# *The Critical Role of Point-of-use Pre-Cleaning in Instrument Reprocessing Workflows*

## Background

Healthcare organizations accredited by the Joint Commission continue to discover serious non-compliance issues with the Infection Prevention and Control Standard IC.02.02.01. Organizations continue to be in non-compliance by not having robust processes in place to reduce the risk of infections associated with medical devices. These breaches are specific to High-Level Disinfection of semi-critical devices and sterilization of critical devices; both pose a potential risk of infection to patients.[1] The risks associated with improperly reprocessing medical devices are serious. A comprehensive review of scientific studies conducted between 1966 and 1996 found 281 episodes of pathogen transmission attributed to GI endoscopy alone.[2] Even with advances in High-level Disinfection and Sterilization techniques since the conclusion of that study, patients continue to contract Healthcare Associated Infections (HAIs) at an alarming rate. Recent data published in the New England Journal of Medicine indicates that every year, 75,000 people die from HAIs[3]. In order to stem the risk of HAI's, it is important for Infection Preventionists to continue to train faculty and staff on current and emerging infection control practices. As pointed out by the Joint Commission, compliance within the High-Level Disinfection and Sterilization processes is an area that many facilities should focus education and training efforts on.[1] Key parts of the instrument reprocessing procedure that are often overlooked are instrument pre-cleaning and transport to the sterile processing department.

## Resources, Definitions and Guidelines to be Familiar with

One of the main ways that the Joint Commission evaluates a healthcare facility's infection prevention practices is through the facility's adherence to widely accepted and contemporary guidelines. Generally, Infection Preventionists and key staff involved in instrument reprocessing should review relevant guidelines and standards every year to stay up to date on new techniques and emerging challenges in infection control[1]. The below sources of information are some of the standards that should be understood thoroughly and offer generally accepted best practices when performing instrument reprocessing

1. **Use the Spalding Classification to identify semi-critical and critical medical devices[4].** This classification is invaluable for facility personnel and helps determine the level of disinfection / sterilization each device needs to go through during reprocessing based on the risk of infection associated with the device's intended use. Devices can be classified into one of three categories:
   - **Critical**: A device that enters normally sterile tissue or the vascular system. Such devices should be sterilized, defined as the destruction of all microbial life.
   - **Semi-critical**: A device that comes into contact with intact mucous membranes and does not ordinarily penetrate sterile tissue. These devices (eg, GI endoscopes) should ideally be sterilized or receive at least high-level disinfection, defined as the destruction of all vegetative microorganisms, mycobacteria, small or nonlipid viruses, medium or lipid viruses, fungal spores, and some, bacterial spores.
   - **Non-critical**: Devices that do not ordinarily touch the patient or touch only intact skin, such as stethoscopes or patient carts. These items may be disinfected by low-level disinfection.

2. **Familiarize all personnel involved in instrument reprocessing with the Joint Commission BoosterPak on High-Level Disinfection and Sterilization[1].** This document contains guidelines and standards that the Joint Commission considers critical in certifying that accredited facilities are following evidence-based best practices when it comes to high-level disinfection and sterilization. A critical standard covered in the BoosterPak is **Standard IC.02.02.01: Reducing the risk of infections associated with medical equipment, devices, and supplies. A main provision of this Standard is EP2: Performing intermediate, high-level disinfection and sterilization of medical equipment, devices, and supplies.** As of 2015 the majority of Healthcare facilities continue to be out of compliance with IC.02.02.01 as demonstrated in the graph below.

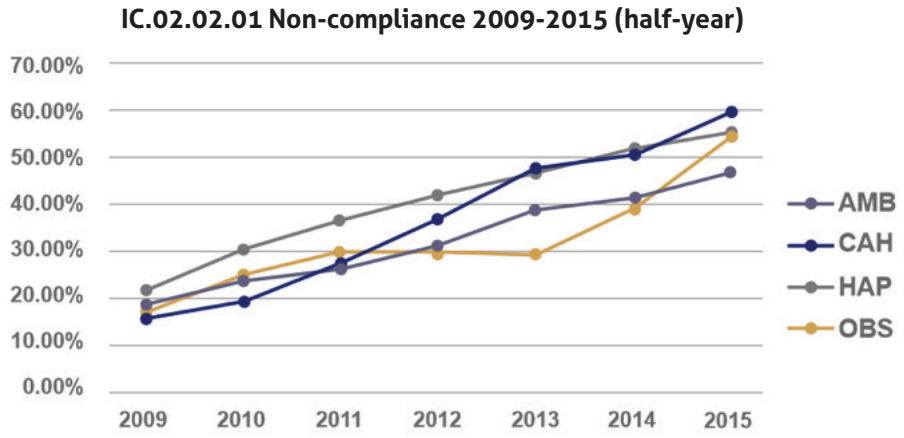


**Figure 1 illustrates IC.02.02.01 non-compliance rates in (AMB) Ambulatory Surgery Centers, (CAH) Critical Access Hospitals, (HAP) Hospitals and (OBS) Office-based Surgery Practice Settings[1]**

The Joint Commission considers any lapse in compliance a source of an immediate threat to life and cause for adverse accreditation decision[1].

3. **The 2008 CDC Guideline on Disinfection and Sterilization in Healthcare Facilities should be reviewed periodically[5].** This guideline continues to serve as the gold standard for disinfection and sterilization practices in the United States. While personnel involved in infection control should be familiar with the entire document, extra care should be taken to review the CDC's recommendations on instrument cleaning and transport. In 2015 the CDC was forced to deliver an official Health Advisory to highlight the "Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices"[6]. A major area of deficiency identified in the advisory was a lack of procedural detail on instrument cleaning promptly following the use of a patient care medical device. CDC recommends that each facility review its workflows for instrument reprocessing and promptly train all relevant personnel in the performance of these procedures once a standards-based process has been developed.

4. **Review the Multisociety guideline on reprocessing flexible GI endoscopes[7].** Endoscopes present a particular challenge for infection control personnel given their complexity. This guideline provides evidence-based recommendations on how to high-level disinfect or sterilize several common types of endoscopes. The importance of understanding this guideline is critical for any healthcare worker in endoscope reprocessing. Each of these procedures carries the risk of harming the patient if they are exposed to pathogens linked to HAIs.

**It is estimated that roughly 20 million endoscopic procedures are performed in the United States annually[11].**

5. **Infection Preventionists should review manufacturer's instructions for cleaning and disinfecting of all devices used in their healthcare facility. Medical device manufacturers ultimately determine the best way that their reusable devices should be reprocessed.** It is important to keep manufacturer instructions for use readily available in case certain devices require special techniques to be adequately reprocessed. The CDC always recommends disinfecting any reusable medical device based on the manufacturer's instructions for use as a way to ensure all parts of the device are disinfected and that the device is not inadvertently damaged during the disinfection process[5].

## From Patient Room to Sterile Processing Department (SPD): The Pre-Cleaning and Transport Process

Before a reusable medical device can be reprocessed, it must be pre-cleaned at the point of use and transported to the unit in the healthcare facility where high-level disinfection and sterilization takes place. Failure to do these two actions properly can expose patients and healthcare personnel to pathogens capable of causing HAIs. Proper pre-cleaning and transportation is also essential for preventing the growth of biofilms on patient care medical devices. Hardened biofilms have been linked to decreased efficacy or outright failure of disinfection and sterilization processes[5]. In fact, data referenced by the CDC suggests that bacteria are up to 1000 times more resistant to antimicrobials when covered with a layer of biofilm[12]. It is therefore critical to follow evidenced-based guidelines when preparing reusable medical devices for terminal high-level disinfection or sterilization. The Joint Commission, CDC, and multisociety guidelines recommend that the following steps be observed when following proper instrument reprocessing procedures[1,5,7]

1. **Always make sure that proper personal protective equipment (PPE) is worn when any instrument reprocessing procedure is being performed.** This includes gloves, eye protection, impervious gown, face shield or simple surgical mask that will not trap vapors[8]. Proper PPE is critical in ensuring that the healthcare worker performing the instrument reprocessing is not exposed to pathogens present on soiled medical devices.

2. **Immediately following the end of a medical procedure, all reusable medical devices should be pre-cleaned. All reusable medical devices, regardless of Spalding Classification should undergo pre-cleaning at their point of use.** Specifically, the affected devices should be cleaned and wiped down so that visible debris is removed and bioburden has no opportunity to harden into a biofilm[7]. Hardened biofilm is difficult to remove and most disinfectants are ineffective if biofilm is present on a device. CDC, Joint Commission and multisociety guidelines all recommend using an enzymatic cleaner or detergent when pre-cleaning reusable medical devices[1,5,7]. These detergents are an excellent way to break down excess proteinaceous soils on used devices[5]. When possible, it is also recommended that the devices be soaked in enzymatic detergents after being wiped down to ensure that all surfaces of the device have visible debris removed from them[9].

   Special care should be taken when pre-cleaning any kind of endoscope. In addition to cleaning the exterior of the endoscope at the point of use, the interior channels, or lumens, of the endoscope must also be pre-cleaned. To do so, suction enzymatic detergent into all lumens until expelled fluid is clear. Suction air to ensure all used enzymatic detergent has been expelled[1].

3. **After a medical device has been pre-cleaned, it can be transferred to the SPD or reprocessing area to undergo disinfection or sterilization.** PPE should be worn at all times during transport and cleaned devices should always be

transported in sealed containers. Containers used for transport should be leak-proof, puncture-proof, and labeled as biohazardous[1]. The contents of the container should also be kept moist (ideally with an enzymatic detergent[10]) to prohibit the hardening of any remaining bioburden. Consult the medical device manufacturer's instructions for use if a special transport container is needed[1]. Proper transport of the device is essential to protect both patients and staff from harmful microorganisms that may still be present on the surface of the device[7]. Once transported to the reprocessing area, most instruments can undergo disinfection or sterilization in line with generally accepted guidelines and the manufacturer's instructions for use.

4. **Additional steps must be taken after transport and before high-level disinfection or sterilization occurs when reprocessing endoscopes.** First, the endoscope must be tested for leaks. Perform leak testing according to the manufacturer's instructions[1]. After leak testing, manually clean the endoscope. This encompasses meticulously disassembling and cleaning the entire endoscope, including valves, channels, connectors, and all detachable parts using only model specific cleaning devices (such as brushes) designed for the endoscope model being cleaned. Additionally, these parts should be submerged in enzymatic detergent and all channels should be flushed with detergent again[7]. Only after manual cleaning is performed may the endoscope be disinfected or sterilized according to the manufacturer's instructions. The goal of this second manual cleaning step is to remove all debris from the interior and exterior of the scope to allow proper penetration of the disinfectant[5]. Recent multisociety guidelines highlight the danger of not performing this extra round of manual cleaning via increased pathogen transmission. From 2012 to 2015, over 25 outbreaks resulting in 250 infections and 30 have been linked to duodenoscope reprocessing failures alone[13].

## Instrument Reprocessing Solutions

Metrex is proud to offer a full line of instrument reprocessing products to help infection control personnel properly perform pre-cleaning and transport procedures.

EmPower™ Foam is used to pre-clean critical or semi-critical medical devices prior to terminal sterilization or high-level disinfection. It is a ready-to-use, foaming dual-enzymatic spray and is ideal for use in the operating room, sterile processing, and other departments where instrument cleaning is not immediately available. It is especially useful when instruments need to be kept moist to prevent the formation of biofilms.

MetriSponge™ is used to pre-clean critical or semi-critical medical devices prior to terminal sterilization or high-level disinfection. Its unique shape easily forms around cylindrical instruments and simplifies pre-cleaning of medical instruments and is pre-soaked with MetriZyme™ dual enzymatic detergent.

Combining proper instrument reprocessing workflows with appropriate products is an effective way to adhere to accepted standards and guidelines while also preventing the spread of HAIs in healthcare facilities.[1,5] Pre-cleaning at the point of use and proper transport of instruments to the SPD are two critical parts of instrument reprocessing that are often overlooked[7]. It is up to Infection Preventionists to educate staff on these procedures and make sure that their facilities are practicing up-to-date and contemporary infection control measures when it comes to reprocessing and disinfection/sterilization of reusable medical devices.

## References


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