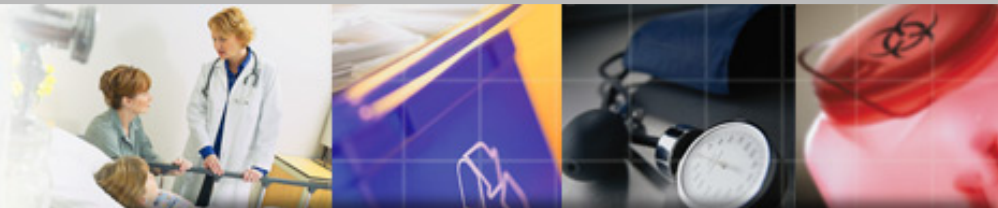


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Single-Use Device Reprocessing

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What is Single-Use Device Reprocessing?

How often do patients see hospital staff open a package, use a device once, and throw it away? In some instances, that package may even contain multiple devices, some of which are never used before they are discarded. Single-use devices (SUDs) represent a significant source of waste in a healthcare facility, both in cost and volume. Driven by a facility's need for "just-in-time" sterile instruments, these devices are the single-serving convenience packages of the health care industry.

The use and waste associated with SUDs has been scrutinized as hospitals look to improve their environmental performance. Hospitals have found that many of the devices labeled for single use can be safely reprocessed and reused. SUD reprocessing is typically done by a third party registered with and regulated by the U.S. Food and Drug Administration (FDA). [The third-party reprocessor inspects, functionally tests, cleans, packages, and sterilizes 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.](#) By reprocessing single-use devices, your facility can reduce the amount of waste it generates and can realize significant cost savings through the reduced purchase of new products.

Common Concerns and Misconceptions

There are many concerns and misconceptions about whether devices that are labeled for single use can be reprocessed and reused without putting patients at risk. The Association of Medical Device Reprocessors (AMDR) dispels several myths regarding single-use device reprocessing:

Myth: Manufacturers label some medical devices for "single use" because these devices are unsafe for more than one use.



Fact: The “single use” label is not an FDA requirement but chosen at the manufacturer’s discretion, often for economic reasons, not patient safety reasons.

Myth: Reprocessed medical devices fail more often than original devices, leading to more patient harm.

Fact: FDA’s adverse event database contains over 6,500 reports of patient deaths associated with original (unreprocessed) devices since 2004. According to the same FDA database, zero deaths have occurred as a result of the use of reprocessed devices.

Myth: Reprocessing is inadequately regulated.

Fact: FDA rigorously regulates the reprocessing industry. In fact, reprocessing must meet the same regulations as original equipment manufacturers and then some.

Myth: Cleaning detergents and other residue cannot be eliminated from certain devices that are reprocessed.

Fact: Reprocessors must prove that a device has been successfully cleaned, sterilized, and is functional, to the same, if not greater, degree as the original device before it is allowed to be commercially reprocessed.

Myth: Because reprocessed devices are riskier, patients should have to sign informed consent papers authorizing their use.

Fact: Reprocessed single-use devices are not investigational or experimental devices, and therefore there is no legal, medical, or ethical basis for imposing a requirement to seek informed consent for the use of reprocessed devices but not for the use of original devices.

Myth: Reprocessing provides no benefits to patients.

Fact: Besides being just as safe as, if not safer than, original devices, reprocessing keeps tons of medical waste from filling community landfills and saves money for local hospitals that they can use to hire more patient care staff, improve technology, or provide care to the indigent.

Myth: If a hospital uses reprocessed devices, it is probably providing inferior service.

Fact: AMDR members reprocess for 13 of the 14 “Honor Roll” hospitals as identified by U.S. News & World Report in summer 2006. Additionally, AMDR member reprocessors serve all ten of the top ten heart and heart surgery hospitals in the nation and nine of the top ten orthopedic hospitals nationwide.

Industry Position Statements

Several healthcare organizations have carefully evaluated the safety and cleaning efficacy of SUD reprocessing and have issued formal statements and guidance on this issue. This information can be used to inform decision makers when SUD reprocessing is evaluated by your facility. Organizations that have issued position statements on this topic range from the American College of Cardiology (ACC) to the Association of Perioperative Registered Nurses (AORN). The American Hospital Association (AHA) and the American Society for Healthcare Central Service Professionals (ASHCSP) have also stated their positions on the issue of SUD reprocessing, as quoted below from the conclusions of their statements:

American Hospital Association

“[P]atient safety is the first and foremost concern of all hospitals and health systems. Appropriate reprocessing poses little or no risk to the public, as evidenced from the findings of the [General Accounting Office] GAO report, the FDA, the [Centers for Disease Control and Prevention] CDC, infection control officials, risk managers and quality consultants. It represents responsible waste management and appropriate use of scarce health care resources. In the absence of evidence that reprocessing and reuse of medical devices labeled as ‘single use,’ are a threat to patient safety, regulating reprocessing by treating hospitals as manufacturers adds costs without adding the benefits of increased patient safety or improved outcomes.”

AHA. June 27, 2000. [Testimony of the American Hospital Association before the Health, Education, Labor and Pensions Committee of the United States Senate on Reuse of Medical Devices.](#)

American Society for Healthcare Central Service Professionals.

“ASHCSP believes a well-developed and managed program for the reuse, resterilization or reprocessing of single-use devices will include the decisions not to reuse, resterilize or reprocess some devices; internal reuse, resterilization or reprocessing of some devices; and the outsourcing of the reuse, resterilization or reprocessing of some devices. These decisions would be consistent with a thorough evaluation process of individual medical devices and institutional resources. For non-critical medical devices all of the options may be selected, for semi-critical medical devices resterilization or reprocessing may be an option, and for critical medical devices only reprocessing may be an option. There are a number of resource materials published on this issue which allow health care facilities to make an informed decision on what specific steps are required for their facilities' process. Reuse, resterilization, and reprocessing of disposable or single-use medical device protocol must be developed to ensure no greater risk to patients exists than in the use of medical devices marked reusable.”

ASHCSP. June 30, 1999. [ASHCSP Position on Reuse of Single-Use Medical Devices.](#)

Advantages of SUD Reprocessing

The two advantages to SUD reprocessing are waste reduction and cost savings, as discussed below:

Waste Reduction

By reprocessing single-use devices, your facility can reduce the amount of waste that it sends out as medical waste and to the landfill, both in terms of product and packaging. All AMDR reprocessors bring devices back to facilities in reusable totes, eliminating the excess packaging from paper and cardboard that new products bring in. Paper and cardboard make up more than 50% of the waste generated by hospitals. One multi-hospital system eliminated six tons of medical waste that would have been shipped to a landfill.

Cost Savings

Reprocessing SUDs also provides a cost savings compared to purchasing new devices for each use. According to AMDR, [On average, reprocessed medical devices offer a 50% cost savings, as compared to purchasing a new device.](#) Additional cost savings may be realized through reduced waste generation and material handling.

Commonly Reprocessed Single-Use Devices

A wide range of SUDs are commonly reprocessed, ranging from cardiovascular and orthopedic devices, to general surgery accessories. The following list provides a sampling of SUDs that may safely be reprocessed; a complete list is [available on AMDR's website.](#)

- Arthroscopic shavers
- Blood pressure cuffs
- Soft tissue ablaters
- External fixation devices
- Electrophysiology catheters
- Scissors and staplers
- Biopsy forceps
- Laparoscopic scissors and forceps
- Clamps and dissectors
- Compression sleeves (DVT)
- Phaco tips
- Pneumatic tourniquet cuffs
- Pulse oximeter sensors
- Orthopedic drill bits and burrs
- Tracers
- Trocars
- Many opened-but-unused items

Tips for Evaluating a Third-Party Reprocessor

AMDR is a trade association for third-party reprocessors whose members account for about 95 percent of the third-party reprocessing done in the United States. AMDR suggests that hospitals ask the following questions to vendors before choosing a SUD reprocessor:

1. Is the company registered with FDA?
2. Does the company comply with applicable Quality System Regulation requirements?
3. Will the company permit you to visit its plant and review its quality manual?
4. Is sterilization performed by a commissioned and certified sterilization system, in accordance with ANSI/AAMI/ISO ST 11135 ST 1994?
5. Is the sterilization cycle requalified annually?
6. Are biological indicators used to monitor routine sterilization?
7. Are the sterilization systems routinely calibrated?
8. Is the residual sterilant level routinely tested?
9. Does the company have reprocessing procedures tailored to the specific types of medical devices you wish to have reprocessed, and has the company validated these procedures?
10. Is the product functionality routinely tested?
11. Does the company track the number of uses per device?
12. Does the company comply with Medical Device Reporting requirements?
13. Does the company have adequate liability insurance coverage?

Case Study: Catholic Healthcare West

Catholic Healthcare West (CHW) has integrated environmental policies into its mission and job descriptions to show its commitment to environmental performance as a core value. Single-use device reprocessing is an important part of CHW's environmental program. Based on its experience, CHW offers the following suggestions for implementing a successful reprocessing program.

People

- An executive sponsor
- A department champion and backup who has credibility with doctors and staff
- At least one champion in the operating room
- A sales representative with visibility and responsive actions (door-to-door department performance reports)

Process

- A commitment to results in which staff can't find a "loophole for failure"
- Staff who believe they are "doing the right thing" and making a difference
- Sufficient education to fight off the original equipment manufacturers' attack on the credibility of reprocessing
- Access to the "data" using the Internet
- A standing agenda item at department meetings
- Results posted for doctors and staff

Communication with Original Equipment Manufacturers (OEMs)

- Know who owns the business – we are the customer.
- Make known that stewardship of resources and the environment is a priority.
- Make the desire to use reusables, reposables known.
- State the belief that it is safe, reliable, and "the right thing to do."
- Warn about potential consequences tied to counter-detailing.
- Move the disposable business if necessary.

Hospitals should be prepared for what to expect

- Post vendor access policy in clinical departments.
- Request immediate copies of any letters from original equipment manufacturers.
- Prevent the possibility that doctors will “buy-in” to false claims about reprocessed devices.
- Know where to go for facts (original equipment manufacturers may have bad information).
- Be prepared at the corporate level to take action with vendors as needed to move business.
- Call on reprocessor representatives to “coach” doctors and staff.

Key Resources:

[Association of Medical Device Reprocessors \(AMDR\)](#)

Provides a wide range of information on single-use device reprocessing, including background information, current news articles, legislative decisions, safety standards, and links to additional information.

[Testimony of the American Hospital Association before the Health, Education, Labor and Pensions Committee of the United States Senate on Reuse of Medical Devices.](#)

American Hospital Association (AHA). June 27, 2000.

Presents testimony of AHA regarding reuse of medical devices.

[ASHCSP Position on Reuse of Single-Use Medical Devices](#)

American Society for Healthcare Central Service Professionals (ASHCSP). June 30, 1999.

Presents ASHCSP's position statement on the reuse of single-use medical devices.

[Cutting Costs Through Reprocessing of Single Use Devices \(SUDs\)](#)

Cecilia DeLoach, Practice Greenhealth, and Pam Johnson, Catholic Healthcare West. August 1-4, 2004.

Provides the PowerPoint presentation given at the Association for Healthcare Resource & Materials Management's (AHRMM) 42nd Annual Conference & Exhibition: Setting the Standard, which includes statistics and suggestions for healthcare facilities to realize cost savings by reprocessing single-use devices.

[Reprocessing of Single-Use Devices](#)

U.S. Food and Drug Administration. September 26, 2006.

Provides links to documents and frequently asked questions about single-use device reprocessing.