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Cleaning Reusable Medical Devices: A Critical First Step



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Introduction

Over 45 million inpatient¹ and 31.5 million outpatient² surgical and non-surgical procedures are performed annually in the United States. During these procedures, patients entrust their well-being to the medical professionals with whom they come in contact. They trust that all necessary measures have been taken to ensure an optimal outcome. One measure that must be reliably performed is the appropriate cleaning of the millions of reusable medical devices which come into contact with patient skin, blood and other body fluids and tissues each year.³ According to the FDA, a medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article."⁴ What if reusable devices were not appropriately cleaned after each procedure? What impact would that have on patients? This article discusses the risks associated with improper cleaning of reusable medical devices and provides medical professionals with the information on the effective use of cleaning solutions.

Risks Associated with Improper Cleaning

Following a procedure, a medical device is contaminated with both visible and hidden bioburden. This bioburden or soil may contain hundreds if not millions of potentially infectious organisms. Any soil left on a device following cleaning can pose a risk to the patient. Therefore, it is imperative that appropriate steps be taken to ensure a thorough cleaning process. Proper cleaning of medical devices is a multi-step process (Figure 1). Before a medical device reaches the reprocessing area, it is critical to remember that contaminated devices should be handled as little as possible following use. Preferably, after use, devices should be soaked or sprayed to keep them moist during transport. Keeping the devices and any residual contaminants moist helps make the cleaning process easier and more effective. Thorough manual and/or mechanical cleaning is needed for all reusable medical devices prior to disinfection or sterilization. This step requires the use

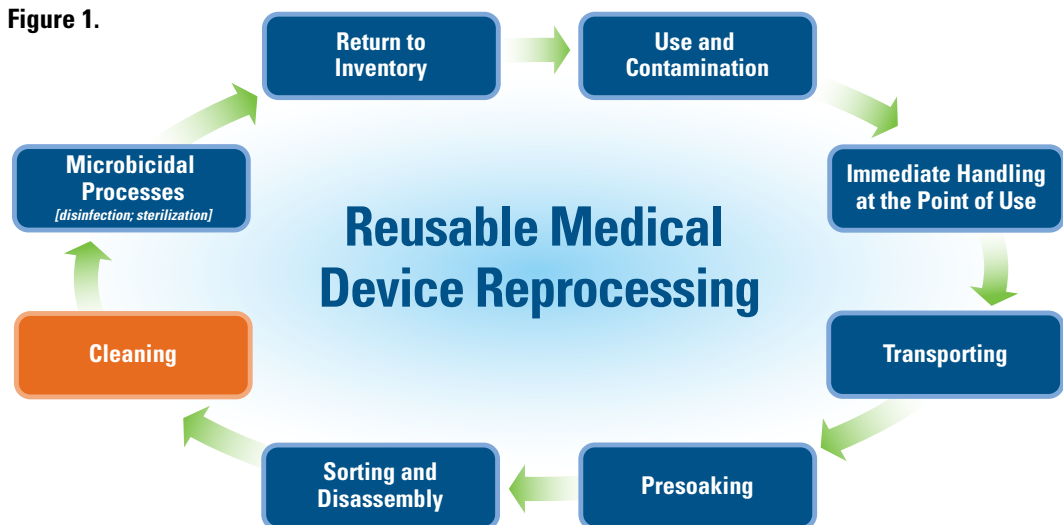
of the proper products and processes to assure that all surfaces, internal and external, are completely free of bioburden. Finally, the devices should be thoroughly rinsed to remove all residual bioburden and detergent. If the device is not going directly into a washer following this step, the device should also be dried. Always remember, if the device is not clean, it cannot be sterilized.

Significant risks have been associated with inadequate or improper cleaning. These risks include healthcare-associated infections (HAIs) due to the presence of residual soil and/or improper disinfection or sterilization, and damage to the medical device.

Healthcare-Associated Infections

It has been reported that HAIs have accounted for an estimated 2 million infections, 90,000 deaths, and \$4.5 billion in excess health care costs in the United States alone.⁵ Due to the significance

Figure 1.



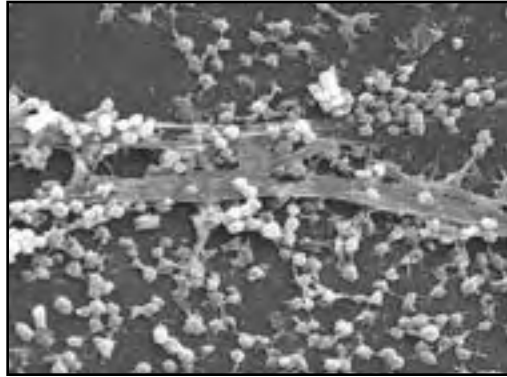
Proper cleaning is essential to reducing the risks associated with improper or inadequate medical device reprocessing.

of this problem, initiatives to monitor and prevent the occurrence of HAIs have been developed. As of February 2007, 16 states have enacted legislation mandating hospitals to publicly disclose HAI rates. Several other states have legislative efforts in progress.⁶ Within the last few years, initiatives such as the Surgical Care Improvement Project (SCIP), the 100 Thousand Lives Campaign, and the 5 Million Lives Campaign were developed to reduce HAIs and to protect patients from medical harm. Additionally, Pay for Performance (P4P) incentives have been established to reward good patient outcomes.

These various initiatives demonstrate the increasing legislative and consumer interest in HAIs and the Centers for Medicare and Medicaid Services (CMS) push toward pay-for-performance (P4P). This focus on reducing medical errors has generated an even greater emphasis on standardized and appropriate cleaning of medical devices.

Improper cleaning has been implicated in patient-to-patient transmission of microbes via contaminated devices such as bronchoscopes contaminated with *Mycobacterium tuberculosis*.³ Documented cases of pathogen transmission via gastrointestinal (GI) endoscopic procedures have been associated with a breach in accepted cleaning and disinfection guidelines, use of an unacceptable liquid germicide for disinfection, improper drying or defective equipment.⁷ In a similar case report, the transmission of Hepatitis C virus to patients during colonoscopy procedures was associated with a breach in following

accepted cleaning and disinfection guidelines.⁸



Scanning electron micrograph of a Staphylococcal biofilm on the inner surface of an indwelling medical device. Bar, 20 μ m. Used with permission of Rodney M. Donlan, Ph.D. and Janice Carr, CDC.

Another risk of infection develops from improperly processed devices which allow for accumulation of microbial biofilms (collections of bacteria and fungi). These biofilms adhere to each other and to the surfaces of medical devices, especially those with lumens, and increase the difficulty of thorough cleaning. Cleaning devices immediately after use has the potential to eliminate this problem of biofilm contamination.^{9,10}

Any soil or bioburden remaining on a device after cleaning poses a clear risk to the next patient. Unfortunately, this incomplete cleaning occurs all too often. For example, the Pennsylvania Patient Safety Authority has received multiple reports citing devices contaminated with bone, tissue, dried fluids and used sutures that were introduced into the sterile field. Specifically, this contamination included bone left in reamers, blood and tissue found on a drill and suture fragments remaining on a tunneler.¹¹

Improper disinfection or sterilization

Another risk associated with improper cleaning is the resultant improper disinfection or sterilization of medical devices. All high level disinfection and sterilization technologies available today are surface agents. They must have unimpeded contact with all surfaces of the device, internal and external, to assure microbial inactivation. Any residuals left on the device, including medical soil, contaminants and detergent residue can interfere with that direct contact. Furthermore, interaction of the residuals with the disinfectant or sterilant could lessen the efficacy of that disinfectant or sterilant.^{3,10,12}

If the error in reprocessing is not identified prior to surgery, serious patient complications may result. For instance, there have been reports of sterilized medical devices that have remained contaminated with bacterial endotoxin residues. These heat-stable toxins are not destroyed during the sterilization process and remain a danger to the patient. Also, inflammatory reactions have been reported when detergents, enzymes and tiny particulate matter have contaminated instruments, tubing or the inside of irrigating cannulas.¹³

There may be a delay in detecting reprocessing errors. If an improperly processed device is introduced into the sterile field, it poses not only a risk to the patient but may also create cost and process challenges. The procedure may be delayed, causing the patient to remain under anesthesia longer than necessary.

This situation also wastes valuable time and increases costs associated with the scheduled procedure.



Errors in reprocessing which are not identified until the medical devices have been introduced into the sterile field or are used on a patient can result in serious consequences to the facility as well as the patient.

Damage to medical devices

A medical device may become damaged by cleaning solutions or medical soils that are not removed properly after the cleaning process.¹² Using cleaning solutions that are not compatible with a device may cause damage as well.¹² Types of damage the device may sustain include staining, pitting or corrosion,¹⁴ clouding or etching of optics¹⁵ and improper function due to accumulation of debris.¹²

In order to reduce the risks associated with improper or ineffective cleaning of reusable medical devices, the basic components and types of cleaning solutions, as well as the factors for the effective use of cleaning solutions, must be understood.

Basic Components of Cleaning Solutions

It is essential that an appropriate cleaning solution be chosen, and that it be used correctly, to assure optimal cleaning of medical devices. To do this, an understanding of the basic components of cleaning solutions is required.

Only those cleaning solutions that are specifically formulated and labeled for use on medical devices should be used in reprocessing. The formulation of each cleaning solution is unique; however, most will contain some combination of the following six components (*Figure 2 on page 6*).

Water is the most common solvent on earth and provides the base for most cleaning solutions.

Detergent helps to loosen debris from surfaces. The detergent then acts to hold the debris in suspension, preventing it from re-depositing on the device and allowing it to be easily rinsed away.

Surfactants increase cleaning efficacy by reducing surface tension thus allowing for better penetration of the soil.

Buffers provide better compatibility with materials and inhibit corrosion.

Chelating agents assist with reducing the potential negative effects of hard water that may be used when diluting the solution. They also bind with hard water minerals to prevent them from depositing on the device or adversely reacting with the cleaning solution. It is important to note that hard water may cause spotting or leave deposits on the device.

Enzymes increase cleaning efficacy, speed the cleaning process and help to minimize the need for manual brushing and scrubbing. There are a variety of enzymes available, each targeting a particular type of soil. The most common enzyme found in solutions used for cleaning medical devices is protease, which helps to break down protein-based soils such as blood and feces. Also available are amylase to break down starches like those found in muscle tissue, cellulase to break down carbohydrates like those found in connective fluid and joint tissue and lipase to break down fats like those found in adipose tissue. Any combination of these enzymes may be present in a solution. Solutions containing enzymes can often be used at a more neutral pH and at lower temperatures than those without enzymes.¹⁶

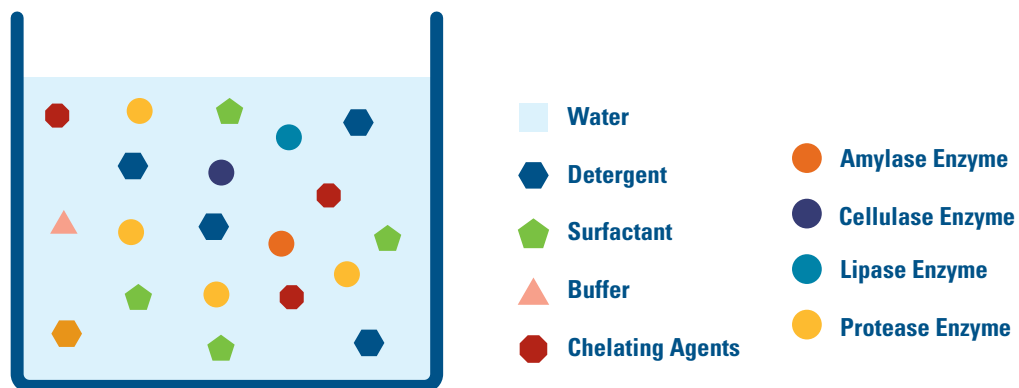
Common Types of Cleaning Solutions

Medical device cleaning solutions are made up of various combinations of the six basic components. The most common formulation categories of cleaning solutions are enzymatic and non-enzymatic. Typically, medical device cleaning solutions will be simply referred to as 'detergents'.

Enzymatic detergents are most commonly used for manual cleaning and include single- dual- and multi-enzyme formulations. Single-enzyme detergents will most often contain a protease enzyme while dual- and multi-enzyme detergents will also contain some combination of amylase, lipase and/or cellulase. These solutions are often designed to be used at room temperature or slightly warmer and provide rapid action at a neutral pH. Due to the selectivity of each enzyme, the enzymatic detergent chosen should correspond with the type of medical soil(s) present.

Non-enzymatic detergents are most commonly utilized in automated washers. They can be of either a neutral or alkaline pH and provide effective cleaning at elevated temperatures.

Figure 2.



Most cleaning solutions for medical devices are composed of the following: water, detergents, surfactants, buffers, chelating agents, and one or more enzymes.

Factors for the Effective Use of Cleaning Solutions

For a cleaning solution to be effective, a number of factors must be addressed including:

1. Personnel training
2. Appropriate use of personal protective equipment (PPE)
3. Proper device preparation
4. Quality of the water used
5. Adherence to guidelines and manufacturer's directions for use

Personnel Training

Personnel training is essential for the effective use of cleaning solutions. It is critical that personnel with responsibility for any part of device reprocessing be properly trained and provided with the tools needed to complete their task effectively and safely.

The training program should include education on:

- OSHA Bloodborne Pathogens Standard
- Standard Precautions
- Mechanisms of disease transmission
- Safe handling of chemicals
- Reprocessing procedures
- Device design and component parts
- Procedures for waste management
- Maintenance of a safe work environment¹⁷

Appropriate use of PPE

When handling contaminated devices, medical professionals should wear appropriate PPE based upon the degree of risk. In the decontamination area, clean uniforms should be donned at the facility.



Appropriate use of PPE is a key factor for the effective use of cleaning solutions.

Liquid resistant coverings with sleeves, surgical face masks and eye protection should be worn in the decontamination area. Protective apparel should be changed daily and immediately if wet, heavily soiled or visibly contaminated by blood or body fluids. Surgical head coverings should completely cover all head and facial hair except for eyebrows and eyelashes. Clean shoes, designated for facility use only, should be skid resistant and durable enough to prevent injury from dropped items. If shoe covers are selected, they should be skid resistant and liquid resistant or liquid proof. Designated shoes and/or shoe covers should be removed upon exiting the decontamination area. Additionally, general purpose utility gloves should be worn. If gloves become torn, they should be replaced immediately after appropriate hand washing. Jewelry and wrist watches should not be worn

in the decontamination area. All PPE should be removed before leaving the decontamination area. Special care should be taken to avoid contaminating clothing and skin.¹²

In addition to personal protective equipment, handwashing is imperative for minimizing organism transfer among personnel, patients, and objects. Hands not visibly soiled should be washed with soap and water or cleaned with alcohol-based, waterless, hand hygiene agents. Hands that are visibly soiled should be washed with soap and water. Additionally, hands should be decontaminated after gloves and other PPE are removed in accordance with good personal hygiene practices and departmental policy.¹²

Proper Device Preparation

Prior to cleaning, proper preparation aids in exposing all device surfaces to the cleaning solution. This includes opening scissors, box locks and jaw type devices, disassembling complex devices and pre-cleaning flexible endoscopes. It should be noted that “more healthcare-associated infections have been linked to contaminated endoscopes than to any other medical device.”¹⁵ Therefore, endoscopes should be pre-cleaned as per the Society of Gastroenterology Nurses & Associates [SGNA] Guidelines.^{3,18}

To prevent damage to sharp objects and to protect health care workers from cuts, always isolate sharp objects from other devices.

Water Quality

Good quality water is essential. Almost all cleaning solutions are packaged as concentrates; and must be diluted with water. Poor water quality can reduce



Proper device preparation aids in exposing all device surfaces to the cleaning solution.

the efficacy of the cleaning solution and cause spotting on devices. Ideally water should be filtered through a 0.2 micron filter. Potable tap water may also be used. Filtered water or sterile water is preferable for rinsing the devices.¹⁷

Adherence to Guidelines and Manufacturer's Directions for Use

It is important to adhere to the manufacturer's directions for use and applicable guidelines. This will ensure optimal performance of the solution. Always refer to the package label for the correct use parameters including temperature, dilution ratio and soak time, as well as rinsing and drying requirements.

Typically, a minimum temperature is required for the solution to become active and to provide adequate cleaning action. Using water that is hotter than recommended is not advisable as it may inactivate enzymes contained in the solution or cause denaturing of protein-based soils making them harder to remove.

The dilution ratio needs to be accurately measured based on the manufacturer's

specifications which may include different dilution ratios for manual vs. automated cleaning. For manual cleaning, it is necessary to measure the volume of the sink or basin being used for cleaning, remembering that the container must be deep enough to fully immerse devices in the solution. The appropriate amount of cleaning solution must then be added based on that specific volume of water. Using less solution than is recommended may decrease cleaning efficacy. More is not necessarily better as using too much solution can make thorough rinsing difficult; however, heavily soiled devices may require higher solution concentrations.

It is important to soak the devices for the minimum time recommended by the manufacturer. This allows the components of the solution to break down the soils present. Note that the manufacturer may recommend a longer soak time for heavy or dried-on soil. It is not, however, recommended to use cleaning solutions for storing devices as soaking for extended periods of time may damage the devices or allow for microbial growth in the solution. If a delay in disinfection or

sterilization is anticipated, devices should be cleaned, rinsed, dried and stored temporarily.

Thorough rinsing is vital to preparing a device for further processing. Residual debris or solution can lead to incomplete disinfection or sterilization and may also cause damage to the device. Always use enough water to completely rinse the device surfaces, both external and internal with extra attention to lumens, hinges and crevices.

Devices should be dried of excess moisture prior to disinfection or sterilization. Excess moisture may cause over-dilution of high level disinfectants, reducing their efficacy below the minimum effective concentration. Excess moisture may also cause cycle cancellation in some sterilization technologies. Leaving moisture on or in devices for extended periods, especially in lumens and internal surfaces, may promote the colonization of waterborne microorganisms and the growth of biofilms.

Conclusion

Inadequate or improper cleaning of reusable medical devices puts patients at risk for healthcare-associated infections. HAIs are a major concern in healthcare today and it is imperative that all medical professionals do their part to reduce these preventable infections. One step toward this goal is to ensure adequate and proper cleaning of reusable medical devices. Cleaning essentials for these devices include a thorough understanding of the risks associated with improper cleaning, the basic components of cleaning solutions and the factors necessary for the effective use of cleaning solutions. With this knowledge, medical professionals will be better equipped to promote optimal patient outcomes.

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