Reprocessing medical devices – Yes or No?

The reprocessing of medical devices is neither explicitly prohibited nor allowed in the EU due to the fact that Appendix I of the Medical Device Directive (MDD) does not contain any specific wording on this matter. In edition 5/2010, we discussed the report of the European Commission to the European Parliament on reprocessing. In the meantime, the European Commission has received a mandate from the European Parliament to arrive at a common European solution by the middle /end of 2012. The latitude in this respect is currently interpreted very differently across the EU.

Germany currently allows the widest scope for the reprocessing of medical devices and regulates the procedure nationally through guidelines and standards. The Federal Ministry of Health does not regard the expression "for single use only" as part of the device's intended purpose. The reprocessed device is not regarded as a remarketing of the device. Liability in this case passes to the operator and the CE mark becomes invalid, but is also not necessary.

Sweden has also regulated reprocessing nationally, however in accordance with the EU directives. A reprocessed single-use product is seen as an in-house product and therefore the reprocessing entity is deemed to be an in-house producer. Consequently, it must meet the requirements of the MDD. The patient is also informed of the re-use and must consent accordingly.

On the other hand, in France the reprocessing of single-use products has been prohibited by law since 2001. CE-marked single-use products have had their purpose defined by the MDD as being for "single use", which prohibits re-use. Currently, no one knows whether reprocessing after recasting is completely prohibited or permitted like the German model – or whether a middle course is taken which strictly regulates the circumstances under which reprocessing is permitted.

A defender and critic of the current practice in Germany each express their views here exclusively for meditec INTERNATIONAL. *Ramona Riesterer*

Comment by Robert Schrödel:
"For over ten years, Germany has been reprocessing highly complex medical devices, quite independently of whether the device is marked as a multiple-use device or not. The crucial factor determining whether or not a device may be reprocessed and used again is solely whether reviewable validated procedures can, in every respect, maintain the safety of the patient and of the associated intervention as regards both hygiene and functionality.

"The trend turnaround has taken effect"

Robert Schrödel, Chairman of Pioneer Medical Devices AG and President of the European Association for Medical Device Reprocessing (EAMDR)

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The single-use medical product industry has resisted this bitterly for years, but now a trend turnaround has taken effect. Ethicon Endo-Surgery, part of Johnson & Johnson, has just bought the US American reprocessing company SterilMed and two years ago, Stryker hit the headlines with its acquisition of Ascent Healthcare.

The European Commission is currently preparing a 'recast' of the MDD which will create a binding regulatory framework for the reprocessing of single-use medical devices in Europe. The advantages are patently obvious. Besides the potential for cost savings of up to 50%, the use of environmental resources is effectively cut back and contaminated waste is avoided.

I welcome stringent rules, because black sheep reprocessing of medical devices damages the image of the entire system. To attempt a comparison - if accidents are caused on motorways by excessive speeding, the solution is not to ban car driving but instead to penalise irresponsible driving conduct in good time. Although I am in favour of the pan-European regulation of reprocessing, in my view the future lies in the development of ultra-complex medical devices with integrated reprocessability. In this respect, we are the first German company to combine production and reprocessing under one roof to the extent that the reprocessing of Pioneer medical devices is already enshrined in the CE."

Comment by Dr. Jürgen Gauer:

"Patients are entitled to expect every action to be taken to rule out any preventable treatment risk. Ultimately, the question is whether the reprocessing of single-use products represents a risk which can and should be medically and ethically acceptable.

Certainly, an across-the-board ban on the reprocessing of single-use products would be a step which I would tend to regard as political. Any reprocessing of single-use instruments is indissolubly linked to questions on reprocessing quality and the resilience of the materials the instruments are made of.

Instrument surfaces easily accessible to the cleaning solution can reliably be purged of contaminants. However, a great problem is posed by the reprocessing of complex single-use instruments, such as are used in micro-invasive surgery, for example. Narrow lumina with internal activation devices present a major obstacle to (or completely prevent) flushing with a cleaning solution. Also, any lubricants important for instrument operation which are present are washed out during reprocessing and the materials are fundamentally compromised by the reprocessing procedure.

This touches on a further challenge for reprocessing - that of totally uncompromised instrument functionality. The mechanical stability of instruments which are commonly made from plastic materials is a crucial aspect here. The surgeon familiar with the properties of an instrument will swap the instrument for another if there is any incalculable change to these properties, which may go as far as malfunction.

There is no group of doctors that would not harbour reservations concerning the use of reprocessed single-use instruments on themselves or family members." (Survey: GfK HealthCare) ←

"Every avoidable treatment risk must be ruled out"

Dr. Jürgen Gauer, Physicist, QM Research Head, SMP GmbH Service für Medizinprodukte

German Summary

Die Wiederaufbereitung von Medizinprodukten ist in der EU nicht eindeutig verboten oder erlaubt, weil in Anhang I der Medizinprodukte-Richtlinie (Medical Device Directive, MDD) nichts Spezifisches dazu formuliert ist. In Ausgabe 5/2010 hatten wir den Bericht der Europäischen Kommission an das EU-Parlament zur Aufbereitung zum Thema. Zwischenzeitlich hat die EU-Kommission ein Mandat vom EU-Parlament erhalten, bis Mitte/Ende 2012 eine gemeinsame europäische Lösung zu erarbeiten. Aktuell wird der Spielraum in der EU sehr unterschiedlich ausgelegt. Ein Verteidiger und ein Kritiker der derzeitigen Praxis in Deutschland melden sich hier exclusiv für meditec INTERNATIONAL zu Wort. Zu Wort kommen Robert Schrödel, Vorstand der Pioneer Medical Devices AG und Präsident der European Association for Medical Device Reprocessing (EAMDR) und der Physiker Dr. Jürgen Gauer, Forschungsleiter QM, SMP GmbH Service für Medizinprodukte. Der deutschsprachige Beitrag ist nachzulesen auf www.meditec-international.com/medi0112yn