Reuse of Single-Use Devices:

Understanding Risks and Strategies for Decision-Making for Health Care Organizations

A White Paper by Joint Commission International

Joint Commission International

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Executive Summary

- The trend of manufacturing single-use medical devices and supplies is paralleled by another trend—attempting to clean and reuse these single-use medical devices and supplies for other patients.
- This practice carries significant risk to the patient.
- These devices and supplies are often complex in design, and cleaning efforts, either by hospitals or third-party reprocessors, may be inadequate.
- Reprocessing and reuse may compromise the product's performance, and the manufacturer is not liable when a product is not being used according to the manufacturer's instructions.
- In response to this threat, Joint Commission International (JCI) accreditation standards for hospitals define very strict requirements for hospitals considering the reuse of single-use medical devices and supplies. The standards include detailed procedures, monitoring, and follow-up on adverse patient events which may be linked to this practice.
- This white paper aims to raise awareness of this threat to patient safety among health care leaders, clinicians, and health care purchasing agents worldwide and to educate and encourage health care organizations to understand the risks when considering this practice and the JCI requirements.

Introduction

A history of the development of medical devices

To supplement the skill of physicians, nurses, and other care providers, medicine has relied on various medical devices as essential tools to support the treatment, cure, or mitigation of disease. Before the 1970s, most medical devices were considered reusable, because being made of rubber, glass, or metal, and usually cleaned with a cleaning solution and wiped down, they were ready for use in the next patient. Some medical devices and supplies were cleaned by steam sterilization for those compatible with this process.[1,2] Beginning in the 1970s, manufacturers began to produce medical devices designated as "single use," due to demand by health care organizations, the complexity of newly designed devices, and the introduction of ethylene oxide sterilization. Sterility is essential to prevent harm associated with the use of many medical devices, and most single-use devices are sterilized with ethylene oxide or gamma or electron beam radiation.[3] Medical devices continue to become more complex and require intricate engineering design. However, this complexity is not always easy to appreciate, and many in the health care world regard these single-use devices as resembling very closely their reusable counterparts.[1]

Definitions of reusable devices *and* single-use devices

It is important to understand the meaning of the terms *reusable devices* and *single-use devices*. As the United States (US) has become the primary government to regulate these devices, the US Food and Drug Administration (FDA) definitions are important to note. The FDA defines *reusable medical devices* as those "devices that health care providers can reprocess and reuse on multiple patients." The FDA uses the classification conceptualized by Earle H. Spaulding almost 50 years ago for reusable instruments based on their risk of transmitting infection and according to the areas of the body in which they will have contact:

- *Critical devices*, such as surgical forceps, come in contact with blood or normally sterile tissue.
- *Semi-critical devices*, such as endoscopes, come in contact with mucus membranes.
- *Non-critical devices*, such as stethoscopes, come in contact with unbroken skin.[4,5]

After thorough cleaning, these devices can be subjected to high-level disinfection or sterilization between individual patient use. The devices are made of materials that can withstand repeated cleaning, disinfection, and sterilization. Manufacturers must also assure that it is possible, through the sterilization process, to remove all infectious and bio debris from one patient that may harm the next patient. The FDA defines a *single-use device*, also known as a *disposable device*, as one which is "intended for use on one patient during a single procedure . . . and is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient."[6]

Reasons for reprocessing single-use devices

The trend toward single-use devices has been matched by the trend to reprocess single-use devices. In part, this was the result of health care organizations seeking cost savings by reprocessing instead of using a single-use device once and then discarding. Some claim environmental advantages, arguing that reusing a single-use device is "greener," resulting in less regulated medical waste. Medical waste contributes to landfills and has considerable costs associated with proper disposal. Admittedly, many health care organizations have seen that reusable and single-use devices might, on the surface, appear to be almost identical, and suspect that single-use devices could be reused with no patient harm, if properly reprocessed. Indeed, health care organizations around the world have made the decision to reuse single-use devices. Perhaps the strongest argument to support reusing single-use devices comes from developing countries and countries with limited resources, where the costs of health care can be prohibitively unaffordable to the typical patient. Reusing single-

use devices can substantially lower the cost of a single procedure and make it feasible for a segment of the population that might not otherwise be able to afford it. Often, countries with limited resources cannot depend on access to supplies and devices when they need them, and they may regard reuse of single-use devices as a way to ensure availability of necessary supplies.

The process of single-use device reprocessing

Single-use medical device reprocessing entails disinfecting, cleaning, sterilizing, packaging, labeling, and storing a used or opened package of a medical device to be placed into service again.[7] Reusing single-use medical devices has been happening since the late 1970s.[8] Single-use medical devices can be reprocessed within health care organizations or by outside vendors, also known as third-party reprocessors, which emerged in the late 1990s. In the US, the FDA conducted a thorough review of this issue in 1999 and 2000 and released a document that provided requirements for reprocessed devices. Specifically, the FDA requires third-party reprocessors to meet the same criteria for the reprocessed devices as the original equipment manufacturers must meet for the original device.[6] After implementation of the FDA regulation, the US Congress formalized these standards and other requirements in the Medical Device User Fee Act of 2002.[9] The outsourcing of reprocessing to these third-party companies may present an advantage to hospitals and other health care organizations that may not be able to reprocess devices adequately or that have downsized their own sterilization, disinfection, and cleaning departments with the advent of single-use devices.

The purpose of this white paper

This white paper's intent is to share the available data on the complex issue of reusing single-use devices and provide strategies for health care organizations that want to evaluate the option of reusing single-use devices. The Joint Commission International standards for accreditation of hospitals provide a framework for hospitals deciding whether or not to reuse single-use devices.

The Complexities of Reusing Single-Use Medical Devices

The medical devices used today are engineering marvels, with intricate materials, parts, and passageways. When a device is labeled as single use, the manufacturer is claiming its safety for use only once. To reprocess such a device after it has been used, one must ensure that it is sufficiently clean or sterile and properly functioning, and will not pose a risk to the patient for whom it is used. Many of the processes required to ensure that the device is safe and suitable for its intended purpose cannot be demonstrated by the reprocessor, and as a result, many single-use devices are reused without being adequately evaluated. This may then result in an increased risk to patients.

Table 1. Difficult-to-Clean Devices

- Cannulae in septorhioplasty set
- Cornary suctions
- All ear trays, suctions, and very fine, delicate instruments
- Flexible scopes, gastroscopes, and bronchoscopes
- Defibrillator paddles
- Lenses
- Trivex system
- Drills
- Gamma nail sets
- Saws
- Extract All set
- Kerrison Rongeurs
- Spring-loaded drill guides
- Bipolar forcepts with delicate tips
- Tympanomastoid set
- Orthopedic reamers

These medical devices are just a few of those identified as being the most difficult to clean.

Source: Azizi J, Basile RJ. Doubt and proof: the need to verify the cleaning process. *Biomed Instrum Technol* 2012 Spring; Suppl:49-54. doi: 10.2345/0899-8205-12.1.49. Used with permission.

Azizi and Basile sought to understand whether current processes for cleaning medical equipment were effective and, if contaminants were left behind, what kind they were. They note that many devices are hard to clean, such as septorhinoplasty sets due to the cannulae within the devices, and coronary suctions due to the cannula shape. The authors, for the purposes of the study, narrowed their analysis to suctions, since they are often contaminated with a variety of debris materials.[10] They also identify other difficult-to-clean devices in Table 1, above.

Azizi and Basile noted that each device has unique challenges to cleaning and verification of cleanliness. With the exception of visible bioburden (for example, blood, tissue), it is virtually impossible to visually inspect the critical surfaces of a device to confirm that all contaminants have been removed. Other cleaning verification methods are needed, but there are often limitations to cleaning staff being able to perform this verification due to lack of staff training, lack of laboratory equipment, and time constraints. How can testing be performed rapidly and reliably? While some tests are commercially available, these tests are often not able to confirm the presence of or type of debris. Even with a variety

of tests to confirm whether organic matter, protein matter, blood matter, or other residue is still present after processing, it isn't until the devices are actually opened up that staining can be observed, suggesting that residue unable to be confirmed with the many tests is still present in the devices. *See* Figure 1, at right, for a photograph of an opened device showing staining or residue.

The World Health Organization (WHO) and the Pan American Health Organization note additional concerns about reprocessing single-use devices, including the following:

- Single-use devices may not be designed to allow thorough decontamination.
- Reprocessing may alter device characteristics, and performance may be compromised as a result.
- Single-use devices do not undergo extensive testing validation and testing for reuse.
- Single-use devices may cause cross-infection due to design (for example, fine bores of tubes).
- Some materials can absorb certain chemicals, which can gradually leach from the material over time.
- Chemicals may corrode or change device materials.
- Device material may experience stress during reuse and may fail, stretch, or break.
- Inadequately cleaned equipment can carry bacterial endotoxins, which remain after bacteria are killed.[11]

Health care organizations should consider additional technical issues when deciding to reprocess single-use medical device, such as the following:

- What are the effects of cleaning, disinfecting, and sterilization on the function of the device?
- Can reprocessing change the design specifications of the device?
- How can the reprocessor confirm that reprocessing has not changed the device's functionality or performance?
- If an issue is identified with a reprocessed device, is there a way to trace that device to the patient on whom it was used?
- If a patient experiences an adverse event that can be linked to a device, is it possible to trace the device to the patient or vice versa to determine which device the patient received? And how are the individual devices identified?

A hospital or other health care organization that reprocesses or uses reprocessed single-use devices needs to develop detailed procedures to mitigate the risks. How will a decision

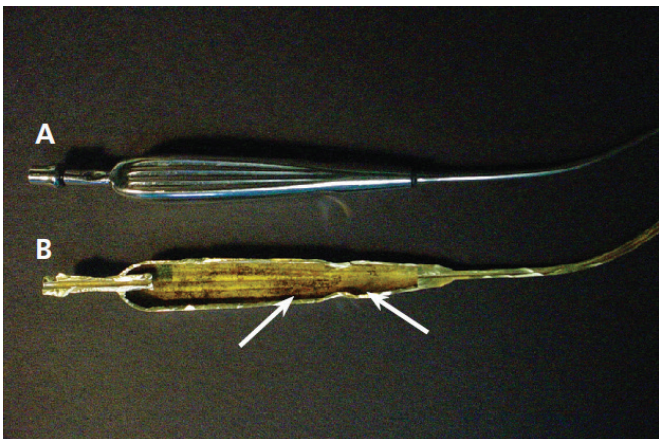

Figure 1. *A suction tip cut open lengthwise to illustrate ample internal debris and staining (arrows, B), not visible on the outside of the device (A). Note the characteristics in the design that make the instrument virtually impossible to clean.*

Source: Azizi J, Basile RJ. Doubt and proof: the need to verify the cleaning process. *Biomed Instrum Technol* 2012 Spring; Suppl:49-54. doi: 10.2345/0899-8205-12.1.49. Used with permission.

be made as to whether a device will be accepted for reprocessing? What will the criteria be for making this decision? How will the risk to patients be determined as part of this decision process? How many times can a device be reprocessed before it is discarded? How will each use be tracked? Detailed reprocessing protocols, standard operating procedures, and associated quality systems must be in place to confirm that the reprocessing work is performed correctly and in a standardized manner. Protocols must direct quality control activities, including collecting metrics associated with the quality of the process and the performance of the device post-reprocessing. A device that has been reprocessed should be labeled as a reprocessed device, but also with an identifier that allows forward and backward tracing if a specific device is recalled. The identifier can be used to track the number of reprocessing events the device has gone through in order to count when these events reach the pre-determined limits established by the organization.

It should be noted that the use of a reprocessed device presents no value to the patient or the physician. The reprocessed device should be labeled as such, with the reprocessing organization identified as the manufacturer. Consideration should be given as to whether the patient has the right to know if a reprocessed single-use device will be used (and the opportunity to consent or object to its use). It could be argued that patient consent may *not* be needed if effective protocols are in place to ensure patient safety. Informing the patient may

cause undue worry. However, it could be argued that, without patient consent, the organization that allows single-use devices to be reprocessed is engaged in hidden cost-savings measures that take away the patient's right to decide on the issue. Some argue, too, that the physician should be aware of when a single-use reprocessed device is being employed and should also consent to its use.[12,13,14]

Variation in country regulations

Once a country or region defines the regulations for reuse of single-use medical devices, the legal requirements become clearer. In the US, the FDA regulates which single-use devices can be reprocessed and has designated 70 such devices.[15] In addition, the Medical Device User Fee and Modernization Act of 2002 requires that all single-use devices prepared for reuse in the US must be labeled as reprocessed and indicate the reprocessor. Validation data must be submitted for many types of single-use devices that are reprocessed. Also, under this Act, the reprocessed medical device is considered the product of the reprocessor, and no longer the product of the original equipment manufacturer. With that designation is the assigned liability of the product.[11]

Health Canada, Canada's department of the government responsible for national public health, has the authority to regulate medical devices, including manufacturing; however, provincial and territorial health agencies have the power to develop their own policies and guidelines related to reprocessing single-use medical devices. There is great variation from one province or territory to another. In February 2015, Health Canada stated that all commercial reprocessors that distribute devices to Canadian health care facilities would be required to meet the same regulatory requirements as the original manufacturer, regardless of whether they are reprocessed in Canada or outside Canada.[16]

In 2003, Australia required hospitals and third-party reprocessors of single-use medical devices to conform to the same regulatory standards as the original manufacturer and to demonstrate that reprocessed devices are equally safe and perform as well as the original manufactured device.[17]

In Europe, the European Union (EU) does not regulate the reprocessing of single-use medical devices, and therefore each country within the EU legislation regulates this practice. Germany allows in-house and third-party reprocessing, but institutions must conform to German regulations on reprocessing, which require the implementation of a quality management system. In the United Kingdom, the Medicines and Healthcare Products Regulatory Agency advises against reprocessing and advises of legal responsibilities for organizations who prepare single-use devices for reuse. In France, the reuse of single-use devices is considered "off label" and therefore illegal.

In the Middle East, Asia, and Africa, the practice of reprocessing is not regulated. Most reprocessing of single-use devices is performed by hospitals because of the lack of third-party reprocessors.[18]

In the US, device manufacturers provide directions for use, or instructions for use (IFUs), to ensure that a practitioner who is licensed by law to administer the devices uses them safely and for their intended purpose.[6] Labeling and IFUs must conform to FDA requirements. The user must review the labeling and IFUs of reprocessed single-use devices carefully and compare these to labeling and IFUs from the original manufacturers. Users of reprocessed single-use devices may not be aware that IFUs can be modified by the reprocessor. Users of reprocessed single-use devices may also not be aware of limits placed on the use of the device, which may not be the same as the single-use device purchased directly from the original manufacturer.[20] Depending on laws and regulations that govern the processing and use of single-use devices in specific countries, the oversight of this documentation can vary. It is important to understand what reprocessors are required or not required to do, according to national and local laws.

A Scan of the Literature: Are There Data to Support or Prohibit the Reuse?

There is a paucity of data that clearly demonstrates harm associated with the use of reprocessed single-use devices. This may be due to the fact that if reporting processes for adverse events exist, they are often voluntary and therefore may not capture all events. There is also a very limited number of peer-reviewed studies that have reported on reprocessed single-use devices. Much of the data that are available are from industry-funded studies. These include studies on the use of reprocessed devices in orthopedic and laparoscopy surgery, and they found a significant rate of physical defects, performance issues, and insufficient decontamination of reprocessed single-use devices.[20–24]

Mues et al compared the performance of new and reprocessed laparoscopic trocars, using visual and microscopic inspection, force of trocar insertion and removal through a porcine wall, trocar seal leak rate determination, and testing of blade shield speed measures. Their sample size included 328 reprocessed trocars and 199 new trocars. The researchers found that there were significant differences in visual trocar defects, and demonstrated significant differences in performance of the trocar, as evidenced by leakage results, shield

response times, and differences in force required to insert and remove the devices.[25]

Bhatia et al in India, in a prospective independent evaluation, studied ten endoscopic ultrasound aspiration needles, designated as single-use devices, which were used once and then reprocessed using a standard protocol. These devices were selected for study because they are often reprocessed in many parts of the world. Bhatia et al demonstrated that even after rigorous mechanical cleaning and sterilization attempts, there remained significant bioburden. They concluded that it is impossible to adequately clean and sterilize endoscopic ultrasound aspiration needles and that they should not be reprocessed.[26]

Several other researchers have attempted to determine whether clinical outcomes are affected in patients who receive reprocessed single-use devices by conducting meta-analyses of other published reports.[27,28] The researchers who performed the literature reviews and analyzed the published reports complained of the poor quality of most of the studies and the difficulty of comparing outcomes among different types of single-use devices. Some studies found no measurable differences between outcomes in those who received a new single-use device or those who used a reprocessed single-use device. Other studies found inconsistent differences.

Researchers who studied the reuse of cardiac pacemakers and implantable cardioverter defibrillators (ICDs) found that the devices continued to perform adequately in their second life and that the battery was sufficient for this reuse. The results focused on the function of the devices; the risk of transmitting infection was not addressed.[29,30] Conflicting results were reported by Pantos et al who reviewed a number of studies on reuse of various single-use devices for cardiac procedures. Because of conflicting results, there was concern about reuse of percutaneous coronary intervention catheters, while other devices such as pacemakers and ICDs were considered more safely reused.[31] Soman et al reported on five cases of infective endocarditis with rapidly growing mycobacterium in patients who were known to have had intravascular stent placement which involved reprocessed percutaneous transluminal angioplasty balloon catheters.[32]

There are some single-use devices that should never be reused on other patients, such as needles and syringes. Yet in some parts of the developing world, these items are frequently reused. In 2008, WHO estimated that unsafe injection practices resulted in the 340,000 human immunodeficiency virus infections, 15 million hepatitis B infections, 1 million hepatitis C infections, and 850,000 injection site abscesses worldwide. As a response to these statistics, WHO launched the Safe Injection Global to work with local communities to promote safe injection practices.[33]

Joint Commission International (JCI) Standards for Reuse of Single-Use Devices

JCI promotes safe practices through its standards in the 6th edition of the *Joint Commission International Accreditation Standards for Hospitals*. A chapter in the manual, "Prevention and Control of Infections," includes specific requirements when single-use devices are reused. Standard PCI.7.1 requires that if single-use medical devices are reused in the hospital, a hospital policy must be created which guides such reuse. When national laws or regulations exist, the policy must be consistent with these as well as professional standards. JCI also requires the hospital to identify which single-use devices it will allow to be reused—again, this needs to be specified in official hospital policy. The value of this policy is that it transmits expectations to all in the organization who must be familiar with the hospital's decisions on this topic. A hospital policy will create a standard interpretation of the hospital's decision on what is allowed, supporting the correct implementation of the policy throughout the organization.

JCI also requires that the hospital develop and implement a process for determining when a single-use device is no longer safe or suitable for reuse. This may entail some type of testing or inspection of the device. While a hospital may limit the number of times that a single-use device can be reprocessed and reused, there should be a process for evaluating each device that is reprocessed to determine if there are safety or performance concerns. This places a strong responsibility on the hospital that decides to allow reprocessing of single-use devices.

Prevention and Control of Infections standard PCI.7.1 also requires that the hospital has and follows a clear protocol for cleaning, disinfecting and sterilizing each single-use device which is reprocessed. Ideally, the protocol should be device specific and provide explicit instructions as to how these processes should be carried out. Detailed protocols create a correct and standard work process that reduces the risk of variation.

Of course, devices can fail, whether they are single use or reusable. Because of concerns that reprocessed single-use devices may be at higher risk for failure, it becomes important to be able to trace an adverse outcome related to device failure if that device was a reprocessed single-use device. The hospital needs to be able to confirm which patient received a single-use device that was reprocessed. JCI standard PCI.7.1 therefore requires hospitals to develop and follow a process

for identifying patients on whom reusable medical devices were used. JCI then expects that these patients will be tracked or followed if an adverse event or outcome occurs. The final requirement of standard PCI.7.1 is that the hospital must analyze the adverse event data and use the results to identify and implement improvements.

Standard PCI.7.1 references two other relevant JCI standards. These two standards direct the collection and analysis of data relating to adverse events or outcomes in patients who receive reprocessed single-use devices.[34] Access to Care and Continuity of Care (ACC) standard ACC.6 focuses on identifying risks for infection during transportation of patients, medications, and supplies and taking steps to prevent transmission of infection. For example, used single-use devices might be packaged for transport to the reprocessing facility in a manner that could result in the acquisition or transmission of infectious contaminants. Quality Improvement and Patient Safety (QPS) standard QPS.8 directs how hospitals collect, analyze and use data to improve the quality and safety of patient care. In particular, the standard requires that hospitals gather and analyze data on health-care associated infections and infectious disease outbreaks, which are risk points for the reuse of single-use devices.

Strategies for Decision-Making

This white paper aims to improve understanding of the complexities and risks of single-use device reprocessing. Each hospital must make a formal decision as to whether it will or will not allow the reprocessing of single-use medical devices. Without a formal decision by the hospital as a whole, the hospital is at risk for the decision to be made by unauthorized individuals within the organization, and such decisions could place the hospital and patients being treated at considerable risk.

Understanding the laws pertaining to reuse of single-use devices in the locations where the hospital provides patient care services is an important first step. Depending on the country, laws may or may not exist that apply to these practices. Some countries allow reprocessing, but require the reprocessor to assume considerable responsibility for the safety and functionality of the final device, with significant liability in the event of failure. The hospital must consider its options for reprocessing and reusing single- use devices very carefully. If third-party reprocessors are available to serve the needs of the hospital's reprocessing, the hospital must perform due diligence of the reprocessor to evaluate the business and operating procedures by which the devices are reprocessed. Table 2, at right, provides some questions that should be asked during such due diligence. Please note that these questions emanated from the US FDA, but have been revised for international use.

If a hospital wants to perform in-house reprocessing, it should critically evaluate the strengths of its cleaning, disinfection, and sterilization department, procedures, and personnel.

JCI-accredited hospitals or those pursuing JCI accreditation need to ensure their compliance with the applicable JCI standards discussed in this white paper. JCI also requires compliance with country laws and professional standards. Hospitals that wish to reuse single-use devices may establish internal requirements that are stricter than country laws, professional standards, or JCI standards. This is their prerogative. In this case, JCI surveyors will survey the hospital to its own standard. (JCI surveyors always survey to the strictest requirement, whether that is the hospital's policy, the JCI standard, or the country's laws.)

A hospital should carefully consider which types of single-use devices to be reused and the processes for confirming that they are safe and effective after reprocessing. Detailed standard operating procedures, or protocols, as well as specialized training and competency assessment prior to allowing staff to perform these duties, are essential foundational elements of an in-house reprocessing program that will support highest levels of practice. It is also critical that the hospital has a tracking process to trace a device to a patient and vice versa.

As data continue to be collected on this topic, it is important to keep abreast of new developments published in the medical, engineering, instrumentation, infection prevention and control, or other related professional publications. For instance, Canada Health, in collaboration with the Canadian

Table 2. Recommended Questions to Ask Potential Third-Party Reprocessing Vendors[35]

- ➤ Has the reprocessing facility been inspected by an authorized governmental agency?
- ➤ Which government authority has approved the reprocessing facility to reprocess single-use devices? Can documentation of this approval be provided?
- ➤ Which aspects of the reprocessing process have been validated?
- ➤ Does the reprocessing facility have limits on how many times items can be reprocessed?
- ➤ How are those limits determined? What process is in place to make sure those limits are not exceeded?

Source: Adapted from *Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff.* Food and Drug Administration. July 6, 2001.

Healthcare Association (CHA), published some additional recommendations for hospitals considering the merits of reuse:

A quality system for reprocessing single-use devices should include the following components:

1. A reuse committee including members from the facility with responsibility for administration, risk management, epidemiology, infection prevention and control, biomedical engineering, medical device processing and procurement, medical departments and accounting. The committee should establish policies, ensure that protocols exist for each reprocessed device, and monitor adherence to approved procedures.

2. Written reprocessing procedures for each type of single-use device.

3. Validation of the effectiveness of reprocessing procedures to ensure both sterility and functionality of the device.

4. Quality assurance. This includes monitoring of control points and quality indicators, regular sampling and inspection of devices, and a periodic review of external factors that could affect the safety or function of reprocessed devices, such as changes in hospital use practices, changes in the supplier of the device, or changes in the design or materials of the device.[36]

The WHO provides the following additional recommendations[11]:

- Health care organizations must have written policies on single-use medical devices:
- Critical and semi-critical medical devices labelled as single-use are not reprocessed and reused unless a licensed reprocessor does the reprocessing.
- Devices that cannot be cleaned safely should not reused (for example, burrs).
- Reusable devices with small lumens, such as catheters, drains, and fine cannulae, should be deemed single-use only and not be reprocessed and reused.
- Devices owned by the patient that are reused in his or her home must be adequately cleaned before reuse.
- Home care organizations may consider reusing single-use, semi-critical medical devices for a patient in his or her home when reuse is safe.
- The health care organization has a written policy and procedure on single-use device reprocessing.
- Single-use critical and semi-critical medical devices are considered disposable and discarded at point of use, except when reprocessed by an approved third party reprocessor.

Conclusion

The decision to reprocess and reuse single-use devices is complex, with little or poor data to provide clear direction. Hospitals considering this practice must understand the limitations of reprocessing and its risk to patients. Understandably, JCI standards about reusing single-use medical devices are exceptionally stringent because of the risk of patient harm. More and more countries around the world are incorporating language about reprocessing and reusing single-use items in regulations and oversight. It is important to remember that patients come to the hospital for care and surrender themselves with trust and a lack of knowledge of these types of issues. The hospital must advocate for practices in the best interest of patients.

References

1. Feigal DW. Reuse of Single Use Devices: Testimony to Subcommittee on Oversight and Investigations, House Committee on Commerce. February 10, 2000. https://www.fda.gov/NewsEvents/Testimony/ucm115002.htm Accessed March 29, 2017.
2. Caruthers B, Price P, Junge TL. *Surgical Technology for the Surgical Technologist: A Positive Care Approach,* 3rd edition. Chapter 4, p. 81, Association of Surgical Technologists, Cengage Learning.
3. *Sterility Assurance Compliance: A Guide for Medical Device Manufacturers*. Pacific BioLabs, Hercules, CA. Rev. 1.2, December 2010. http://www.pacificbiolabs.com/downloads/Booklet%20Sterility%20Assurance.pdf Accessed March 29, 2017.
4. Spaulding EH. Chemical disinfection of medical and surgical materials. In Lawrence C, Block SS, eds. *Disinfection, Sterilization, and Preservation*. Philadelphia: Lea & Febiger, 1968:517-31.
5. *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for industry and Food and Drug Administration Staff.* US Food and Drug Administration. Issued March 17, 2015. https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf Accessed March 29, 2017.
6. *Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA.* US Food and Drug Administration. July 30, 2001. https://www.fda.gov/RegulatoryInformation/Guidances/ucm071058.htm Accessed March 29, 2017.
7. "Reuse of Medical Devices Labeled for Single-use." Statement of David Feigal, MD before the Senate Committee on Health, Education, Labor and Pensions. June 27, 2000. https://www.fda.gov/NewsEvents/Testimony/ucm114926.htm Accessed March 30, 2017.
8. Guidance for industry and for FDA staff enforcement priorities for single-use devices reprocessed by third parties and hospitals [Internet]. Silver Spring (MD): US Department of Health and Human Services, Food and Drug Administration; 2014 Aug 14. [cited 2014 Nov 7]. Available from http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107172.pdf Accessed April 3, 2017.
9. *Summary of the Medical Device User Fee and Modernization Act of 2002, Including Changes Made by the Medical Devices Technical Corrections Act.* US Food and Drug Administration. April 1, 2004. https://www.fda.gov

/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/ucm109123.pdf Accessed March 30, 2017.
10. Azizi J, Basile RJ. Doubt and proof: the need to verify the cleaning process. *Biomed Instrum Technol* 2012 Spring; Suppl:49-54. doi: 10.2345/0899-8205-12.1.49.
11. *Decontamination and Reprocessing of Medical Devices for Health-care Facilities*. World Health Organization and Pan American Health Organization, 2016.
12. Committee opinion no. 537: reprocessed single-use devices. Committee on Gynecologic Practice, The American College of Obstetricians and Gynecologists, *Obstet Gynecol* 2012 Oct; 120(4):974-6.
13. Collier R. The ethics of reusing single-use devices. *CMAJ* 2011 Aug 9;183(11):1245.
14. Hussain M, Balsara KP, Nagral S. Reuse of single-use devices: looking back, looking forward. *Natl Med J India* 2012 May-Jun;25(3):151-5.
15. Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data. *Federal Register* 70 (188) Thursday, September 29, 2005. https://www.gpo.gov/fdsys/pkg/FR-2005-09-29/pdf/05-19510.pdf Accessed April 3, 2017.
16. *Reprocessing of Single Use Devices: An Environmental Scan*, April 2015, vol. 48, Canadian Agency for Drugs and Technologies in Health.
17. Therapeutic Goods Administration, Department of Health. Australian regulatory guidelines for medical devices (ARGMD). Woden ACT, Australia: Australian Government; 2014. [cited 2014 Nov 10]. Available from http://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd)
18. Association of Medical Device Reprocessors. AMDR summary: international regulation of "single-use" medical device reprocessing. Washington: The Association; 2014. [cited 2014 Nov 10]. Available from
19. If You Haven't Read the IFU, You Don't Know What You're Missing. Instructions for Use (IFUs) Often Differ between Original Manufacturer and Reprocessed Devices. Ethicon Endo-Surgery, Inc, 2008.
20. King JS, Pink MM, Jobe CM. Assessment of reprocessed arthroscopic shaver blades. *Arthroscopy* 2006; 22: 1046-52.
21. Weld KJ, Dryer S, Hruby G et al. Comparison of mechanical and in vivo performance of new and reprocessed harmonic scalpels. *Urology* 2006; 67: 898-903.
22. Roth K, Heeg P, Reichl R. Specific hygiene issues relating to reprocessing and reuse of single-use devices for laparoscopic surgery. *Surg Endosc* 2002; 16:1091-7.
23. Granados DL, Jimenez A, Cuadrado TR. Assessment of parameters associated to the risk of PVC catheter reuse. *J Biomed Mater Res* 2001; 58:505-10.
24. Hambrick D. 3rd. Reprocessing of single-use endoscopic biopsy forceps and snares. One hospital's study. *Gastroenterol Nurs* 2001; 24:112-5.
25. Mues AC, Haramis G, Casazza C et al: Prospective randomized single-blinded in vitro and ex vivo evaluation of new and reprocessed laparoscopic trocars. *J Am Coll Surg* 2010 Dec; 211(6):738-43. doi: 10.1016/j.jamcollsurg.2010.08.003.

26. Bhatia V, Gupta A, Sharma S et al. Residual contamination and bioburden after reprocessing of single-use endoscopic ultrasound needles: An ex vivo study. *Dig Endosc* 2017 Mar; 29(2):175-181.
27. Hailey D, Jacobs PD, Ries NM et al. Reuse of single use medical devices in Canada: clinical and economic outcomes, legal and ethical issues, and current hospital practice. *Int J Technol Assess Health Care* 2008 Fall; 24(4):430-6.
28. Jacobs P, Polisena J, Hailey D et al. Economic analysis of reprocessing single-use medical devices: a systematic literature review. *Infect Control Hosp Epidemiol* 2008 Apr; 29(4):297-301.
29. Hughey AB, Desai N, Baman TS et al. Heart Rhythm Society members' views on pacemaker and implantable cardioverter-defibrillator reuse. *Pacing Clin Electrophysiol* 2014 Aug; 37(8):969-77.
30. Jama ZV, Chin A, Badri M et al. Performance of re-used pacemakers and implantable cardioverter defibrillators compared with new devices at Groote Schuur Hospital in Cape Town, South Africa. *Cardiovasc J Afr* 2015 Jul-Aug; 26(4):181-7.
31. Pantos I, Efstathopoulos EP, Katritsis DG. Reuse of devices in cardiology: time for a reappraisal. *Hellenic J Cardiol* 2013 Sep-Oct; 54(5):376-81.
32. Soman R, Gupta N, Suthar M et al. Intravascular Stent-related Endocarditis due to Rapidly Growing Mycobacteria: A New Problem in the Developing World. *J Assoc Physicians India* 2015 Jan; 63(1):18-21.
33. World Health Organization. SIGN meeting report, 2010. Available at: http://www.who.int/injection_safety/toolbox/sign2010_meeting.pdf. Accessed March 24, 2017.
34. *Joint Commission International Accreditation Standards for Hospitals*, 6th Edition. Joint Commission Resources, Oak Brook, Illinois, USA, 2017.
35. Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff. Food and Drug Administration. July 6, 2001. https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070868.pdf Accessed March 30, 2017.
36. Reprocessing of Reusable and Single-use Medical Devices. Health Canada. July 30, 2004. http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/reprocess_retraitement_let-eng.php Accessed April 25, 2017.


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