Quick Safety

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# Ensuring critical instruments and devices are appropriate for reuse

## Issue:

Surgical instruments and other critical devices – those that enter sterile tissues[1] – are reprocessed and reused every day in hospitals, ambulatory surgery centers, and other health care facilities. Because of the costs of physical space, supplies, equipment, and personnel to perform reprocessing and sterilization of reusable devices, some organizations choose to use disposable instruments and devices for critical procedures in some or all areas of their facility. For organizations performing reprocessing, ensuring that those instruments and devices are reusable – that they are in good condition, and can be cleaned and sterilized following validated manufacturer's instructions – is critical to patient safety.

In the United States, the Food and Drug Administration (FDA) considers reprocessing instructions part of labeling and in 2015 provided guidance to ensure that the appropriate level of reprocessing is addressed based on the intended use of the device. The FDA also provided guidance for manufacturers to assist in the formulation and scientific validation of reprocessing instructions for reusable medical devices.

Manufacturers of medical devices must submit evidence to the FDA to demonstrate that the device to be marketed is safe and effective. Reprocessing instructions for medical devices should be validated. However, because of the greater risks to the public health posed by some devices, 510(k) submissions for those devices, but not all, must include protocols and complete test reports of the validation of the reprocessing instructions. Manufacturers of devices intended to be used as a critical device and sterilized are required to provide instructions for decontamination, cleaning, and sterilization. Sterilization instructions for medical devices provide the critical parameters that must be followed to achieve sterility of that device – sterilization method, time, temperature, pressure, and dry times. *Instructions for reprocessing are not provided for single use items, also called single use devices (SUDs), and may include instruments or devices.*

### Special considerations related to SUDs

An SUD 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. However, in the United States there are special circumstances under which third parties, usually through a contracted service with health care organizations that use SUDs, may reprocess medical devices and instruments labeled for single use. These third parties have been approved by the FDA to reprocess specific medical devices labeled for single use and must abide by strict rules that may be even more strict than those applicable to the original manufacturers of the SUD. Other countries have similar guidance[2] or laws that prohibit reprocessing single use or expired items. Contracting with an FDA approved third party to reprocess opened but unused devices, high cost or high-volume SUDs (such as blades, bits and burs) or with a sterilization service, are other ways organizations can mitigate costs associated with providing safe sterile devices.

**Terms, labels for SUDs**

The manufacturers of single use devices (SUDs) may use the following terms to label a device for single-use only: disposable; consumable; not for re-use or do not re-use; discard after single-use; do not use twice; or use a symbol (illustrated below).[2] Manufacturers of SUDs are not required to provide reprocessing instructions as part of their labeling because reprocessing would not be applicable to an item labeled as single use.


Although they may look identical to a reusable instrument or device, SUDs do not have validated instructions for reprocessing and may not be designed to allow for thorough decontamination after use. SUDs also may be made of lower quality metals or components that will not withstand the cleaning and sterilization processes and may deform, rust, pit, chip or crack if they are subjected to reprocessing methods used in health care facilities.

Reprocessing a SUD may alter its physical characteristics and functionality so that it no longer complies with the original manufacturer's specifications, therefore compromising instrument or device performance and patient safety. For example, a device designed to remove tissue or bone within very tight parameters may remove more or less tissue or bone as a result of wear during reuse or undergoing unvalidated reprocessing. This also applies to sterile, single use items that have expired and were never used for patient care. The result could have serious consequences for the patient as well as the organization.

The Joint Commission.

Only a fraction of SUDs may be appropriate to be reprocessed by a third party reprocessor for reuse on another patient. SUDs that have not undergone the extensive testing, validation and documentation required by the FDA cannot be guaranteed to be safe for reuse.[2] *For this reason, the FDA prohibits reprocessing of SUDs by anyone other than an FDA validated reprocessor*.[3] Health care organizations should note that re-sterilizing a SUD is considered reprocessing by the FDA and SUD reprocessors are subject to all the regulatory requirements currently applicable to the original device manufacturer, including premarket submission requirements.

**The goal: Sterile, functional instruments**
Health care organizations must ensure that critical instruments and devices that are being reprocessed are not labeled as SUDs and have validated reprocessing instructions for decontamination, cleaning, and sterilization. Organizations also must maintain reusable instruments in a condition to ensure safe and effective use. Instruments and devices in disrepair or with compromised surfaces – such as oxidation, pitting, cracking or damage from instrument marking – may not be able to be effectively sterilized. Additionally, instruments that have sustained structural damage may not function as intended. For example, scissor blades, forceps tips or teeth may be misaligned, or ratchet performance may be affected. In addition, discoloration or staining of devices may be indicative of a problem with the process such as presence of detergent residues, poor water or steam quality, and lack of sterilizer or washer maintenance.

Manufacturer instructions may contain the maximum number of reprocessing cycles validated for a particular item, provide a description of when an instrument is no longer appropriate for reprocessing, or may make a statement that organizations must inspect for wear and tear and determine when the items "useful life" is over. With the large number of instruments that some organizations are required to reprocess every day, ensuring careful inspection and application of the manufacturer's instructions about useful life can be a challenge. Especially if the organization does not have replacement instruments and access to maintenance or refurbishing resources.

One comparative study analyzed patterns of wear and tear sustained among sets of surgical instruments from two surgical units to provide some perspective on the quality of reprocessing within the institution. The study found patterns of damage to surgical instruments that were still in use. The most common damage was staining, followed by loosening of instrument joints, rust, pitting and malalignment. The most common type of breaks in instruments were broken tips but involvement of the shaft or handle of instruments were also seen.[4] These types of damage to instruments are routinely seen in instruments undergoing reprocessing and should result in the instrument being pulled from service until it is repaired, refurbished or replaced – but often reuse continues.

**Safety actions to consider:**
Reprocessing critical instruments within regulatory guidance can be a cost effective and efficient way for health care organizations to manage resources, and the following safety actions can further protect patients and help ensure that critical instruments and devices are clean, sterile and functional.

***For reprocessing of reusable instruments and devices:***
Careful inspection of critical instruments and devices for soil or damage, including but not limited to bioburden, oxidation, corrosion, pitting, discoloration, cracking, peeling, chipping, lifting or improperly applied identification tape, or etching that leaves rough or frayed edges, is a critical step in protecting patients from potential cross-contamination. *Damaged or soiled instruments should not be released for use as a sterile item.* Soiled instruments cannot be considered sterile because the efficacy of the sterilant or its ability to reach all surfaces may be compromised by soil.[5] All items undergoing reprocessing should also be checked for functionality during the inspection process.

Effective interventions to prevent reprocessing of instruments or devices that are not appropriate for use include:

- Standardized instrument and device visualization occurring during each step of the decontamination, cleaning, and sterilization processes with final inspection prior to use and removal of any instrument inappropriate for use.
- Integration of Infection Preventionist review of critical instruments and devices during the purchasing process.
- Readily available manufacturer's instructions for use and intermittent review of the manufacturer's instructions for use for all critical instruments and devices.

- Education, training, and competency of staff responsible for reprocessing, oversight and/or supervision of reprocessing sterile products on their role in the reprocessing of reusable instruments and related job duties. Staff responsible for reprocessing must understand the important patient safety role that they play and be empowered to prevent reprocessing of an instrument or device that is not appropriate for use.
- Effective maintenance and refurbishment processes to keep instruments in optimal condition and determine when useful life has been met for each instrument undergoing reprocessing.
- Effective replacement plan for items that are no longer suitable for use or cannot be refurbished.
- Use of rinse water that meets the device manufacturer's instructions for use.
- Compliance with maintenance instructions for all devices and equipment used for reprocessing, including but not limited to
    - Automated dilution and flushing devices.
    - Ultrasonic cleaners and washer decontaminators.
    - Sterilizers.
    - Water treatment systems.
- Education, training, and competency of staff handling instruments at the point of use to ensure that they understand which instruments should or should not be reused, even if they appear to have undergone sterilization, and what to do if an item that should not have been reprocessed is identified.
- Education, training, and competency of staff to ensure they understand key issues that can lead to damage of instruments and devices and do not contribute to instrument damage, including:
    - Using fragile instruments meant for delicate procedures (e.g., ophthalmology instruments) for other procedures.
    - Exposing instruments for prolonged periods of time to blood and other body fluids or allowing these substances to dry on instruments.
    - Using saline or corrosives such as bleach or inappropriate cleaning chemicals.
    - Using abrasives.
    - Transporting instruments in a way that places them at risk of damage.

***Additional considerations related to SUDs:***

- Staff handling SUDs in all areas know that SUDs only may be reprocessed as part of a contract service if the organization has chosen to pursue third party reprocessing.
- Disposal of SUDs at point of use (e.g., waste receptacles large enough to accept the SUDs) or a clear process to segregate them from reusable devices and prevent inadvertent reprocessing of SUDs.
- Staff responsible for reprocessing, oversight or supervision and use of sterile products are educated and trained on their role in identifying single use items that should not be reprocessed at the organization and are competent to perform their related job duties.

**Resources:**

1. Alberta Health, Government of Alberta. Reusable & Single-Use Medical Devices Standards: Standards for reprocessing of reusable medical devices and for the use of single-use medical devices in all health care facilities and settings. Sept. 2019.
2. Medicines & Healthcare Products Regulatory Agency. Single-Use Medical Devices: Implications and Consequences of Reuse. Jan. 2021.
3. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health. Guidance for Industry, FDA Staff, Third-Party and Hospital Reprocessors: Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Three Additional Questions. July 16, 2003.
4. Munakomi S, Shah R, and Shrestha S. A pilot study comparing pattern of damage sustained among instruments from different surgical units in a tertiary care centre in Nepal – reappraising the role of instrument reprocessing in retaining their value. F1000 Research. Jan. 23, 2018. doi:10.12688/f1000research.13699.1
5. Association of Surgical Technologists. Standards of Practice for the Decontamination of Surgical Instruments.

*Note: This is not an all-inclusive list.*