

infection prevention

By Sylvia Garcia–Houchins, RN, MBA, CIC

Keeping Instruments Appropriate for Reprocessing

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In 2018 approximately 14.4 million operative procedures took place during inpatient stays[1] and an estimated 129 million outpatient surgical procedures were performed.[2] Add that information to results from an American College of Surgeons study reporting that 5.9 percent of trays delivered to the operating room (OR) contain broken instruments, and the statistics are staggering. It means that during that single year, more than eight million OR trays potentially contained at least one broken instrument.

The Joint Commission's infection prevention and control department focuses its efforts on the cleanliness of instruments since we have been taught that, "if it isn't clean, it isn't sterile."[3] If there is tissue, bone, or other soil left behind from a prior surgery, the instrument's unsterile condition could carry risk of infection. The Joint Commission does not just focus on cleanliness of instruments when tracing sterilized instruments. Our surveyors also are trained to determine if an item is appropriate for reprocessing. Since potential exists for organizational liability related to surgical instruments that should not be reused, part of The Joint Commission survey process is to work with customers to identify these potential areas of liability. There are a variety of reasons that surgical instruments are not appropriate for reprocessing including but not limited to: pitting, oxidation, cracks, damaged insulation, or connectors, flaking and sticky tape, and bioburden. ECRI noted that 34 percent of soiled instruments resulted from inadequate cleaning – a violation that should be caught during the instrument inspection process prior to packaging – not at point of use.

In addition to instruments in disrepair making their way to the sterile field, Joint Commission surveyors have noted with increasing frequency the reprocessing of single-use devices (SUDs) – items labeled by their manufacturer as "single-use" or disposable. These devices are often made of lower quality materiel and as a result, develop pitting and oxidation which indicates to the surveyor that something might be amiss. SUD reprocessors are regulated by the Food and Drug Administration (FDA)and are subject to all the regulatory requirements currently applicable to the original device manufacturer, including premarket submission requirements. If a healthcare organization reprocesses a single use device, it is dangerously

Healthcare organizations follow key measures to ensure that their instruments are appropriate for reprocessing. These include:

- Before reprocessing any device, obtain the manufacturer's validated reprocessing instructions. Review to ensure they meet the intended level of reprocessing based on intended use of the item and to ensure your organization has the appropriate equipment and products to follow the instructions.
- Ensure staff who are performing inspection are competent and able to perform the inspection process. Ensure staff knows which equipment dismantles and how to inspect it. Healthcare organization leadership should provide staff with good lighting and tools such as lighted magnifiers and other helpful equipment to ensure ample vision while inspecting.
- Empower staff to identify instruments of subpar quality and prevent their use – even if it means delaying or rescheduling affected cases.
- Establish effective maintenance and refurbishment processes to keep instruments in optimal condition. Determine when to remove an instrument that is no longer safe to undergo reprocessing.
- Ensure staff at point-of-use can identify when an instrument should not be used – even if it is in sterile packaging- and how to return and report the occurrence for quality monitoring.
- Train users to appropriately discard SUDs and support the process by ensuring disposal containers at point of use for safe disposal.
- Train users on key issues that can lead to damage of instruments and devices, including erroneously using delicate instruments meant for tissues on other items (e.g., gauze, tape, tubing, etc.), prolonged exposure to blood and other body fluids, or allowing these substances to dry on instruments, use of saline or corrosives such as bleach or inappropriate cleaning chemicals, use of abrasives, or transporting instruments in a way that places them at risk of damage.
- Sometimes instruments are damaged during use. Create and effective process for identifying instruments that require repair or replacement.
- When tracing sterilization practices at your organization, periodically open and inspect instruments in peel pouches and trays to ensure that they are appropriate for sterilization and -use.

allowing itself to become a manufacturer of a medical device – and thus assuming all the manufacturer's liability should that device fail. In addition, it takes on the liability of possible FDA rule violation.

• Create a "good catch" reporting process that rewards identification of instruments that should not be reprocessed so that tracking and trending is accurate for budgeting and quality purposes.



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