

The Future of Reprocessing in Europe

Abstract

Medical devices have become increasingly important with regard to their impact on patient health and influence on health care expenditures. According to latest data from the European Medical Technology Industry Association (EUCOMED), the total market volume of medical devices in Europe (EU-27 plus Switzerland and Norway) sums up to one third of the world market, amounting to € 62.6 billion in 2005. Aging populations and a general commitment of societies to improving the quality of life tend to foster the medical devices industry. Yet the sector faces pressures from national cost-containment policies that are curbing the trend of increasing expenditures towards a more rational and sustainable use of modern medical devices.

Over the last years the medical device industry has enlarged the number of instruments that are labelled single use and this in particular for complex, expensive and innovative devices. For these devices the industry does not provide manuals to reprocess these items as they do for the so called multiple use instruments.

Within the last years, the market of professional third-party reprocessing service providers has only started due to recent economic and political developments. The reprocessor's role as a service provider to the owner of the product (e.g. a hospital), is to clean, disinfect and test (and where appropriate sterilise) a medical device that has already been used in a patient or opened and but not used. By this way, the medical device is prepared for a safe re-use in the next patient.

Different health care systems in the EU member states show a fragmented market: In some member states reprocessing is accepted and regulated under high quality standards, in some not recommended or explicitly prohibited, and in some member states a regulation does just not exist - despite the fact that reprocessing is common practice throughout all of Europe.

The reason for this inconsistency lies in misleading implications of single-use labelling and in the lack of a legal framework at EU level that could give a clear guideline on which medical devices are reprocessable under certain quality requirements for re-use and which are not.

Demonstrating that professional reprocessing means interlinking patient safety and cost effectiveness, EAMDR called upon the European institutions during the latest revision of the medical devices directive with the aim to establish a legal framework which gives a clear guideline on this issue throughout Europe. As a result, the Commission is requested to submit a report on the reprocessing of medical devices within the next three years and to come forward with proposals on how to ensure a high level of patient safety. The competent Directorate-General Enterprise and Industry has just started the consultation

process by assessing the current practices and their real costs as well as existing national regulations and market studies.

- EAMDR believes that the development of consistent EU legislation will enhance patient safety whilst paving the way for significant cost savings in the health sector as well as securing ecological improvements throughout Europe.
- EAMDR believes that only binding quality standards and validated procedures offer convincing solutions since label categories do not serve as an appropriate link for regulation.

It will be demonstrated in the following why the current labelling practice is inadequate and that the focus has to be shifted to quality standards for medical device reprocessing, independent from the labelling chosen by the original manufacturer.

Misleading Labelling

Through the last decades more and more medical devices have been declared 'single-use'. It is the sole decision of the manufacturers to declare their medical device as either 'single-use' or 'multiple-use'.

The single-use label says little about the actual reprocessability of a medical device; still many national regulations recommend to follow this label, thereby hindering the reprocessing and re-use of these medical devices despite technological innovations allowing safe reprocessing. Interpretations of single-use can either be that the product cannot be reprocessed safely, that the manufacturer

- limits his liability to one use only, or/ and
- that he has not developed a validated procedure for reprocessing, and/ or
- economic incentives.

It also happens that the manufacturer sells the device in one member state as single-use whilst in some others as multiple-use device.

Despite being labelled 'single-use' many medical devices today are in fact reprocessed and re-used. This is common practice – worldwide. Recent technological developments have facilitated safe reprocessing considerably. However, the notion of 're-using' labelled 'single-use' devices raises confusion and opens a field of debate, leaving the impression that reprocessing of any type of medical devices labelled as 'single-use' generally poses a risk for patient safety. In fact, professional third-party reprocessors have proven that manufacturers use the label 'single-use' more often than is scientifically needed.

On the other side, many examples can be found for allegedly 'multiple-use-instruments' that can not be reprocessed sufficiently when following the reprocessing instructions of the manufacturer.

Further, reprocessors have shown in the last decade that a significant proportion of 'single-use' labelled devices can be reprocessed safely.

EAMDR estimates that 16 % of all medical devices often labelled as 'single-use' are in fact 'multiple-use' devices technically reprocessable for a limited term: 20,000 devices have been tested of which 3,000 were proven to be reprocessable for a limited term. To date, 6,5 million of these medical devices have been reprocessed safely through members of the EAMDR, applying strict quality standards for reprocessing approved by national hygiene boards (such as the Robert-Koch-Institute in Germany or the Staten Serum Institute in Denmark).

The difficulty to give a clear guidance on which devices are able to be re-used is primarily caused by the fact that the reprocessability of a medical device does often not correspond to the label 'single-use' or 'multiple-use'.

EAMDR estimates that 16 % of all medical devices labelled as 'single-use' are in fact 'multiple-use' devices technically reprocessable for a limited term: 20,000 devices have been tested of which about 3,000 were proven to be reprocessable for a limited term. As these medical devices have to be reprocessed with special equipment at specialised production sites. This particular kind of reprocessing is therefore sometimes called "special reprocessing".

As a result, current labelling does not reflect today's reprocessing practice. In practice, there are rather three types of medical devices:

Non-Reprocessable	Reprocessable	
<div style="background-color: #ff0000; color: white; padding: 5px; margin: 10px auto; width: 80px;">Single Use Devices</div> <p>No safe reprocessing possible Reprocessing should not be allowed</p>	<div style="border-left: 1px dashed black; border-right: 1px dashed black; padding: 5px; margin: 10px auto; width: 80px;"> <div style="background-color: #00ff00; color: black; padding: 5px; margin: 10px auto; width: 80px;">Multiple Use Devices (limited term)</div> <p>Reprocessing possible for a limited number of times with specific technology (mainly by third party reprocessors) Quality management system and process validation should be mandatory</p> </div> <p style="font-size: small; transform: rotate(-90deg); position: absolute; left: -40px; top: 50%; transform: translateY(-50%);">„Third Category“ of medical devices</p>	<div style="background-color: #00ff00; color: black; padding: 5px; margin: 10px auto; width: 80px;">Multiple Use Devices</div> <p>Reprocessing poses no major challenges Validated procedures are mandatory</p>
Labelled as single-use	Labelled as multiple-use	

In an atmosphere of legal uncertainty and deliberately stoked fears of possible health risks, hospitals and patients are alienated by the alleged trade-off between patient safety and cost effectiveness. Therefore, many hospitals hesitate to reprocess medical devices which are reprocessable but labelled by the manufacturer as 'single-use' – and miss out on huge cost saving potential. Others reprocess their devices in-house, without any specified procedures and quality management – with this unqualified approach putting patient safety at risk.

Patient Safety, Cost Reduction and Environmental Benefits

Today, this alleged trade-off can be surmounted. Over the last ten years a fast growing, highly innovative industry of third-party reprocessors has evolved in Europe, guaranteeing a high level of patient safety while at the same time reducing costs and realising environmental benefits:

- **Patient Safety:** Reprocessing companies have developed validated reprocessing methods guaranteeing that the reprocessed medical devices leave their premises in an impeccable hygienic and functional condition. They follow documented and well-defined reprocessing procedures. Devices are cleaned, disinfected, inspected, and sterilised. Furthermore, the function of every device is checked before it is sterilised and returned to the client, in order to guarantee a level of patient safety at least comparable to the new product. The traceability of the reprocessed device is guaranteed by a tracking software.
- **Cost Savings:** Through special reprocessing of 'multiple-use devices limited term' ('a new' EAMDR category as described above) cost savings on a substantial scale can be achieved. EAMDR estimates that cost savings of about € 5 billion a year could be achieved within the EU by making use of the existing potential of medical device reprocessing. The annual potential savings accruing from re-use are an estimated € 45,000 for smaller hospitals and up to several million Euros for large hospitals. For example, a new electrophysiological ablation catheter (originally labelled as single-use) for diagnostic treatment of cardiovascular constrictions costs between € 200 and € 2000; by reprocessing this device up to 50 % of these costs can be saved. In Germany alone, about 300,000 catheters are used each year: hence considerable savings can be made with reprocessing this medical device alone.
- **Environmental Benefits:** An increased re-use of medical devices reduces hospital waste. Further environmental benefits result from optimising the use of resources for producing new medical devices and reducing the use of environmentally problematic material like PVC.

Current legal situation

Currently, the reprocessing of medical devices is not regulated at EU-level. Only some national legislations, as far as they exist, provide a coherent framework in some countries (e.g. Germany). Although standards governing reprocessing exist at international and

European level (ISO, EN), they often do not include instruments that are declared as 'single-use'. Nonetheless, many of them should also apply to the so called "single-use" devices.

Without a binding legal framework introducing quality standards and validated procedures, patient safety is at risk. Even prohibition of reprocessing will not help, but will set wrong incentives: A recent study from Spain shows that although the reprocessing of single-use devices is prohibited, 85% of Spanish hospitals reprocess medical devices labelled as single-use – without any legal or validated quality standards. Prohibition has proven to not favour safety.

The introduction of high quality standards and the obligation of validated procedures is a better way of regulation. This can be seen in Germany where respective regulation and control has been implemented for the past few years. Denmark and the Netherlands have chosen the same path.

Due to patient's free choice to use medical services in different countries of the European Union, there is an obligation of quality standards in treatment and for the used technical equipment in health care.

However, as long as there is no European or national regulation, patient safety is at risk and the largest part of the above mentioned potential for cost savings and environmental benefits remains unused. Therefore, EAMDR is working together with national and European legislators and key stakeholders to establish a legal framework for medical device reprocessing throughout Europe in order to develop the essential quality standards.

Regulative Considerations and Suggestions

For finding objective criteria to define whether a medical device is re-usable or not, some national regulations introduced the so called risk categories for medical devices. By help of this classification of instruments, it is possible to create safe and efficient systems for reprocessing all medical device independent of the manufacturer's declaration.

Although the approach of introducing the de-facto-category of multiple-use devices limited term (as introduced above, see figure page 3) seems logical at first glance – since the manufacturers decide on the labelling – , this would only be another source of insolvable practical problems. Most likely, such a regulation is going to be controversial and could lead – in the worst case scenario – to a series of legal actions of the reprocessing industry against the manufacturers banning single-use labelling for several thousand medical devices. Moreover, both the medical device industry and the medical device reprocessing industry are highly innovative and dynamic. Therefore, the number of devices labelled as single-use which will be made re-usable by the reprocessing industry is likely to increase over time.

To summarise: The label categories single-use, multiple-use (limited term) and multiple-use (long term) serve for understanding medical device reprocessing but are an inappropriate link for regulation.

Focus on quality standards and validated procedures

To avoid these problems, EAMDR recommends that the focus of national and European legislation on medical device reprocessing should lie on quality standards and validated procedures for reprocessing based on proper risk assessment – instead of on labelling. Valuable experience has been made in countries such as Denmark, the Netherlands and Germany: German regulation does not refer to the type of labelling but introduces risk categories for medical devices and requirements for reprocessing which have to be fulfilled and certified by an accredited body. These requirements apply to any type of medical device, no matter which label the manufacturer has chosen. In other words, the labelling single-use or multiple-use should not be interpreted as being part of the devices' earmarking, it is just a noncommittal recommendation the manufacturer has made – sometimes even for irreproducible reason. This regulation increases patient safety and sets incentives to further develop innovative procedures for medical device reprocessing. Further it offers manufacturers an incentive to design products with a higher life cycle.

Therefore, the EAMDR calls upon national governmental authorities and the European Commission to clarify that the manufacturers labelling of a medical device as single-use is considered to be disproved should a validated procedure for the reprocessing and re-usability of a medical device has been demonstrated to a national authority or a notified body.

Such a regulation would clarify the procedure on how to verify whether a product is re-usable or not and therefore avoid bureaucratic struggles for the definition of the adequate labelling of thousands of medical devices. The label single use would lose its guidance role if a procedure for a safe re-use has been acknowledged.

Liability Solution

The liability for reprocessing will be allocated between the manufacturers and the reprocessing industry:

- In those cases where the original manufacturer decides to provide a validated procedure for reprocessing, he is responsible for the implications of reprocessing along the guidelines provided.
- In those cases where independent professional reproprocessors develop validated procedures for reprocessing, the reproprocessors can be held responsible for the implications of reprocessing along the guidelines provided.
- If no validated procedure has been acknowledged by national authority or a notified body, the reprocessing should be prohibited.

Closing request

The development of the health care market with regard to medical devices and increasing reprocessing show that patient safety and economic savings cannot be complied with without a framework. EAMDR calls upon the national governments and the European Commission to analyse how a European regulation as recommended above can be implemented at national and European level. High quality reprocessing in all member states can only be guaranteed if it is done independent of the labelling chosen by the manufacturer. It has to be kept in mind that reprocessing in general is an important part for the provision of hygienic, fully functioning and safe medical devices for being used in a patient. It contributes significantly to the success of the treatment.

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