s. Several studies analyzed whether reuse had been associated with increased patient risk without reaching clear results. With the introduction of synthetic filters, instead of cellulose filters, and the introduction of manufacturer-owned dialysis clinics where no reuse of filters takes place, the issue is no longer relevant, except in some developing countries where reuse has shown good results without increased patient risk [24-26].

Orthopedics

In orthopedics, reprocessing occurs without reuse of implants, ie. the implants are inserted sterile on so-called grids so that the operator can easily choose between different sizes. The implant sizes that are not used are returned to the sterile unit for reprocessing. There are no clinical studies that have shown that this practice carries increased risks for the patient. An experimental study showed that repeated reprocessing of small implant screws could show small residues of detergent, saccharides and oxidation. The study did not specify what material the implants consisted of or how the implants were reprocessed [27]. All surgeries, including orthopedics, also use reusable instruments that come into contact with patient tissue. Scotland in 2006 introduced individually packaged implants for fear of prion infection, a risk that can actually be ruled out for implants as the implants are never reused. Due to the requirements in MDR that every individual product, even small implants, can be traced, a certain introduction of individually packaged implants takes place in Swedish practice. Unpacking implants in the operating room entails a risk of infection and extended operating time, but saves the costs of reprocessing, which we analyze in the financial impact assessment.

In orthopedics, external fixation frames are also used that are marked as a disposable product, but in practice are reused for wrist and lower leg fractures, without the frames losing their function or resulting in poorer treatment results [28-30]. In this case, it is a product that does not penetrate the skin and thus has a lower patient risk.

In minimally invasive peephole surgery (arthroscopy) for the treatment of joints, a number of disposable products have been reprocessed and reused. The product that is most documented is the so-called shaver that is used to mill or suck away loose or damaged tissue from the joint space. Studies have shown that it is difficult to reprocess a shaver blade without tissue remaining on the blade [31, 32].

[20] During the project group's site visit to the Sterile Technology Unit at the University Hospital in Örebro, an intracardiac ultrasound probe for single use was identified and reprocessed.

Laparoscopy

In laparoscopy, there were early instruments for both single-use and reusable use. In some cases, the design of the products does not differ either, which can lead to some unintentional reprocessing and reuse of disposable products. A number of studies have shown that limited reprocessing of certain laparoscopic products such as trocar [33], electrothermal bipolar vascular sealing system [34, 35], ultrasound dissector [36] is possible without loss of performance or patient risks. Some other studies that have used clinically or scientifically inappropriate methods have shown the difficulty in removing microbiological residues and impaired product function [37 - 39].

Endoscopy

In endoscopy as a diagnostic method, reusable endoscopes are generally used, which are reprocessed and thus not included in the investigation assignment. A large number of studies show the difficulty of disinfecting the reusable endoscope. In the part of the endoscopy where surgical procedures are performed, so-called endoscopic retrograde cholangiopancreatography, abbreviated ERCP, both disposable and reusable products are used, which has led to unintentional reprocessing and reuse of disposable products.[21] All identified studies that showed that reprocessing and reuse of disposable products within ERCP were possible without increased patient risk were published up to and including 2001.
Subsequently, some studies were published that were critical for reprocessing and reuse of disposable products within the ERCP [40, 41].

Urology and gynecology

The disposable products in urology that were mainly used for reuse were the work instruments used at ERCP for stone extraction, mainly stone baskets, grasping forceps and snares. In the ureteroscope, a guidewire (conductor) is used to navigate the ureteroscope through the ureter. One area of treatment in urology where reuse of disposable product has occurred is in the treatment of enlarged prostate with transurethral resection of the prostate (TURP), where disposable electrodes for diathermy resection are reused [42]. Urinary catheters are an area where the reuse of disposable products has been discussed without reaching consensus [43].
In gynecology, reprocessing and reuse of disposable tools have been considered in laparoscopy for sterilization, ectopic pregnancy and hysterectomy [44]. Other disposable products that may be used for reuse in gynecology are speculum and ultrasound tests.

IVA / Anesthesia

In anesthesia and intensive care, both reusable and disposable products are used for invasive respiratory treatment, e.g. bronchoscopes, endotracheal tubes or laryngeal masks and products for non-invasive ventilation, e.g. nasal masks or facial

[21] Accidental reprocessing and reuse of single-use polyp extraction baskets was identified during the summer of 2020 in the Västerbotten Region.

masks. Few scientific studies specifically address the reuse of disposable products [45-47]. Lipp et al. could show that a disposable endotracheal tube (Combitube) could be reused without risking patient safety. The study showed that the product retained shape and functionality after the sterilization process [46]. Lipp et al. mentioned that even single-use laryngeal masks made of materials similar to endotracheal tubes were reused without demonstrating risks to patients [46, 48, 49]. Rowley et al. showed, on the other hand, that the material for certain disposable products is of lower quality than the material in reusable products, which in the long run may entail a risk for patients [50].

Other medical areas

Other areas where reprocessing and reuse of certain disposable products according to an FDA document have been documented are in ophthalmology, endocrinology and diabetes, dentistry and ear, nose and throat surgery (ENT) [51]. In ophthalmology, the reuse of keratome blades and phacoemulsification needles used in eye surgery has been documented. A study from 2000 stated that the keratome leaf could handle two to three uses, but that tissue traces from previous use could remain and therefore make reuse inappropriate [52]. In cataract surgery, studies with phacoemulsification needles have shown that the performance of the needle deteriorates during reuse [53]. Another case of repeated use of disposable products is the repeated use of disposable eyedropper pipettes which may present risks of transmission of infections [54]. In the FDA's review of products that are reprocessed, braces were mentioned, and a Swedish article from 1999 addressed the occurrence in Sweden [55]. In the area of ENT, there are some reusable products such as nasopharyngoscopes and laryngoscopes, but not reuse of disposable products [56].

Conclusions of the literature review

The literature review shows that a large number of disposable medical technology products have been reprocessed and reused routinely and safely in several countries' health care systems. However, it is obvious that certain disposable medical devices are more or less suitable for reprocessing and reuse depending on the design of the products and how invasive and thus risky their clinical use is. It can be stated that in a number of medical areas it has either not been possible to identify any negative case of reprocessing and reuse of disposable products, or any increased incidence of complications. Examples are electrophysiological catheters, pacemakers and ICD treatment, all of which, according to Spaulding's risk classification, constitute high-risk procedures in the bloodstream and heart.

The main reason why reprocessing and reuse of medical devices has taken place is the financial savings that can be realized, but reprocessing and reuse of disposable medical devices has also taken place to ensure access to limited products and thus be able to guarantee that patients are offered a certain treatment.

Whether it is safe and economically justified to reprocess and reuse disposable medical devices depends on a large number of factors that can change over time. These include on technical development, competition between different products and forms of treatment, their relative price and the control over the products' logistics and clinical use. A number of products that were considered justified for re-use during a certain period were later ceased to be reprocessed and re-used, e.g. balloon catheters and dialysis filters. The issue of reprocessing and reuse of disposable medical devices can safely affect many strong interests and has also had a political impact on studies on the issue.

Review of incident reporting in various national databases

The Swedish Health and Care Inspectorate (IVO)

IVO has not been able to find any reported cases of incidents in the authority's diary system where it is stated that disposable products have been reused.

Searches have been made among lex Maria cases and individual complaints according to PSL during the period 2013-2020. A limitation in the searches that have been made is that there are no special search fields for this particular parameter, but well because if a medical device has been involved in the reported event. In a manual review of cases that have registered that a medical device has been involved, IVO has not been able to find a case where a reused disposable product was part of the incident. This does not necessarily mean that there are no such cases, but no such incidents have been reported to the authority. The fact that no such incidents have been reported could be due to under-reporting, or that the personnel using a disposable product do not know if the product is new or reused and thus do not state this in cases where a deviation occurs. It could also be the case that there are simply no incidents with re-used disposable medical devices that can be reported to IVO.

The Medical Products Agency

The Medical Products Agency has carried out data searches in the Medical Products Agency's database for accidents and incidents with medical devices (LVIS) during the period 1995-2020. Since any reprocessing of disposable medical devices today takes place within the framework of in-house production (SOFS 2008: 1), there is no obligation for the health service to report incidents to the Medical Products Agency or to manufacturers.

In the LVIS database, five product types were identified where manufacturers of disposable medical devices reported suspicion that a product deviation may be related to the fact that their disposable product would have been reprocessed by another player. The products identified were:

1. intravascular conductor for pressure measurement that has shown corrosion
2. cardiac catheter stuck to the back of the mitral valve
3. diathermy handles that showed cracking
4. ultrasonic needle where the manufacturer suspects reuse
5. orthopedic hip implants that were returned and during the manufacturer's analysis showed signs of having been exposed to a heat source.

The summary shows that there are reported cases where the manufacturer considered that product defects were probably due to reprocessing, although in the case of a heart catheter stuck in the mitral valve, it can not be ruled out that the event was due to handling.

Deviation database Reidar

Searches have been carried out in ReidarMTP, which is a deviation database for medical devices (MTP) and their use in Swedish healthcare. All reports are deidentified with regard to healthcare organizations and individuals and are reported voluntarily by certified staff to a common database for healthcare quality audits and suppliers' product development. Reporting is performed by certified reporters who have undergone special training to be able to report to an open register. The business is run by the Management Network for Medical Technology (LFMT) and the Swedish User Association for Medical Technology and IT (SAMTIT).

The searches carried out in August 2020 showed that, out of 2,180 items in the database, there were 169 items relating to disposable medical devices. All these items were analyzed on the basis of the possibility that one reason for the incident could be that reprocessing was carried out. No case of this possible cause has been identified.

The County Council's Mutual Insurance Company

According to the chief physician at LÖF, when reviewing various patient cases since 2014, not a single case has occurred where reprocessing of orthopedic implants has been replaced by the insurance. There is also no knowledge of any other case of disposable medical devices that have been reprocessed and caused patient injury, according to LÖF's chief physician.

Experience from quality registers for commonly reprocessed products

The literature review showed that electrophysiological catheters for ablation and diagnostics are largely reprocessed and reused, and that none of the articles identified in the literature review could show any complications. As can be seen from the later chapters' review of reprocessing in Sweden, electrophysiological catheters are reprocessed and reused on a large scale and it is therefore interesting to examine the quality register for catheter ablation.

Swedish catheter ablation register

A review of all published registry reports (just over 47,000 ablations since 2010) and published articles based on the registry clearly show the lack of an infection-related complication problem with catheter ablation (www.ablationsregistret.se). Reprocessing and reuse of catheters thus do not affect the risk of infections. No technical complication related to the catheters used is also reported, which must be linked to the fact that the majority of the catheters used have been reprocessed and reused.

The most common complications are bleeding, tamponade and thrombosis or emboli in connection with the procedures and at the vascular entrance. The complications vary with the type of procedure, where ablation of atrial fibrillation and ventricular arrhythmias have relatively the most complications. The frequency and severity of complications during surgery are also related to the experience and skill of the surgeon, usually depending on the volume of surgery performed. Of the relatively few complications that can occur, the tamponade, that a bloodshed in the pericardium occurs through the catheter penetrating the heart muscle, is a special challenge to deal with. To reduce this risk in procedures with a higher risk (atrial fibrillation ablation) and patients with a higher risk (children) of tamponade, some doctors therefore prefer to use reprocessed catheters that are slightly softer than the new factory-made products. This is an example of how the legal scope for self-manufactured products, described in the National Board of Health and Welfare's regulation SOSFS 2008: 1, can be used to produce a product that the market does not offer.

An overview of the development of catheter ablation operations during the last ten years up to the most recent report 2020 is given in Table 1 below.

Table 1. Complications of catheter ablation

Quantity

Complications	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Other deviation	1	-	1	7	3	0	10	6	0	0
Died within 30 days	1	6	8	8	-	2	-	3	5	10
Tamponad	18	20	19	21	26	-	15	18	20	19
Tromboemboli *	11	9	9	8	4	-	12	12	6	4
Deviations	52	63	58	84	79	52	93	42	91	67
Procedures	3 541	4 036	4 302	4 430	4 764	4 764	5,022	5,036	5,672	5,925

Source: www.ablationsregistret.se; * Cerebral and other peripheral thromboses and emboli.

Other quality registers

Based on the literature review in medical areas where reprocessing and reuse of disposable medical devices takes place, some quality registers have been identified as possible to use for follow-up of re-processing and reuse - Swespine (implants), Riksgall (ERCP), Gynop and the Swedish Hernia Registry (laparoscopic meadow).

Back surgery uses a large number of small implants that are regularly reprocessed, but in Swespine's reports there is no follow-up of surgical infections, which would be a way to measure complications that could be due to repeated reprocessing of disposable products.

In the literature review, it was also identified that disposable products within ERCP were reused. According to previous experience made by IVO, this assignment's survey and contact with the quality register Riksgall, it appears that disposable products within ERCP are not reprocessed or reused in Swedish clinical practice. The ERCP operations' register Riksgall also has no registration of whether disposable or reusable products have been used. Even in laparoscopy, disposable products do not appear to be reprocessed and reused in Swedish clinical practice. The two contacted registers Gynop and Svenskt Bråckregister announced that they do not follow up on disposable or reusable products. They also did not know that reprocessing and reuse of disposable products would take place in Swedish practice.

Reprocessing and reuse of medical devices in Swedish clinical practice

Developments in Sweden

Many of the new medical technology products and methods that were introduced into clinical practice during the 1950s and up to the 1980s were, as can be seen from the literature review, partly developed in Sweden, e.g. angiography, pacemaker treatment, ultrasound examination, laparoscopy and dialysis. The proximity to Swedish companies probably made the need to reuse products less for the reason that they were difficult to access. Nevertheless, we could see that expensive products such as pacemakers were reused from the 1970s [57], electrophysiological catheters since the 1990s [58] and even less expensive orthodontic braces in dentistry [55]. One factor that may have affected the readiness to reuse disposable medical devices was the economic crisis and rationalization that healthcare underwent during the 1990s [59].

During the 1990s, the Medical Technology Directives on active medical implants (90/385 / EEC) and (93/42 / EEC) on medical devices were also introduced, which clarified how the use of the products was intended and was the manufacturer's liability ceases [60]. The National Board of Health and Welfare's regulations and general guidelines at the time (SOSFS 1994: 21) on liability for medical devices showed that reuse of disposable products could be considered a form of in-house production. But in-house production must also meet certain design and production requirements (SOSFS 1994: 2 and the National Board of Health and Welfare's regulations and general guidelines [SOSFS 1994: 20] on medical devices).

The issue of reprocessing and re-use of disposable medical devices became somewhat more topical through the information efforts of the medical technology industry associations before the European Commission in 2005 announced an update of the legislation in this area. This update was adopted in 2007 [16]. At both European (Eucomed) and national (Swedish Medtech) levels, these industry organizations produced policy documents on the issue of re-use of disposable medical devices [61, 62]. The issue has also been repeatedly discussed in various professions. In recent years, since the decision to introduce MDR, many practical questions about which products are affected and how operations must meet the requirements have become more relevant.

Extent of reprocessing in Sweden

The image that the project group has been able to create of the extent of reprocessing of disposable medical devices is that a number of "simpler" disposable products, which in some cases also exist as reusable products, e.g. tubing sets, worms and filters, certain surgical scissors, pliers, drills, saw blades, blood pressure cuffs, diathermy and ECG electrodes, etc., are reused to a lesser extent, while reprocessing and reuse on a larger scale mainly takes place in electrophysiological examinations and treatments and in orthopedics. The project has also taken part in solutions that the health service has had to use to solve acute problems in stressful situations and crises, which have been relevant in the management of patients with covid-19. It has been about reusing the hose set for fans and humidifiers,

Survey conducted by IVO

In January 2019, IVO sent out a questionnaire to all business managers in somatic hospital care, both private and public. Almost 600 business managers received the survey and IVO received 319 unique answers, which gives a response rate of 53 percent. The purpose of the survey was to find out whether medical technology products intended for single use (disposable products) are reused and whether the operations in such cases ensure that they are safe through in-house production.[22] Of those who responded to the survey, 14 percent answered that they reuse disposable products within their business. It was not entirely clear in the questionnaire responses whether the companies took responsibility for these products through in-house production.

The activities that, according to the survey, reuse disposable products are spread across all seven university hospitals in the country, but are also found at other hospitals and care activities. The survey showed that at the same hospital or care facility, there could be both businesses that stated that they reuse disposable products and those that stated that they do not.

IVO also asked what the reason is for the business reusing disposable products. It was possible to choose between cost reasons, environmental reasons and / or other. The most common responses were cost reasons (76 percent) and environmental reasons (60 percent). Among other things, it was stated e.g. the following reasons:

- The quality of the product holds for more than one-time use
- It is logistically simpler
- Has always been done
- The product is unused, but unsterile
- Working environment
- Unclear

The free text answers to the question "How do you ensure that the product is safe when it is reused?" was varied - everything from detailed descriptions of how the product is cleaned and tested to answers such as "does not work if it is broken". No

[22] Self-manufactured medical device: a medical device for which a care provider has taken responsibility as a manufacturer and which has been designed and manufactured to be used exclusively in its own operations (Chapter 2, Section 1 of the National Board of Health and Welfare's regulations (SOSFS 2008: 1) on the use of medical devices in health care).

activities referred to routines for in-house production. IVO followed up the survey with a number of inspections in 2019, which is described later in this text. The following Table 2 contains the products that respondents indicated were reprocessed and reused.

Table 2. Disposable medical devices that are reprocessed according to IVO

Operation	Products that are reprocessed
Surgery / urology	Pliers, bracket for conductors at ERCP, diathermy loop TUR-P, knife blade
Kidney medicine	Glycosorb-AB0 Immunoadsorption column, Bicart cartridges (sampling of dialysates in dialysis machines)
Cardiovascular	Electrode for esophageal ECG, electrophyseal catheters, electric cable for catheter
Neurophysiology	Breathing mask for CPAP machine
Orthopedics	Cannulated drill, saw blade, Fogarty insert for vascular clamps, drills for cruciate ligament surgery, implant material for osteosynthesis, fixation guide pins for directional instruments, external fixation of fracture
Anesthesia / IVA / surgery	Bone screw, Self tapping, 6.5 mm; mask to CPAP, disposable bronchoscope, inhalation mask, respirator tube for transport fan, tube conductor
Emergency care	Inhalation unit, electrode to esophageal ECG, Quickel filter electrodes, overpressure cuff, inhalation mask
Eye Clinic	Disposable syringes, tonometer measuring bodies
Women's clinic	Tests
Obstetrics / gynecology	OAE adapter, Fornix presenter in gynecological robotic surgery
Medical clinic	Endoscope cleaning brushes
Imaging diagnostics	Hoses for contrast sprayers (within DT)
Transplantation	Columns for immunoabsorption of antibodies

Source: IVO, 2019

Most commonly reprocessed products according to IVO - electrophysiological catheters and orthopedic implants

Electrophysiological catheters

In electrophysiological examinations of arrhythmias and treatment with ablation, catheters that are reprocessed between five and ten times have been used throughout Sweden since the 1990s. However, not all types of electrophysiological catheters are reprocessed. It is the simpler diagnostic catheters and the simpler ablation catheters with radio frequency energy without irrigation that are reprocessed and reused. Some irrigated catheters have been reprocessed by external reprocessors, but not in the hospitals' sterile technical units. More advanced cryoablation catheters with cooling instead of heat, and catheters that use liquid cooling, are not normally reprocessed and reused.

As the previous review of the Swedish catheter ablation register showed, there are no reported complications that can be traced to the use of reprocessed catheters.

Orthopedic implants

For orthopedic implants, the larger prostheses used in various operations are not reprocessed or reused but come to surgery as individually sterile-

packaged products. On the other hand, there are a large number of standard products in the form of screws, nails, staples, fixing pins and plates that

is used for various orthopedic osteosynthesis operations and which come to surgery sterile and presented on so-called grids. These smaller implants are reprocessed several times, especially the products that occur in unusual sizes that are not normally used, but it looks different in hospitals. Several hospitals have replaced unusual sizes with individually packaged products.

Crisis management in connection with covid-19

During the project, the pandemic caused by an outbreak of coronavirus SARS-CoV-2 occurred. The disease itself and the measures that many countries introduced to manage the spread of the virus caused major disruptions in the availability of disposable medical devices, at the same time as an increased burden on infected patients for healthcare to handle. A large proportion of disposable products are manufactured in China, which during the months of February to April introduced closures of several provinces and thus did not produce equipment during this time period. In addition, many countries introduced restrictions in customs and trade that led to disrupted or suspended flows of goods.

Table 3. Requests from regions for aid for disposable products

Product	Level of care	Number of regions
Aeroneb nebulizer f LM	General	1
Infusion tubing	General	1
Spray Luerlock	General	1
Suction catheter	General	1
Oxygen halter	General	2
Oxygen mask	General	2
Blood gas syringes	Intermediate	4
CPAP	Intermediate	1
High flow system / Opti-flow / Airvo	Intermediate	12
Invasive pressure measurement	Intermediate	3
Revivator	Intermediate	2
Hoses for fan / respirator	Intermediate / IVA	4
Hoses for CPAP	Intermediate	1
Aqua Uno water purification for dialysis	IVA	1
Humidifier for fan	IVA	5
CO2 absorber	IVA	2
Dialysis filter	IVA	1
Dialysis cassette	IVA	1
Endotracheal tube	IVA	2
Filter humidvent	IVA	1
Filter sterivent to fan	IVA	1
Filter suction	IVA	1
Filter for fan / respirator	IVA	4
Flow sensor	IVA	2
Foley catheter with temperature sensor	IVA	1
Infusion hose Inf pump	IVA	1
Hose for syringe pump	IVA	1
Syringe for syringe pump	IVA	4
Pressure measurement set	IVA	1
Y-coupling dialysis	IVA	1

Source: National Board of Health and Welfare, 2020.

As part of this project, a digital meeting was organized on 16 September 2020 with a number of representatives from different regions with the aim of documenting experiences of the material shortage management that prevailed during the initial phase of the covid-19 pandemic. The material shortage was mainly handled within each region. Subsequently, a number of regions sought support from the National Board of Health and Welfare to obtain improved access to a number of products (Table 3). However, a number of regions refrained from applying for support, as the National Board of Health and Welfare also found it difficult to obtain several shortage products.

The meeting was attended by chief physicians, emergency physicians and persons responsible for crisis and emergency medical preparedness from five different regions and from the National Board of Health and Welfare's special organization, a total of ten people. The participants agreed that the crisis could not be handled without the possibility of reprocessing and reusing medical devices and consumables as well as personal protective equipment.

Participants were asked how they saw the project's mission and the need for a national exemption, according to Article 17 of the MDR, to enable the reprocessing and reuse of disposable medical devices. All participants raised the need for a national exemption that enables continued reprocessing and reuse of disposable medical devices.

One of the participants summarized what several participants had previously stated: “As others have pointed out, it is about having processes and routines for reusing products in peacetime / everyday life in order to have organization and know-how in place in the event of crisis and war. . These processes / routines / systems can probably be used for reprocessing / in-house production of both medical devices and protective equipment. ”

In a crisis or war situation, it was stated that it is an absolute necessity to be able to reuse disposable materials in the event of a threatening or actually difficult shortage situation. Being able to reprocess in peacetime was considered to strengthen the capacity to reprocess in crisis and war by maintaining competence in how different materials in different products can be reprocessed in a safe and efficient manner. It is also about access to certain equipment that needs to be available at the sterile technology units, e.g. equipment for sterilization with hydrogen peroxide.

All representatives emphasized the need for national guidelines for the reuse of disposable materials in times of crisis and war, concerning both medical devices and protective equipment. The guideline should also describe other deviations from the normal procedure, e.g. to allow the use of material whose best-before date has passed. It was also mentioned that the National Board of Health and Welfare has previously published Healthcare Technical Methods in Crisis and War (1993) and that this guideline should be published in a new revised edition.

The National Board of Health and Welfare's survey study on reprocessing

As shown in Table 4 (below), the response rate of 66 percent was relatively good and the proportion that reprocesses disposable medical devices as self-manufactured product with the support of SOSFS 2008: 1 was 40 percent, which was significantly higher than in IVO's survey from 2019 where the

proportion was 14 percent.

Table 4. Response frequency and share with reprocessing per business area

Percent

	In total	Sterile unit	Gastro	IVA / An-estesi	Cardiol ogy	Surgery	Orthopedi cs
Response rate	65.9	78	54.2	66.7	58.3	70.2	67.9
Reprocess	40.4	73.9	18.8	33.3	45.7	20	44.7

Source: National Board of Health and Welfare, 2020; Response rate is given by answer / (sent-out-deregistered) Reprocesses is the proportion yes (single or plural) in the introductory question

The activities that reprocess to a greater degree than the others are cardiology and orthopedics, which was also the result that IVO's survey showed.

Table 5 shows that all regions except Halland reprocess disposable medical technology products. It should be emphasized that not all reprocessing means that the product is sterilized on a sterile technical unit. Region Västernorrland does not sterilize disposable medical devices at its sterile devices. The reprocessing in the form of dish disinfection that takes place takes place in the respective operations.

Table 5. Regions that reprocess disposable products per business area

Regions	Sterile unit	Gastro. (ERCP)	IVA / anesthe sia	Cardiol ogy	Surgery	Orthope dics
Stockholm	x		x	x		x
Uppsala	x			x		x
Sörmland	x		x		x	x
Östergötland	x			x		
Jönköping	x		x			x
Kronoberg	x		x	x		
Kalmar	x			x	x	
Gotland	x	x	x	x	x	
Blekinge	x					x
Skåne	x		x	x		x
Halland						
V. Götaland	x	x	x	x		x
Värmland	x		x	x	x	
Örebro	x		x	x		x
Västmanland	x					
Dalarna	x	x		x		x
Gävleborg	x	x	x		x	
Västernorrland *			x *	x *		
Jämtland H.	x		x	x		
Västerbotten		x		x	x	x
Norrbotten	x		x			x

Source: National Board of Health and Welfare, 2020; * No sterilization of disposable medical devices, only dish disinfection locally.

The questionnaire study asked which products are reprocessed and reused. A total of 80 different unique product types were identified. The complete list of products is given in Table 1 in Appendix 5. Table 6 below shows that a large number of products, which make up 61 per cent, are reprocessed locally in the various operations. It is then about reprocessing without sterilization,

ie. cleaning and

disinfection, which is only done for products with a low risk of infection. In Gastro, IVA / anesthesia and cardiology, the specified reprocessed products were to a large extent unique products that are not reprocessed in other operations.

Table 6. Reprocessed products by business area

Products	Sterile unit	Gastro (ERCP)	IVA / anesthesia	Cardiology	Surgery	Orthopedics	Total
Number of specified products	37	6	14	11	13	15	96
Number of unique products specified	26	5	12	9	7	6	65
Number of products also mentioned by other activities	11	1	2	2	6	9	31

Source: National Board of Health and Welfare, 2020

Table 7 shows which products are reprocessed on a sterile technical unit for a large number of cycles and which products are reprocessed only a limited number of times. The right-hand column indicates the number of respondents that form the data base for the estimates of volume and reprocessing cycles. For products where the number of cycles or the volume was stated to be 100 or higher, it was stated with 100 or more, as the amounts could not be validated. Table 7 shows that there is a group of products, mainly in orthopedics, surgery that is resterilised a large number of times, but also some products where only one resterilization cycle is performed. Origin data are reported in Table 2 in Appendix 5.

Table 7. Extent of reprocessed products on sterile technical unit

Specified response range per product, specified in volume order

Products	Volume per year (interval)		Number of cycles (interval)		Number (s)
	My	Max	My	Max	
Orthopedic fixation implants	0	≥100	0	≥100	23
Surgical cutting accessories	0	≥100	0	≥100	3
Drills	0	≥100	0	≥100	14
Guidewire (leader)	0	≥100	0	≥100	12
External orthopedic fixation instruments	0	≥100	0	≥100	8
Diathermy electrode	20	21	10	≥100	2
Inhalation mask / unit	0	52	0	≥100	2
Orthopedic drills	0	≥100	0	≥100	11
Posts for vascular clamps	50	50	50	50	1
Dressed disposable pants	50	50	50	50	1
Saw blades	0	200	0	40	13
Finger trap (wrist repositioning)	20	20	20	20	1
Pliers	2	100	2	15	3
Spray flask	400	400	15	15	1
Surgical clothing (coats)	50	50	12	12	1
Arthroscopy instrument (shaverblad)	2	20	2	10	2
Drill pin (drill pin)	30	30	10	10	1
Diathermy loop at (TUR-P)	69	69	10	10	1
Carpal tunnel knife	20	20	10	10	1
Ablation catheter	3	49	8	9	2
Angiographic catheters	59	59	9	9	1
Acetubular cement pressure (pressurizer)	300	300	5	5	1

Holding needles (for brachytherapy)	15	15	3	3	1

Products	Volume per year (interval)		Number of cycles (interval)		Number (s)
3D-printed products	50	50	1	1	1
Rubber hose	20	20	1	1	1
Slides (for microscopes, for example)	3	3	1	1	1
Tablecloths (sheets, clothing)	36	36	1	1	1
PD buttons (gastrostomy port)	43	43	1	1	1
Peritoneal dialysis catheter	40	40	1	1	1
Screwdriver for pacemaker	30	30	1	1	1

Source: National Board of Health and Welfare, 2020

Table 8 shows the volumes per year that different clinical activities estimate that the reprocessing of different products amounts to and the number of cycles that the products in question are reprocessed. The right-hand column indicates the number of respondents that form the data basis for the estimates of volume and reprocessing cycles. Unlike Table 7, Table 8 also includes products that are only disinfected and not sterilized. In the survey, no larger volumes than 100 per year could be stated. Therefore, greater than or equal to 100 is used.

Table 8. The extent of reprocessed products in the operations

Specified response range per product, specified in volume order

Products	Volume per year (interval)		Number of cycles (interval)		Number (s)
	My	Max	My	Max	
External orthopedic fixation instruments	10	≥100	3	≥100	10
Flexible drills (reamers)	100	≥100	10	≥100	5
Orthopedic fixation implants	2	≥100	0	≥100	13
Surgical drilling machine	0	≥100	0	≥100	5
Mask (for CPAP)	0	≥100	0	≥100	5
Orthopedic drills	1	≥100	0	≥100	9
Straight / angled piece of fan hose	90	≥100	10	50	3
Respirator therapy and anesthesia / respiratory system	60	≥100	2	50	3
Tubledare	5	≥100	2	50	11
Overpressure cuff	100	≥100	50	50	1
Esophageal ECG electrode	100	≥100	1	40	7
Screw fixing of osteosynthesis template to knee prosthesis	100	≥100	40	40	1
Back pieces for electric catheters	100	≥100	30	30	1
Endoscope cleaning brushes	90	≥100	5	24	2
Endoscope sleeve (cap)	50	≥100	5	20	3
Cannulated screws	100	≥100	20	20	2
Polypaptor basket / extraction basket	100	≥100	20	20	1
Pulse oximetry sensor	100	≥100	10	20	2
Dental protection during gastroscopy	100	≥100	20	20	1
Blood emptiness cuff	20	75	3	15	2
Drain bag dialysis	50	50	10	10	1
Drain hose (transurethral procedures)	100	≥100	10	10	1
Blood pressure cuff	80	≥100	2	10	2
Drill pin (drill pin)	100	≥100	10	10	1
Diagnostic electrophysiological catheter	5	≥100	5	10	6
Cables for navigation systems	100	≥100	10	10	1
Quickels filter electrodes	100	≥100	10	10	3

Saw blades	0	50	0	10	8
Ultrasound catheter	50	≥100	5	10	4

Products	Volume per year (interval)		Number of cycles (interval)		Number (s)
Ablation catheter	20	≥100	3	5	4
Pliers	20	20	5	5	1
Bitblock	50	50	5	5	1
Diathermy lobe resection of prostate (TUR-P)	100	≥100	3	5	3
Cables for electric catheters	30	30	5	5	1
Spool syringe	50	50	5	5	1
Visor	90	90	5	5	1
Device filter fan	100	≥100	3	3	1
Disposable bronchoscope	3	≥100	0	3	4
Extraction Balloon / Basket (ERCP)	3	3	3	3	1
Guide pin for orthopedic sawing	5	5	3	3	1
Immobilization system in case of amputation	50	50	3	3	1
Sampling hose (gas analysis in fan)	100	≥100	3	3	1
Vaginal frame	30	30	3	3	2
Fan hoses	100	≥100	3	3	1
Arm loop (wrist lock) wrist arthroscopies	50	50	2	2	1
Pacemaker	1	1	2	2	1
Marrow nail unpacked, not used	5	5	1	1	1
Sondspruta	1	1	1	1	1

Source: National Board of Health and Welfare, 2020

Possible restrictions on reprocessing and reuse of certain disposable products?

Through the various documents collected, in addition to the own web survey study and the site visits that have been carried out, the project has gained a good idea of which products are being reprocessed. The literature review, which also covers Swedish articles, shows that the products that are reprocessed have changed over time as a result of technical development, changed clinical practice and price changes as a result of a changed competitive situation in the medical technology markets.

The project's assignment includes submitting proposals for restrictions or bans on reprocessing or reuse of disposable medical devices in accordance with Article 17 (9) of the MDR. In the light of a changing clinical practice with changing needs for room for maneuver, proposals for restrictions may quickly become obsolete. In addition, the European Commission has in the common specifications identified various types of disposable medical devices that are less suitable for reprocessing and reuse.[23] The project therefore sees no reason to propose further restrictions on this issue.

Management system for patient-safe reprocessing in clinical practice

In this section, based on the previous section's description of how reprocessing and reuse of disposable products takes place in sterile technical units and in Swedish clinical practice, we will answer the question of the conditions in Swedish healthcare.

[23] See recital (3) of the common specifications.

to apply Article 17 (3) of the MDR, as well as the common specifications. In this context, it is of interest to give a brief account of the supervision that IVO carried out at the Swedish university hospitals in 2019.

IVO's inspections at the university hospitals

As part of IVO's market control plan for 2019, inspections were carried out of how the university hospitals take responsibility for the reuse of disposable products through the process of in-house production. This was done as a follow-up to the questionnaire sent out, which was widely distributed to all heads of operations in somatic hospital care.

The inspections showed that none of the seven university hospitals could present complete documentation of how reprocessing and reuse of disposable products took place. Of all the products and operations that were inspected, only for one product, electrophysiological catheters at Skåne University Hospital (SUS), documentation for self-manufactured medical device could be presented. In most hospitals and operations, there were prepared and decided processes and routines for self-manufactured products in general, but no documentation that these routines had actually been applied in the reuse of medical devices intended for single use.

At the time of the inspection at Sahlgrenska University Hospital in June 2019, a regional joint work was underway to prepare a generic process for self-manufactured medical devices, which was not completed or implemented.

Regarding a few products at a university hospital, there was risk analysis, risk management and follow-up of the number of reprocessing cycles that a product has undergone. At the University Hospital in Uppsala, the unit for sterile technology required the care units to present a risk analysis and a signature from the head of operations stating that responsibility is taken over for the product to carry out reprocessing of the product in question.

The main shortcoming was that, despite existing routines in some cases, there was no complete documentation for in-house production for each product. The inspectorate found no evidence that patients were injured.

Use routines for reprocessing according to the National Board of Health and Welfare's questionnaire study on reprocessing

In order to gain knowledge about Swedish healthcare's compliance with regulations regarding reprocessing of disposable medical devices as self-manufactured products, according to SOSFS 2008: 1, a number of questions were asked about how risk analysis, function tests are performed, what evidence basis for reprocessing and reusing disposable products used and how traceability is ensured.

In general, these questions can be answered by the fact that compliance with the rules shows a low degree of formalization, but which in our opinion is compensated by personal responsibility according to the requirements that can be placed on legitimate occupational groups. The sterile technical units consistently show a better compliance with the rules than the medical operations. Less than half of the operations in the medical areas have reprocessing routines

documented. On the other hand, about three quarters of the sterile technical units have documented routines for reprocessing disposable products. Risk analyzes are based on own experiences, function tests are performed on a selection of products and mainly ocularly, few companies evaluate the management system's routines annually. The adaptation of the management system to a higher level or other related activities takes place only in a few cases, with the exception of a sterile technical unit that adapts its routines to orthopedics to a great extent.

The survey asked about the risk assessment of various medical devices that the respondents made. Throughout, the respondents have assessed the risk of reprocessing and reusing the specified products as low. Only a few exceptions are stated, such as anesthesia cuff, surgical drill, orthopedic drills, sampling hose for gas analysis in a fan and tubular conductors, for which the risk is judged to be medium.

The predominant evidence used as a basis for reprocessing and reuse of disposable products is the experience of one's own operations. IVA and anesthesia and surgical activities showed a lower proportion who indicated that they used published studies or statistical evaluation as evidence for decisions to reprocess and to assess the number of cycles that reprocessing can be done. As can be seen from Table 9, the decisions within IVA and anesthesia and surgery are based to a greater extent on one's own experience.

Table 9. Evidence basis for reprocessing and reuse and the number of cycles per business area

Specified percentages per product

Activities	Proportion of stated evidence for reprocessing and reuse			Proportion of stated evidence for the number of reprocessing cycles		
	Own experience	Own statistical valuation	Published studies	Own experience	Own statistical valuation	Published studies animal
Gastro	67	33	0	67	33	0
IVA, anesthesia	94	0	6	89	6	6
Cardiology	81	19	31	81	19	13
Surgery	75	13	0	75	25	0
Orthopedics	94	18	12	82	24	12

Source: National Board of Health and Welfare, 2020; In some operations, the sum may exceed 100%, as several alternatives are possible.

Table 10 shows that few respondents carried out a documented risk analysis. Of the respondents who represented Gastro, 33 percent stated that a documented risk analysis for all products that are reprocessed exists. No medical area indicates that a function test is performed on each product.

Table 10. Documentation of risk analysis and function tests

Stated percentages per business area

Operation	Risk analysis documented, percentage			How function tests are performed on the products, percentage		
	All products	Some products	No product	Ocular inspection	Test on product selection	Test of each product
Gastro	33	0	0	67	50	33
IVA, anesthesia	6	0	0	94	100	0
Cardiology	19	0	6	75	100	19
Surgery	13	13	0	75	100	13
Orthopedics	6	0	12	82	100	18

Source: National Board of Health and Welfare, 2020; In some operations, the sum may exceed 100%, as several alternatives are possible.

The main responsibility for conducting a risk analysis lies with the respective clinical areas of activity. It is therefore not surprising that the sterile center's involvement in risk analyzes, according to Table 11, is low, especially as risk analyzes according to Table 10 are not carried out to a sufficient extent within the various areas of activity.

Table 11. The Sterile Center's involvement in risk analysis at product level

Sterile centers' risk analysis of reprocessing	Percent
Carried out own risk analysis on all reprocessed products	6
Participated in another's risk analysis on all reprocessed products	18

Source: National Board of Health and Welfare, 2020

Table 12 shows that all respondents for gastroenterology, cardiology and orthopedics have documented routines for reprocessing as part of the management system at some level, from specifically for individual products to being part of the hospital's overall management system. In surgery and IVA and anesthesia, this proportion was lower. Of the representatives surveyed for the various business areas, the proportion that had routines that ensure traceability, with the exception of gastroenterology, was less than 100 percent. For all areas of activity except surgery, it was still a majority who stated that they have routines that ensure documentation of traceability, either traceability to the patient, the number of cycles or the number of incidents.

Table 12. Documentation of reprocessing and traceability in management systems

Stated percentages per business area

Operation	Proportion with documented routines for reprocessing in management systems			Proportion with routines for documentation of traceability		
	Own business in general	Own business product specifically	Overall at a higher level (hospital)	To patient	Of bicycles	By incident
Gastro	33	50	17	17	17	100
IVA, anesthesia	11	17	11	0	0	72
Cardiology	38	38	25	31	31	63
Surgery	25	25	13	13	25	38
Orthopedics	35	41	24	18	18	76

Source: National Board of Health and Welfare, 2020; In some operations, the sum may exceed 100%, as several alternatives are possible.

Table 13 shows that three out of four sterile technical units have routines in the quality management system that concern the reprocessing of disposable products and systems for monitoring the number of reprocessing cycles that a disposable medical device undergoes. Approximately 40 percent of the sterile centers have also adapted their management systems to the various clinical areas of activity.

Table 13. The Sterile Center's quality management system

The sterile center's management system	Percentage
Proportion of sterile centers with their own quality management system that concerns reprocessing; of disposable products	74
of which: Proportion of sterile centers with quality management systems that are certified according to ISO standards	52
Proportion of sterile centers that have systems for monitoring the number of reprocessing cycles at product level	76
Proportion of sterile centers that have systems for reporting waste when re-processing disposable products	56
Proportion of sterile centers with quality management systems whose routines are adapted to customers' quality management systems	41

Source: National Board of Health and Welfare, 2020

Table 14 shows that the various areas of activity have a slightly lower proportion who have adapted management systems to an overall level at hospital or regional level, with the exception of IVA and anesthesia who, with the exception of one respondent who has adapted their routines to the sterile center, have not adapted. its management system to external operations.

Table 14. Organizational adaptation of management systems for reprocessing

Stated percentages per business area

Actions	Gastro	IVA / anesthesia	Cardiology	Surgery	Orthopedics
To the overall level	17	0	25	25	35
To sterile center	50	6	44	50	71
To external reprocessor	0	0	6	13	0

Source: National Board of Health and Welfare, 2020

When it comes to ensuring the staff's competence for reprocessing, this takes place in more orderly forms such as reviews of routines and checklists in groups within sterile units, gastroenterology, cardiology and orthopedics. Reprocessing also seems to be a more common theme at sterile unit and orthopedic professional meetings (Table 15).

Table 15. Ensuring competence for reprocessing

Stated percentages per business area

Actions	Sterile unit	Gastro	IVA / anesthesia	Cardiology	Surgery	Orthopedics
Individual guidance	82	100	89	94	63	94
Knowledge tests	24	17	22	13	25	6
Practical tests	38	50	39	50	63	53
Reviews of routines, checklists in groups	71	67	44	69	38	82
Joint quality development meetings	41	17	11	6	25	24
Education (external)	56	50	11	6	25	41
Courses (external)	50	17	6	6	13	18
Professional meetings (regular meetings)	59	17	22	25	13	53

Source: National Board of Health and Welfare, 2020

As can be seen from Table 16, there are few clinical areas of activity that carry out annual regular evaluations of the reprocessing activities. The highest proportion is stated in surgery at 38 percent. However, all operations state that evaluations take place, even if it does not take place annually. Only a few of the operations state that a formal takeover of responsibility has taken place through the signature of the current operations manager, even though the proportion is 44 per cent for cardiology and 41 per cent for orthopedics.

Table 16. Evaluation of reprocessing

Stated percentages per business area

Actions	Sterile unit	Gastro	IVA / anesthesia	Cardiology	Surgery	Orthopedics
Proportion that evaluates reprocessing routines at least annually*	21	17	17	0	38	18
Percentage who evaluate reprocessing routines less often**	79	83	83	100	63	82
Percentage indicating that the is performed by an external sterile center / to an external customer	18	0	6	0	0	0
Proportion who used commercial reprocessing company	-	0	0	0	0	6
Percentage indicating that the declaration for reprocessing has been signed by current operations manager	-	50	6	44	25	41

Source: National Board of Health and Welfare, 2020; * once a year or more often, ** less often than annually.

Table 16 also shows that 18 per cent of the sterile centers reprocess to customers outside their own operations (outside hospitals and regions). An example of this is Örebro University Hospital, which is ISO-certified

according to the medical technology industry's quality standard 13485.

As can be seen from Table 17, control, reporting, follow-up and development of the management system for reprocessing takes place primarily through the company's own personnel. In some cases, this is done with the support of staff such as

business developers or similar. However, external validation takes place within the sterile center's operations and within surgery and orthopedics. External validation will be a requirement for clinical activities that want to continue reprocessing disposable products when MDR takes effect on 26 May 2021.

Table 17. Organizational roles involved in various actions

Stated percentages per business area of those who reprocess

Actions	Answer options	Sterile central	Gastro	IVA / anesthesia	Cardiology	Surgery	Orthopedics
Self-control / validation	Employees in the business	97	83	94	94	88	94
	Staff person	18	0	11	25	0	0
	External	18	0	0	0	13	24
Reporting etc. of deviations	Employees in the business	91	83	89	94	100	100
	Staff person	32	17	39	25	13	24
	External	3	0	0	6	0	0
Development of management systems met	Employees in the business	88	83	83	88	100	94
	Staff person	35	17	33	25	13	18
	External	6	0	0	6	0	0

Source: National Board of Health and Welfare, 2020

External reprocessing of disposable products

According to the project's information, external reprocessing takes place between the regions of a hospital's sterile technology unit to operations outside its own region. During our site visit to the sterile technology unit in Örebro in early February, it was revealed that the sterile technology unit in Örebro has about 200 unique customers that can be made up of various clinics at the hospital and health centers and private care units in the region, but also further afield as in Motala and Lund.

Sterilteknik's customers in the region are part of the same legal unit, with the same organization number and the same quality system. Sterile technology has its own specific quality management system that is ISO-certified according to ISO 13 485, quality system for medical devices. Örebro's sterile technology has a number of equipment that allows them to reprocess special products that cannot withstand high temperatures, with special methods such as formalin and hydrogen peroxide. Hydrogen peroxide is used i.a. for the optics of their DaVinci operating robot, but also for invasive heart catheters.

In this project, the National Board of Health and Welfare has not received any information that indicates that reprocessing of a clinical practice's products is CE-marked and then sold to other customers in a market. It is exclusively about reprocessing of a product which is then returned to the same unit or customer who sent it for reprocessing.

External reprocessing of healthcare's own products abroad

A number of university hospital arrhythmia operations have, during varying periods, hired an external company in Germany (Vanguard AG) for reprocessing of catheters and other equipment. This has taken place during the periods listed in Table 18.

Table 18. Swedish arrhythmia clinicians' use of external reprocessing

Hospital	Started	Completed
Linköping	Oct -06	Sep -15
Arrhythmia Center Stockholm	Nov -09	Jun -20
Uppsala	Jan -12	Mar -16
Örebro	Mar -13	Oct -17
SWISH	Jul -16	Feb -18
Gothenburg	Feb -17	Nov -17

Source: Vanguard, 2020

Vanguard in Berlin in Sweden has only worked with cardiology products in the special area of arrhythmia diagnostics and treatment. During the project, all Swedish customers were contacted and asked to answer a number of questions to assess the extent of external reprocessing and whether the external reprocessing entailed any problems or benefits.

Table 19. Swedish arrhythmia clinicians' experiences of external reprocessing

Questions	Linköping	Arrhythmia Center Stockholm	Sale	Örebro	SWISH	Gothenburg
Only own reprocessed products?	Own, only transsexual needles	Own, irrigated ablation catheters 30 pcs / year, transseptal needles	Own	Own, trans-septal needle, advanced ablation catheters	Own	Own
What cycle times does Vanguard have had?	4 weeks	Three weeks	4 weeks, but varied	8 weeks depending on the number of dukter	2 weeks	1 week
How well have you been informed about Vanguard's process?	Do not remember when it is 5 years ago	Comprehensive information at start-up	Full transparency in their process	Do not remember how well we were involved	Documentation for procurement that was approved by sterile technology	Highly detailed information on action and start
Do you have documented routines for traceability?	No, no own routines for traceability.	Traceability by following Vanguard's system.	ID number / number of cycles in own system	Yes, four cycles for needles and a re-processing of the ablation catheter	No own, Vanguard's update on current bike etc. worked well.	Vanguard's process was followed to ensure traceability.

Positive or negative experiences you want to share?	Experienced to work well.	Good service, quality-assured solid process, relatively expensive, not all catheters managed the process.	Positive, all catheters worked	Overall positive. Delivery worked well, time consuming	Worked well overall, all catheters worked well.	Overall positive, but time consuming. Some trans-septal needle was a little sluggish.

Source: National Board of Health and Welfare, 2020

The answers shown in Table 19 are generally positive, although several customers state that the external reprocessing has been labor-intensive in collecting, washing and packaging products. The products will then be packaged and transported to Berlin. Most Swedish customers have only used external reprocessing for more advanced special products such as the trans-septal needle, which is used to create an entrance through the septum to the left atrium during atrial fibrillation, or advanced irrigated ablation catheters. The advanced ablation catheters in particular have a noticeably higher purchase price, which makes reprocessing economically interesting, even though the cost of the external reprocessing corresponds to approximately 50 percent of the purchase price.
The University Hospital's sterile technical unit.

Possible restriction of reprocessing via foreign actors?

As stated in the previous section, reprocessing of certain products in cardiology has taken place by hiring a foreign company. Experience showed that reprocessing worked well over a long period of time.

The project's assignment includes submitting proposals for restrictions or bans on reprocessing or reuse of disposable medical devices in accordance with Article 17 (9) of the MDR. A Member State which allows the reprocessing of disposable products may, in accordance with Article 17 (9) (a) of the MDR, introduce national provisions restricting or prohibiting the reprocessing of disposable products and the transfer of disposable products to another Member State or to a third country for reprocessing.

Based on the experience gained in Sweden of Swedish healthcare providers hiring a foreign, external company with operations in Germany, there is no reason to propose any restrictions or prohibitions against reprocessing taking place in an EU country. Regarding the issue of the transfer of disposable products to third countries for reprocessing, a number of other aspects, in addition to patient safety, need to be investigated and analyzed. These may be issues relating to the transfer of personal data, vulnerability, transfer of knowledge, etc. In the project, we have not been able to identify that reprocessing of disposable medical devices has taken place through external reprocessors in a third country. We therefore do not have enough data or knowledge to be able to make the necessary analysis.

Economic consequences of reprocessing and reuse of disposable medical devices

Economic analyzes

The starting point for economic analyzes is that resources are limited and that by using resources for a certain purpose, alternative uses are lost. When assessing costs from a societal perspective, it is important to include all relevant resource consumption that has arisen in health care and which also includes possible negative health risks due to an injury or illness. The costs are usually divided into direct, indirect and intangible costs.

The direct costs arise as a result of the care and treatment provided. The direct costs mainly consist of the consumption of health care resources, but can also consist of municipal initiatives (home care, transport services, etc.), informal care (performed mainly by relatives) and time and travel costs for patients. Direct health care costs are often divided into inpatient, outpatient and drug costs. Indirect costs are dominated by production losses, ie. costs related to reduced work capacity due to ill health or injury. Intangible costs refer to costs for pain, suffering and reduced quality of life that arise due to the injury. They are difficult to value in kronor.

Virtually all treatments and procedures can pose health risks. Thus, both intangible, direct and indirect costs may arise in the future due to a treatment, which is difficult to predict. In addition, the individual's personal suffering and costs in the form of loss of income must be taken into account, but also society's costs for investigation and treatment of people who have suffered a serious injury, a serious illness, permanent injury and the spread of infection. In this context, it should be pointed out that the project has not been able to identify any evidence of increased patient risks with correctly performed reprocessing.

In the literature review, the National Board of Health and Welfare has also searched for articles with economic aspects of reprocessing and reusing disposable medical devices. The articles have looked for cost-effectiveness by comparing the effects of the two alternatives and their costs. An article from 2008 made a literature review in the field to study the effects and costs of reprocessing and reuse of disposable medical devices in studies that collected data on patient outcomes [63]. The literature review resulted in nine articles that met the mentioned criteria. Seven of them showed cost savings through reprocessing and reuse.

ning. The studies included in the literature reviews were all published earlier than 2008 and thus not entirely relevant. In summary, the literature review showed that each time a unit is reused through reprocessing, the hospital saved the original cost of a new product minus the cost of the reprocessing itself. Comparing different countries' cost data and clinical data entails a number of methodological problems, where above all costs vary greatly between different healthcare systems depending on different salary levels and ways of reporting costs. It is therefore difficult to determine the cost-effectiveness of reprocessing and reuse of disposable medical devices.

The National Board of Health and Welfare has, as far as possible for two product areas, electrophysiological catheters and orthopedic implants, compiled actual costs based on data from hospitals that reprocess and reuse disposable medical devices, but also based on information from procurements and doctors at clinics that perform operations.

A complete socio-economic analysis could not be carried out as data for a comparative analysis of differences in the number of patient injuries that could be traced to reprocessed products are not available in any registers or databases. We have also not been able to calculate the environmental consequences if reprocessing is not allowed compared to if it is still allowed.

Method aspects

In this analysis, the National Board of Health and Welfare has tried to calculate the direct costs for reprocessing and reuse of disposable medical devices and estimated certain financial consequences that may arise.

It has not been possible to carry out a comprehensive analysis of all products that are reprocessed and reused. However, we have been able to analyze the two product areas where reprocessing takes place regularly on a larger scale, ie. for electrophysiological catheters and orthopedic implants. The working method has been according to the following model where reprocessing is allowed or not allowed (Table 20).

Table 20. Analysis of costs that arise if reprocessing is allowed or not allowed

Allow reprocessing	DO NOT allow reprocessing
Cost of reprocessing (cleaning, disinfection, function check, packaging and sterilization)	Cost for a larger amount of purchases of disposable products
Cost for logistics (storage and transport within the hospital / to other hospitals)	Cost of storing large volumes of disposable products (building up new stores in hospitals)
Personnel costs for reprocessing	Cost for logistics (more deliveries to the hospital)
Cost of a possible approval process that must be established to allow reprocessing	Cost for environmental aspects (more disposable products, ie more materials will be used das, and more transports)
Cost of environmental aspects (chemical substances for cleaning, disinfection, sterilization)	

Source: National Board of Health and Welfare, 2020

The analysis is based on information that the National Board of Health and Welfare has obtained from site visits at the University Hospital in Örebro, St. Göran Hospital, Karolinska University Hospital Huddinge and Danderyd Hospital. Costs for catheters, screws and implants, time required for staff, premises costs, personnel costs, administration costs and logistics costs have been used. One difficulty has been the way in which the country's hospitals are organized, as it has not made comparative calculations possible. Some costs have not been able to be separated from the hospital's overhead cost, and it happens that the costs for the sterile center's operations are not included in its own budget.

A questionnaire was sent to various operations managers for clinics in somatic hospital care and operations managers at sterile centers in the country, and the answers to questions such as flows and the number of processes have been used to calculate costs.

Financial calculation results

Reprocessing of disposable products at the sterile centers constitutes about 3–5 percent of the total activity, according to information during site visits. At the sterile centers, various products are reprocessed from the clinics, where orthopedic implants and electrophysiological catheters are the most common products in terms of volume. The National Board of Health and Welfare has therefore selected these two areas and tried to calculate what costs arise if reprocessing or only one-time use takes place. As can be seen from the calculations below, a saving of approximately SEK 65-70 million per year can be made by reprocessing compared to if only one-time use takes place. The calculations for orthopedic implants have been based on the most common operation, which are wrist fractures, and in these calculations have come to the conclusion that the costs in both cases are comparable, ie.

Electrophysiological catheters

Electrophysiological catheters are used in the diagnosis and treatment of heart rhythms at all University hospitals, as well as some other major hospitals and clinics. According to our information, the catheters have been reprocessed and reused routinely for several years at these clinics. Information for the calculation of time and costs has been obtained from the operations manager and controller at the sterile center at Karolinska University Hospital Huddinge.

In Table 21 below, the National Board of Health and Welfare presents a calculation for electrophysiological disposable catheters according to the working model above. For the description, the number of procedures with diagnostics and ablation has been taken from the quality register [64]. Information on the number of ablation catheters that are reprocessed has been obtained from several independent sources, mainly the cardiologists themselves, but also via study visits to sterile centers, the National Board of Health and Welfare's questionnaire. The number of cycles per diagnostic catheter and ablation catheter has also been obtained via the same sources.

Table 21. Number of catheter procedures for arrhythmia diagnosis and ablation

Process	Allow reprocessing, number	Do not allow reprocessing, number
The number of procedures with diagnostics	6 500	6 500
The number of procedures with ablation	6,000	6,000
Number of diagnostic catheters per procedure	3	3
Number of ablation catheters per procedure	1	1
Proportion of diagnostic catheters that are reprocessed	100%	0%
Proportion of ablation catheters reprocessed	55%	0%
Number of cycles per diagnostic catheter	8	1
Number of cycles per ablation catheter	8	1
Total diagnostic products per year	2 438	19 500
Total ablation catheters per year	3 113	6,000
Total connectors catheter	934	1 800
Number of atrial fibrillation procedures	2 700	2 700

Source: National Board of Health and Welfare, 2020

Information on the costs in Table 22 is taken from the latest procurements in Visma-Opic's database (Skåne, VGR and Västerbotten) and from the sterile center at Karolinska University Hospital Huddinge. Total cost includes the average cost per diagnostic catheter and ablation catheter times the total number of cycles of catheters per year. The costs for the catheters also include costs for disposable cables and connectors.

Table 22. Costs for different catheters

Process	Allow reprocessing, kronor	Do not allow reprocessing, kronor
Average cost per diagnostic catheter (incl. Cables and connectors)	3,000	3,000
Average cost per ablation catheter (incl. Cables and connectors)	5,000	5,000
Couplings for irrigated ablation catheter	4,000	4,000

Source: National Board of Health and Welfare, 2020. Based on procurements in Visma-Opic database.

Table 23 shows the number of products in stock based on an assumption of nine catheters in surgery or sterile process per day plus three consumption days in buffer (3 x 12), which gives 45 catheters during reprocessing. For single use, 2 weeks of consumption corresponding to 150 catheters is counted on. Capital tied up for stocks is calculated at an interest cost of 5 percent of average stock tying times ten clinics. The storage space is calculated that 150 catheters in product packaging require 15 square meters (10 catheters per square meter) and that 45 reprocessed catheters require 3 square meters (15 catheters per square meter) multiplied by ten clinics in the country. The information on price per square meter comes from the Uppsala Region of SEK 6,000, which was confirmed by a controller at Karolinska Hospital Huddinge.

The total cost of reprocessing has been calculated as cost per product times the number of procedures with diagnostics and ablation and added the number of catheters per procedure.

If reprocessing is allowed, there will be additional regulatory costs for the clinics. These are both initial costs and annually recurring costs for developing management systems and maintaining the documentation for external audits. In order for all staff to know and work according to a validated protocol, continuous training is needed, primarily initially but also annually to ensure that the operations comply with the legal requirements. The cost in the table includes the estimated cost for ten clinics in Sweden.

Table 23. Inventory, transport, reprocessing and regulatory data

Process	Allow reprocessing,	Do not allow reprocessing,
Number of products in stock	45	150
Stock capital tied up national, kronor	378 000	1,260,000
Inventory interest / interest cost 5%, SEK	18 900	63 000
Stock turnover per year	79	79
Storage space per product	1	1.5
Storage space throughout Sweden for catheters, sqm	30	150
Warehouse cost per sqm and year, kronor	6,000	6,000
Warehouse cost rent, kronor	180 000	900 000
Handling cost for storage space per product	Internal cost per hospital	Internal cost per hospital
Transport cost between warehouse and clinic	Internal cost per hospital	Internal cost per hospital
Reprocessing cost, per product	122	0
Total reprocessing cost	3 111 000	0
Transport cost between sterile and clinic	Internal cost, hospital	Internal cost. hospital
External investment to set up a regulatory system, at 10 clinics in the country	1,500,000	0
Internal investment, training, etc., business developer at 10 clinics	3,000,000	0
Annual cost for maintenance, business developer at 10 clinics	500 000	0

Source: National Board of Health and Welfare, 2020

Summary of costs in the tables

The tables above show actual cost data for reprocessing at a sterile center in the field of cardiology and specifically for catheters. Table 24 shows the costs of reprocessing catheters in comparison with not allowing reprocessing.

Table 24. Summary of costs for catheters

Cost items	Allow reprocessing, crowns	Do not allow reprocessing, crowns
Total number of diagnostic catheters x average cost per catheter	7,314,000	58,500,000
Total ablation catheters * average cost per catheter	15,565,000	30,000,000
Total connectors irrigated catheter * average cost	3 736 000	7,200,000
TOTAL	**26,615,000**	**95 700 000**

Source: National Board of Health and Welfare, 2020

The National Board of Health and Welfare has received data for costs and reports the total cost for the two tracks. Reprocessing has been around since the 1990s and routines are well established. The cost for the use of reprocessed catheters is currently SEK 26.6 million, compared with not reprocessing but buying all products in disposable packaging at a cost of SEK 95.7 million, which gives a difference of SEK 69.1 million. Disposable packaging requires increased handling of packaging and unpacking, but also increased transport to hospitals. There is generally no room for increased stocks at hospitals. To handle this limitation, just-in-time deliveries are generally applied, which means that goods are delivered in exactly the quantity and at the time needed.

Another aspect of disposable products is the increased time before each operation required to unpack all the material to be used for a patient. After surgery, surgical personnel need to take care of paper and plastic packaging. The increased time also means that the planning of the operation time changes, and this in turn leads to schedule changes for the operated clinic. This aspect is more important in orthopedics, which is described in the next section.

Table 25. Summary costs for catheters and the regulatory costs

Cost items	Allow reprocessing, crowns	Do not allow reprocessing, crowns
Total costs for catheters	26,615,000	95 700 000
Inventory cost (rent plus cost of capital)	198 900	963 000
External investment to set up systems, at 10 clinics in the country	1,500,000	0
Internal investment, training, etc., business developer at 10 clinics	3,000,000	0
Annual cost for maintenance, business developer at 10 clinics	500 000	0
TOTAL	**31 813 900**	**96 663 000**

Source: National Board of Health and Welfare, 2020

Table 25 above shows the summary costs associated with reprocessing and with not allowing reprocessing of electrophysiological catheters. In this comparative calculation, for the first year, an external investment from external consultants is calculated to set up a regulatory system for catheter ablation at each cardiology clinic of SEK 150,000 in addition to internal training and the establishment of routines of SEK 300,000 per clinic. The annual cost of maintaining the system and paying for external validation of the notified body is estimated at 50,000 per clinic.

Orthopedic implants

Reprocessing and reuse takes place to a greater extent in the areas of electrophysiological examinations and treatments in orthopedics. The costs for electrophysiological catheters are described above, and in the following sections, costs for reprocessing of orthopedic implants are reported.

The National Board of Health and Welfare makes a calculation below for reprocessing of orthopedic implants according to the flow for reprocessing in hospitals that has previously been reported. Data for costs and time have been obtained from the sterile technical unit at Huddinge University Hospital. Both the time required and the process for checking grids can differ between the hospitals in the country, but the total time for the checks is estimated at 30-45 minutes. The machine can take a maximum of twelve grids, but it is rare for the machine to run full, which is why the National Board of Health and Welfare has calculated five grids for dishwasher and autoclave-related costs.

The cost of a dish disinfector and an autoclave process has been obtained from procurement documents and discussions with several sterile technology managers and also suppliers of the equipment. The most important information was obtained from the CEO of AD-Medical. According to the overall assessment, the cost for a dish disinfector corresponding to that used at Huddinge Hospital is SEK 70 per process and for the autoclave SEK 140 per process. For the cost per grid, we have calculated an average of five grids per process, ie.
70/5 = 14 and 140/5 = SEK 28.

Table 26. Costs and time required for reprocessing of orthopedic implants at Huddinge Hospital

Work process	Time required, minutes	Costs per grid, kronor	Total costs per year *, SEK
Disposal of clean grilles from surgery	15 min / assistant nurse	84	41 496
Control bill of grids	20 min / sterile technician	103	50 882
Disinfectant washing	60 minutes	14	6 916
Control function of grille	20 min	103	50 882
Packing container for autoclave	20 min	103	50 882
Autoclave process	60 minutes	28	13 832
TOTAL		**435**	**214 890**

Source: National Board of Health and Welfare, 2020; * Calculated on 494 implant grid processes.

According to Statistics Sweden's salary statistics 2019, the salary for an assistant nurse is SEK 29,200 per month, with a standard value of 84% which includes holiday pay, employer contributions and an overhead cost. Economic effects of new rules; Tillväxtverket 2017.
Salaries for sterile technicians are based on data from the head of operations at the sterile operations at Huddinge University Hospital.

In Table 26, costs for water, electricity, compressed air or disinfectants are included in the cost of the dish disinfector and autoclave process. The cost of an autoclave compared to a disinfectant is about twice as high and has to do with the energy consumption for heating and cooling as the temperature must be quickly raised and lowered a number of times in the process. It is also about several cubic meters of water for autoclave and only about 60 liters for dish disinfector. Normally, the depreciation period for the machines used in the process is seven years, but depends on how much they are used in the business. According to the sterile operations at Karolinska University Hospital Huddinge, 494 processes were performed per grid with implants for 2019. In Sweden, there are about 50 emergency hospitals with an average slightly smaller volume than those at Karolinska University Hospital

Huddinge.

with reprocessed implants at more than 50 hospitals in Sweden. The total volume of grids with implants in Sweden could therefore be estimated at Karolinska University Hospital Huddinge's volume of almost 500 multiplied by 50, ie. about 25,000 grids per year in Sweden. This corresponds in costs to SEK 215,000 x 50, ie. approximately SEK 10.7 million per year for the whole of Sweden.

The National Board of Health and Welfare summarizes the cost items and shows in Table 27 below for wrist fractures, the most common operation where implants that are reprocessed are used, what costs arise when reprocessing is allowed and when it is not allowed.

In sterile technical operations, the cost per reprocessed grid is taken from table SEK 27: 435 multiplied by 1.2 grids per operation as more material may be needed. In the column for "reprocessing is not allowed", the authority has estimated that reprocessing of orthopedic instruments constitutes 15 percent of the cost of reprocessing a grid. Operation planning is calculated at 20 minutes for an assistant nurse to find out which products are to be used and produce them before each operation. The cost of storage space is based on information from the sterile operations at Karolinska University Hospital Huddinge of SEK 6,000 per square meter and year. A product is approximately one week in stock and the storage area is estimated at twice for sterile-packaged products. As the product is estimated to be in stock for one week, SEK 6,000 divided into 52 weeks is stated in the column for reprocessing is not permitted. In the column for reprocessing is allowed, the storage area is not as large, because no extra wagons are needed, but the cost is estimated at half the sum. The National Board of Health and Welfare has estimated the extra cost of unpacking ten sterile-packaged implants of 2 minutes to 20 minutes per operation. The calculation is made for an assistant nurse with an hourly wage of SEK 336, which is SEK 112 extra per operation. The National Board of Health and Welfare has estimated the extra cost of unpacking ten sterile-packaged implants of 2 minutes to 20 minutes per operation. The calculation is made for an assistant nurse with an hourly wage of SEK 336, which is SEK 112 extra per operation. The National Board of Health and Welfare has estimated the extra cost of unpacking ten sterile-packaged implants of 2 minutes to 20 minutes per operation. The calculation is made for an assistant nurse with an hourly wage of SEK 336, which is SEK 112 extra per operation.

Table 27. Comparison of costs for orthopedic implants that are reprocessed or only disposable material for wrist surgery

	Reprocessing allowed, SEK	Reprocessing is not allowed, kronor
Sterile technology activities	522	65
Operation planning (20 min)		111
Cost for storage space per week and square meters, based on SEK 6,000 / sqm	58	115
Additional operating costs for unpacking during ation (20 min x 336 kr)	0	112
Implant waste (that components are not used /		150

discarded)		
Total special cost	580	554

Source: National Board of Health and Welfare, 2020

A cost that can arise is for the implants that are not needed during surgery but which are already unpacked and which are thrown away unused after the operation has been performed. The National Board of Health and Welfare has obtained an award from Region Stockholm's procurement in orthopedics, and specifically the area of plate fixation for fractures in the distal radius.

In that data, it appears that an ordinary system with a plate and ten screws costs about SEK 3,000. The authority calculates an average component cost of SEK 300. After discussion with orthopedics at Huddinge University Hospital, the disposal of a product is estimated at ten for every other operation, ie. 5 percent, and the cost of the waste is estimated at SEK 150.

The National Board of Health and Welfare has not included costs in the calculation above that may arise in the event of delays due to unpacking and preparation of disposable material during operations in the ward. The cost of operations is calculated on the basis of the hospital's own costs, and according to doctors at the orthopedic clinic at Karolinska University Hospital Huddinge, the operating room cost there is approximately SEK 100 per minute. If one minute per package, in a normal wrist operation with ten components, needs to be added for unpacking individually packaged disposable products during surgery, the sales operation cost will be SEK 1,000 more. In the long run, this may mean that fewer patients can be operated on per day due to delays in unpacking and cleaning of disposable material after each operation.
This indicates a possible cost saving for reprocessing compared to reprocessing not being allowed.

In case only individual individually disposable products are used, all material must be picked out of the cabinet and taken out of its packaging. It is not possible to pick out all the material in advance as you cannot always determine the dimensions or number until you see the operating area. It also happens that materials are delivered in multi-packs that then need to be opened at the time of surgery. If not all products are used, and reprocessing is not done, this also means that some material needs to be discarded even though it has not been used.

Environmental consequences

The National Board of Health and Welfare has not had the opportunity or sufficient data to calculate the total environmental consequences in the report.

There are environmental benefits from reusing products as you avoid packaging, packaging and a large number of transports to warehouses. The disposable packaging is in several layers and consists of plastic and is then packed in outer enveloping cardboard of paper.

When it comes to reprocessing without reuse of medical orthopedic implants, ie. the products are reprocessed in their grids between operations and during the operation are unveiled and available to the surgeon without use, the authority assesses that this means a higher environmental impact through water and electricity consumption for dish disinfector and autoclave. On the other hand, a large number of small packages will be added to implants that are now packed in fewer and larger packages. This means a certain greater environmental impact through more packaging material than if reprocessing of implants can continue, which now takes place in most cases.

Discussion and conclusions

In this concluding chapter, the questions of the assignment are discussed and answered on the basis of the analyzes carried out. In the discussions, we also consider other relevant studies. In the concluding paragraphs, our conclusions are summarized.

Prerequisites for patient-safe reprocessing of disposable products

The National Board of Health and Welfare believes that there are conditions for reprocessing and reusing disposable medical devices in Sweden in a patient-safe manner

The main question for the entire assignment is whether, from a patient safety perspective, there may be conditions for allowing reprocessing and reuse of disposable medical devices. The review of evidence consisted mainly of a literature review, but also a review of relevant quality registers and incident databases, and it showed that it is possible to reprocess and reuse certain disposable medical devices in a patient-safe manner. However, the literature review showed that simple rules or risk classifications, such as Spaulding's scheme, which indicates the degree of invasiveness of an intervention, can not be used to assess which products are suitable for reprocessing and reuse.

Get documented problems with Swedish practice

A majority of the literature showed that it is possible to reprocess and reuse certain disposable products in a patient-safe manner, but reprocessing and reuse is not suitable for all disposable medical devices. It is also important to follow the routines described in SOSFS 2008: 1 or in Article 17 of the MDR and the common specifications, in order to guarantee patient safety.

Cardiology

An example of a product for reprocessing and reuse are electrophysiological diagnostic catheters and ablation catheters. They are included in Spaulding's highest risk class because they penetrate the bloodstream and are used in the heart, but no serious case of complication due to reprocessing and reuse is found in the literature. On the other hand, it is shown that the overall use has been safe. Nor did the review of the quality register for catheter ablation in Sweden show any case of technical complication or infection due to reprocessing or reuse during 2005–2019, based on a patient base of approximately 60,000 patients. It is likely that the reuse of reprocessed catheters has also contributed to a safer treatment of patients at higher risk of complication such as children,

Orthopedics

Orthopedic implants are also reprocessed in Swedish clinical practice, but are not reused. Practice internationally and in Sweden is to set up the orthopedic implants before an operation so that the surgeon can quickly choose between different sizes and products. The products that are not used are returned to the sterile unit for reprocessing. Asked orthopedic experts on e.g. Karolinska University Hospital saw no problems with current practice. An evaluation of the patient injuries reported to LÖF or IVO has also not shown any such adverse events due to current practice.

In the literature review, no clinical studies were found that show that this practice is problematic, but neither that it would be completely without problems. A few articles have addressed the risk that repeated reprocessing over time may lead to the formation of a biofilm on certain implants with more complex geometry, if the reprocessing method does not guarantee complete cleaning. In these few studies, manual methods have often been used and the re-processing protocol used in Sweden has not been used. These are also implants that are only unveiled for a short time during surgery and then immediately sterilized and stored sterile between operations. The relevant quality registers, e.g. Swespine, has no follow-up of the frequency of infection after operations that could be used to evaluate current practice.

External fixation frames used in orthopedics are another example of disposable products that are reprocessed and reused. In these cases, the risk of infection is very low because the frames do not penetrate the skin. In arthroscopy, certain disposable products have been reprocessed and reused, e.g. shaver instruments which in studies have proved difficult to obtain completely clean and sterile.

Laparoscopy, endoscopy and urology

Other medical-surgical areas examined in the literature review were reprocessing of disposable products in laparoscopy and endoscopy. Both the National Board of Health and Welfare's and IVO's survey, and a follow-up with professional representatives, showed that this does not occur to any great extent in Swedish practice. In the USA, several studies have recently been carried out on laparoscopic bipolar vascular sealing systems and it has been seen that they were able to be reprocessed around 10–15 times without any negative consequences. In endoscopy and what is called ERCP, disposable instruments are also used that also penetrate tissue, which entails greater risks of infection than normal diagnostic endoscopy. Examples of products used in ERCP are biopsy forceps or extraction baskets which are reprocessed to a very limited extent in Sweden.

Similar disposable instruments used for ERCP also occur in urology in the treatment of kidney stones, and in urology it also happens that the same patient reuses a disposable catheter for intermittent emptying of the bladder.

IVA and anesthesia

The literature review addressed the reuse of disposable IVA products and anesthesia such as respirators and endotracheal tubes, which according to studies can be used without increased patient risk if established reprocessing protocols are followed. In addition, other products used in IVA and anesthesia were reprocessed and reused, e.g. nebulizers, filters and hoses for CPAP and fans during the covid-19 pandemic.

The methods vary and have improved

A common problem in the review is that the methods for cleaning, disinfection and sterilization have developed over time. For example, SPRI's guidelines from the 1980s prescribed sterilization before cleaning, which according to later research makes cleaning more difficult as proteins become more difficult to remove [65, 66]. Previous studies have also been conducted in countries with other technical, organizational and clinical conditions, which makes it difficult to immediately transfer the results from an older study in another country to Swedish current conditions. In general, the methods for reprocessing have been improved and Swedish sterile technical units maintain a high standard. This means that older studies in other countries with poorer economic conditions, warmer and wetter climates,

Reasons for cessation of reprocessing and re-use The literature review revealed that certain single-use products have been discontinued because it was no longer economically justified, because technology has developed, because other products have replaced the reprocessed products or because evidence has emerged of performance deficiencies over time. Examples of such products in cardiology are diagnostic angiography and angioplasty catheters, pacemakers and ICDs. Nowadays, they are rarely reprocessed and reused. In the case of angioplasty catheters, it proved difficult to reprocess smaller sizes without degrading performance. For ICDs and pacemakers, sharp price falls have made reuse uninteresting, although several studies have shown that it is possible to reprocess and reuse them while maintaining patient safety.

Reprocessing has also ceased over time in other medical areas. One example is dialysis, where products were reprocessed mainly in the USA during the 1990s, but then new synthetic dialysis filters were introduced and there was a shift from dialysis at hospitals to specialized dialysis clinics run by dialysis manufacturers. There, the filters are used only once without being reprocessed and reused.

A restrictive attitude with a focus on patient safety

Based on the historical review of medical literature, the National Board of Health and Welfare makes the assessment that learning has taken place over time and has been reported by professionals in published studies and clinical experiences. This has led to a more restrictive reprocessing and reuse of disposable medical devices, but more consciously and patient-safe than before. One

The reason for this is also the method development that has taken place in the reprocessing of medical devices in general. This can be exemplified by the advanced equipment used on sterile technical units with hydrogen peroxide plasma for low-temperature sterilization of certain products.

Conclusion on patient safety

Based on the completed analyzes of literature, incident databases, questionnaire studies, quality registers and site visits that have been carried out, the National Board of Health and Welfare assesses that there are conditions for reprocessing and reusing disposable medical devices in Sweden in a patient-safe manner.

Application of Article 17 (3) and (4) of the MDR for reprocessing

The National Board of Health and Welfare considers that articles 17.3 and 17.4 of the MDR should be applicable, but will involve great efforts by care providers in order to be fulfilled.

Article 17 (3) of the MDR becomes applicable when a healthcare institution reprocesses and reuses disposable medical devices and 17.4 of the MDR applies if the health service hires an external reprocessor to reprocess the products on their behalf.

To assess whether 17.3 and 17.4 in the MDR can be applied, we have first examined the impact on patient safety in relation to the current national regulations in accordance with the Medical Technology Directives (90/385 / EEC, 93/42 / EEC) and SOSFS 2008: 1. The National Board of Health and Welfare's assessment is that many of the new requirements in 17.3 and 17.4 in MDR are already met in SOSFS 2008: 1, but they still entail significantly higher requirements for the care provider who in the future wants to reprocess and reuse disposable medical devices.

Article 17 (3) entails some stricter requirements

According to Article 17 (3) of the MDR, the safety and performance of the reprocessed product must correspond to the original product, and the requirements for self-manufactured products in Article 5 (5) (a), (b), (d), e, f, g, hi MDR must be met. In particular, it is the requirement in Article 5 (5) (e) that entails a tightening - to establish a declaration that the product meets the safety and performance of the original product and the requirements of the common specifications. The main difference is that a notified body must certify that the care provider complies with the common specifications. The requirements in the common specifications were described in the chapter "MDR - reprocessing and reuse of disposable medical devices". They mean that the person reprocessing also validates the process and can justify the number of reprocessing cycles that means equal security and perform as the original product. According to Article 21 of the common specifications, the healthcare provider's quality management system must also include corrective and preventive measures for safety. These measures shall ensure that reprocessed disposable products are traceable, that a responsible

person for reprocessing is appointed, that the product is marked as reprocessed and that the reprocessing cycle of each product is documented on an ongoing basis.

Many of the requirements for reprocessed and reused disposable products are thus included in SOSFS 2008: 1, but with MDR there are also a number of requirements that significantly contribute to guaranteeing the safety of a reprocessed product.

Few care providers meet today's requirements

The National Board of Health and Welfare's review shows that few care providers fully or only partially met the requirements in SOSFS 2008: 1 for reprocessed products. However, we believe that the players have become more aware of the requirements that apply to having to reprocess and reuse disposable medical devices, through the supervision that IVO carried out in 2019 and through this project's survey.

IVO's inspection showed that a number of hospitals had routines for self-manufactured products where the operations manager formally took over manufacturing responsibility through a signature. However, the audited university hospitals did not have a system for documenting reprocessing and reuse. According to the survey, most regions have some activity that reprocesses and reuses disposable medical devices, even though in some cases it is only about cleaning low-risk products and not sterile products.

About 40 percent of those who responded to the survey reprocess disposable medical devices. Of these, all respondents for gastroenterology, cardiology and orthopedics had documented routines for this as part of their management system. In surgery and IVA and anesthesia, the proportion was lower. Few clinical areas of activity perform risk analyzes and there are also few who annually evaluate the reprocessing activities. The highest proportion is stated in surgery with 38 percent. However, all activities state that evaluations are made, but not every year. Only a small part of the operations have formally taken over the responsibility, even though the proportion is 44 per cent for cardiology and 41 per cent for orthopedics.

External reprocessing is relatively uncommon

Article 17 (4) of the MDR applies to the use of an external party who reprocesses the products on behalf of a healthcare operation. The National Board of Health and Welfare states that this is happening today by a hospital's sterile technology unit reprocessing certain medical technology disposable products to other external care providers. This means that the reprocessed disposable product in its entirety is returned to the health care institution from which it came. According to the survey, 18 percent of the sterile technical units have been involved in external reprocessing. The National Board of Health and Welfare has not identified any Swedish external reprocessor that completely takes over manufacturer responsibility by CE-marking the product, as stated in Article 17 (2) of the MDR.

It should be possible to apply Article 17 (3) and (4) of the MDR, with great efforts from the care providers as a result

The National Board of Health and Welfare's assessment is that Article 17 (3)

and 17 (4) of the MDR should be applicable and that this will put many care providers before a clear choice, to either ensure that the articles are complied with or to stop reprocessing disposable medical devices. We assess that reprocessing of

certain products will be able to continue, if this is done consistently, if it is possible to ensure the same safety and performance as for original products and if the care provider can save large amounts. The National Board of Health and Welfare considers that the health service needs to make great efforts to ensure compliance with the rules.

Article 17 (3) of the MDR mentions that Member States shall encourage healthcare to inform patients about the use of reprocessed products and, where appropriate, provide other relevant information about the reprocessed product with which patients are treated. Member States may also provide that healthcare shall provide such information. The National Board of Health and Welfare's assessment is that the reprocessing that will be relevant according to MDR will provide equivalent security as in other activities where new products are used, and that there is therefore no reason to introduce special information provisions on this. We believe that the current regulation on information in the Patient Act is sufficient. According to ch. Section 1 of the Patients' Act provides the patient, for example, with information on the methods available for examination, care and treatment. The provision is generally formulated and according to the preparatory work for the Act, Chapter 3, Section 1 shall not be interpreted exhaustively. The provision must also be adapted to what is relevant to the individual patient.[24]

The National Board of Health and Welfare assesses that it may initially be difficult for the health service's operations to meet all the requirements in Article 17 (3) of the MDR and the common specifications. During a transitional period, it is a probable scenario that a number of the care providers who intend to continue with reprocessing and reuse use an external reprocessor that meets the requirements in Article
17.4. In the next section, we address foreign external reprocessors.

One way to increase compliance with regulations and facilitate supervision is for care providers who reprocess disposable medical devices to report it to a competent authority (IVO or the Medical Products Agency). Then, within the framework of its supervision, the relevant authority receives information about which care providers reprocess disposable medical devices.

Prohibitions or restrictions on reprocessing

A Member State which allows the reprocessing of disposable products may, according to Article
17.9 of the MDR, introduce national provisions restricting or prohibiting

a) disposable products are reprocessed and disposable products are transferred to another Member State or to a third country for reprocessing;
b) reprocessed disposable products are provided[25] or reused.

This applies regardless of the way in which a Member State allows the reprocessing of disposable products, whether in accordance with Article 17 (2) or Articles 17 (3) and 17 (4) of

[24] See prop. 2013/14: 106 Patient team, p. 114.

[25] The term provide is not defined in MDR but is included in e.g. Article 2, paragraph 27 of the MDR: 'to make available on the market'. In the English translation it says "making available". According to SAOL, providing means making it available to someone.

MDR. Article 17 (9) means that Sweden may state where (in Sweden, the EU or a third country) the external reprocessor must be established for a Swedish healthcare provider to be allowed to use that company. It also means that Sweden may restrict or prohibit certain products from being reprocessed and reused.

No ban on external reprocessing in other EU countries

The National Board of Health and Welfare proposes that external reprocessing of disposable medical devices to another EU country is permitted, but that the transfer of disposable products for reprocessing to a third country is currently prohibited, according to Article 17 (9) (a) of the MDR.

Today, it is sterile technical units at hospitals that perform external reprocessing, but also an external reprocessing company where the actual reprocessing takes place in Germany. According to the National Board of Health and Welfare, there is nothing to prevent Swedish care providers from hiring external reprocessors who are established within the EU because they have the same regulations to comply with.

It is not as obvious to allow the transfer of disposable products to a third country for reprocessing as there may be other aspects, in addition to patient safety, that need to be investigated and analyzed. These can be questions about the transfer of personal data, vulnerability, transfer of knowledge, etc. Today there is not enough data or knowledge for us to be able to make such an analysis. Therefore, the National Board of Health and Welfare considers that the transfer of disposable products to a third country should be prohibited, in the first place. An initial ban does not exclude the possibility of taking a position in the future on whether there are conditions to allow the transfer of disposable products for reprocessing to third countries.

It is important to follow the development of technology and knowledge

The National Board of Health and Welfare does not propose any prohibitions or restrictions regarding the provision or reuse of certain reprocessed product types, according to Article 17.9 to MDR.

When it comes to restrictions or prohibitions, the National Board of Health and Welfare wants to emphasize that things change over time, organizationally and technically, and there may be new alternatives to today's disposable products. This means that the products that are reprocessed and / or reused today may not be relevant to reprocess and / or reuse in the future.

The person who reprocesses disposable products shall apply Article 17 of the MDR and the common specifications, and thus any product will not be reprocessed and reusable. Although the literature review indicates that certain product types are safe to reprocess and reuse, we have not been able to make a complete inventory of all disposable products that are reprocessed and reused. Therefore, the National Board of Health and Welfare considers that it would not be appropriate to regulate in detail which product types may and

may not be reprocessed and reused. It will show in the assessment including risk analysis that the one who wants to reprocess

and reuse a product is required to do, according to Article 17 (3) of the MDR and the common specifications.

Advantages and disadvantages of reprocessing and reuse of disposable products

The National Board of Health and Welfare considers that reprocessing and reuse of certain disposable medical technology products is positive for the environment and strengthens the health service's crisis preparedness and resilience. Due to the increased requirements that MDR entails, the necessary learning about product risk, risk management and quality management will have to take place with extra costs for administration.

The project has not identified any significant difference in patient safety between reprocessing that follows a validated protocol, in hospitals, and the manufacturers' own activities to provide safe, clean and in some cases sterile products. We also do not go into the possible economic benefits of reprocessing disposable medical devices, which will be discussed in the next section.

Increased crisis preparedness

A clear advantage of reprocessing disposable medical devices is that it increases the flexibility of health care in everyday life, which also provides better conditions for coping with stressful situations and crisis situations. Many actors who reprocess disposable products have special equipment, knowledge and routines that are lacking in the routine reprocessing of reusable products. This was also presented by all participants in a digital follow-up meeting on the product and material shortage in connection with the covid-19 pandemic. The meeting was conducted in collaboration with the National Board of Health and Welfare's special organization for material supply during the pandemic. Routines, equipment and competence to handle disruptions and crises are crucial to ensure the resilience of health care. The participants agreed that many patients with covid- 19 could not have been treated without the possibility of reprocessing disposable medical devices, e.g. disposable hoses for humidification during oxygen treatment.

Reduction of transports, warehouses and environmental impact Other advantages are that reprocessing generally results in less warehousing, smaller transports, fewer packages and thus less environmental impact. Less warehousing also means a lesser need for premises, something that is often lacking in hospital environments. The ability to reprocess existing products also makes healthcare less vulnerable to delivery disruptions and contributes to a more robust and resilient

healthcare, not only in a crisis situation but also in day-to-day operations.

More responsibility and more knowledge

Allowing the reprocessing of disposable products would in itself be a signal of confidence in the medical-clinical professions that strengthen their position,

but which also needs to take greater and clearer responsibility when MDR is introduced. The stricter requirements in Article 17 (3) and (4) of the MDR, and the common specifications, mean that the clinical professions must become more active in matters of product risk, risk management and quality management systems. This will probably also mean a more intensive dialogue with medical technology units or external consultants at the various hospitals and in the regions, which in turn will lead to learning and knowledge development. The responsibility for reprocessing also becomes clearer through the requirement for external validation of a notified body and a possible notification obligation to a competent supervisory authority before reprocessing begins.

More administration and extra costs

The stricter requirements probably mean benefits for patient safety, but also mean more administration and extra costs. These increased costs arise as a result of the requirements for a notified body to certify the management system in accordance with the requirements in the MDR for the reprocessing of disposable medical devices.

Economic impact assessment of reprocessing

The National Board of Health and Welfare estimates that reprocessing and reuse of disposable medical devices in the event that products are reused entails significant cost savings, approximately SEK 65-70 million per year only for electrophysiological catheters. For products that are reprocessed, but not reused, the economic consequences are much smaller and more

Our calculations for comparing reprocessing and disposable use of disposable medical devices apply to the clinical areas where reprocessing occurs most in Sweden - electrophysiological arrhythmia examinations and treatments in cardiology and orthopedic implants. The calculations show that current practice in the field of electrophysiology can result in savings of approximately SEK 65–70 million per year. This practice means that all diagnostic catheters are reused a defined number of times, as well as simpler ablation catheters and other peripherals such as cables and connectors. These are 25,500 used diagnostic and ablation catheters for single use, but only 5,550 catheters with consistent reprocessing and reuse. It also gives a clear less environmental impact, despite the fact that energy,

For orthopedic implants, we do not see any major economic benefits with any alternative, but a certain possible environmental saving from switching to only disposable packaged implants, since the reprocessing itself involves water and energy consumption. At the same time, individually packaged products mean a significantly increased volume of packaging, so it is difficult to draw any definite conclusion.

Summary of conclusions

The National Board of Health and Welfare's main conclusion is that there are conditions for reprocessing and reusing disposable medical devices in a patient-safe manner in Sweden.

This conclusion is mainly based on our comprehensive analysis of available evidence on reprocessing, which shows that reprocessing according to a validated protocol can be considered patient-safe and does not entail any higher risk for patient safety compared with an initial use of products from a medical device manufacturer. Reprocessing is also important to ensure resilience in daily operations and preparedness for a crisis situation.

The National Board of Health and Welfare considers that Articles 17.3 and 17.4 of the MDR should be applicable. With the increased requirements, it should be possible to reprocess and reuse disposable products to a certain extent, but not all disposable products are suitable for reprocessing (something that is also mentioned in recital 3 of the common specifications). All healthcare providers currently reprocessing and reusing disposable products are unlikely to have sufficient resources or capacity to go through the process set out in Article 17 (3) and the common specifications. Therefore, it should also be possible to apply 17.4 in the MDR so that a care provider can hire an external reprocessor to reprocess disposable medical devices on their behalf.

The National Board of Health and Welfare proposes that external reprocessing (according to Article 17 (9) a) of disposable medical devices to another EU country is permitted, but that the transfer of disposable products for reprocessing to a third country is currently prohibited.

We do not propose any prohibitions or restrictions on the provision or reuse of certain reprocessed product types, in accordance with Article 17 (9) (b) of the MDR.

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