

Reprocessing Single-Use Devices

Legislative issues in the EU

Reprocessing single-use medical devices raises issues of patient safety, ethics, the environment and costs. The aim of this paper is to raise awareness of the problems related to the reprocessing of single-use medical devices in the EU, with a focus on Portugal's position regarding this issue.

With the technology evolution, medical devices increasingly became more complex and difficult to clean and sterilise. In response, single-use medical devices were developed. Due to economic factors, hospitals and companies now practice the reprocessing of single-use medical devices. This raises important issues concerning patient safety, ethics, the environment and costs (Abreu I, Abreu M J, Coelho A, 2014).

Medical devices were initially intended to be reusable, as was favoured by their design, size, shape, and manufacture from materials that could withstand sterilisation. In 1948, the first single-use medical device was developed (Cohoon, 2002).

As technology developed, so too did medical devices becoming more complex and sophisticated, with specific characteristics and properties. Devices with polymeric compounds were resistant neither to physical and chemical aggressive treatments, nor to high temperatures and, hence, were not resistant to sterilisation processes. Also, new devices for mini-invasive procedures were developed with narrower diameters and more intricate and delicate mechanisms. Some of these devices can be difficult to clean and sterilise properly, rendering manufacturers unable to demonstrate safe reuse. For this reason, some devices are labelled with the designation 'single use'.

Interest in these products swelled with the appearance of HIV and hepatitis transmission (Dunn, 2002). Consequently, the use of single-use medical devices has considerably increased in hospitals, in particular to reduce the risks of cross contamination between patients. Definition and classification of single-use



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medical devices emerged in Council Directive 93/42/EC concerning medical devices was adopted on 14 June 1993 and amended by Directive 2007/47/EC as “a device intended to be used once only for a single patient”.

In the last few years, hospitals have been faced with financial changes resulting in the need to reduce costs. In response, many hospital entities are now exploring the reprocessing and reuse of single-use products.

Council Directive 93/42/EEC amended by Directive 2007/47/EC does not define reprocessing, but instead imposes the need to ensure that the reprocessing of medical devices does not constitute a danger to the safety or health of patients by clarifying the definition of ‘single use’ and the establishment of labelling and instructions for uniform use.

With regards to reusable devices, the Council Directive only states that “if the device is reusable, information must be provided on the appropriate processes to allow reuse, including cleaning, disinfection and packaging and, if applied, the method of sterilisation of the device to be re-sterilised and any restriction on the number of reuses.”

European variations

Council Directive 93/42/EEC of 14 June 1993 amended by Directive 2007/47/EC concerning medical devices establishes laws that all countries in the EU must follow regarding product conception, manufacture, commercialisation and entry into service. Each country then transposes the Directive to its national legislation.

Different health institutions across Europe have practiced reprocessing of single-use medical devices, and it has received special attention from the Competent Authorities of each country. The reprocessing practice of single-use medical devices is not currently regulated at the community level; instead, different national legislations regulate this practice throughout

Europe. Few countries allow the practice and have developed guidelines; in other countries it is prohibited. The majority of Member States do not have any specific regulation on this aspect (European Commission, 2010). As seen in Table 1, the position concerning reprocessing of single-use medical devices is held at the legislative level of each EU country.

Reprocessed single-use medical devices could introduce an increased risk to the patient when compared to the use of a new single-use device. It is important, therefore, to take into account the issue of information available to the patient and their informed consent before being subjected to a medical procedure involving reprocessed devices. Reprocessing of single-use medical devices raises ethical issues in terms of potential inequalities between patients. With regards to legal responsibility, it is necessary to clarify the responsibilities of each intervenient and inform health professionals in case of using reprocessed medical devices.

Reprocessing should be performed according to the instructions provided by the manufacturer and must follow technical specifications that ensure the conformity of the device at the time of its use towards the essential requirements of the apply Directive (INFARMED, 2008). This creates a difficult situation, as manufacturers’ instructions for single-use medical devices don’t indicate any reprocessing procedures. ▶

Table 1. Some European countries’ positions regarding the reprocessing of single-use medical devices

Permitted	Not recommended	Prohibited
Germany	United Kingdom	France
Sweden	Italy	
Belgium	Czech Republic	
Holland	Austria	
Portugal	Spain	
	Ireland	

Challenges of reprocessing

Single-use medical devices are designed to be used only once, therefore, any reprocessing may damage or alter the device, potentially making it unsafe to reuse. Re-use can involve issues including infections, inability to clean and decontaminate residues such as from chemical decontamination products, material alteration and mechanical failure, and reactions to endotoxins (Abreu I, Abreu M J, Coelho A, 2014).

A satisfactory cleaning process must be able to access all parts of the device. If this is not possible then the device's cleanliness is compromised and the risk of cross-infection may increase due to the inability of the reprocessing system to completely remove the viable microorganisms. For example, once in the device endotoxin (cell-associated gram-negative bacteria) cannot be removed by cleaning, nor can it be inactivated by sterilisation, even when these two processes are effective in killing bacteria.

Another problem related to cleanness and sterilisation is the chemical product used. Some materials can absorb or adsorb certain chemical agents and, in this way, device performance can be compromised, increasing patients' risk of being in contact with malefic chemical agents. These chemical agents can cause corrosion and change the material, causing degradation. This can lead to mechanical failure and direct patient contact with the corroding and degrading products (Eucomed, 2009; INFARMED, 2010; MHRA, 2011).

On the other hand, reprocess and reuse of single-use medical devices can reduce costs to the health entity in a number of ways:

- *By reducing the price of products, as on average a device undergoes five reprocessing cycles, saving around 50% per cycle (Bracklo, 2012)*
- *Reducing costs related to primary and secondary packaging and informative brochures, leading to decrease of hospital residues volume and better management of environmental recourses*
- *By avoiding non controlled and non-quality reprocessing (Neves, 2008)*
- *Traceability of the medical device from its first availability on the market as a single-use medical device, to its use as a reprocessed single-use medical device*
- *Correctly label the device in order to avoid potential mistake with non reprocessed devices*
- *The single-use medical device can only be reprocessed and used in accordance with Decreto-Lei 145/2007, of 17 June 2007*

The gains from the environmental impact of reprocessing procedure related to residues decreasing, however, can be annulled by the increase of resources consumed, like water and energy, and by the increased use of chemical products, sewage and intensive materials transportation (Mercedes, 2012).

Reprocessing in Portugal

In Portugal, reprocessing single-use medical devices is covered by national law *Despacho* 7021/2013, of 24 May 2013, and must meet the following requirements:





- The reprocessed devices can only be used in the National Health Service establishment (Serviço Nacional de Saúde, SNS) responsible for reprocessing
- The reprocessed device cannot be marketed in any form nor can it bear CE markings and associated information
- Information that it is a reprocessed single-use medical device and the number of reprocessing cycles already performed are mandatory – this endorsement must appear on the reprocessed device itself, or when this is not possible, on its primary packaging and any other level of packaging

Despacho 7021/2013 also mentions that the decision to use a reprocessed single-use medical device must evaluate the cost-effectiveness of this practice, when realised in proper conditions of quality and safety, as well as considering direct and indirect costs and environmental impacts.

Conclusion

Reprocessing and re-use of single-use medical devices raises questions about the safety, quality and correct performances of the product, which in turn create questions concerning ethics.

The healthcare system has been challenged to find equilibrium between patient rights and society's goal to give health cost-benefit for everyone. Nowadays, legislation in the EU countries concerning the reprocessing of single-use medical devices varies from member state to member state. In Portugal, reprocessing of single-use medical devices is accepted if the device's quality and security are maintained. ■

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