Chapter 12. Interventions To Allow the Reuse of Single-Use Devices: Brief Review (NEW)

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Introduction

Many hospitals choose to reprocess single-use devices (SUD)—those intended by the manufacturer to be discarded after one use—for reuse in additional patients. Reprocessing includes cleaning, sterilization, and if necessary, refurbishing. Specific information on the size of the reprocessing industry is not available. According to the Association of Medical Device Reprocessors Web site, disciplines that commonly use reprocessed devices include: cardiovascular; arthroscopic/orthopedic; general surgery; gastroenterology; laparoscopic surgery.

A wide variety of SUDs are reprocessed. Commonly reprocessed SUDs include: arthroscopic shavers; biopsy forceps; blood pressure cuffs; clamps and dissectors; compression sleeves; electrophysiology catheters; external fixation devices; laparoscopic scissors and forceps; opened but unused items; orthopedic drill bits and burrs; phaco tips; pneumatic tourniquet cuffs; pulse oximeter sensors; scissors and staplers; soft tissue ablators; trocars. Opened but unused items are not technically reused but also must be reprocessed.

Using SUDs is money-saving and generally thought to be safe. However, SUDs are only required to be demonstrated to the Food and Drug Administration (FDA) as safe for one use; some manufacturers and the Medical Device Manufacturer’s Association contend that reusing SUDs is unsafe because the devices are frail and cannot be adequately cleaned and resterilized. Potential risks to patients include infection, toxicity, particulate contamination, and mechanical failure.

Although reuse of single-use devices is common and perhaps even pervasive, little evidence on its safety and efficacy has been published. To gather the available evidence, a literature search of PubMed was conducted for English language articles published between January 1, 2001 and November 2, 2011.

What Are the Practices for Assuring the Safety of Reused Devices?

Reprocessing used SUDs is subject to FDA oversight. On August 14, 2000, FDA issued a policy on the reuse of single-use medical devices making hospitals and third-party reprocessors subject to all the requirements of the Federal Food, Drug, and Cosmetic Act—a requirement formerly imposed only on original equipment manufacturers (OEMs). In response, many hospitals that had been reprocessing SUDs in-house began using third parties to reprocess the devices. Unused items are not subject to FDA oversight.

The Medical Device User Fee and Modernization Act of 2002 expanded regulatory requirements. Premarket notification submissions (510(k)s) for certain reprocessed SUDs identified by FDA must now include validation data. Validation data include cleaning, sterilization, and functional performance data, which confirm that each SUD will remain substantially equivalent to a predicate device after the maximum number of times the device is reprocessed. In addition, the reprocessor must be indicated with a mark or label for each reprocessed SUD.
According to FDA regulations, “a third-party or hospital reprocessor must comply with the same requirements that apply to original equipment manufacturers, including:

- Submitting documents for premarket notification or approval for each device and model reprocessed
- Registering as a manufacturer with FDA and listing all products
- Submitting adverse event reports
- Tracking devices whose failure could have serious outcomes
- Correcting or removing from the market unsafe devices
- Meeting manufacturing and labeling requirements.”

The FDA considers hospitals that reprocess devices as device manufacturers subject to the requirements of the Quality System (QS) Regulation. However, most hospitals who use reprocessed SUDs obtain them from third parties who perform the reprocessing. An estimated 95% of reprocessing in the U.S. is completed by two firms, Stryker Sustainability Solutions (formerly Ascent Healthcare Solutions, Phoenix, AZ) and SteriMed Inc. (Minneapolis, MN). According to their Web site, Stryker claims the majority of the reprocessing market and has over 2,000 hospital members. Their service includes delivering orders and picking up used equipment (which hospital personnel leave in marked bins), and at their facility, sorting, cleaning, refurbishing/repairing, repackaging, and resterilizing equipment. The FDA has cleared or approved a variety of sterilizing agents that can be used in reprocessing and inspects reprocessing facilities for compliance with regulations, with steep penalties for violators.

How Have These Practices Been Implemented?

Reprocessing protocols in the peer-reviewed published literature vary but generally include cleaning and sterilization. Cleaning may consist of manual or automated washing with water and detergent or enzymatic solution. Sterilization may entail pressurized steaming (i.e., in autoclave), ethylene oxide (especially for heat sensitive items) or gamma radiation. Quality assurance is intended to verify sterilization success. The FDA urges the use of biological indicators to verify that test organisms are killed. Chemical indicators verify that sufficient temperatures were achieved or sterilant was present in the sterilizer in each sterilization run. Repairs and part replacements should be made as necessary. The FDA does not require the use of particular protocols, but may prefer standard procedures such as those recommended by the Association for the Advancement of Medical Instrumentation.

Reprocessing is performed in hospitals or by independent third parties at separate facilities. Data suggest the majority of hospitals that reprocess devices use third parties. When such a vendor is used, implementation for the hospital should not pose challenges. Personnel must remember to place used devices in bins provided by the reprocessing vendor; the vendor provides pick up, reprocesses the items, and delivers ready-to-use items. Ordering reprocessed devices should not differ from ordering new devices.

What Have We Learned About These Practices?

Cleaning. Theoretically, cleaning should remove all debris and sterilization should inactivate potentially infective viruses, bacteria, and fungi. Literature searches performed for this review identified nine laboratory studies published in the last 10 years that tested an array of reprocessed SUDs for microbiological contamination. Devices studied included laparoscopic instruments.
various catheters, trocars, sphincterotomes, diathermy pencils, and tracheostomy tubes. While most studies could not demonstrate microbial contamination after reprocessing, four found that reprocessed SUDs were contaminated. Two of the studies also reported damage, incomplete kits, and/or compromised functioning. Another study assessed cleaning to remove test soils from biopsy forceps and found up to 95% of the material was removed.

**Effect on patient outcomes.** The literature search spanning the last 10 years identified only one randomized controlled study that compared new and reprocessed SUD laparoscopic instruments used to perform cholecystectomy; the study found no significant differences in outcome. This study is small (125 patients) and may be underpowered to detect rare events. A single study may not be representative of outcomes in general; devices and protocols will vary.

A meta-analysis of nine studies that compared new and reprocessed hemodialyzers found reuse was associated with an increased risk of hospitalization but no difference in mortality. The U.S. Government Accountability Office (GAO) published a report in January 2008 discussing FDA oversight of reprocessed SUDs and the available information on the potential health risks of using reprocessed SUDs. The report concluded: “The limited number of peer-reviewed studies related to reprocessing that we identified were insufficient to support a comprehensive conclusion on the relative safety of reprocessed SUDs. Despite the limitations of available data, FDA’s analysis of reported device-related adverse events does not show that reprocessed SUDs present an elevated health risk.”

**Cost savings.** If using reprocessed SUDs is as safe as using new devices, saving costs on materials would free hospital resources for other uses without compromising patient safety. Our searches identified four cost studies published in the last 10 years. A modeled European study found that the cost savings for reprocessing cardiac electrophysiology catheters was 33% for ablation applications and 41% for diagnostic. A modeled Canadian study found savings of $0 to $739 per year per patient when hemodialyzers were reprocessed. Hemodialyzers are typically reused only by the same patient. A meta-analysis of nine studies in which various devices were used had an overall savings rate of 49%, but stipulated that the few studies identified were of poor quality and had missing data, including adverse event cost data. A meta-analysis of nine studies that compared new and reprocessed hemodialyzers found reuse was associated with small cost savings, an increased risk of hospitalization, and no difference in mortality. The Stryker Web site states that member hospitals can save 50% over purchasing new equipment in acquisition costs, and 70%–80% in operating room medical waste disposal costs. Reusing devices should also reduce wastes for landfill.

**What Methods Have Been Used To Improve These Practices?**

Healthcare Risk Control (HRC) is a service ECRI Institute offers for risk managers. HRC provides resources for a variety of patient safety issues, and specifically recommends that hospital systems considering use of reprocessed SUDs should “at a minimum, establish written policies, procedures, and policies for such practices... [and] should be widely circulated throughout the organization.” They further recommend establishing a reuse committee comprised of individuals from multiple departments, including materials management, risk management and/or hospital legal counsel, infection control, clinical and/or biomedical
engineering, administration, central sterile supply, surgery, finance, and physician(s) advocating reuse.\(^1\) A third party reprocessor should be selected based upon registration with the FDA and compliance with FDA regulations; the types of devices to be reprocessed; and support (including logistical support such as device pickup).\(^1\) Reprocessors usually provide template policies and procedures to hospitals to support implementation.\(^1\)

**Conclusions and Comment**

Reprocessing SUDs with appropriate quality controls should theoretically guarantee sterilization. Less information is available on the integrity of the devices themselves after reprocessing; the FDA recommends that reprocessors test all devices to ensure that functionality is maintained.

Some laboratory studies in the clinical literature found that various devices were not sterile; however, quality assurance should prevent unsterile devices from being reused. Some devices remained unsterile after multiple attempts; use of the protocols or reuse of the particular device warrants reconsideration in such circumstances.

Clinical literature and data on real-world use are currently not robust enough for the GAO or independent authors to firmly conclude that reused SUDs are safe. However, one systematic review found an increased rate of adverse events in patients treated with reused SUDs. The protocols in the peer-reviewed literature may differ from those used by third party reprocessors.

A summary table is located below (Table 1).

**Table 1, Chapter 12. Summary table**

<table>
<thead>
<tr>
<th>Scope of the Problem Targeted by the PSP (Frequency/Severity)</th>
<th>Strength of Evidence for Effectiveness of the PSPs</th>
<th>Evidence or Potential for Harmful Unintended Consequences</th>
<th>Estimate of Cost</th>
<th>Implementation Issues: How Much do We Know?/How Hard Is it?</th>
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<tr>
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<td>Low</td>
<td>Low</td>
<td>Low</td>
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**References**


