Reprocessing single-use medical devices

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Introduction

European regulation 2017/745 [1] relating to medical devices (MD) has been applicable since May 26, 2021. Article 17 provides for the reprocessing of single-use medical devices ("single-use devices reprocessing" in the original text), and specifies that this practice will only be possible in a State if the legislation of the country authorizes it. Reprocessing is defined as "the process that a used device undergoes to enable its safe reuse, including cleaning, disinfection, sterilization and related procedures, as well as the testing of the used device and the restoration of its technical and functional characteristics in terms of safety". This definition is compatible with the definition of single-use medical device (SUD), specified in the European directive of 2007 [2] and included in the new regulation (article 2, paragraph 8): "Any device intended to be used on a natural person during a single procedure."

At the origin of reprocessed single-use medical devices

In the 1970s and 1980s, the risk of nosocomial transmission through the reuse of contaminated syringes aroused growing interest in the production of disposable injection MDs. The discovery of the human immunodeficiency virus (HIV) increased the pressure for the production of SUDs. In addition, technological advances have led to the production of more elaborate and complex MDs, allowing the development of sophisticated medical and surgical techniques which present more and more risks of infection. These devices, made of plastic materials, do not support traditional high-temperature sterilization methods: they are labeled single-use by the manufacturers, without any other scientific basis.

But the increase in medical device prices and the explosion in the quantity of waste, packaging, plastics and various sharp products have called into question this principle of "all disposable"; health facilities, since the 1990s, have made choices between reusable devices and SUDs, depending on financial constraints, their organization, the product offer on the market and their needs. The concept of reprocessing is emerging in some European countries: Germany, the Netherlands, Denmark, Slovakia, Sweden.

Reuse of single-use medical devices

Historically, the reuse of SUDs has developed according to two different circuits:

- re-sterilization, carried out in health establishments with the conventional means available;
- reprocessing, outsourced to external companies, such as Stryker in the United States or Vanguard in Germany, with resources specifically dedicated to this activity. In this context, the reuse of a SUD is evaluated according to quality specifications which make it possible to define the maximum number of possible uses to maintain optimal performance. Vanguard, for example, provides SUD reprocessing in cardiology, electrophysiology, arthroscopy, ophthalmology, endoscopy and urology; for each SUD, the reprocessing process is defined according to the structure and materials making up the SUD via a "reverse engineering" phase; the critical stages of the process are specified on the basis of the risk analysis. After reprocessing, each medical device is checked individually, particularly in terms of its integrity and technical performance. The SUD is withdrawn from circulation if security is no longer guaranteed. Using a coding system for each device, the service provider traces each step of the process and controls and ensures that the SUD is delivered to its initial owner, the hospital or the user. Reprocessors use industrial sterilization methods at low temperatures, similar to those of the original producer.

A national regulatory framework

European Union regulations relating to the safety and performance of MDs were harmonized in the 1990s with three directives, 90/385/EEC (European Economic Community) relating to active implantable medical devices, 93/42/EEC relating to to MD, 98/79/EC (European Community) relating to in vitro diagnostic medical devices (IVMD):

- the labeling of SUDs must include an indication that the device is for single use (“2” crossed out);
- for reusable MDs, the manufacturer must provide information on the appropriate processes to be able to reuse them, including the sterilization method, as well as any restrictions on the number of reuses.

Directive 2007/47/EC clarifies the concept of single use, which must be uniform throughout the European Community, and the instructions for use must include information on the risks associated with reuse.

Over the next ten years, the European Commission will analyze the issue of reprocessing of SUDs, with a view to ruling on this technique within the framework of the new regulation published in 2017 and repealing the directives of 1990 and 1993. Consultation of groups of experts, a public consultation and referral to the Scientific Committee on Emerging and Newly Identified Health Risks or CSRSEN (Scientific Committee on Emerging and Newly Identified Health Risks or SCENIHR) resulted in the publication of a report in 2010 [3].

The European Commission notes: “To cope with increasing financial pressures, the reprocessing of certain medical devices, although intended for single use, has sometimes continued, either in hospitals or through reprocessing service providers.”

“Currently, the reprocessing of single-use medical devices is not regulated in the European Union; it is the different national laws that govern this practice throughout Europe. A small number of Member States allow it and have developed guidelines, while others prohibit it (such as France) or have no specific regulations in this area.”

In Germany, the MPG law (Medizinproduktegesetz, law on medical devices introducing Directive 93/42 EEC) was amended in 2002 to provide a framework for the reuse of medical instruments; the recommendations of the RKI (Robert Koch Institute), and those of the BfArM (Federal Institute for Medicines and Medical Devices) define a level of classification into critical, semi-critical and non-critical medical devices (according to the Spaulding classification), without distinguishing between reusable medical devices and so-called single-use medical devices.

In the United Kingdom, the Medicines and Healthcare products Regulatory Agency (MHRA) published in 2016 a guide “Single-use medical devices: UK guidance on re-manufacturing”, favorable to this practice. This guide defines “reprocessing” for reusable MDs, and “remanufacturing” for SUDs. The MHRA prohibits the reprocessing of SUDs and authorizes remanufacturing by manufacturers, who alone have sufficient means to assess the eligibility of a MD for reprocessing.

In Switzerland, the order on medical devices of October 17, 2001 (ODim SR 812.213) was revised on April 1, 2010: "[...] a hospital is considered to be a manufacturer from the moment it reprocesses and sterilizes for the purposes reuse of a single-use product for which the original manufacturer has not planned to re-sterilize (art. 20a)”.

In the United States, a reprocessing third party or hospital must comply with the same requirements that apply to original equipment manufacturers; a favorable opinion from the Food and Drug Administration was confirmed by the GAO (Government Accountability Office) in 2008, following analysis of the possible causal link between reprocessed devices and adverse events recorded [4].

In Canada, some provinces have banned the reuse of critical SUDs; others have established that hospitals must use an approved reprocessing company.

In Australia, a company that reprocesses a SUD becomes the manufacturer of the reprocessed device and must apply the corresponding conformity assessment procedure to the product.

Three major risks to patient safety have been identified by the CSRSEN, namely the persistence of contamination, the persistence of chemicals used during the reprocessing process, and the alteration of device performance as a result. of his retirement. Exposure during the reprocessing cycle to chemical cleaning agents, chemical sterilants, high pressure, can cause corrosion and changes in MD materials: plastics can soften, crack or become brittle; a mechanical failure may appear after several reprocessing cycles and alter its performance. Some of the materials used in the manufacture of MDs can absorb or adsorb certain chemicals, which can then be gradually released. Chemical residues resulting from reprocessing may present a toxic hazard when the device is reused.

Continued contamination may be the result of improper cleaning, disinfection and/or sterilization; the cleaning process, for example, must provide access to all parts of the device to allow complete decontamination: sharp angles, coils, long or narrow lumens, specialized surface coatings, etc., may limit its effectiveness.

Endotoxins are gram-negative bacterial breakdown products and can be a significant problem if the device has a high bacterial load after use, which cannot be adequately removed by cleaning.

The removal of prion contamination is a specific problem, as only relatively aggressive cleaning methods, incompatible with frequently used materials, can guarantee the inactivation of prions. Devices likely to be contaminated are therefore excluded from reprocessing in countries that practice it.

The European Commission has analyzed other aspects of reprocessing, such as ethical issues, the responsibility of the healthcare professional who uses a reprocessed SUD, the responsibility of the reprocessor, of the hospital, but also the cost-effectiveness of the process and environmental impacts, and finally the obligation of traceability.

Reprocessing of single-use medical devices in France

In France, several circulars (circular DGS/DH/DPHM/no 669 of April 14, 1986 relating to the ban on re-sterilization of non-reusable medical and surgical equipment known as "single use"; circular DGS/SQ3, DGS/PH2 – DH /EM1 no 51 of December 29, 1994 on the use of single-use sterile medical devices in public and private health establishments), supplemented by case law, have prohibited the reuse of SUDs, and two decrees (May 15, 2006 and August 30, 2010) amended the Public Health Code (article R6111-21) accordingly.

Several steps have been taken with the Ministry of Health, with a view to defining the secure framework in which this practice could be authorized, have taken place since 2018, at the initiative of a working group bringing together the Club of purchasers of health products (CLAPS) and representatives of the Hospices Civils de Lyon, supported by the hospital federations, without success to date.

As of 2018, three European States, Belgium, Sweden and the Netherlands, transposed Regulation 2017/745 into their national regulations with the possibility of reprocessing SUDs. The Swedish National Board of Health notes at the end of 2020, in a preparatory report: "Reprocessing according to a validated protocol can be considered safe for the patient and does not entail a higher risk for patient safety compared to the use initial product from a device manufacturer" [5]. They also mention that the practice of routine reprocessing of SUDs has enabled healthcare facilities to deal with medical device supply disruptions during the pandemic.

Several projects for the reuse of SUDs and personal protective equipment (PPE) took place at the start of the pandemic in France in the face of the shortage of certain health products, such as the work on FFP2 masks carried out by a consortium including the Commissariat to atomic energy and alternative energies (CEA), the National Center for Scientific Research (CNRS) and the Grenoble University Hospital. Despite conclusive results (concerning the reduction of the viral load and the maintenance of technical filtration performance after sterilization by various sterilizing agents, ethylene oxide, plasma gas, etc.), reuse could not be implemented in France, for lack of an appropriate regulatory and logistical environment. Ordinance No. 2022-582 of April 20, 2022 adapting French law to Regulation (EU) 2017/745 modifies the 5th legislative part of the Public Health Code: Art L.5211-3-2- reprocessing of devices single use mentioned in Article 17 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, their placing on the market and their use are prohibited.

Three essential points directly related to the SUD were put forward to change the French position:

- the absence of increased risk in countries where this practice has been recognized by health agencies for several decades;
- potential savings;
- reduction of waste.

Regarding waste, several regulatory texts have been published or are in preparation in the context of environmental preservation:

- in Europe, Directive (EU) 2019/904 of June 5, 2019 of the European Union, relating to the reduction of the impact of certain plastic products on the environment;
- in France, law no. 2020-105 of February 10, 2020 relating to the fight against waste and the circular economy, and its implementing decrees [6-8] concern hospitals and the health system in general, in the level of waste sorting and potential recovery of used products

They complement articles L541 & following of the Environmental Code which give priority to the prevention and reduction of waste production through their reuse.

The principle of "extended producer responsibility" (EPR) requires that the producer waste is responsible for its collection and treatment, even when the waste is transferred for treatment to a third party.

According to decree no. 2020-1455 of November 27, 2020, twenty-one new families of products are concerned by EPR, including a few medical devices: "Perforating medical devices used by patients in self-treatment and users of the self-tests mentioned in article L3121-2-2 of the same code, etc., associated electrical or electronic equipment (EEE)". Medicines and single-use sanitary textiles (such as wipes) are also concerned. However, for the moment, the vast majority of MDs used in healthcare establishments remain outside this obligation.

According to the Environment and Energy Management Agency (ADEME), the volume of waste from health care activities with an infectious risk (DASRI) reached 700,000 tonnes in 2011, the cost of treatment ranging from 1,400 € to €6,500 including tax per ton, to which must be added the costs of removal and transport (i.e. €150 to €360/ton). Reducing the volume of waste from healthcare establishments is one of the objectives of reprocessing SUDs. Today, this waste is systematically destroyed and most often incinerated.

Regarding potential savings, the AMDR (Association of Medical Device Reprocessors) estimates that, on average, the cost of a reprocessed SUD is 60% of the price of a new MD and that it can undergo between three and 15 reprocessing cycles. It assesses the average proportion of retired SUDs at 38%.

The report drawn up by Germany to the European Commission on a single family of products within the framework of the overhaul of the European regulations confirms this advantage: the use of reprocessed ablation catheters rather than new ones for a specific type of cardiovascular pathologies had leads to savings of more than 23 million euros per year [9]. A study published in June 2016 estimated the global market for reprocessed SUD to exceed $1 billion in 2015 and values it at $2.4 billion in 2022, targeting cardiovascular MDs, orthopaedics, gastroenterology, general surgery and laparoscopy [10].

Retired SUDs generally belong to these families. It is not possible to set relevant rules for targeting SUDs that can be reprocessed, but two elements should be emphasized: we note that critically invasive SUDs, such as electrophysiology and ablation catheters, used at the central level of the cardiovascular system, are retired with no reported incidents; some SUDs are no longer retired after a few years, because the devices or technologies have evolved.

The common specifications for the reprocessing of SUDs published in 2020 [11], additional constraints in the reprocessing process and a certification process with a notified body could have an impact on reprocessing costs. A preliminary analysis to assess the relevance of reprocessing a targeted SUD in relation to the price of a new MD should be considered.

Reprocessing, Regulation 2017/745 (EU) and Implementing Regulation 2020/1207 (EU)

Article 17 of the new regulation concerning medical devices, "Single-use devices and their reprocessing", comprises 10 paragraphs, of which the following can be retained:

> 2. The company reprocessing the SUD becomes the manufacturer of the reprocessed device. According to the regulation, the “manufacturer” is a natural or legal person who manufactures or refurbishes a device or has a device designed, manufactured or refurbished, and markets this device under their name or trademark; "refurbishment" means the complete restoration of a device already placed on the market or put into service, or the manufacture of a new device from used devices, so as to bring it into conformity with this Regulation, as well as assigning a new lifespan to the refurbished device. Article 10 of the regulation, “General obligations of manufacturers”, details the obligations of the manufacturer in relation to the regulation; thus, paragraph 6 provides:
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> 3. By way of derogation from paragraph 2, a State may decide not to apply to healthcare institutions that reprocess SUDs all of the rules relating to manufacturers' obligations, under certain conditions:
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> – the safety and performance of the reprocessed device are equivalent to those of the original device,
> – the requirements of article 5 of the regulation, concerning devices manufactured and used exclusively in healthcare establishments, are applied, in particular the impossibility of transferring the devices to another legal entity,
> – the restatement is carried out in accordance with the common specifications detailed in the implementing regulations of August 2020;
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> 4. The same derogation may be applied to the reprocessing of SUDs by an external reprocessing company at the request of a healthcare establishment, provided that the reprocessed device is returned in its entirety to this healthcare establishment;
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> 5. Conformity with common specifications is certified by a notified body;
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> 8. The name and address of the reprocessor and the other relevant information referred to in Annex I, Section 23 ('Labelling and instructions for use') of the Regulation shall be indicated on the label and, where applicable, in the instructions for use of the reprocessed device. The name and address of the manufacturer of the original SUD no longer appear on the label, but are mentioned in the instructions for use of the reprocessed device;

9. A state may introduce stricter national provisions;

10. The Commission shall draw up a report on the implementation of this article by 27 May 2024 at the latest.

Implementing Regulation (EU) 2020/1207 [11] details the common specifications for the reprocessing of SUDs within a healthcare establishment, or in an external reprocessing company, in application of paragraphs 3 and 4 of the article 17 of regulation 2017/745 (establishment and company are not subject to all the manufacturer's obligations according to regulation 2017/745, article 10).

When a health establishment asks an external company to ensure the reprocessing of SUDs, the two parties must conclude a written contract (article 3) containing elements such as the allocation of tasks and responsibilities to both parties, the requirements relating to in reprocessing, the collection of information on reprocessed devices and the exchange of information between the health establishment and the external reprocessing company. The regulation specifies the specifications relating to personnel, premises and equipment in reprocessing establishments (article 4).

The evaluation of the suitability of the SUD for reprocessing takes into account the available and updated manufacturer data: composition of materials, leachable materials; technical and geometric characteristics; destination and normal use of the SUD (to assess microbiological contamination) (article 5). The results of physical, electrical, chemical, biological and microbiological tests complete this data to define the reprocessing process (article 7). The “reprocessing cycle” includes several steps, and for each of them, a procedure is written and validated: pre-treatment at the point of use, transport, preparation before cleaning; cleaning; thermal or chemical disinfection; drying; inspection, maintenance, repair and functionality testing; conditioning; labelling, provision of instructions for use; sterilization, storage.

The quality management system makes it possible to find all the recorded data, including those concerning incidents, the management of corrective and preventive measures, and traceability data.

Reprocessors have at least one annual external audit of reprocessing activities carried out. The audit report is made available to the notified body competent for the certification of the establishment, pursuant to Article 17(5) of Regulation (EU) 2017/745 and, upon request, to the disposal of the competent authority (Article 22).

They set up a tracking system allowing the identification of the single-use device throughout the reprocessing cycle and the lifetime of the reprocessed SUD. This tracking system records the number of reprocessing cycles to which the SUD has been subjected; it guarantees that the retired SUD returns to the original healthcare establishment.

Conclusion

The application of the new European regulation concerning medical devices is an opportunity to question the regulatory restrictions on the practice of reprocessing of medical devices in France. The reprocessing of SUDs could be authorized within a strict framework, to limit hazardous and uncontrolled practices; with the objective of controlling hospital expenditure on medical devices, indirectly by reducing the quantity of waste from risky healthcare activities, and directly by facilitating competition between new exclusive devices and

reprocessed devices. This reduction in expenditure as well as patient safety should be monitored to confirm the value of the practice of reprocessing in France.

European regulation 2017/745 gives each country the possibility of choosing a level of requirements adapted to its practices:

- a first level where the reprocessing is carried out in the hospital, in application of article 17, paragraph 3, of the MD regulation:
    - a notified body certifies the compliance of the reprocessing processes with the common specifications of the implementing regulation,
    - reprocessed devices are reused in the establishment;

- a second level where the reprocessing is subcontracted to an external company, in application of article 17, paragraph 4, of the MD regulation:
    - a notified body certifies the compliance of the reprocessing processes with the common specifications of the implementing regulation,
    - the reprocessed devices are reused in the healthcare facility of origin;

- a third level where the reprocessing is carried out by an external reprocessing company:
    - the company has the status of manufacturer within the meaning of the MD regulation, pursuant to article 17, paragraph 2,
    - reprocessed MDs comply with the essential requirements of the MD regulation, compliance is certified by a notified body.

Given the lack of experience in this field in France, the authors recommend this third level, because it reconciles high safety for the patient and less risk-taking for the hospital.

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