CE ONLINE

The Role of Detergents and Disinfectants in Instrument Cleaning and Reprocessing

An Online Continuing Education Activity
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The Role of Detergents and Disinfectants in Instrument Cleaning and Reprocessing

(An Online Continuing Education Activity)

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OVERVIEW

Preventing infections in patients undergoing surgical procedures is a primary goal for all members of the healthcare team. This is especially important in today's dynamic healthcare environment, in the face of newly recognized pathogens, well-known microorganisms that have become resistant to treatment modalities, and the economic pressures to reduce healthcare-associated infections. A key infection control practice for reducing the likelihood of a surgical site infection is proper reprocessing of surgical instruments. However, effective reprocessing of instrumentation can only take place after thorough cleaning, as any disinfection or sterilization process is adversely affected by the presence of bioburden. The detergent or disinfectant agent used to clean surgical instruments is a key factor in instrument reprocessing, as well as safe patient care. Because there are various types of detergents available today, all personnel involved in the care and cleaning of surgical instruments must be knowledgeable about these agents and the proper instrument cleaning process. This continuing education activity will provide a review of the key considerations related to the selection and use of detergents and disinfectants for instrument cleaning. It will outline the steps of the instrument cleaning process. The characteristics of the various types of detergents and high-level disinfectants will be described. Troubleshooting steps for the cleaning process and mechanical equipment will be presented. Finally, the applicable regulations and standards related to instrument care and cleaning will be reviewed.

LEARNER OBJECTIVES

After completing this continuing education activity, the participant should be able to:

1. Identify the steps for proper instrument cleaning and care.
2. Differentiate the types and performance of detergents used for instrument cleaning.
3. Describe the various types of high-level disinfectants available today.
4. Identify troubleshooting steps for the cleaning process and mechanical equipment.
5. Discuss the regulations and standards related to instrument cleaning and care.

INTENDED AUDIENCE

This continuing education activity is intended for perioperative nurses, surgical technologists and central sterile personnel responsible for instrument care and cleaning and who are interested in learning more about the decontamination process and the various types of detergents available today.

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INTRODUCTION

Proper reprocessing of reusable surgical instruments and other medical devices is a critical infection prevention strategy. In regards to instrument sterility and ultimately patient safety, one important fact prevails: an instrument that has not been properly cleaned cannot be effectively sterilized. While this point cannot be refuted, effective cleaning of instruments and other devices often remains a challenge for Sterile Processing Department (SPD) and Operating Room (OR) personnel.[1]

In its 2008 Guideline for Disinfection and Sterilization in Healthcare Facilities, the Centers for Disease Control and Prevention (CDC) notes that failure to properly disinfect and sterilize equipment carries not only the risk associated with breach of host barriers, but also the risk for person-to-person transmission as well as transmission of environmental pathogens; furthermore, thorough cleaning is required before disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes.[2] The CDC estimates there are 274,098 Surgical Site Infections (SSIs) per year (approximately 2 per 100 surgeries).[3] The costs for treating these infections can reach as high as $60,000 per patient infection.[4] Moreover, since 2008, the Centers for Medicare and Medicaid Services, no longer reimburses the costs associated with Healthcare-associated Infections (HAIs), including SSIs; i.e., if a condition is not present upon admission, but is acquired during the course of the patient's hospital stay, Medicare no longer pays the additional costs of the hospitalization and the patient cannot be billed.[5] As a result, hospitals are placing increased emphasis on the prevention of HAIs. Therefore, it is imperative that SPD and OR personnel involved in the care and cleaning of surgical instruments and other devices understand the importance of thorough cleaning, proper cleaning methods, and the implications of the various types of detergents and disinfectants used for instrument cleaning and reprocessing.

INSTRUMENT CLEANING PROCESS

Overview

Any method of reprocessing, e.g., sterilization or High-level Disinfection (HLD), is adversely affected by the amount of bioburden and also the number, types, and inherent resistance of microorganisms, including biofilms, on the items to be reprocessed.[6] Soil and other materials may shield microorganisms from contact with the sterilant or disinfectant, or combine with and inactivate the agent. Therefore, precleaning instruments and items to be sterilized lowers the bioburden to the lowest possible level.[7] In addition to keeping instruments free of gross soil during surgical procedures, cleaning and decontamination of instruments and other devices should occur as soon as possible after they are used.[8]

All personnel handling contaminated instruments and equipment *must* wear appropriate Personal Protective Equipment (PPE) and should be vaccinated against the hepatitis B virus.[9] Personal protective equipment helps to protect the employee from exposure to bloodborne pathogens and other potentially infectious materials. Personal protective equipment appropriate for the anticipated exposure must be worn, as splashes, splatters,

and skin contact can be reasonably anticipated when handling contaminated instruments. The appropriate PPE for these types of exposures include, but are not limited to:

- A fluid-resistant gown;
- Heavy-duty gloves;
- A mask; and
- Face protection.

Association for the Advancement of Medical Instrumentation (AAMI) Guidance on Instrument Processing[10]

To assist personnel in the development and implementation of appropriate decontamination processes and procedures for the various types of medical devices used today, AAMI provides guidance on instrument processing in its *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.* Healthcare facilities should develop policies and procedures for all methods of decontamination of reusable items. Process audits to monitor compliance with the various policies and procedures should be performed on a scheduled basis, with appropriate follow-up addressing problems.

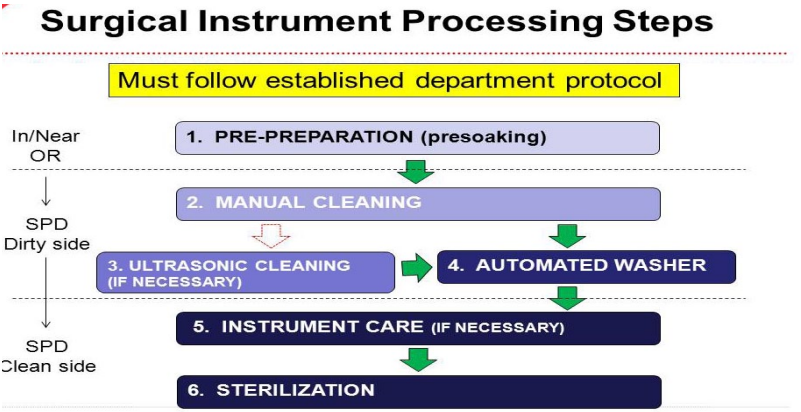
For all reusable medical devices, the first and most important step in reprocessing is thorough cleaning and rinsing. Cleaning primarily removes, rather than kills, microorganisms. Because the cleaning process is not microbicidal, a subsequent disinfection or sterilization process may be necessary in order to ensure that an item is safe for handling and use.

The type of decontamination required for any particular contaminated device depends on the biohazard that the device presents. The cleaning and/or microbicidal process appropriate for a particular device depends on several factors, including:

- The device manufacturer's written instructions. All device manufacturers are responsible for providing complete and comprehensive written instructions for the decontamination of their products, and also a summary and interpretation of the test results that verify their products can be safely and effectively decontaminated. The device labeling should identify the specific methods of cleaning and sterilization that have been validated by the manufacturer. The written instructions provided by the manufacturer should always be followed.
- The necessary level of microbial kill; for example, a higher assurance of lethality is needed for items that may come in contact with blood, body tissues, or body fluids than for items that will only come in contact with unbroken skin.
- The design of the device; for example, items that have sharp points or edges capable of puncturing or abrading the skin should be subjected to a decontamination process that includes disinfection or sterilization.
- Other characteristics of the device; for example, whether the device can tolerate high temperatures or whether it is fully immersible.

Effective cleaning is a multistep process. The instrument cleaning and reprocessing steps defined in AAMI's *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* are outlined below. See Figure 1.

Figure 1 – Instrument Cleaning Protocol



- *Pre-preparation or presoaking*. Presoaking instruments moistens and loosens the gross soil and therefore makes the cleaning step more efficient. In general, presoaking with a specialized product (e.g., an enzymatic solution) is recommended. If a prespray product is used, a neutral detergent without enzymes is best. Skin and eye irritation can result from exposure to enzymes. Therefore, enzymatic product should not be sprayed around hospital personnel. When presoaking instruments, personnel should refer to the solution manufacturer's written instructions for the correct dilution, temperature, and soak time.

  Presoaking should begin as soon as possible after instruments and equipment are used; therefore it is recommended this occur in or near the OR, not the SPD (see Figure 2).

Figure 2 – Pre-Preparation of Instruments In or Near the OR

Immediately after use, the items should be kept moist in the transport container by adding a towel moistened with water (not saline) or a foam, spray, or gel product specifically intended for this use. Allowing blood and tissue to dry can cause the instrument to rust and pit. Presoaking keeps bioburden moist until full cleaning begins. Presoaking also extends the life of the surgical instruments, reduces the risk of cross contamination, and provides the most complete cleaning.

Instruments should be thoroughly rinsed after presoaking. Rinsing the items thoroughly ensures the removal of any potentially harmful residue from the soaking solution (e.g., detergent enzymes, which are proteins, and/or patient secretions).

- *Manual cleaning.* Manual cleaning is done prior to automated cleaning to remove gross organic material from instruments. Any instrument or medical device should be able to be cleaned manually. Manual cleaning is often recommended for delicate or complex medical devices, e.g., microsurgical instruments, lensed instruments, and air-powered drills. Items that are immersible should be cleaned under water to minimize aerosolization; items that cannot be immersed should be cleaned in a way that will not produce aerosols and should be rinsed and dried according to the device manufacturer's written instructions.

  Lukewarm water and detergent solutions (at temperatures ideally in the range of 27°C to 44°C [80°F to 110°F], but not to exceed 60°C [140°F]) will prevent coagulation, thereby facilitating the removal of protein substances. The temperature of the soaking solution should be monitored and documented. Because several factors, e.g., water hardness, pH, temperature, and the type of soil affect the effectiveness of enzyme cleaners and detergents, the detergent manufacturer's written instructions should be consulted. After cleaning, devices should be rinsed thoroughly to remove debris and detergent residues.

  Abrasive cleaning compounds as well as metal scouring pads can damage items; these should not be used without specific written instructions from the instrument or device manufacturer. Brushes and other cleaning implements should be designed for use on medical devices; they should either be disposable, single-use, items or, if reusable, be decontaminated at least daily. The manufacturer should provide information regarding the appropriate brush size for cleaning devices with lumens.

  A three-sink process is recommended for manual cleaning (see Figure 3):

  1. The first sink is the wash sink with detergent and water solution.
  2. A plain water rinse is performed in the second sink.
  3. The third sink contains processed or purified water to prevent spotting and other soils from redepositing.

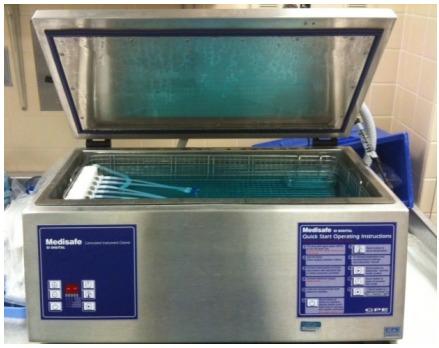
Figure 3 – Three-Sink Process for Manual Cleaning

Detergents used for manual cleaning should be:

- Low sudsing for the safety of the worker;
- Free-rinsing;
- User-friendly (i.e., safe and pleasant);
- Able to be used on surgical instruments, delicate instruments, and scopes; and
- Easily dispensed or have a dispensing mechanism.

- *Ultrasonic cleaning* (if needed). The ultrasonic cleaning process removes even the tiniest particles from hard to reach areas, such as box locks, cracks, crevices, and lumens. Ultrasonic cleaners (see Figure 4) work by cavitation – a process in which bubbles implode (i.e., burst inward) to dislodge soil from the instrument. Ultrasonic cleaning is very effective with scopes and cannulated instruments because the cavitation process reaches small areas that manual cleaning cannot.

Figure 4 – Ultrasonic Cleaners



It is important to note that ultrasonic cleaners designed for cleaning medical devices are used for fine cleaning, not for disinfection or sterilization. Additionally, ultrasonic cleaning should be used only after the gross soil has been removed from items. The medical device manufacturer's written instructions should be followed to ensure that ultrasonic cleaning will not damage the device. Not all metals can be intermixed in the ultrasonic process; therefore, the device manufacturer should specify any restrictions.

A low sudsing formulation from one of the following categories should be used:

- Enzymatic detergents;
- A neutral pH detergent; or
- An alkaline detergent.

The cleaning solution should be changed before it becomes heavily soiled, so that effective ultrasonic cleaning is not inhibited by soil and also to minimize the risk of cross-contamination. Ultrasonic cleaning should be followed by thorough rinsing to remove dislodged particles.

- *Automated cleaning*. An automated washer will remove the majority of soil and microorganisms on instruments through a cleaning and rinsing process, thus preparing it for sterilization. With automated cleaning equipment (see Figure 5), detergent and water are forced through nozzles or rotating spray arms for cleaning.

Figure 5 – Box or Cube Automated Washer

The following steps comprise a typical automated cycle process:

1. Prewash with cold water.
2. Enzyme wash.
3. Rinse.

4. Wash with detergent.
5. Rinse.
6. Thermal rinse.
7. Lubricant.
8. Dry.

A low or no sudsing, neutral pH detergent or a buffered alkaline detergent should be used in an automated washer to break up and disperse soil. High suds formulas can cause damage to washer components, such as the motor. An automated cleaning process can be used for general surgical instruments, but not for delicate instruments or scopes. Consult instrument manufacturer's directions for use to confirm instrument compatiblity with automated washers.

- *Rinsing.* Whether instruments are cleaned manually or in an automated cleaner, they should be thoroughly rinsed to ensure that loosened debris and detergents are adequately removed. Tap water can be used for rinsing, providing that copious amounts are used. However, the final rinse should be performed with treated water that is of a quality that does not contribute to staining or contamination of the instrument. Sterile physiological saline should not be used for final rinsing as the salts in this solution will remain on the device after it dries and could eventually lead to deterioration of the surfaces of surgical instruments; additionally, saline could interfere with disinfection and sterilization. The final rinse after cleaning is very important because any residuals after this stage will likely remain on the instrument and could therefore adversely affect the efficacy of the disinfection and/or sterilization process and potentially cause adverse reactions in the patient on which the instrument is subsequently used.
- *Instrument care (manual lubrication and stain removal, if needed).*
    - Manual lubrication eases stiffness and does not interfere with sterilization. It helps keep edges sharp, prevents rust, and extends the life of stainless steel instruments.
    - Stain removal is performed to remove rust and stains.

  These steps should be performed on all surgical instruments, when needed and on delicate instruments and scopes when possible. There are various lubricants, lubricant sprays, and stain and rust remover products available today.
- *Verification of the cleaning process (i.e., wash monitoring)*. Cleaning involves the removal of patient secretions and excretions and also microorganisms from the patient or from handling or water exposure during reprocessing. Upon completion of the cleaning process, personnel should visually inspect each item carefully for any visible soil. Inspection using magnification may be used to identify residues more readily than the unaided eye.

In addition to visual inspection, verification of the cleaning process consists of:

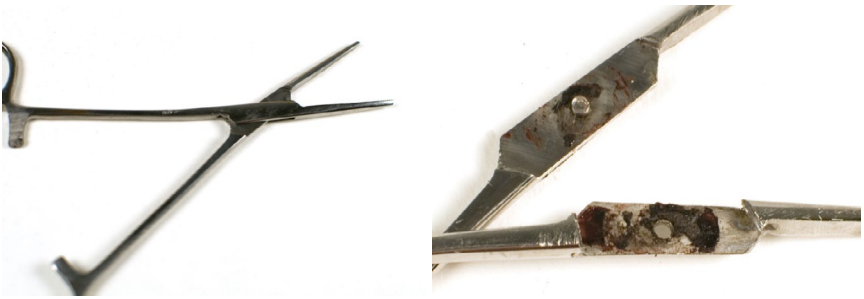
- Defining a cleaning process and its critical aspects so that each step is fully verifiable through personnel training and observation to ensure that it can be followed completely, accurately, and without variation by all individuals who perform it; and
- Providing process controls along with validation and verification methodologies that ensure adequate, consistent cleaning levels.

Two principles are involved in verification of the cleaning process. The first consists of establishing, clarifying, and documenting a standard cleaning process that is based on published and validated recommended practices or guidelines. The second concerns measuring and evaluating residual contaminants on medical devices after performing the established cleaning process.

Although validation of the cleaning process may not be realistic in healthcare facilities, verification is possible. Device manufacturers should provide any test procedures that can be easily replicated and that can help users recognize whether cleaning was effective for all areas of an instrument or device. These tests are particularly important for devices with components that cannot be readily inspected for cleanliness (e.g., spring hinges, lumens, porous materials, crevices).

Using indicator tests for verification of cleaning processes in healthcare facilities became prevalent in the late 1990s in Europe. In the U.S., until recent years, the accepted practice for verification of washing was “visibly clean,” which sometimes is not enough, as seen in Figure 6.

Figure 6 – A “Visibly Clean” Instrument



Today, SPD personnel are increasingly aware of the need to control and standardize the steps taken to ensure the sterility of instruments and devices for patient use. Because disinfection and sterilization cannot be assured unless the cleaning process is successful and effective, professionals in the field should seek out whatever means are available and practical to verify the cleaning process. A quality system would include monitoring and documenting decontamination processing parameters, regardless of how the process is accomplished (i.e., manually or mechanically).

To ensure that mechanical cleaning equipment is working properly and according to the manufacturer's specifications, healthcare personnel may perform verification tests as part of their overall quality assurance program. Methods of verification include the use of devices that directly test individual instruments for residual soils, challenge cleaning effectiveness with standardized test methods, or measure specific key parameters to evaluate the functionality of the cleaning equipment.

Furthermore, in 2004, The Joint Commission's survey process was substantially modified to be more data-driven and patient-centered thereby enhancing its value, relevance, and credibility.[11] The survey process now has a greater focus on evaluating actual care processes because patients are traced through the care, treatment and/or services they receive. In addition, surveyors conduct "systems tracers" to analyze key operational systems that directly impact the quality and safety of patient care. Thus, both standard and regulatory organizations advise wash monitoring as a "Clinical Best Practice."

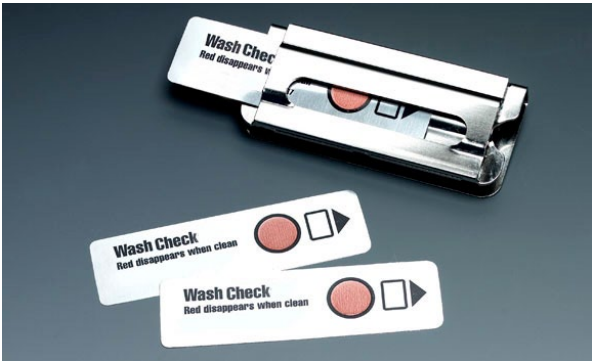
Wash monitoring is important because an item on which dirt, blood, or other debris remains cannot be effectively disinfected or sterilized, as previously discussed – it must be thoroughly cleaned before subjected to a high-level disinfection or terminal sterilization process. Furthermore, washers often fail to remove all debris. Any debris that is not removed in the washing process will not be removed during the sterilization process; furthermore, it can be "baked" onto the instrument, thereby increasing the risk for the development of a surgical site infection.

Types of Wash Monitors

There are various types of wash monitors available today, as described below.

- Wash monitors for automated washer. This type of monitor evaluates the efficiency of the washing process of an automated washer. The test soil simulates human blood and tissue debris; the lip of the holder covers a portion of the test soil, creating a challenge similar to the joint of a hinged surgical instrument (see Figure 7).

Figure 7 – Wash Monitor for Automated Washer

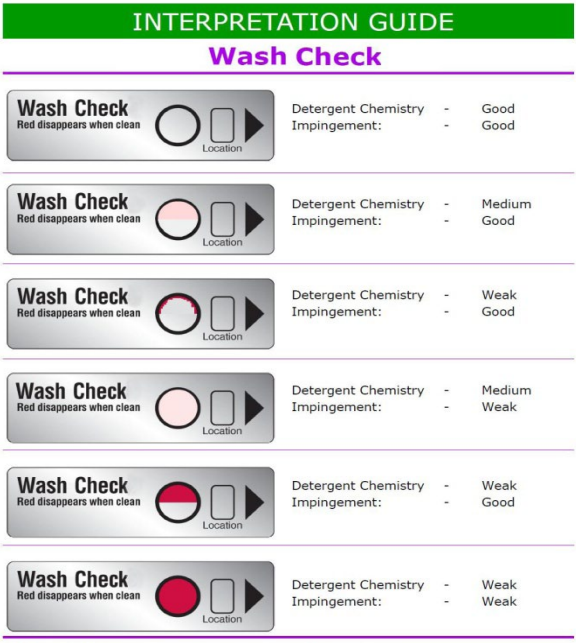


The AAMI guidelines recommend that mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs.[12] Every level on every rack for each automated washer in use should be monitored as part of a machine release protocol. Each load should be routinely monitored throughout the day, using a single indicator as a best practice.

The suggested steps for using a sample wash monitor typically involve:

- With an indelible marker, mark the location of the indicator in the washer chamber; varying the positioning helps identify weaker, more challenging areas of the chamber.
- Insert the wash monitors in the reusable holder, positioned face up in a basket (with or without instruments).
- Run a complete wash cycle.
- After the cycle, remove the indicator and compare the results to the interpretation guide (see Figure 8).

Figure 8 – Sample Wash Monitor Interpretation Guide



Attach the indicator to the wash monitor cleaning record; then record results and cycle information (see Figure 9).

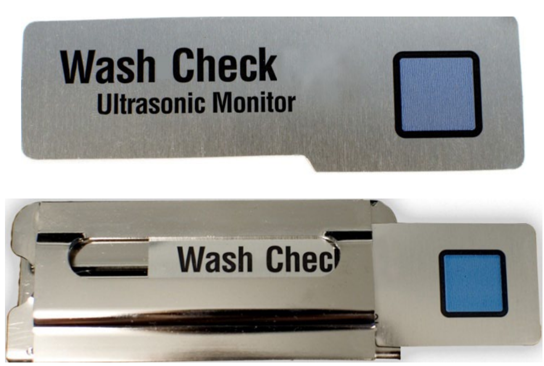
Figure 9 – Sample Wash Monitor Cleaning Record

Wash Check Cleaning Record

Date/ Initials	Load Information	Result	Staple Wash Check Monitor Below
Date: __/__/___ Time: _______ Initials: ______	Washer: _______ Cycle #: ________ Rack # : ________	O Pass O Fail O Marginal	
Date: __/__/___ Time: _______ Initials: ______	Washer: _______ Cycle #: ________ Rack # : ________	O Pass O Fail O Marginal	
Date: __/__/___ Time: _______ Initials: ______	Washer: _______ Cycle #: ________ Rack # : ________	O Pass O Fail O Marginal	
Date: __/__/___ Time: _______ Initials: ______	Washer: _______ Cycle #: ________ Rack # : ________	O Pass O Fail O Marginal	
Date: __/__/___ Time: _______ Initials: ______	Washer: _______ Cycle #: ________ Rack # : ________	O Pass O Fail O Marginal	
Date: __/__/___ Time: _______ Initials: ______	Washer: _______ Cycle #: ________ Rack # : ________	O Pass O Fail O Marginal	
Date: __/__/___ Time: _______ Initials: ______	Washer: _______ Cycle #: ________ Rack # : ________	O Pass O Fail O Marginal	

Wash monitors for ultrasonic cleaners. This type of monitor evaluates the effectiveness of instrument cleaning in automatic ultrasonic wash cycles. The test soil simulates the removal of bioburden from instruments in wash cycles. The reusable holder maintains the positioning of the monitor above the transducer for accurate testing (see Figure 10).

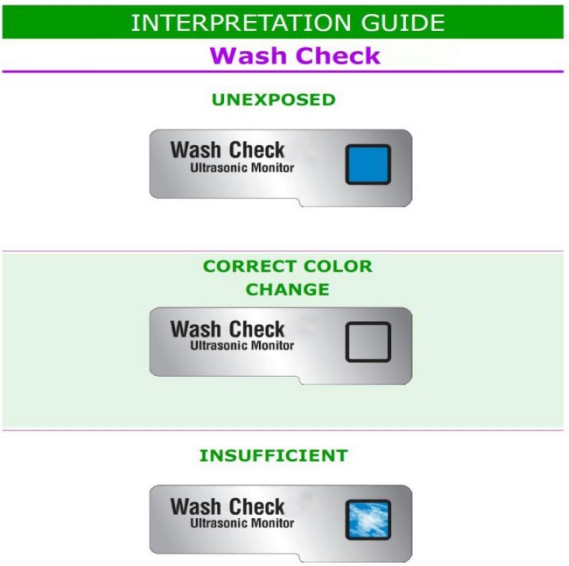
Figure 10 – Wash Monitor and Holder for Ultrasonic Cleaners



As noted, mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs. Suggested steps for a sample ultrasonic wash monitor typically involves:

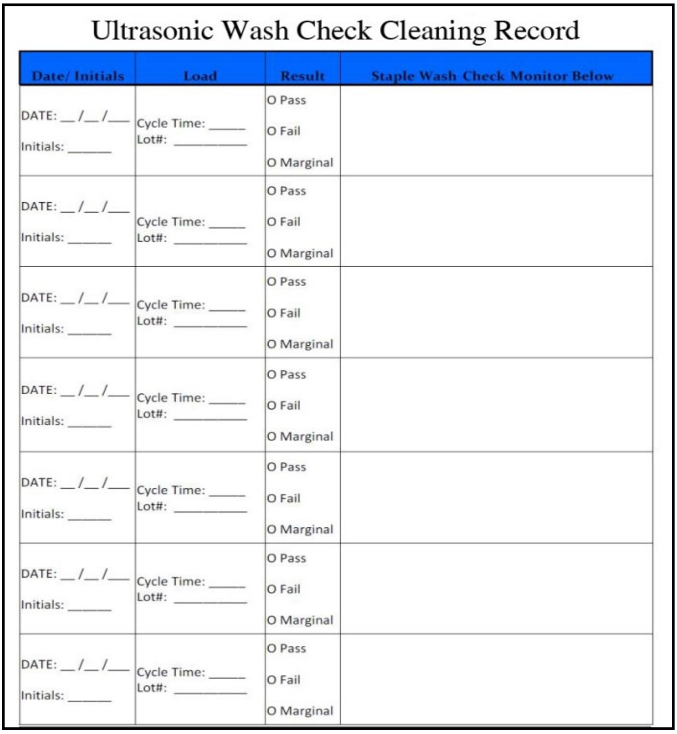
- Insert the wash monitor indicator into the holder with the blue square fully exposed.
- Place the indicator and the holder into the ultrasonic washer, above one of the transducers ensuring that the blue square is facing up.
- Run a complete cycle.
- After the cycle, remove the indicator from the holder, examine and compare the results to the interpretation guide (see Figure 11).

Figure 11 – Sample Ultrasonic Wash Monitor Interpretation Guide



- Attach the indicator to the cleaning record (see Figure 12); record results and load information.

Figure 12 – Sample Ultrasonic Cleaning Record



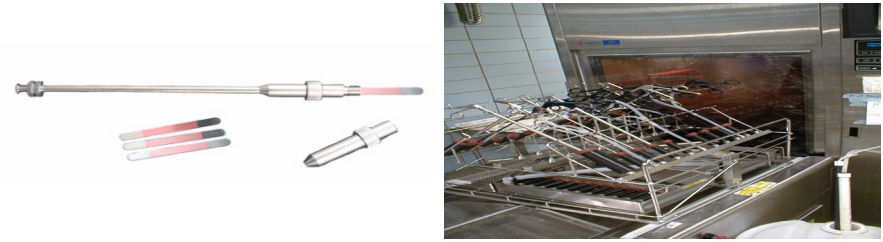
Ultrasonic Wash Check Cleaning Record

Date/ Initials	Load	Result	Staple Wash Check Monitor Below
DATE: __/__/__ Initials: ______	Cycle Time: _____ Lot#: __________	O Pass O Fail O Marginal	
DATE: __/__/__ Initials: ______	Cycle Time: _____ Lot#: __________	O Pass O Fail O Marginal	
DATE: __/__/__ Initials: ______	Cycle Time: _____ Lot#: __________	O Pass O Fail O Marginal	
DATE: __/__/__ Initials: ______	Cycle Time: _____ Lot#: __________	O Pass O Fail O Marginal	
DATE: __/__/__ Initials: ______	Cycle Time: _____ Lot#: __________	O Pass O Fail O Marginal	
DATE: __/__/__ Initials: ______	Cycle Time: _____ Lot#: __________	O Pass O Fail O Marginal	
DATE: __/__/__ Initials: ______	Cycle Time: _____ Lot#: __________	O Pass O Fail O Marginal	

Wash monitors for ultrasonic cleaning assure that the washer is functioning properly and instruments are exposed to proper cleaning conditions. In addition, they test multiple parameters to assure that the time, temperature, detergent dosages and mechanical function are adequate for cleaning instruments.

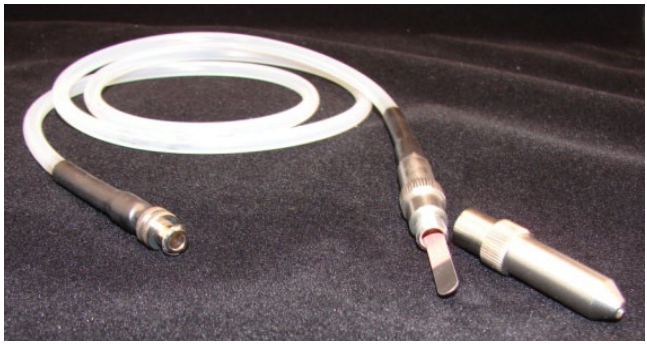
- Wash monitors for rigid and flexible lumens. This type of wash monitor is similar to the one for a washer disinfector, as described above, with the difference being in the holder design – the different monitors fit inside the metal end of both applicable holders. Each is made with similar protein-like test soil and uses a similar interpretation guide and cleaning record.
    - Wash monitors for rigid lumens. For use with hollow devices, wash monitors assure that hard-to-reach internal areas have been exposed to proper cleaning conditions. Used with Minimally Invasive Surgery (MIS) washer disinfector manifolds and ultrasonic cleaners, this type of monitor easily attaches to lumen ports to test the conditions that hollow instruments encounter in automatic wash cycles (see Figure 13).

Figure 13 – Wash Monitors for Rigid Lumens



- Wash monitors for flexible lumens. Wash monitors used for hollow, flexible scopes and devices assure that hard-to-reach internal areas have met proper cleaning conditions. Used with MIS washer disinfector manifolds and ultrasonic automatic cleaners, they attach easily to lumen ports to test conditions flexible devices encounter (see Figure 14).

Figure 14 – Wash Monitors for Flexible Lumens



Why Wash Monitors Show a "Fail" Result

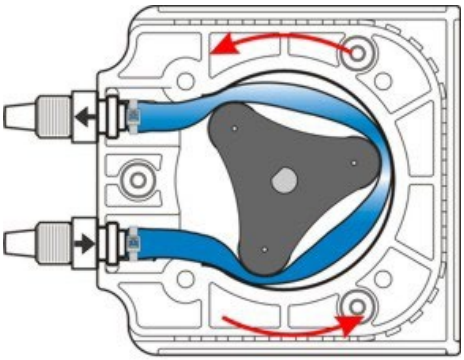
On occasion, wash monitors fail for various reasons, as outlined below.

- Spray system. Over time, spray arms can become filled with debris (see Figure 15) reducing direct impingement (i.e., spray velocity). Spray holes in the spinner arms often become clogged with dried solution. Loose or broken spray arms are also common. Improper seating of the manifold rack on the water source (coupler) affects overall water pressure needed for effective cleaning.

Figure 15 – Debris Found Inside a Single Spray Arm

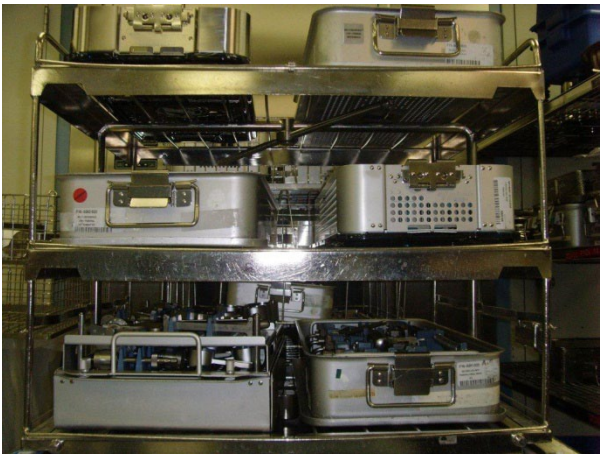
Washing solutions. Pumps that are not calibrated correctly can dispense insufficient dosages of washing solutions needed for proper cleaning. In addition, the temperature (either too high or too low according to manufacturer specifications) affects the effectiveness of certain washing solutions. Detergent lines can also become clogged or kinked, reducing or stopping the flow of solutions (see Figure 16). Excessive foam from too much detergent has a dramatic impact on the effectiveness of wash cycles.

Figure 16 – Kinked Detergent Lines



- User challenges, such as:
  - Overloading or incorrect loading of instrument trays and sets (see Figure 17);
  - Choosing incorrect cycles or cycle settings;
  - Closed lids on rigid containers block impingement and chemicals from direct exposure to instruments; and
  - Multi-level sets not broken down properly for adequate cleaning.

Figure 17 – Overloading/Incorrect Loading of Instrument Trays and Sets



Benefits of Wash Monitoring

The benefits of wash monitors include:

- Excellent record keeping; provides evidence of continuous quality improvement efforts for regulatory and accreditation surveys.
- Multi-parameter test assures instruments have met proper cleaning conditions in automated washers, thereby indicating that the items are safe to handle and ready to sterilize.
- A reusable holder presents part of the challenge, indicating internal areas of hinged instruments are exposed to proper wash conditions.

- *Sterilization.* The final step before returning the instruments to use is sterilization. Saturated steam under pressure is the most preferred method, but for instruments and devices that are heat- or moisture-sensitive, an alternative method (e.g., ethylene oxide or low-temperature hydrogen peroxide gas plasma should be used, when indicated by the device manufacturer).[13] When neither is available, a high quality cold chemical sterilant, such as a glutaraldehyde or orthop-phthalaldehyde, should be used.

  It must be emphasized that all of the above steps should follow an established department instrument cleaning protocol, as depicted in Figure 18.

- *Cart Washers.* Cart washers, used for cleaning carts, racks, containers, and other larger medical equipment (see Figure 18), are also important considerations in proper instrument reprocessing.

Figure 18 – Cart Washer

A cart wash detergent or an alkaline detergent can be used; a neutral detergent should be used for washing aluminum containers in a cart wash. Rinse aids should also be used to manage water conditions, allowing water to "sheet" off the surface of surgical case carts and other equipment and also to promote drying of surfaces. Rinse aids should be compatible with materials used in the manufacture of case carts (e.g., aluminum).

DETERGENTS: TYPES AND PERFORMANCE

Overview

As discussed above, thorough cleaning of instruments and other medical devices prior to high-level disinfection or sterilization is critical. The primary agent that affects cleaning is the detergent solution or the combination of detergent and enzymatic solution.[14] The delivery system used to bring the detergent solution to the items should do so effectively, but the actual cleaning is accomplished by the detergent solution. Personnel should consult the device manufacturer's written instructions to determine the appropriate type of cleaning agent and always follow the cleaning agent manufacturer's written instructions for proper use.

AAMI Characteristics of the Ideal Detergent

There are various types of detergents available for cleaning instruments and other medical devices. According to the AAMI guidelines, the characteristics of an ideal cleaning agent include that it would.[15]

- Be nonabrasive;
- Be low-foaming;

- Be free-rinsing;
- Be biodegradable;
- Rapidly dissolve/disperse soil;
- Be nontoxic;
- Be efficacious on all types of clinical soil;
- Have a long shelf life; and
- Be cost-effective.

Selection Criteria

There are several factors to consider when selecting a detergent in SPD, as outlined below (see Figure 19).

- Type of detergent:
  - pH: acidic, neutral, alkaline.
  - Enzymatic: none, single, dual, multiple.
  - Suds: no suds, low suds, high suds.
- Type of instrument:
  - Hand-held.
  - Microsurgical.
  - Instrument material, i.e., stainless steel, aluminum, plastic, etc.
  - Powered – this type of equipment must be disassembled and never immersed in water.
  - Endoscopic and laparoscopic – this type of equipment and instrumentation also must be disassembled.
- Type of washer:
  - Automated.
  - Ultrasonic.
  - Manual.
  - Parameters of time, temperature, and force or friction.
- Water quality:
  - pH.
  - Hardness.

- Total dissolved solids.
- Chlorine.
- Iron.
- Copper.

Figure 19 – Considerations In Selecting a Detergent in SPD

When selecting detergents and other cleaning agents for use in healthcare facilities, it is also important to remember that the agent should be compatible with the medical device to be cleaned, and also with the materials used in the cleaning equipment itself.[16] For example, the chemicals should not cause corrosion in any type of automated cleaner (e.g., ultrasonic cleaner, washer disinfectors, or washer sterilizers); and they should not promote electrolytic action between the equipment and the items being cleaned. In addition, any chemical should be easily removable from the item by rinsing it with readily available water with specific properties so that the item does not retain residual chemicals in amounts that could potentially be harmful to patients, damage the device itself, or create other hazardous situations.

Detergents: Types, Characteristics, and Clinical Benefits

A detergent is defined as a synthetic or man-made blend of ingredients for cleaning. The components of a high quality detergent are:

- Water – high quality tap, filtered, or purified water;
- A surfactant system – to reduce water tension and help remove dirt from surfaces;
- Chelating agents – to inactivate water hardness and prevent mineral deposits;
- Stabilizers – to protect enzymes from degrading;
- Buffers – to keep the pH steady for consistent cleaning;
- Corrosion inhibitors – to enhance material compatibility;

Other characteristics include that is should be free rinsing; environmentally friendly, i.e., biodegradable, phosphate-free, non-polluting; and bacteriostatic, i.e., it is shelf stable if properly stored.

The concentration of a detergent formula is also an important characteristic. One of the greatest developments in surgical instrument cleaning has been the emergence of the super concentrates, which were originally introduced as ultra-concentrated detergents and lubricants. Super concentrates deliver a stronger product in a smaller bottle that is easier to store, carry and pour, thus helping to reduce costs and also free up storage space.[17] As a result, more SPD departments moving toward super concentrates.The dilution ranges for a super concentrate detergent versus a standard detergent are outlined in Table 1.

Table 1 – Example Dilution Ranges

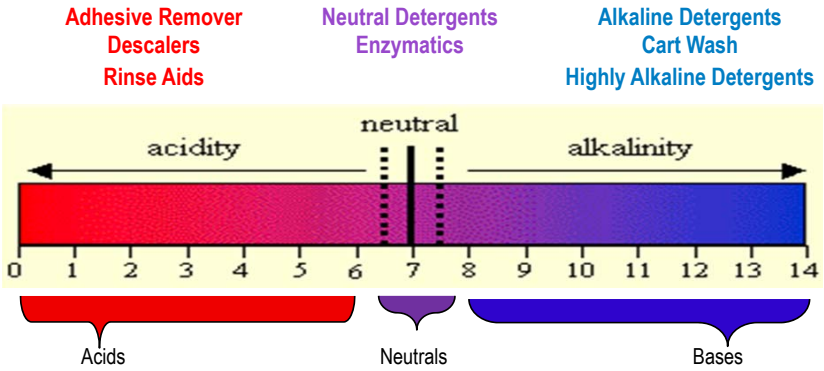
Super Concentrate Detergent	1/20 to ¼ ounce per gallon
Standard Detergent	1/8 to 2 ounces per gallon

Another important characteristic of a detergent formula is its pH, since it also affects cleaning. Neutral refers to the pH level of the formula (see Figure 20). The true neutral on the pH scale is 7. In regards to instrument care solutions, a pH from 7 to 9 is considered neutral. This is because detergents within that range will not harm instruments and offer better cleaning performance. Too high a pH detergent, without proper buffering, can damage an instrument's passivation layer. The properties of the various detergent formulas are outlined and described in greater detail below.

- Acids
  - Good for removing mineral deposits
  - Stain and rust removal
  - Rinsing alkalines
  - Destabilize enzymes

- Neutrals
  - Good detergency
  - Enzymes stable
  - Good rinsibility
  - Safe on metals – no free acids or alkalines
- Bases
  - Excellent detergency
  - Poor rinsibility; leave deposits
  - Corrosive to metals
  - Destabilize enzymes

Figure 20 – Effects of pH on Cleaning



- *Neutral Detergents.* These types of detergents are specially formulated for effective and safe cleaning of glass, plastic, rubber and soft metals, including anodized aluminum sterilization containers. They also provide effective cleaning for delicate fiberoptic instruments and can be safely used in instruments immediately following the surgical procedure. Neutral detergents are available in low suds formulas required for automated washers. Low or high suds formulas can be used for manual cleaning. Low suds formulas are recommended for manual cleaning for the safety of personnel. High suds formulas obscure the users view of sharp instruments under the water potentially leading to sharps insury. A powder form is also available for manual cleaning, if preferred.

  A neutral detergent may also be used for presoaking surgical instruments immediately after use. As noted above, presoaking is ideally started in the OR, but can also be used in SPD. Liquid foaming spray, gel spray, and enzyme packet options are available, based on user preference.

- Gel spray. Gel stays wetter longer than foaming spray, thus keeping bioburden moist longer and making it easier to clean the instruments. Its blue color provides visualization of full coverage.
- Enzyme packets. Pre-measured enzyme detergent packet added to water in the OR to soak instruments.

The characteristics and clinical benefits of various types of neutral detergents are outlined in Table 2.

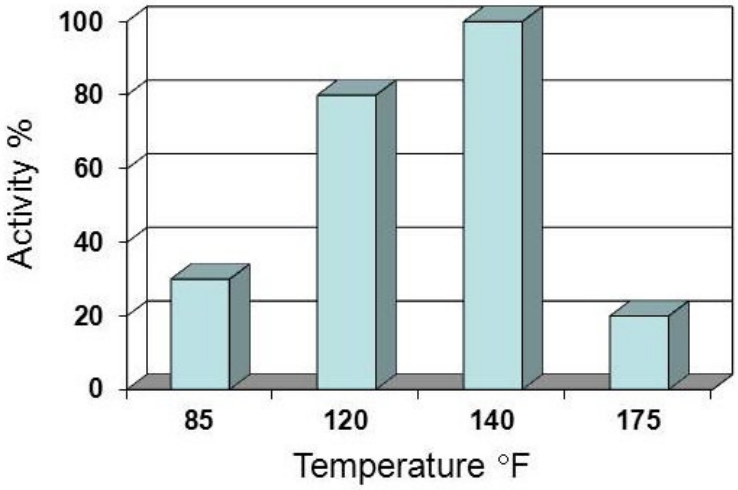
Table 2 – Characteristics and Clinical Benefits of Neutral Detergents

Characteristic	Benefit	Low Suds	High Suds Liquid	High Suds Powder	Pre-Soak Gel Spray	Low Suds Super Concentrate
Neutral pH	Safe and compatible with all metals	√	√	√	√	√
Rust inhibitors	Reduces the risk of rust, tarnish, corrosion damaging instruments	√	√	√	√	√
Rinsing Agents	Helps to deliver spot free rinsing	√	√	√	√	√
High Suds	Some users prefer to see foam during manual cleaning		√	√		
Low Suds	Improved visibility in manual cleaning; compatible with large automatic washers, ultrasonic washers, and pump systems	√			√	√

- *Enzymatic Detergents*. This type of detergent is a neutral detergent with added enzymes. Enzyme solutions dissolve biofilms, which keeps instruments from staining and becoming breeding grounds for bacterial growth. Enzymes are proteins which act as catalysts to break down bioburden and other organic materials, as follows:
  - Protease – removes protein contained in blood and saliva
  - Amylase – removes starches and carbohydrates
  - Lipase – removes fats
  - Cellulase – removes fibers and biofilm

Enzymatic detergents are used to dissolve organic materials and help clean instruments; they are most effective at 3 to 5 minutes exposure at 60° to 140°F (15° to 60° C); see Figure 21.

Figure 21 – Effectiveness of Enzymatic Detergents



The characteristics and clinical benefits of various types of enzymatic detergents are outlined in Table 3.

Table 3 – Characteristics and Clinical Benefits of Enzymatic Detergents

Character-istic	Benefit	Multiple Enzyme	Dual Enzyme	Dual Enzyme, Low Suds	Dual Enzyme, No Suds	Single Enzyme	Single Enzyme, Super Concen-trate
Four Enzymes	Protease, amylase, lipase and cellulase break down complex bioburden containing blood, carbohydrates, fats and fiber	√					
Two Enzymes	Protease and amylase break down protein and carbohydrates		√	√	√		
One Enzyme	Protease breaks down protein soils, e.g., blood					√	√
Rust Inhibi-tors	Reduce risk of rust, tarnish, corrosion damaging instruments	√	√	√	√	√	√
Rinsing Agents	Help deliver spot free rinsing	√	√	√	√	√	√
Neutral pH	Safe and compatible with all metals	√	√	√	√	√	√
High Suds	Some users prefer to see foam during manual cleaning		√				
Low or No Suds	Improved visibility in manual cleaning; compatible with large automatic washers, ultrasonic washers, and pump systems	√		√	√	√	√

- *Alkaline Detergents*. An alkaline detergent is the most effective type of detergent in hard water situations. They are suitable for cleaning of stainless steel surgical instruments, but may react with aluminum, zinc, nonferrous metals, rubber, and latex. A low sudsing, neutral pH detergent or a buffered alkaline detergent should be used in an automated washer; otherwise the instrument can spot, stain, freeze up and corrode. A specially formulated alkaline for thorough cleaning of carts in automated cart washers is also available. The differences between alkaline detergents and highly alkaline detergents are outlined in Table 4.

Table 4 – Differences Between Alkaline and Highly Alkaline Detergents

Alkaline Detergents	Highly Alkaline Detergents
➢ Do not require a neutralizer rinse ➢ Generally used for automated washers ➢ Often used in cart washers ➢ Buffered to protect metals from corrosion	➢ Very uncommon in the U.S. ➢ Used in low impingement washing equipment, mostly found in Europe ➢ Requires the use of a neutralizer rinse to prevent damage to instruments due to the high pH

Table 5 lists the characteristics and clinical benefits of the various types of alkaline detergents.

Table 5 – Characteristics and Clinical Benefits of Alkaline Detergents

Characteristic	Benefit	Alkaline Detergent	Highly Alkaline Detergent	Alkaline Detergent Super Concentrate	Cart Wash Detergent
Alkaline	Alkaline components provide excellent detergent cleaning power for tough cleaning tasks	√		√	√
High Alkalinity	High alkaline is especially designed for industrial strength cleaning of highly soiled instruments in low impingement washers		√		
Low Suds	Compatible with automatic washers and pump systems	√			√

- *Rinse Aids*. Rinse aids are used in cart washers to promote spot free drying, similar to rinse aids used in household dishwashers. A neutralizer rinse is an acidic product used to neutralize a highly alkaline detergent for spot free rinsing of instruments.

The characteristics and clinical benefits of various rinse aids are noted in Table 6.

Table 6 – Characteristics and Clinical Benefits of Rinse Aids

Characteristic	Benefit	Rinse Aid	Neutralizer Rinse
Highly Concentrated	Very low dilution (2 to 3 ounces per 100 gallons rinse water)	√	
Acid Final Rinse	Promotes sheeting off surfaces and faster drying; spot free drying of glass and metals; specially formulated for cart wash rinse cycle	√	
Neutralizer	To be used with highly alkaline detergents to promote free rinsing and remove water deposits		√
Low or No Foam	Compatible with automatic washers and pump systems	√	√

- *Instrument Care.* Instrument care, when needed, involves lubrication and removing stains, rust, and adhesives.
    - Lubricants. Specially formulated lubricants for use with surgical instruments are available today. Cleaning, especially ultrasonic cleaning, removes all lubrication and may cause frozen box locks. An instrument lubricant eases stiffness and does not interfere with the sterilization process. It also prevents electrolysis on points and edges to help keep cutting edges sharp. Instrument lubricants are compatible with carbon steel and contain corrosion inhibitors to protect all types of metal instruments, thereby prolonging instrument life. These lubricants are often referred to as “instrument milk.” Lubricants are used in both manual and automated processes:
        - Manual – After manual lubrication, the instruments should be dried thoroughly before proceeding to sterilization; there is no need to rinse or wipe the instruments.
        - Automated – Lubricants are used in a separate lubricating cycle of automated washers.

The characteristics and clinical benefits of instrument lubricants are outlined in Table 7.

Table 7 – Characteristics and Clinical Benefits of Instrument Lubricants

Characteristic	Benefit	Instrument Lubricant	Instrument Lubricant, Super Concentrate
Non-Silicone Lubricant	Frees instrument box locks and hinges; extends instrument life	√	√
Neutral pH	Safe and compatible with all metals	√	√
Rust inhibitors	Reduces the risk of rust, tarnish, and corrosion damage to instruments	√	√
Rinsing Agents	Helps deliver spot free rinsing	√	√
Highly Concentrated	Lower dilution per automated cycle		√

- *Stain and Rust Remover.* Many times, instruments that have been improperly cared for develop stains and rust. The use of a stain and rust remover can be used after instrument cleaning to restore the luster to stainless steel instruments. These agents are intended to remove hard water deposits, rust scale, and discoloration from surgical steel and the equipment used for processing. Most stain and rust removers are acid-based compounds (i.e., 0 – 6.9 pH) that react with minerals and iron on the instruments. They remove minerals and detergent buildup, leaving the surfaces bright and shiny and the instruments moving freely. After using a stain remover, the instruments should be recleaned prior to reprocessing. See Table 8 for the characteristics and clinical benefits of stain and rust removers.

Table 8 – Characteristics and Clinical Benefits of Stain and Rust Removers

Characteristic	Benefit	Instrument Stain and Rust Remover
Removes Rust and Stains	Prolongs instrument life and restores luster to stainless steel instruments	√
Buffered Acid Solution	Does not harm tungsten carbide	√
Rust Inhibitors	Reduces the risk of rust, tarnish, corrosion damaging instruments	√
Rinsing Agents	Helps deliver spot free rinsing	√

- *Adhesive Removers*. Adhesive removers are used on the clean SPD side to remove tape and other adhesives completely and effectively from equipment, containers, instruments and skin. Adhesive removers are specially formulated products that are safe for use on various metals, glass, rubber and other components of surgical instruments and devices.

  Adhesive removers are classified by the U.S. Food and Drug Administration (FDA) as a Class I medical device that is 510(k) exempt. The U.S. FDA has been regulating medical devices since 1976, at which time three regulatory classes for medical devices were established, based on the degree of control necessary to assure that the various types of devices are safe and effective.[18] Class I devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices; approximately 47% of medical devices fall in this category. Class I devices are subject to "general controls," including labeling and current good manufacturing processes. If a device falls into a generic category of exempted Class I devices, a premarket 510(k) notification application and FDA clearance are not required before the device can be legally marketed in the U.S. However, the manufacturer is required to register their establishment and list their generic product with FDA.

HIGH-LEVEL DISINFECTANTS

Overview

High-level Disinfectants (HLDs) are used to provide HLD and sterilization for heat sensitive instruments that cannot be heat sterilized. All items should be thoroughly cleaned and decontaminated before HLD, as any debris, blood, mucous, fat, tissue, or other organic matter remaining on the item will interfere with the action of the disinfectant.[19] Glutaraldehyde and other high-level disinfectants used today are described below.

- *Glutaraldehyde.* Glutaraldehyde is a saturated dialdehyde that is widely accepted as an overall effective high-level disinfectant and chemical sterilant.[20] Glutaraldehyde has a broad antimicrobial range and is effective against vegetative bacteria, Mycobacterium tuberculosis, fungi, and viruses.

  Glutaraldehyde solutions are compatible with the following devices and materials [21]:
  - Respiratory therapy equipment,
  - Anesthesia equipment,
  - Rubber,
  - Most stainless steel instruments,
  - Plastic,
  - Most dental instruments (not including dental hand-pieces),
  - Many types of metals, such as stainless steel, carbon steel, and aluminum, and

- Plated metals such as nickel plating or chrome plating.

  Users should refer to the device labeling and consult with the device manufacturer for additional information regarding compatibility with specific reusable devices. This solution is compatible with enzymatic detergents which are mild in pH, low foaming, and easily rinsed from equipment. Detergents that are either highly acid or alkaline are contraindicated as pre-cleaning agents since improper rinsing could affect the efficacy of the solution by altering its pH.

Glutaraldehyde-based products are used primarily for medical devices that cannot be steam sterilized, particularly heat-sensitive, lensed instruments that are commonly subjected to high-level disinfection between patient uses.[22] Several manufacturers now produce glutaraldehyde-based liquid sterilants and high-level disinfectants. These products are referred to as either "acid glutaraldehyde" or "alkaline glutaraldehyde." Products designated as "alkaline" are usually supplied in two parts (an active glutaraldehyde solution and an activator buffer), which require mixing prior to use to impart an alkaline pH to the solution (i.e., a pH of approximately 8). Those designated as "acid" usually do not require an activator. Glutaraldehyde-based sterilants usually are used as high-level disinfectants for semicritical devices. Conditions for HLD generally range from 5 minutes to 90 minutes at 20ºC to 35ºC (68ºF to 95ºF), depending on the product formulation and glutaraldehyde concentration. For the products currently available, the contact time for sterilization is 10 hours at temperatures ranging from 20ºC to 25ºC (68ºF to 77ºF) or 7 hours and 40 minutes at 35ºC (95ºF), depending on the product formulation and glutaraldehyde concentration. For use in Automated Endoscopic Reprocessors (AERs), a 2.5% glutaraldehyde solution with surfactants at 35ºC (95ºF), 5 minutes must be used in an AER with the FDA-cleared capability of maintaining the solution at 35ºC. The AER manufacturer's directions for use should be consulted and followed.

Glutaraldehydes are considered a Class II medical device and are subject to FDA regulations. Class II medical devices are considered to pose potential risks requiring "special controls," including 510(k) notification and approval for sale.[23] That is, Section 510(k) of the Food, Drug and Cosmetic Act requires those device manufacturers who must register to notify the FDA of their intent to market a medical device; this is known as Premarket Notification or 510(k). Under 510(k), before any manufacturer can legally market a medical device in the United States, it must demonstrate – to FDA's satisfaction – that the device is substantially equivalent (i.e., as safe and effective) to a device that is already on the market. The submission must include a completed application, extensive data, documentation of testing and validation studies, special labeling, intended use, and instructions for use. If FDA rules the device is "substantially equivalent," the manufacturer can then market the device.

- *Activation and Shelf-Life of 3% Glutaraldehyde Solutions*.
  - 3% Glutaraldehyde is available in 14-day and 28-day solutions. Once a glutaraldehyde solution is activated, it can be used for 14 or 28 days, providing the test strip passes its Minimum Effective Concentration (MEC) level for solution potency before each use.

- The solution must be discarded after either 14 or 28 days, regardless of whether it passes the test strip. If a solution falls below its MEC, it should be discarded even if the designated expiration date has not been reached.[24]
- A 28-day glutaraldehyde solution is typically used when there is lower frequency of instruments being processed. The more instruments processed, the more contaminants enter the solution; therefore, it takes fewer days before the solution fails the test strip.

Glutaraldehyde is also relatively inexpensive to use, as it costs less than other high-level disinfectants/liquid sterilants. The characteristics and clinical benefits of 3% glutaraldehyde solutions are summarized in Table 9.

Table 9 – Characteristics and Clinical Benefits of 3% Glutaraldehyde Solutions

Characteristic	Benefit	28-Day 3% Glutaraldehyde	14-Day 3% Glutaraldehyde
Liquid High-level Disinfectant and Sterilant	Effectively high-level disinfects and sterilizes heat-sensitive medical instruments, such as endoscopes	√	√
Broad-spectrum High-level Disinfectant	Kills all microorganisms except high numbers of bacterial spores	√	√
Fast High-level Disinfectant	Delivers high-level disinfection in 25 minutes so instruments can be processed faster	√	√
Sterilant	Kills all microorganisms including, bacterial spores, in 10 hours soak time	√	√
28-day and 14-day Reuse Solution Options	28-day solution for lower volume, extended use practices; 14-day solution for high turn practices	√	√
Neutral pH	Safe on all scope materials	√	√
Powder Activator	Attached to each solution container	√	√

- *User Precautions.* It is important to note that direct contact with glutaraldehyde is corrosive to exposed tissue and can cause eye damage as well as skin irritation or damage; it is also harmful if inhaled or swallowed.[25] Therefore, glutaraldehyde and other chemical disinfectants/sterilants should be contained and used in well-ventilated areas; personnel should wear appropriate protective apparel to reduce the potential for

exposure to the chemical agent.[26] In addition, chemical disinfectants should be used according to the manufacturer's written instructions and federal, state, and local regulations.

- Other HLDs

  In addition to glutaraldehydes, there are other solutions available today for HLD and cold sterilization, as outlined below.

  - *ortho-Phthalaldehyde (OPA).*[27] *Ortho*-phthalaldehyde solution is an HLD intended for use in reprocessing heat-sensitive devices; it is used manually and in AERs. It is especially active against mycobacteria, including glutaraldehyde-resistant strains of *Mycobacterium chelonae. Ortho*-phthalaldehyde has several potential advantages over glutaraldehyde: it does not require activation and has a mild to no odor. One OPA product contains 0.55% OPA, corrosion inhibitors, chelating agents, and a dye in phosphate buffer. This OPA product has been cleared for use as a high-level disinfectant for manual reprocessing (12 minutes at 20ºC [68ºF]) and for processing in AERs (5 minutes at 25ºC [77ºF]) that have FDA-cleared capability to maintain solution temperature at 25ºC (77ºF). If the solution temperature cannot be maintained at 25ºC (77ºF) in an AER, the device should be processed manually. Both applications have a reuse life of 14 days. Another OPA formulation is designed for single use in an automated system. In this system, concentrated (5.75%) OPA is diluted with buffers, chelating agents, corrosion inhibitors, and a dye to its 0.05% "in-use" solution. The labeled contact conditions for high-level disinfection are 10 minutes at 50ºC to 55ºC (122ºF to 131ºF).

    Ortho-phthalaldehyde solution should not be used to process any urological instrumentation used to treat patients with a history of bladder cancer. In rare cases, OPA solution has been associated with anaphylaxis-like reactions in patients with bladder cancer undergoing repeated cystoscopies.

    The medical device manufacturer's instructions should be consulted to determine the compatibility of the device with the selected OPA solution. If an AER will be used, the manufacturer should be consulted to determine the compatibility of the equipment with OPA solution.

    As with glutaraldehyde, a solution test strip or chemical monitoring device should be used to test the concentration of OPA before each reprocessing cycle. Only those test strips or chemical monitoring devices recommended by the OPA product manufacturer should be used. *Ortho*-phthalaldehyde solutions should not be used beyond their shelf life; the solution should be discarded after 14 days, even if the OPA solution test strip or other chemical monitoring device indicates a concentration at or above the MEC.

    Breathing OPA vapors may be irritating to the nose, throat, or respiratory system and may cause coughing, chest discomfort and tightness, difficulty

breathing, or headache. Conditions such as preexisting bronchitis or asthma and skin conditions such as dermatitis may be aggravated by exposure to OPA. Eye contact with dilute solutions of OPA can cause eye irritation and damage. OPA can also stain skin and patient tissue if processed instruments are not rinsed properly. At use concentrations, OPA can be a contact sensitizer through the dermal route of exposure; OPA is a potent sensitizer that, in susceptible individuals, might result in anaphylaxis. As with glutaraldehyde, OPA should be used in well-ventilated areas; personnel should wear appropriate protective apparel to reduce the potential for exposure.

- *Peracetic Acid.*[28,29] The strong microbicidal effects and broad-spectrum activity of peracetic acid have been known since the early 1900s. Liquid peracetic acid is a biocidal oxidizing agent; it is an effective biocide at low temperatures and is effective in the presence of organic matter. It has a chemical formula of acetic acid plus an extra oxygen atom, which is highly reactive. The extra oxygen atom reacts with most cellular components, causing cellular death. The ability of peracetic acid to inactive various critical cell systems are responsible for its broad-spectrum antimicrobial activity. As peracetic acid is converted to acetic acid, the oxygen decomposes; it is rendered nontoxic and environmentally safe. The diluted (i.e., use) solutions have a slight vinegar-like odor.

  One peracetic acid formulation, which has been available since 1988, is designed for single use reprocessing of immersible instruments and surgical items (when indicated by the device manufacturer) in an automated processing system. This formulation is FDA-cleared for the sterilization of cleaned, reusable medical devices. In this system, concentrated (35%) liquid peracetic acid is diluted with buffers, a surfactant, and an anticorrosive dry powder to its 0.2% (2000 parts per million) “use dilution,” since peracetic acid is highly corrosive to instruments. The labeled contact conditions for sterilization are 12 minutes at 50ºC to 56ºC (122ºF to 133ºF). During the sterilization cycle, time and temperature are automatically controlled and monitored. The cycle includes rinsing with sterile water produced by passing tap water through a 0.2-micron filtration membrane. The efficacy of this filtration process depends on the quality of the incoming tap water. The purpose of rinsing is to remove sterilant residues. Although the actual cycle time depends on inlet water temperature and pressure, the nominal total cycle time is approximately 30 minutes. Biological and chemical indicators designed for this system are available from the manufacturer.

  To ensure compatibility, users should consult the medical device manufacturer’s instructions before using a peracetic acid sterilization system. If an AER is to be used, the manufacturer should be consulted to determine the compatibility of the equipment with peracetic acid. A solution test strip or chemical monitoring device (as recommended by

the product manufacturer) should be used to test the concentration of the active ingredients prior to each use. Quality control checks of the test strips or chemical monitoring devices should be performed according to the manufacturer's instructions. When the concentration of the active ingredients falls below the MEC, the solution should no longer be used. Solutions should not be used beyond the reuse period indicated on the label, even if the concentration of the active ingredients is at or above the MEC. (For the currently available products, the reuse period is 5 to 14 days.) Solutions should not be used beyond their shelf life.

Procedures should be developed to assist in preventing eye and skin contact with undiluted, concentrated peracetic acid solutions and reduce exposure to peracetic acid and hydrogen peroxide vapor. Personnel should always wear appropriate protective apparel when handling undiluted peracetic acid; the sterilant manufacturer's written instructions should be consulted regarding when personnel should wear PPE when using the diluted product. The effects of exposure can vary from product to product and manufacturer to manufacturer. Eye contact with undiluted solutions is corrosive and can cause irreversible eye damage, including blindness. Skin contact with undiluted solutions can cause severe burns; hydrogen peroxide burns are indicated by a whitening of the skin. Inhalation of vapors and mists will irritate the nose, throat, and lungs, but typically will subside when exposure ceases; coughing and difficulty breathing may also occur.

CLEANING PROCESS AND MECHANICAL EQUIPMENT: TROUBLESHOOTING

At times, SPD personnel may notice that automated washers or other mechanical equipment are cleaning poorly. One measure to maintain and improve the cleaning efficacy of automated equipment is the routine use of descalsers. Descalers can be used to safely remove hard water scale, rust, mineral scale, organic waste and stubborn residue and buildup from the inside of automated washers, washer/disinfectors, cage/cart/rack washers, as well as autoclave chambers. It may also be used as an acidic pre-wash to minimize the buildup of scale, soil and stains due to the daily use of equipment.

Automated washers have a descaler setting, or the product can be applied manually. The solution should be diluted according to the manufacturer's instructions for use, applied to chamber walls, and allowed to soak for the time indicated in the instructions. In general, descalers are compatible with most metal equipment when used as directed; they should not be used on aluminum surfaces or galvanized metal. As with all products, the manufacturer's instructions for use should be consulted.

REGULATIONS AND STANDARDS

Because various regulations and standards have been reviewed throughout this course, it is important to clarify the definition of these terms, as related to their impact on policies and procedures for instrument cleaning and reprocessing.

- *Regulations.* A regulation is a mandatory law or rule that is issued by a governing body.[31] Regulations must be followed and are enforceable by law. Regulations are set by both state and federal agencies. State regulations vary by state. The federal agencies involved in regulations related to instrument decontamination include:
  - U.S. FDA, which regulates:
    - Medical devices;
    - Labeling of products and devices used in SPD and the OR; and
    - Third-party reprocessors.
  - Department of Transportation (DOT), which regulates transportation inside and outside of the facility.
  - Environmental Protection Agency (EPA), which regulates disposal of waste and chemicals.
  - The Occupational Safety and Health Administration (OSHA), which regulates worker and workplace safety.
- *Standards.* A standard is defined as a uniform method of defining basic parameters for processes, products, services and measurements.[32] Standards are not written by government agencies, but are developed and published by professional associations. They have no authority on their own, but may be adopted into regulations making them legal requirements, as they are written to reflect evidence-based best practices. Professional associations involved in instrument care, cleaning, and use are:
  - Association for the Advancement of Medical Instrumentation (AAMI)
    - Develops recommended practices and standards related to all aspects of instrument care, cleaning, decontamination, high-level disinfection, and sterilization.
  - American National Standards Institute (ANSI)
    - Reviews and approves all standards for the U.S.
  - Association for Professionals in Infection Control and Epidemiology (APIC)
    - *Bioterrorist Readiness Plan*
    - *Guidelines for Infection Prevention and Control in Flexible Endoscopy*
  - International Standards Organization (ISO)
    - International standards adopted from organizations such as AAMI

Other groups that have developed applicable standards and recommendations related to cleaning and decontamination of surgical instruments and other reusable devices include:

- Society of Gastroenterology Nurses and Associates (SGNA)
- Centers for Disease Control and Prevention (CDC)
- Association of periOperative Registered Nurses (AORN)
- International Association of Healthcare Central Service Materiel Management (IAHCSMM)

SUMMARY

Preventing infection for all patients undergoing surgical intervention is a primary goal for all team members, especially in today's dynamic healthcare environment. A key infection prevention practice for reducing the risk for a surgical site infection is proper reprocessing of surgical instruments. Effective sterilization or high-level disinfection can only take place after the items have been thoroughly cleaned. Therefore, the first and most important step in the reprocessing of reusable medical devices is thorough cleaning and rinsing. Since the cleaning process is not microbicidal, i.e., it primarily removes rather than kills microorganisms, a subsequent disinfection or sterilization process may be necessary to ensure that an item is safe for handling. Cleaning can be accomplished manually, mechanically, or by a combination of both methods. Because medical devices vary in size, complexity, fragility, sensitivity to cleaning agents, immersibility, and other properties that affect the choice of cleaning method, the device manufacturer is responsible for ensuring that a device can be effectively cleaned and sterilized and also for providing written reprocessing instructions. Moreover, heat-sensitive devices have distinct cleaning and sterilization protocols.

Detergents and disinfecting agents available today are specially formulated to meet specific cleaning needs from the most basic cleaning functions to proper high-level disinfection and sterilization. Variable factors include ingredients, chemical composition, foaming properties, chelating ability or performance, and free-rinsing ability; thus, detergents are not interchangeable and differ from each other in many ways and by manufacturer. For these reasons, it is recommended to use products made for the facility's specific instrument cleaning and reprocessing needs.

Personnel responsible for instrument cleaning and reprocessing should also be aware of appropriate troubleshooting procedures for mechanical equipment, as well as the applicable regulations and standards. Through this knowledge and understanding, SPD and OR personnel can play an integral role in proactively minimizing the risk for surgical site infections, thereby promoting positive patient outcomes.

GLOSSARY

Aerosolization	The production of a fine mist or spray containing minute particles.
Automated Endoscope Reprocessor (AER)	A unit for mechanical cleaning, disinfecting, and rinsing of flexible endoscopes.
Bioburden	The number of microorganisms (i.e., microbial load) with which an object is contaminated.
Biofilm	A thin coating containing biologically active organisms that have the ability to grow in water and water solutions, which coat the surface of structures (e.g., the inner surfaces of catheters, tubes, implanted or indwelling devices, instruments and other medical devices). Biofilms contain both viable and nonviable microorganism that adhere to the surface and are trapped within a matrix of organic matter, which prevents antimicrobial agents from reaching the cells.
Cavitation	The formation and then immediate implosion of cavities in a liquid. In ultrasonic cleaners, ultrasonic energy (i.e., high-frequency sound wave energy) is passed through a water bath, creating bubbles that implode; this process of implosion creates a suction action that pulls particles of debris off of instrument surfaces and from crevices in instruments.
Cleaning	The removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil, blood, protein substances, microorganisms and other debris from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.
Contamination	The presence of potentially infectious pathogenic microorganisms on animate or inanimate objects or surfaces.
Corrosion	The action, process, or effects of corroding, i.e., the gradual wearing away usually due to chemical action.

Decontamination	The use of physical or chemical means to remove, inactivate, or destroy bloodborne microorganisms on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface is rendered safe for handling, use, or disposal.
Detergent	A synthetic or man-made blend of ingredients for cleaning.
Disinfection	A process that kills most forms of microorganisms on inanimate surfaces. Disinfection destroys pathogenic organisms (except for bacterial spores) or their toxins or vectors by direct exposure to chemical or physical means.
Enzymatic Cleaner	A cleaner that uses enzymes to remove protein from surgical instruments.
Free Rinsing	The ability to be removed without leaving residue.
High-level Disinfection (HLD)	A process that kills all microbial organisms but not necessarily large numbers of bacterial spores. For a process that can be used for both liquid chemical sterilization and high-level disinfection, the contact time for high-level disinfection is shorter than that necessary for sterilization, under otherwise identical conditions.
Instrument Automated Washers	A machine intended to clean and disinfect loads containing surgical instruments, anesthetic accessories, bowls, dishes, receivers, utensils, glassware and similar items.
Minimum Effective Concentration (MEC)	The minimum concentration of a liquid chemical germicide that achieves the claimed microbicidal activity as determined by dose-response testing.
Passivation	The process of chemically treating or coating stainless steel to build up a corrosion-protective layer.

Personal Protective Equipment (PPE)	Specialized protective equipment (e.g., masks, gloves, goggles, face shields, and gowns) for the eyes, face, head, and extremities; protective clothing; respiratory devices; and protective shields and barriers designed to protect the wearer from injury. PPE is used by healthcare workers and others whenever necessary to protect themselves from the hazards of processes or environments, chemical hazards, or mechanical irritants encountered in a way that is capable of causing injury or impairment in the function of any part of the body through absorption, inhalation, or physical contact.
Regulation	A mandatory law or rule that is issued by a governing body.
Standard	A uniform method of defining basic parameters for processes, products, services and measurements.
Sterile	The state of being free from all living microorganisms. In practice, usually described as a probability function, e.g., as the probability of a microorganism surviving sterilization being 1 in 1,000,000.
Sterilization	A validated process that removes or destroys all viable microorganisms, including bacterial spores, to an acceptable sterility assurance level, usually 1 in 1,000,000. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to this very low number, it can never be reduced to zero.
Ultrasonic Cleaner	A processing unit that transmits ultrasonic waves through the cleaning solution in a mechanic process known as cavitation. Ultrasonic cleaning is especially effective in removing soil and other debris from hard-to-reach areas.
Validation	A documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

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ADDITIONAL RESOURCES

- AAMI (Association for the Advancement of Medical Instrumentation) - www.aami.org
- AORN (Association of periOperative Registered Nurses) - www.aorn.org
- CDC (Center for Disease Control) - www.cdc.gov
- IAHCSMM (International Association of Healthcare Central Service Materiel Management) - www.iahcsmm.org
- SGNA (Society of Gastroenterology Nurses and Associates) - www.sgna.org

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