

Background information: Reprocessing in the United States – A desirable model for other countries?

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Reprocessing of both multiple use (reusable) and disposable (“single use”) medical devices (SUDs) is common in the United States. Whereas the reprocessing of reusable devices is generally done by hospitals within the hospital’s own central sterile department, SUD reprocessing is predominantly performed by third-party reprocessors. The debate between original equipment manufacturers (OEMs) and third-party reprocessors is ongoing and U.S. Food and Drug Administration (FDA) regulations over the practice are constantly being adapted or amended. The result is that over the years, a regulatory structure has developed in the U.S. whereby the reprocessors are now more stringently regulated than even the original manufacturers, reports Dan Vukelich, Executive Director of the U.S. Association of Medical Device Reprocessors (AMDR).

Accreditation System in the U.S.

In the U.S., the labelling of a medical device (either reusable or single-use) is not designated by the FDA, but is chosen by the manufacturer. The 1980s marked a shift by the OEM of labelling devices from “reusable,” to “single use,” without substantive changes being made to the devices themselves (if at all). The trend to mark more and more devices as “single use” rather than as reusable is on-going. The U.S. General Accounting Office (GAO) found that hospitals distrust OEM use of the “single use” label because manufacturers seem to have an economic incentive to label their products as SUDs: FDA clearance of a SUD requires only that the manufacturers show it is safe and effective for one use, making the procedure for clearing a “single use” device far easier and less expensive than for multiple use devices (MUDs). The result is that many hospitals in the U.S. have turned to third-parties to reprocess their SUDs.

Facts & Figures¹

- Providers: Ascent Healthcare Solutions and SterilMed are covering third-party reprocessing market with a total share of together 95%.
- Market: 1,400 health care facilities throughout the U.S. and Canada including major hospital networks and group purchasing organizations, with 2 million reprocessed devices per year, altogether 7 million devices till now.
- Savings: 40 million dollars per year, altogether 120 million dollars within the last three years; preventing around 585 tons of waste per year, altogether 1,750 tons of waste till now.
- Safety: 13 out of 14 nation's "Honor Roll" hospitals (i.e. Johns Hopkins University) use reprocessed devices, so do all ten hospitals considered by U.S. News & World Report to be the top ten heart and heart surgery hospitals in the U.S.
- Products: 68 products can lawfully be reprocessed in the U.S. (listed by FDA).

Continuous Legislation

Until 2000, third-party reprocessors had to comply with all manufacturer requirements except for premarket review requirements. Up until 2000, FDA repeatedly noted the complete lack of evidence indicating that reprocessed devices had caused adverse clinical outcomes. With the emergence of third-party reprocessors during the 1990s, however, manufacturers' lobbying activities for regulation of reprocessing increased, often using campaigns that made the public believe that reprocessing is a threat to patient safety.

In 2000, FDA decided that reprocessors (both third-party and in-hospital) had to meet *all* manufacturer requirements, including premarket review which meant that all reprocessors needed to also obtain FDA clearance before marketing certain devices.

In 2002, reprocessors, but not manufacturers, had to meet additional requirements, including increased validation data and labelling requirements. Exemptions from premarket submission requirements were terminated for reprocessors but not for OEMs.

In 2005, a device marking requirement was applied to reprocessors but not to OEMs. The result is that today reprocessors in the U.S. are more stringently regulated than even the

¹ Based on SterilMed data, 2005.

original equipment manufacturers, thereby creating an unlevel playing field, not only between reprocessors and manufacturers, but also among reprocessors: as of today, there is still no FDA regulation for in-hospital reprocessing of MUDs in the U.S.

Whereas in the beginning these requirements placed additional strains on reprocessors' business, today, the practice of reprocessing is commonplace among America's top health institutions. Hospitals are assured, by FDA oversight, that reprocessed SUDs are as safe and effective as original equipment.

Different Approaches

Protecting public health and patients' security is the overall principle of both, the European and U.S. American system. However, EU legislation is also dedicated to the principles of the single European market and is currently developing a comprehensive approach on validation and certification requirements throughout the whole European Union.

As a result of the FDA regulation, the expensive trend towards placing even more single use products on the U.S. market in comparison to the EU market has been significant. Consequently, it places even more stress on the health care budget. The AMDR regards the regulations in some EU countries (i.e. Germany) as more supportive for the health care system and thus more appropriate.

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