

### Reprocessing Single Use Medical Devices: A Manufacturer's Viewpoint

Prior to the 1960's, most medical devices were made of stainless steel and other durable materials. These reusable products required disassembly, cleaning, decontamination, and resterilization between patient uses. With the development and availability of many types of plastics in the 1960's, hospitals began to request a larger selection of convenient, sterile, low-cost disposable items. To accommodate these requests, manufacturers explored the possibilities of the development of sterile, single use devices (SUDs).

The research and development process for new medical devices includes:

- Customer need
- Design and engineering
- Sterilization process
- Clinical trials
- FDA guidelines
- Production and packaging considerations

Product development may take five years or more.

The intended use of a product is a key consideration. In order to design a product for reuse and/or resterilization, the materials should be resistant to heat, distortion, warping, and corrosion. Gas sterilizable items should be resistant to chemical and physical changes due to repeated exposure to the gas or its diluents at sterilization conditions.<sup>1</sup>

Materials selected for a SUD do not include the requirement of reprocessing, nor do the components need to withstand repeated use. Instead, the focus is on appropriate materials, components, and packaging that provide single use, high-volume convenience to the user. Manufacturers choose the most cost-effective materials that will still provide customers with the quality, safety, and reliability they need and expect. Plastics chosen for SUDs generally will have a significant reduction in strength as well as increased embrittlement, if subjected to the high temperatures of an autoclave. Other chemical reactions may occur if the item is repeatedly exposed to ethylene oxide (EtO), hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>), or other sterilization methods. Even small temperature increases during any type of sterilization cycle could intensify chemical reactions.

The research and development process does not stop there. Once the initial design is completed, and product performance has been confirmed, an extensive process of validating the design takes place.

- **SUDs** are designed to be assembled only once, by the manufacturer. They must demonstrate safety and capability for one use. As an example, validation of a single use electrosurgical pencil would include, among other things, a minimum number of insertions of the plug into an electrosurgical generator and a specified number of cut and coag on/off activations equivalent

© Valleylab 2001



Jan Fickling RN, CNOR  
Clinical Product Specialist



Jennifer Parsons RN  
Clinical Product Specialist



Cherie Ryan Loeffler RN, BSN, CNOR  
Clinical Product Specialist

Clinical Information Hotline News is a free service provided by Valleylab for the advancement of perioperative safety. To request additional copies, please contact:

#### Clinical Information Hotline

1-800-255-VLAB (8522) x2005

clinical.hotline@valleylab.com

For Hotline News-www.valleylab.com

For Accredited Continuing Education-www.valleylabeducation.org

to what would be expected during one surgical procedure. SUD validation also includes at least one sterilization method (such as EtO or ionizing radiation) that must assure a SAL (Sterility Assurance Level) of  $10^6$ . (The probability of microorganism survival of  $10^6$  means that there is less than or equal to one chance in a million that a particular item is contaminated or nonsterile. It is generally accepted that a sterility assurance level of  $10^6$  is appropriate for items intended to come into contact with compromised tissue<sup>1</sup>). The packaging that will protect the product and its sterility during shipment and storage must also be validated. The requirement for disassembly, cleaning, and multiple sterilization cycles are not part of the validation testing for SUD products.

- A **reusable** electrosurgical pencil on the other hand, would require more rigorous function testing and would include validation for disassembly, cleaning, disinfecting, reassembly and one or more sterilization method(s) such as EtO, steam, low temperature gas plasma, or peracetic acid. The number of reprocessing cycles that the customer may expect during the life of the product should be validated and noted in the instructions for use for that product. All these qualities and capabilities must be designed into a reusable product by the selection of materials and components for the intended reuse and reprocessing.

Some devices cannot be safely or economically produced with plastics and have continued to be available only as reusables. In certain cases, manufacturers are able to supply reusable and disposable versions of the same item. The products may look very similar, but their materials and components are different and have been designed for the intended use shown on the product labeling. A few products on the market are “reposable” or “limited reuse” items. This type of product should be clearly labeled as such. The label and instructions for use should include validated reprocessing guidelines and may include the number of expected uses. Manufacturers generally will accommodate kit packers by providing single use items in nonsterile bulk. The kit packers will then assume the responsibility as the primary sterilizer using specific guidelines as recommended by the manufacturer (usually EtO or ionizing radiation) and in accordance with regulatory guidelines.

Ultimately, the customer has the final choice in the selection of reusable, reposable, or SUDs. Should your hospital plan to develop a reprocessing protocol for single use devices or plan to use a third party reprocessor, the product must undergo the same testing and verification steps required by the original manufacturer. The U.S Food and Drug Administration (FDA) views any reprocessor as a manufacturer and, as such, subject to federal regulations.<sup>2</sup>

These regulations include:

- Registration and listing
- Medical device tracking
- Medical device reporting
- Corrections and removals
- Device labeling
- Quality system regulation
- Premarket notification requirements<sup>2</sup>

The decision to reuse SUDs may be time consuming and financially prohibitive.

According to the AORN Guidance Statement: “Reuse of Single-Use Devices:”

- If a device cannot be cleaned, it cannot be reprocessed and reused.
- If sterility of a post-processed device cannot be demonstrated at a  $10^6$  level, the device cannot be reprocessed and reused.
- If the integrity and functionality of a reprocessed, single use device cannot be demonstrated and documented as safe for patient care and/or equal to the original device specifications, the device cannot be reprocessed and reused.<sup>2</sup>

So why can't manufacturers provide reprocessing instructions for devices labeled single use? Simply stated, the device was not designed and is not qualified for that purpose. The original manufacturer will not have guidelines to follow because the product was not designed or intended for reuse and/or reprocessing.

References:

<sup>1</sup> Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers, “Sterilization efficacy test”, Association for the Advancement of Medical Instrumentation (Arlington, VA, 1994) 30-31.

<sup>2</sup> “AORN Guidance Statement: Reuse of Single-Use Devices,” AORN Journal (Denver, CO May 2001) <http://www.aorn.org/about/positions/Reuse.dpf> (Accessed April, 2001)



**Clinical Information  
Hotline News**

is also available for  
viewing and printing from  
our website:

**[www.valleylab.com](http://www.valleylab.com)**