

IMPLEMENTATION MODULE:

Medical Device Reprocessing

Reusable to “Single-Use” to Reprocessed

Hospitals have accepted that third-party reprocessing of medical devices labeled “single use” is a safe and effective process that can help redirect valuable financial resources back into patient care while significantly reducing the volume of regulated medical waste generated by the organization. The US Food and Drug Administration (FDA) requires third party reprocessors to meet the same standards as originally manufactured single-use devices (SUDs).¹ The reprocessing industry has safely reprocessed over 50 million devices and prevented over 10,000 tons of medical waste from entering landfills between 1997 and 2007.² Reprocessing is now common practice, with all of US News and World Report’s “Honor Roll” hospitals choosing to reprocess single use devices,³ and 77% of Practice Greenhealth Award winners in 2010 choosing to reprocess medical devices with a combined savings of over \$10.8 million dollars.⁴ Original equipment manufacturers, however, continue to drive efforts to stop the adoption of this program touting patient safety concerns while quietly acknowledging that reprocessing can severely impact their bottom lines. Practice Greenhealth supports reprocessing as an environmentally beneficial, clinically proven, patient-safe method of reducing waste while also reducing cost to the healthcare organization.

Hospitals historically reprocessed a myriad of medical devices onsite in the Sterile Processing Department. Over time, as equipment changed from durable materials like stainless steel to plastic versions, different hospitals utilized different standards for onsite reprocessing and FDA became concerned about the lack of standardization among reprocessing procedures. As a result, FDA—the oversight authority for medical devices and equipment, created new stringent standards for reprocessing of medical devices. Concurrently, concerns around infection prevention and healthcare-associated infections (HAIs) grew, and many of

the original equipment manufacturers (OEMs) began to market a set of products labeled “single-use”—a label not required by the FDA. Many of these products appeared to be similar or identical with little to no change in product formulation to products once reprocessed onsite at hospitals, only with a new label that indicated they should be disposed of after a single-use. Many hospitals, struggling to meet the new stringent standards for onsite reprocessing and confused about whether devices labeled single-use were acceptable to reprocess, began using greater volumes of the disposable devices and discontinued the vast majority of onsite reprocessing.

A new service industry arose in 1997, called third party reprocessors—these companies collected a set of devices (many now labeled “single-use”) specifically approved by the FDA and reprocessed them, making them available for resale to hospitals. Each and every device was cleaned, function-tested, packaged and sterilized then returned to the hospital for purchase at a significantly discounted price. Third party reprocessors were tightly regulated and reviewed by the FDA as of 2000,⁵ and any liability for a faulty reprocessed device was transferred to the third party reprocessor. The FDA set up a reporting system to capture any adverse events related to reprocessed medical devices as a mechanism to build accountability.

OEMs provided considerable push-back, selectively educating surgeons and clinical staff on the risks of reprocessing single-use devices, touting liability and patient safety as drivers for avoiding third party reprocessing. But many in healthcare—cost-conscious and environmentally engaged, and having long understood the

In the US in 2007, nearly 45% of hospitals had agreements with third-party reprocessing companies, a number that increased to 70% in 2008 after the economic recession.⁶

value of reprocessing their own devices in-house—forged ahead with a commitment to third party reprocessing after studying the process in detail, visiting reprocessing plants and putting reprocessors through their own quality assurance programs. Third-party reprocessors inspect, functionally test, clean, package, and sterilize medical devices labeled for single-use in such a manner that the quality, physical characteristics, and performance functions of the device are not significantly affected and that the device remains safe and effective for its appropriate clinical use. Reprocessors encourage hospital clients to tour their reprocessing plants—demonstrating through a multi-step process that each device is carefully scrutinized and tested before being sent back to hospitals for resale. It is useful to note that OEMs often only test a sampling of the millions of devices they produce, while reprocessors test and inspect each and every device.

Multiple stakeholders across the healthcare sector have position statements supporting medical device reprocessing and remanufacturing. These include arguably the most important—the Association of Professionals in Infection Control (APIC) and the Association of Perioperative Registered Nurses (AORN) as well as the American Hospital Association, its personal membership group the American Society for Healthcare Central Service Professionals. Other groups with position statements supporting third party reprocessing of medical devices include the American Medical Association, the American College of Cardiology (ACC) and the American Association of Orthopedic Surgeons (AAOS). For a complete list of position statements supporting medical device reprocessing and the specific language, visit www.GreeningTheOR.org. In 2008, the Government Accountability Office released a study demonstrating that the FDA’s analysis of reported device-related adverse events indicates that reprocessed SUDs present no increase risk as compared with originally manufactured SUDs. The report also notes that



Surgical staff divert reprocessable single-use medical devices into a special collection container in the OR.

Figure 1. Commonly reprocessed medical devices⁷

Device type	New device price	Reprocessed price
Cardiac catheters	\$280	\$60
Orthopedic surgical blades	\$30	\$14
Deep vein thrombosis compression sleeves	\$125	\$11
Laparoscopic instruments	\$1,240	\$250
Torniquet cuff	\$25	\$12
Saw blade	\$40	\$18
Ultrasound catheters	\$2,900	\$1,400
Laparoscopic shears	\$120	\$55
Cardiac stabilisers	\$900	\$380
Pulse oximetry sensor	\$10-\$20	\$6-\$10

third party reprocessors are more stringently regulated by FDA than the original equipment manufacturers.^{8,9}

From an environmental perspective, most single-use disposable devices that are not collected for reprocessing make their way into the regulated medical waste (RMW) stream. Healthcare organizations pay a premium to dispose of RMW—6 to 10 times the amount it costs to dispose of solid waste. Reprocessing provides a way to divert these devices from RMW or solid waste and put them back into meaningful use. A single hospital can divert over a ton of devices from the waste stream each year.¹⁰ Additionally, these devices typically cost between 40-60% less than the original device,¹¹ which can mean huge cost-savings for the organization, as the OR arguably utilizes the most expensive medical devices across the healthcare sphere. There is typically no up-front capital investment other than appropriately educating and engaging clinical staff. Reprocessors collect devices in color-coded reusable totes designed specifically for medical instrumentation and deliver packaged sterile devices back to the hospital in reusable totes—eliminating excess packaging brought in by new devices. Most of the major third party reprocessors also track waste diversion data for their customers, as well as estimated device purchase savings.

With some surgeons and OR staff still skeptical of a transition to the collection and use of reprocessed single-use medical devices, how then does one make the case to move ahead and operationalize the change? There are several finite steps that an organization can follow to ease the transition to reprocessed single-use devices.

Figure 2. Figure 2: FDA-Recommended Questions to Ask Potential Third Party Reprocessors¹²

- *Has the reprocessing facility been inspected by the FDA?*
- *Can you provide documentation showing that the FDA has approved the firm to reprocess single-use devices?*
- *Which aspects of the process — cleaning, packaging, sterilization — have been validated?*
- *Do you have limits on how many times items can be reprocessed?*
- *How are those limits determined?*
- *How do you make sure items are not reprocessed too many times?*

Step 1. Create the Project Team

Before starting down the road of convincing OR staff and surgeons that a reprocessing program makes sense, begin by reaching out to Purchasing, Infection Prevention, the Sterile Processing Department (SPD), Risk Management and others who might be helpful. Lay out the hospital's sustainability goals (if applicable) and point to staff's desire to reduce the organization's environmental impact. Help them understand the dramatic cost-savings that can occur as a result of collecting and purchasing reprocessed devices. It will also be important to lay out the quality assurance process and stringent regulatory oversight for reprocessed medical devices. Point out that reprocessors actually become the "manufacturers" of the reprocessed devices. It is the reprocessor, rather than the OEM, who becomes liable for any defects or quality issues.¹³

Step 2. Identify a Potential Reprocessing Partner

Work with the project team to determine the best potential reprocessing partner. Ask your GPO who they recommend or other hospitals within your system or nearby. When you have narrowed down your choices, ask each candidate company to address the questions suggested by the FDA, and other questions about their service model. Do they provide containers for collection of devices? How often do they pick up collection containers? Can they help you understand how containers will be stored onsite before collection? What kinds of devices do they reprocess and are they able to track cost-savings and waste diversion benefits for you? What happens to devices that are collected but cannot be reprocessed? One hospital mentioned their reprocessor provides them with device collection containers that allow them to avoid buying 18-gallon sharps containers at \$19 each.¹⁴ Ask about additional opportunities to save money, reduce waste or supply costs or ease handling concerns for staff. You're the customer—a good reprocessor will be happy to lay out the benefits of partnership.¹⁵

Step 3. Educate-Educate-Educate Surgeons and Staff

A proactive education effort is a key ingredient in building understanding, acceptance and support for reprocessing among OR staff and surgeons. Take a stakeholder approach and tailor education for different audiences. Nurses and surgical technicians may have concerns about infection prevention and the process for separating appropriate devices in the OR—what standards are used for cleaning and sterilization? Will segregation be time-consuming? Surgeons are going to be concerned about functionality of devices—are the blades sharp, are there quality concerns? They may also need an in-depth briefing on how the FDA considers the third party reprocessor the manufacturer of these supplies and that they must meet the standard of original device functionality in order to be placed back into service. A thorough update on product liability is helpful here as is a referral to the GAO report that demonstrated that reprocessed devices are equally safe if not safer than the original devices, which are batch tested, and highlight the industry's outstanding safety record. Many hospitals have found that having OR staff take an onsite tour of the reprocessing plant can build comfort levels with the new process and address any questions or fears different stakeholders might have.

Step 4. Pilot the Program and Start Small

Once the program has gained a basic level of acceptance amongst OR staff and the program is ready for roll-out, hospitals may find it easier to start small or begin with a trial period. Some begin by collecting all devices for reprocessing, but only buying back non-invasive devices as a way to gain a comfort level with the process. Others move directly into buying back all kinds of devices but work slowly with surgeons to gain acceptance—never forcing a surgeon to use a reprocessed device without his/her knowledge. Some surgeons—supportive of the program have suggested a blind test where they use both kinds of equipment to see if they can sense any difference in quality. But that strategy requires surgeon leadership, and each hospital needs to figure out a formula that works with its own culture, staff and surgeons. Hospitals find that engaged OR staff can build on their existing relationships with surgeons to gently reiterate the dual benefits of cost reduction and decreased surgical care impact on the environment.¹⁶ Recruit engaged nurses and techs to be the eyes and ears of the new initiative and to flag areas of concern to be addressed.

Figure 3. Commonly reprocessed medical devices¹⁷

Estimated Savings for a 500 Staffed Bed Acute Hospital	Annual Est. Savings Potential Based on Best Demonstrated Practices	Annual Est. Waste Diversion (lbs) Potential Based on Best Demonstrated Practices
Laparoscopic	\$93,700	4,288
Trocars	\$124,345	1,985
Ultrasonic Scalpels	\$202,193	1,072
Compression Devices	\$209,217	13,540
Diagnostic Ultrasound Catheters	\$289,430	282
EP Catheters & Cables	\$433,585	994
Pulse Oximeter Probes	\$191,576	2,883
Total Annual Savings Potential	\$1,544,144	25,045

Step 5. Evidence Based Decision-Making

Increasingly, clinical leaders are interested in their role in environmental stewardship.¹⁸ It is important to help OR staff and surgeons understand this is not a decision being pushed on them, but rather one they have chosen to support and adopt. The ongoing discussion between reprocessors and OEMs can be fierce at times and many hospitals find that they have some issues with OEMs trying to selectively “re-educate” surgeons or staff. Hospitals have found various ways to deal with this issue—ranging from outreach to OEMs asking them not to interfere in the hospital’s decision to reprocess single-use medical devices, to instituting policies that force OEMs to come into the hospital only through pre-approved appointments with materials management. How your organization deals with this issue will again be site-specific, but these counter efforts can leave surgical staff confused and conflicted about the program if not quickly addressed by OR management. If necessary—use this as an opportunity to pull staff together to address any remaining concerns or new information that has been brought to their attention by OEMs.

Step 6. Setting Up for Success

Smooth implementation requires support from a diverse team of players—as demonstrated by the Environment of Care committee—and it is no different with operating room strategies. As the hospital initiates program roll-out, it is important that everyone is clear about the new procedures for handling these devices. Bring in the reprocessor to provide In-Services to staff about:

- Placement of the collection containers;
- Which devices can and should be placed in the container during and after surgeries;
- Which devices the hospital has chosen to reprocess initially (if a shortened list);
- Which devices should be cleaned in SPD before being sent for reprocessing;
- How this fits with medical waste disposal regulations; and
- General information on how the process works.

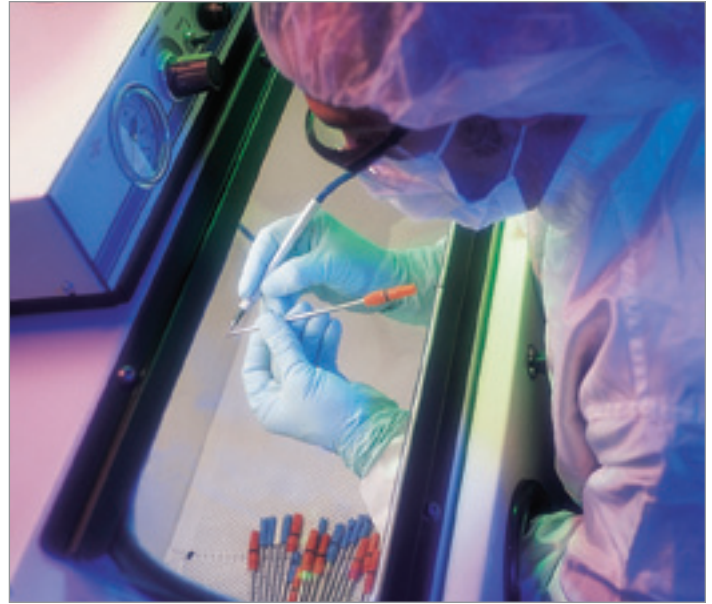
Work with Environmental Services (EVS) to develop a process for collection of containers from the OR to onsite storage to pick-up by the vendor. Even determining the staging area for onsite storage can sometimes be challenging when dealing with limited dock space. And strategizing with EVS around how to structure collection so that it doesn’t require additional labor or pick-ups on their part can be key to gaining this department’s support for the new initiative. When reprocessed devices are brought back into the facility—newly cleaned, packaged and sterilized, talk to Central Sterile Supply about where these items get stocked. Reprocessors often try and use the same size packaging utilized by the original equipment manufacturer as a means to allow unified storage of new and reprocessed devices. Some hospitals have encountered early resistance to utilizing the reprocessed devices as the program gains traction and separate storage areas can aid that resistance. Having integrated supply areas for both kinds of devices can assist in program uptake. While the program will immediately begin to provide environmental benefits in the form of waste reduction back to the organization, many of the deeper savings come from replacing the purchase of new devices with the purchase of reprocessed devices. Troubleshooting the case cart process or reaching out to resistant staff and offering an opportunity to express and address concerns can be a good way to continue to build momentum for this program across the organization.

Step 7. Troubleshoot and Expand the Reprocessing Program

Once the program is up and running, and clinicians and staffers are comfortable with the transition, the organization may consider more aggressive reprocessing goals. This can mean moving to the reuse of invasive devices if you began with non-invasive devices. It can mean upping the collection rate in the ORs by re-educating staff. Or it can mean troubleshooting the selection of reprocessed devices for new surgeries. Use this as an opportunity to reach out to OR staff and ask how the program is working and whether there are things that can be done to aid implementation or collection. Check in with EVS to make sure the collection process and pick-ups are proceeding smoothly. Hospitals also find that reprocessing is applicable to other areas of the hospital beyond Surgical Services. Consider adding additional departments to the service contract. Electrophysiology labs, for example, can save up to \$150,000 by reprocessing electrophysiology and imaging catheters.¹⁹ The use of reprocessed SCD sleeves and pulse oximetry sensors is another area where huge savings are possible. Some of these items may also be available for reprocessing from a variety of different companies beyond those who can provide large-scale reprocessing of the most complicated devices. Compare and contrast your existing reprocessor's service model and savings with other companies who may specialize in reprocessing these more non-invasive devices. Extending this program into labs and critical care units can offer the organization significant additional savings.

Step 8. Track Improvements and Recognize Success

Like with any other quality improvement initiative, tracking performance and reporting positive outcomes can support the value of program maintenance. Ensure that waste tracking continues in order to capture volume and cost reductions associated with this program. Work with Environmental Services in advance to set up a system to track improvements in RMW reduction coming from the OR. This can be as exact as data from a waste tracking or bar-coding system that specifically identifies OR RMW volumes and fluctuations or an estimate, based on a bi-monthly audit where OR waste is pulled aside and weighed separately. EVS can be very helpful in determining how best to track or estimate waste reductions.



When sent for reprocessing, each device is individually cleaned and function-tested before packaging and sterilization.

Work with Purchasing to track cost savings from purchasing reprocessed versus new devices. Typically, the reprocessor will be able to track many of these savings for you and provide these figures on your monthly statement. Though double-checking doesn't hurt, it may be a redundant effort. Report cost reductions, waste diversion volumes and other environmental or other benefits back to leadership and OR management and keep a running tally of savings to demonstrate payback. Congratulate OR staff and surgeons on their success in decreasing environmental impact while continuing to protect patient health and safety. Make sure the organization's sustainability leader or green team (if applicable) knows about the success the OR is having, and includes it in any award applications or recognition opportunities.

For More Information: Go to www.GreeningTheOR.org for a list of key resources that can assist you in this program area. Because this list is updated often, we keep it online, so as not to date this implementation module. Also available are case studies on reprocessing programs at different facilities. Learn from your peers!

Endnotes

- 1 Food and Drug Administration. Executive Summary: survey on the reuse and reprocessing of single-use devices (SUDs) in US hospitals. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidanceReprocessingofSingle-UseDevices/ucm121678.htm>. Accessed March 13, 2011.
- 2 Association of Medical Device Reprocessors. 1997-2007-Ten Years of Excellence in Reprocessing. 2007. Available at: [http://www.ascenhs.com/docs/AMDR_10_Years_\(00051493\).pdf](http://www.ascenhs.com/docs/AMDR_10_Years_(00051493).pdf). Accessed on March 12, 2011.
- 3 Razor, T. *Recycling boosts Iowa Health's bottom line*. Des Moines Business Record. December 4, 2010. Accessed on March 28, 2011. Available at: <http://www.ihs.org/body.cfm?id=67&action=detail&ref=187>
- 4 Practice Greenhealth. Sustainability Benchmarking Report. 2010. Accessed on March 21, 2011.
- 5 Jobe-Lockwood, S and Nguyen, T. *Are you Reprocessing Single Use Devices?* Outpatient Surgery. 2009. Available at: <http://www.outpatientsurgery.net/guides/going-green/2009/are-you-reprocessing-single-use-devices&pg=2>. Accessed on March 12, 2011.
- 6 Moduga, A. *Reduce, Reuse, Recycle: Reprocessing Medical Devices*. HospitalManagement.net March 31, 2010. Available at: <http://www.hospitalmanagement.net/features/feature80981/> Accessed on March 13, 2011.
- 7 Ibid.
- 8 US Government Accountability Office. Report to the Committee on Oversight and Government Reform, House of Representatives: Reprocessed single-use medical devices. January 2008. <http://www.gao.gov/new.items/d08147.pdf>. Accessed March 13, 2011.
- 9 Boone, PK. Transition to Reprocessing-One OR's Success. Nursing Administration Quarterly. 2010. Vol. 34, No. 4, pp. 343-345.
- 10 Practice Greenhealth. Sustainability Benchmark Report. 2010. Available at www.practicegreenhealth.org.
- 11 Hurst, D. Leaner and Greener Operations- The Environmental Benefits of Reprocessing. The Source- HealthTrust Purchasing Group. Summer 2009. pp. 14-17. Available at: <http://viewer.zmags.com/publication/b1fe9b7d#/b1fe9b7d/16>. Accessed on March 12, 2011.
- 12 Jobe-Lockwood, S and Nguyen, T. *Are you Reprocessing Single Use Devices?* Outpatient Surgery. 2009. Available at: <http://www.outpatientsurgery.net/guides/going-green/2009/are-you-reprocessing-single-use-devices&pg=2>. Accessed on March 12, 2011.
- 13 Jobe-Lockwood, S and Nguyen, T. *Are you Reprocessing Single Use Devices?* Outpatient Surgery. 2009. Available at: <http://www.outpatientsurgery.net/guides/going-green/2009/are-you-reprocessing-single-use-devices&pg=2>. Accessed on March 12, 2011.
- 14 Jobe-Lockwood, S and Nguyen, T. *Are you Reprocessing Single Use Devices?* Outpatient Surgery. 2009. Available at: <http://www.outpatientsurgery.net/guides/going-green/2009/are-you-reprocessing-single-use-devices&pg=2>. Accessed on March 12, 2011.
- 15 Jobe-Lockwood, S and Nguyen, T. *Are you Reprocessing Single Use Devices?* Outpatient Surgery. 2009. Available at: <http://www.outpatientsurgery.net/guides/going-green/2009/are-you-reprocessing-single-use-devices&pg=2>. Accessed on March 12, 2011.
- 16 Boone, PK. *Transition to Reprocessing-One OR's Success*. Nursing Administration Quarterly. 2010. Vol. 34, No. 4, pp. 344.
- 17 Brannen, L., Guity, A. and DeLoach Lynn, C. *Improving Sustainability Performance in a High-Paced, "Big" Cost-Center, and Resource-Constrained O.R. Setting*. ASHE International Summit and Exhibition on Planning, Design and Construction. March 15, 2011.
- 18 Kwakye, G., Pronovost, P., and Makary, M. *Commentary: A Call to Go Green in Health Care by Reprocessing Medical Equipment*. Academic Medicine. Vol. 85, No. 3. March 2010. Accessed on March 4, 2011.
- 19 Moduga, A. *Reduce, Reuse, Recycle: Reprocessing Medical Devices*. HospitalManagement.net March 31, 2010. Available at: <http://www.hospitalmanagement.net/features/feature80981/> Accessed on March 13, 2011.



**PRACTICE
Greenhealth**

Practice Greenhealth • 12355 Sunrise Valley Drive, Suite 680 • Reston, VA 20191 • Ph: 888-688-3332
E-mail: greeningOR@practicegreenhealth.org • www.practicegreenhealth.org



The Greening the OR™ Initiative is defining best practices in the OR to reduce environmental impact, reduce cost, increase efficiency, and improve worker and patient safety. Practice Greenhealth is grateful for the support of a number of sponsors of the Greening the OR™ Initiative. For a complete list, please visit: www.GreeningTheOR.org

© 2011 Practice Greenhealth.