

Progress Report June 2010

LNE/G-MED: Sharing a Passion for Progress

Reuse of Single-Use Devices: Recognizing the Business and Risk Issues of this New Reality

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Hospitals and other medical providers point to cost savings and the reduction of environmental waste as key reasons for favoring reuse of medical devices – even those labeled specifically for single use.

Despite labeling a device as single use, manufacturers have little ability to prevent the third party reprocessing of their devices once in the possession of their customers. Yet, such manufacturers still need to be aware of continual regulatory, business and other implications resulting from how significant portions of their devices are used.

For manufacturers selling in Europe, two recent items bring new light to this issue:

- Last month's release of an European Union Scientific Committee opinion paper
- Added labeling requirements in Directive 2007/47/EC for single-use device (SUD) manufacturers, as well as a European Commission (EC) report to be provided later this year.

In this month's newsletter, find out the potential hazards associated with device reuse and what manufacturers can do to safeguard patients, minimize liability and provide for safe use of their devices.

Competing Business Interests

The reuse of SUDs appears as a pure contradiction. After all, who knows better than the manufacturer what risks are associated with the re-use of its products? If the manufacturer has decided to provide the product as single use, doesn't that automatically imply reusing it inherently unsafe?

That's one possibility. However, the European medical device regulations don't require a company to weigh in on the feasibility and efficacy of reuse. Therefore, a manufacturer could decide not to certify its device for multiple use for a variety of strictly business reasons as opposed to those involving safety. That gives hospitals and providers justification for having their single-use products recycled, particularly as proponents claim reprocessing is technically achievable without increasing significantly the risks associated with the re-use of the device.

A May 2008 study of nearly 400 Canadian hospitals (*Infection Control and Hospital Epidemiology*) found that as many as 28% reused single-use items, much of it performed in-house. As hospitals and medical practices face increasing cost pressure, as well as initiatives to reduce medical waste, manufacturers could find it to their advantage to provide reprocessing services (or partner with companies that do). In

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this way, manufacturers may even be able to share in that post-sale revenue and maintain better control over the reprocessing.

Those manufacturers that offer reusable medical devices must provide reprocessing instructions, backed up by evidence citing safety and the performance of the reused device. Clear guidelines can be found in harmonized standard [EN ISO 17664: 2004](#) (Sterilization of Medical Devices - Information to be Provided by the Manufacturer for the Processing of Resterilizable Medical Devices).

Risks Associated with Reuse

However, reuse isn't appropriate in all cases. The European Commission (EC), through one of its committees, recently concluded that certain medical devices are unsuited to reprocessing and reuse, in: [The Safety of Reprocessed Medical Devices Marketed for Single Use](#).

The opinion, adopted on April 15, 2010 by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), examines the main risks associated with re-use, which fall into the following two categories:

- Inadequate sterilization or cleansing of the devices. Reusing devices invites the possibility of cross contamination of biological agents. Sterilizing all such agents in small or complex devices can vary in difficulty. An even greater challenge is removing or inactivating prions, such as those that cause transmissible spongiform encephalopathies (TSEs) or Creutzfeldt –Jakob disease (CJD). Prions are particularly resistant to commonly used methods of cleaning. Finally, the chemical agents used during the sterilization process, if not completely rinsed away, can also pose a serious risk.
- Change in Functionality of the Device: The sterilization process can also affect the integrity of reprocessed devices, degrading or weakening plastic in a way can lead to device failure.

The SCENIHR report cites a handful of studies that demonstrate specific effects of reprocessing on certain devices, which could be a valuable resource to manufacturers.

http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_027.pdf

Regulatory Perspectives

The issue of reusing SUDs is not regulated at the European Union level and legislation in Member States differs. Nevertheless, the directive 2007/47/EC introduces a new article (12a) to the Medical Device Directive, which requires the European Commission to present a report on this topic, as well as any additional proposal it deems appropriate.

Documented Adverse Events Associated with SUD Reuse

In a review of the FDA database by Industry newsletter *RAJ Devices*, 434 adverse events related to the reuse of SUDs, were found from December 2005 and July 2006, including 65 where device reuse was considered casual.

A separate presentation at a December 2008 workshop in Brussels provided actual examples that illustrated the range of potential risks:

- Death of a nine year old boy by blockage of a reused breathing tube
- Patient death by Creutzfeld-Jakob's disease after infection by a reused endoskop [endoscope]
- Cluster of tuberculosis cases in North Carolina: possible association with atomizer reuse
- A pseudo-outbreak of aureobasidium species lower respiratory tract infections caused by reuse of single-use stopcocks during bronchoscopy
- Unintended events in anesthesia due to reuse of disposable equipment (Tracheal tube introducers)
- Severe patient injury following cuff rupture after reprocessing a tracheal tube

Source: [Is there proof for the safety of reprocessed single use devices?](#) Dr. Hans Haindl

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Already, directive 2007/47/EC modified the Essential Requirements applicable to SUDs in two areas:

- the same device cannot be offered in Europe in both single use and reusable versions (E.R.# 13.3.f);
- if a device bears an indication that it is for single use, the manufacturer must provide information on known characteristics and technical factors that could pose a risk if the device were to be re-used (E.R. 13.6.h).

This last point serves as the main method of alerting reprocessors to the potential impact of reprocessing. By knowing which risks were identified by the manufacturer, the reprocessor may setup the relevant validation and in-process inspections.

Whereas previously, the reprocessor held the entire responsibility for the safety of a SUD, directive 2007/47/EDC effectively shifts some responsibility to manufacturers to explicitly warn about the device characteristics that present specific hazards related to reprocessing.

As regulators, providers and reprocessors continue to weigh on the issue of SUD reuse, device manufacturers would be wise to recognize the business, safety and liability issues facing them.

A World of Views on Medical Device Reprocessing

A workshop in Brussels in 2008 focused on the reprocessing of medical devices. The European Commission has all of the presentation slides posted on its [Enterprise and Industry Newsroom page](#), including:

- How to assess whether the design of a single use medical device allows appropriate cleaning and sterilization
- Workshop on the reprocessing of medical devices medical devices
- French Association for Sterile Supply viewpoint
- Hygienic requirements for the reprocessing of medical devices
- Economic study on the impact of reprocessing of single-use medical devices in Belgium
- Workshop on reprocessing of medical devices
- Re-use of single use of medical devices
- Danish experience and considerations on the reprocessing of single use medical devices
- How to assess whether the design of a single use medical device allows appropriate cleaning and sterilization
- Report on reprocessing of medical devices in Germany
- Reprocessing of medical devices (single use) - UK viewpoint
- Is there a proof for the safety of reprocessed single use devices? (See box above)
- Legal and ethical aspects of reprocessing single-use medical devices

Direct Link to Presentations: http://ec.europa.eu/enterprise/newsroom/cf/itemshortdetail.cfm?item_id=3280

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