


Reprocessing: What's to Fear?

More hospitals are adopting medical device reprocessing programs. By Cheryl Schwanke, MBA

One of the tenets of environmental efforts is “reuse.” And more hospitals, looking to save cash and avoid unnecessary medical waste, are taking this tenet to heart with medical device reprocessing programs.

The reprocessing industry has experienced steady growth in recent years, and this trend continues as hospitals accept reprocessing as an effective way to save cash, as well as the environment.

More than 3,000 U.S. hospitals have adopted reprocessing as a standard of care. Moreover, it is not just the small or physician-employed facilities. The list of those who use reprocessing programs comprises many of the top 100 hospitals, as ranked by US News & World Report, including all of the “honor roll” hospitals and the top 10 cardiovascular hospitals. In addition, leading medical 



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▲ Many OR de can be reprocessed as well as EP catheters/cables and non-invasive devices, including pulse oximeter probes and compression sleeves. Photo courtesy SteriMed

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Regulatory oversight of the reprocessing industry has further safeguarded reprocessing, especially since the Medical Device User Fee and Modernization Act of 2002. This act requires a reprocessor's manufacturing, testing and quality processes be equal to the standards in place by the original equipment manufacturer.

organizations support the use of reprocessed devices, including American Academy of Orthopaedic Surgeons, American Society for Gastrointestinal Endoscopy, Association of Perioperative Registered Nurses and American College of Surgeons.

Many hospitals only reprocess a small range of devices in the operating room. Common reprocessed devices include pulse oximeter probes, compression sleeves and trocars. Since reprocessing has become more widely embraced, the interest in using a wider range of reprocessed devices has expanded to include items such as laryngeal masks and external fixation devices.

Reprocessing saves nearly 2.5 million pounds of medical waste from being sent to landfills each year. A typical 300-bed hospital would divert 35,000 pounds of medical waste from landfills and reduce device purchase costs up to 50 percent with savings of \$410 a bed, according to Brian Sullivan, President and CEO of SterilMed, a third-party reprocessor.

► Why Fear?

Of course, some hospitals and doctors don't like reprocessing for fear of infection and also trepidation over possible equipment malfunction.

However, regulatory oversight of the reprocessing industry has further safeguarded reprocessing, especially since the Medical Device User Fee and Modernization Act of 2002. This act requires a reprocessor's manufacturing, testing and quality processes be equal to the standards in place by the original equipment manufacturer (OEM). This means each reprocessed device must meet 510(k) standards for cleanliness, functionality and sterility.

Over the past 10 years, third-party companies have reprocessed millions of devices with no evidence, from any source, of an increased risk to patient safety. As Makary →

SterilMed uses microscopic analysis to ensure effective reprocessing. >

Photo courtesy SterilMed



et al stated in “A Call to Go Green in Health Care by Re-processing Medical Equipment,” which appeared in the March 2010 issue of *Academic Medicine*, “the practice has a reliable safety record of excellence identical to that of new equipment.”

In addition, a 2008 report by the Government Accountability Office (GAO) found no evidence to indicate that reprocessed devices present an elevated health risk to patients and no evidence linking usage of reprocessed devices and hospital acquired infections.

In some respects, reprocessors must meet ever stricter requirements than the OEMs. Since reprocessors will reprocess some devices several times, the companies must demonstrate that the device does not degrade during repeat reprocessing. Thus, each manufacturer needs to disassemble the device and put it back together, testing functionality, cleanliness and sterility.

> **Checking Functionality**

Different from OEMs that typically lot test, reprocessing standards requires that 100 percent of devices be inspected and tested using customized and FDA-validated procedures.

Functionality testing processes confirm durability and functionality after usage and reprocessing. Tests are device-specific and include mechanical and electrical tests such as sharpness, sealing pressure, spring actuation, component alignment, energy delivery, diagnostic and imaging functionality. In addition, companies also need to identify and refurbish device-specific physical degradation and potential

failure modes through reverse engineering. For example, SterilMed uses computer-controlled equipment to resharpen orthopedic shavers. It also microscopically hones bladed trocars and replaces pads for ultrasonic scalpels.

> **Choosing a Partner**

Not all reprocessing partners are the same, so we suggest using the following criteria when choosing your reprocessing company.

Device collection. Treating single-use devices like reusables enhances clinical acceptance while increasing the percentage of devices yielded from the reprocessing operation. Higher collections and yield equal fewer devices sent to the landfills.

Breadth of devices. Ensure your reprocessor has FDA clearance to reprocess devices for all OR departments, including cardiology, general surgery, orthopedics, urology as well as for GI and EP/cath labs. Reprocessed devices include compression sleeves, pulse oximeter probes, EP

catheters, lap instruments, ultrasonic scalpels, shavers and blades.

Material flow. Managing inventory is easier if your reprocessed devices are returned on a regular schedule. Make sure devices are returned automatically on a pre-scheduled basis, typically weekly or bi-weekly, depending on your facility's needs.

On-site support. Ensure that your reprocessing partner offers the necessary field support team, including regularly scheduled pick-up service, device care and handling support, as well as clinical in-services. Select a partner that will help maximize savings by optimizing implementation and driving continuous improvement.

To analyze the effectiveness of a reprocessing program, you need to follow the money. Cost savings of programs are typically measured in dollars per staffed bed and medical waste diverted from landfills. The more rigorous the process, the better the cost savings.

SterilMed has increased the savings of current customers by 15 percent annually over the past five years. For customers who fully embrace reprocessing, SterilMed increased savings by an average of 71 percent.

If physicians at your facilities are hesitant to consider using reprocessed devices, they should meet with reprocessing company representatives. Also, have them visit a reprocessor for a tour and demonstration. These experiences will help alleviate concerns about the safety of using reprocessed devices and the decision to “reuse” could save your organization cash in the process. **EI**

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