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CLEANING OF INSTRUMENTS

By Charles A. Hughes

Introduction

The first step in preparing an instrument for reuse after it has been used on a patient is cleaning. The importance of this step cannot be underestimated, as studies [Alfa, 1998] have shown that a soiled instrument cannot be effectively sterilized. This is because the soil shields bacteria and viruses from the sterilizing agent. As a result, bacteria and viruses may very well survive the sterilization process and can cross infect the next patient.

Cleaning is defined by AAMI "as the removal of contamination from an item to the extent necessary for further processing or for the intended use. NOTE—In health care facilities, cleaning consists of the removal, usually with detergent and water, of adherent soil (e.g., blood, protein substances, 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". The appropriate cleaning method for a particular medical device depends on the device's characteristics.

General Precautions

Before any specific methods of cleaning instruments can be discussed, the issue of how to protect the staff from the possibility of infection must be considered. Healthcare workers who do the hands-on work of cleaning soiled instruments should be protected from the possibility of infection from infectious material on the instruments. This is not just a good idea; it is the law. OSHA (Occupational Safety and Health Administration) of the U.S. Department of Labor has issued regulations (29 CFR 1910.1030 subpart Z) concerning handling of blood-borne pathogens that spell out universal precautions that must be taken to avoid, or at least minimize the chance that a healthcare worker will be exposed to infectious material. The health care facility is responsible for providing PPE for all service personnel and ensuring that used, contaminated PPE is decontaminated and/or disposed of properly. Such equipment must comply with OSHA regulations, and can include protective gloves, liquid-resistant or liquid-proof clothing, face shields, and surgical face masks. Some of the most important points discussed in the regulations are:

- provide initial and annual training on the blood-borne pathogen regulations,
- provide personal protective equipment such as disposable gloves,

- dispose of soiled dressings and potentially contaminated waste according to bio-hazardous material regulations, but,
- the use of personal protective equipment is required only when there is reasonably anticipated exposure to blood or other potentially infectious materials.

Manual Cleaning

The oldest method of cleaning instruments is manual cleaning and any device should be able to be cleaned manually. This method is still used frequently in areas ranging from the small medical or dental office to the largest hospitals. Manual cleaning has the advantage of flexibility, in that any type of instrument can be cleaned. It also has the weakness that the cleanliness of the instruments will be different from worker to worker, since each person will vary in technique to some degree. It; however, has the drawback that the healthcare workers are exposed to possible cross infection as they are in contact with soiled instruments.

Manual cleaning often is recommended for delicate or complex medical devices, such as microsurgical instruments, lensed instruments, and air-powered drills. Recommended procedures for manual cleaning are to first soak the instrument in a tepid or lukewarm water or detergent bath for at least 10 minutes, preferably until all soil on the instrument is softened.

This step softens and loosens much of the soil that may have dried on the instrument between the time it was used and the time cleaning is begun. The duration of the soak depends upon how much soil is on the instruments and how long the soil has been allowed to dry. Note: The use of enzyme detergents is preferred, as they help to break up organic soil more readily and rapidly than do conventional detergents. The instrument manufacturer should be consulted to determine the appropriate type of cleaning agent and the cleaning agent manufacturer's instructions for use should be followed.

The next step is to completely brush the instrument with a medium-soft brush while it is in the soak bath. In the case of tube devices like endoscopes and hand-pieces, the insides (tubes, lumens, channels, etc.) should be brushed out as well. Care should be taken to use brushes recommended by the manufacturer to avoid damaging the instrument. Note: Brushing must be done under the surface of the water with brush strokes away from the body to avoid exposure to spray from the brush and to minimize aerosolation, removing the instrument from the soak bath only to inspect its cleanliness. The instrument must then be rinsed with clean water, and if difficult-to-remove soil remains, another enzyme soak followed by brushing and rinsing must be done. Clean detergent solutions must be used for each session, so as to make sure that soil that was removed from one instrument does not deposit on the next instrument, creating the chance for cross infection.

Ultrasonic Cleaning

Unless specified by the instrument manufacturer not to, ultrasonic cleaning is the follow-up to manual cleaning. While manual cleaning removes most or all of the visible soil from an instrument, it may not remove small or microscopic particles that are protected by the texture of a surface or design features like hinges. Ultrasonic creates microscopic bubbles in the solution that collapse when they contact the instrument releasing energy. This energy "kicks" any soil that is in the area off the instrument. This process is called cavitation. The detergent in the ultrasonic bath suspends the soil particles and keeps them from attaching back to the instrument. Ultrasonic cleaning should be done for a duration as specified by the detergent or ultrasonic machine manufacturer, whichever is longer. The detergent solutions must be changed following the instructions of the manufacturer of the detergent or the ultrasonic, whichever states a shorter change interval? This procedure ensures that the potential for

cross contamination of instruments is minimized. Following ultrasonic cleaning, the instruments are rinsed with clean water and dried. Distilled water is preferred, to ensure removal of as much detergent as possible, but is only essential if the tap water has a high mineral content that could cause spotting. After drying, the instruments may be packaged for sterilization. Be sure to check with the instrument manufacturer to determine which sterilization process(s) have been validated.

Automatic Washers

Larger facilities need to reprocess more instruments than can reasonably be done by hand, and so use automatic cleaning machines. These machines may resemble home dishwashers or be specialized for the specific needs of cleaning endoscopes or dental hand-pieces and have been validated to meet the special needs of cleaning these instruments. These needs may include specialized racks that allow cleaning of the interior of anesthesia tubing, for example, and a wide range of temperature settings that allow the items to be processed at the maximum safe temperature for their use. Higher temperatures both speed cleaning, which is important in a high-volume setting, and provide some disinfection.

In the USA, there are three categories of washers which are defined and regulated by the FDA. Only washers and washer-disinfectors intended to process "general purpose" articles, such as laboratory glassware, pipettes, bottles and containers, are exempt from FDA review, unless they are promoted for use in the reprocessing of reusable medical devices [FDA, 1998]. These categories are:

Category	Performance
Washer	removes soil from instruments
Washer-disinfector	removes soil from instruments and provides at least a 1,000-fold reduction in the number of viable organisms present by use of a hot-water (180-200°F) or chemical disinfectant cycle.
Washer-sterilizer	removes soil from instruments, and provides a sterility assurance level of one chance in one million that the items processed will have a viable organism after processing.

Washers

Washers provide the basic function of cleaning that is needed to successfully reprocess instruments. The capabilities of a specific model and variability of cleaning results from one washer to then next must be taken into account to make an informed purchase decision. FDA approval to market provides a baseline, but the best information, including information on reliability, cost of ownership and ease of use, can be found by surveying the literature for so-called "round-robin" studies in which products are compared.

Washer-Disinfectors

Washer-disinfectors' performance meets certain criteria, which were described in the table above. Per FDA, there are three levels of disinfection that may be claimed. The least demanding is low-level disinfection, in which 6-log (one-million fold) reduction of a suspension of vegetative organisms such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli* or representatives of the Klebsiella-Enterobacter group is accomplished. The next is intermediate-level disinfection in which 3-log (one-thousand fold) reduction of an appropriate mycobacterium species is accomplished. The most demanding is high-level disinfection, in which 6-log (one-million fold) reduction of an appropriate

mycobacterium species is accomplished [FDA, 1998a]. In order to meet these criteria, washer-disinfectors must thoroughly clean the instruments as well as subsequently disinfect them. Again, some washer-disinfectors are better suited for certain cleaning tasks than others, so review of the manufacturer's literature and published articles is an essential part of a purchase decision.

Washer-Sterilizers

These units are used to clean and sterilize instruments and materials that do not require packaging before use, i.e. pans and trays that receive instruments in an Operatory. For those situations in which a sufficient number of these items are to be reprocessed, washer-sterilizers are a good investment. Remember that washer-sterilizers are steam sterilizers and cannot be used for reprocessing materials or devices that cannot tolerate the heat and pressure of a steam sterilization cycle. Note: Sealed glass ampoule biological indicators are commercially available for routine quality assurance testing of these processes and should be performed to verify the sterilization cycle.

Instrument Preparation for Cleaning in an Automatic Washer

Regardless of the washer type used, instruments must be prepared for processing before being placed into a washer, with the extent of preparation depending upon the capabilities of the washer. The actual preparation must be done in accord with the washer manufacturer's instructions.

For the simplest washers, manual presoaking and sonication remain as necessary reprocessing steps. More-sophisticated washers include a presoaking step in the automated process. In all cases, standard operating procedures must be developed that take the capabilities of the washer into account, as assumption of a capability that is not present can compromise worker and patient safety.

Use of Containers

In many practices, instrument cassettes are used to hold instruments both during washing and sterilization. These cassettes use rubber strips to hold the instruments in place and should have many perforations that allow free flow of wash water/detergent solution through the cassette and over the instruments. Their use is only recommended in conjunction with automatic washers, as manual methods will not provide sufficient penetration of the cassette and the instruments within. Following the cleaning procedure, the cassette is dried and wrapped for sterilization.

Care of the Washing Equipment

Automated washers and washer-disinfectors provide a consistent level of cleaning if maintained properly. However, the internal parts of the unit, which are normally in a warm, moist atmosphere, can provide sites for the growth of pathogenic organisms in the form of biofilm [Health InfoCom Network News, 1991]. These organisms can cross contaminate patients if the instrument is not sterilized after cleaning. The best approach is to use a program of preventative maintenance that includes disinfection of the areas of the unit that are exposed to moisture and not actively rinsed. The manufacturer of the unit should be consulted to determine where these areas are located. Since around 1992, the FDA has required manufacturer's to document these potential problem areas to receive their approval to market the device.

Multi-Step Automatic Cleaning

The ultimate in automatic cleaning is the multi-step or "tunnel" washer. These units incorporate separate soaking, sonication, washing, rinsing and drying stations and automatically transfer racks of instruments between these stations. These are expensive machines whose cost can be justified only by

the highest-volume instrument processing requirements. However, these machines also provide the most-complete automation of instrument processing possible, permitting soiled instruments to be placed in a rack at one end of the unit and to be removed clean and dry and ready to be wrapped for terminal sterilization at the other end of the unit.

Difficult to Clean Instruments

Dental and Orthopedic Hand-pieces

Cleaning of hand-pieces is more difficult and requires more attention than cleaning of less-complex instruments. Hand-pieces are precision, turbine-driven instruments that have both air and water flowing through them. In normal use, these devices are in direct contact with internal body tissues. Because of their design and use, there is a good chance that body fluids and tissues may contaminate the inner surfaces and mechanism of the hand-piece. If this soil is not removed, it may be sprayed out of the hand-piece and into the next patient. To avoid this, the manufacturers' instructions for cleaning procedures must be followed closely [CDC, 1993]. In addition, the usable life of these expensive instruments is shortened by allowing soil to accumulate in their mechanisms, providing an economic reason as well as a patient care reason to clean the units properly.

All water and air channels in a hand-piece are small, making it difficult to gain access to them and making cleaning difficult. Also, when the hand-piece is turned off, the water supply tends to suck water back, pulling soil into the hand-piece, and into the areas most difficult to access. How then, does one clean these instruments? The same sort of sequence described above for regular instruments is used. This is to remove gross soil, fine soil and microscopic soil, in that order.

Gross Soil Removal

There are two very different parts to removal of soil from a hand-piece. These are the cleaning of the outside and the cleaning of the insides. Cleaning of the outside is no different than cleaning of a less-complex instrument, and is described above. Cleaning of the inside; however, is very different.

The first step in cleaning the inside of a hand-piece is to attempt to remove the soil that was sucked into the water channels. To do this, you simply operate the hand-piece in the normal manner for 20-30 seconds, pointing the instrument into a narrow-necked receptacle or drain, or a high-speed evacuation receptacle. The hand-piece head must be inside the neck of the receptacle, ensuring that none of the spray or spatter is allowed to escape and contact the healthcare worker doing the cleaning.

This action flushes out most or all of the soil in these channels. Some hand-piece manufacturers also suggest the use of lubricating oil fed through an automatic hand-piece lubricator for this rinsing. Following this, the hand-piece should be disassembled in accordance with the manufacturer's instructions and cleaned following the manual and ultrasonic procedures described above unless specific cleaning procedures are provided by the manufacturer.

Endoscopes

Endoscopes may be even more difficult to clean than hand-pieces and are considered the most challenging reusable medical device to reprocess. This is because of their longer length and the relative narrowness of the tubing in them. Rigid endoscopes, like those used in arthroscopies and laparoscopic cholecystectomies, are typically able to be disassembled for cleaning, which makes their cleaning relatively easier. Flexible endoscopes, like those used in colonic procedures, are more complicated and generally cannot be disassembled which present the greatest challenge to cleaning.

Manual Cleaning-Rigid Endoscopes

Cleaning of endoscopes is done in a manner similar to normal instruments, with the exception that both the inside and outside of the endoscope must be cleaned. The first step is a presoak in enzyme detergent solution, followed by disassembly of the endoscope. All parts of the endoscope are then cleaned by brushing beneath the surface of the detergent solution to remove visible soil from the instrument. At this point, all surfaces of the endoscope are rinsed and inspected for soil. If any is found, the previous steps should be repeated. The inside of the outer tube that makes up the endoscope requires special attention, as it is frequently coated with a low-friction material like Teflon®. If scratched during cleaning, the operation of the endoscope may be adversely effected. However, the tube must also be clean, which is not easy to accomplish without brushing, so only brushes recommended by the manufacturer should be used in these areas. After all visible soil is removed, the endoscope components should be rinsed with clean water or a final rinse with 70% ethanol or isopropanol may be used to both provide final disinfection and drying of interior channels of an endoscope [BSG, 1997].

The next step is ultrasonic cleaning which is done in a manner similar to what is done for normal instruments. After cleaning, the endoscope components are to be rinsed with water or alcohol and allowed to dry. Any joints requiring lubrication are then lubricated and the endoscope may be reassembled in preparation for sterilization. If the endoscope is to be disinfected using a liquid disinfectant, reassembly and lubrication should be done after disinfection.

Manual Cleaning-Flexible Endoscopes

The initial steps of cleaning of flexible endoscopes are similar to what has been described above, except that all valves on the endoscope must be locked open to ensure flow of cleaning and disinfecting solutions through them. All removable components must be removed and cleaned separately. The external surface is brushed clean in a manner similar to the rigid endoscopes described above. A syringe is used to direct cleaning solutions through the endoscope toward the end of the endoscope that is normally in contact with the patient. That end of the endoscope must remain submerged in the detergent solution to avoid splashing workers with soil. While the endoscope is being flushed, any directional controls should be manipulated through their full range of motion to ensure that as much of the endoscope as possible is contacted and rinsed by the detergent and rinse water. Since it is impossible to inspect the inner channels of the endoscope for cleanliness without special instrumentation, this is a case where the adage, "If you can't be good, be thorough," applies. As is the case for rigid endoscopes, a final rinse of clean water or alcohol should be used. The alcohol provides low-level disinfection, an important consideration for devices that even when cleaned correctly can harbor living microorganisms [Forbes, 1999].

Ultrasonic cleaning should follow manual cleaning for all submersible parts of the endoscope. Note: Due to the small diameter of the lumens, ultrasonic waves will not penetrate much more than one inch from the end of the tube, so this cleaning is limited to the outside of the endoscope.

Automatic Cleaning

Automated systems exist for cleaning endoscopes and include special racks for normal washers and dedicated endoscope washers. Performance will vary between different washers from different manufacturers, with FDA approval effectively providing a minimum performance standard. Preparation for washing depends upon the capabilities of the washer, but pre-cleaning and disassembly are always an appropriate first step, since it is difficult for any washer to remove hard, dried soil. Some

automated endoscope washers also employ ultrasound to aid in cleaning, but as discussed before, ultrasound does not effectively penetrate a lumen for any significant distance, and this approach therefore primarily benefits cleaning of the outside of the endoscope. Prior to making a purchase decision, the literature must be reviewed for performance and reliability information.

Verification of the Cleaning Process

Upon completion of the cleaning process, it is up to the healthcare worker to visually inspect each item to detect any visible soil. While validation of the cleaning process is not realistic in health care facilities today, verification is possible. Instrument manufacturers should recommend test procedures that can be easily replicated and help users recognize whether cleaning was effective for all surfaces. Such tests are particularly important for instruments with components that cannot be readily inspected for cleanliness (e.g., spring hinges, lumens, porous materials, crevices). For example, a 2 % hydrogen peroxide solution has been used to verify the removal of protein from the lumens of instruments such as needles and tracheostomy tubes; the solution bubbles if it comes into contact with blood or protein surfaces.

Conclusion

Cleaning is the first and most important step in the reprocessing of instruments. The sequence soak, wash, rinse, dry (with appropriate preparation of the instrument) will provide a clean instrument that can be readily disinfected or sterilized prior to its next use on a patient. Automated systems improve both the number of instruments processed in a given time period and the consistency of cleaning of these instruments. Furthermore, as discussed, difficult-to-clean instruments, like hand-pieces and endoscopes require special attention and care on the healthcare worker's part to ensure their fitness for reuse.

About the Author

Charles Hughes is General Manager/Educator for SPSmedical Supply Corp. located in Rochester, NY. A certified Health Education teacher, he has over 20 years experience in sterilization training, marketing and regulatory affairs. A corporate member of AAMI, AORN, APIC, IAHCMM, ASHCSP and OSAP, Charles speaks on sterilization standards to medical device manufacturers and health care facilities throughout the USA and Canada. For more information, please feel free to contact the author @ 800-722-1529 or e-mail: chughes@spsmedical.com

References

Alfa, 1998: "Comparison of liquid chemical sterilization with peracetic acid and ethylene oxide sterilization for long narrow lumens," Michelle J. Alfa, Pat DeGagne, Nancy Olson, Romeo Hizon, American Journal of Infection Control 1998; 26: 469-77.

AAMI, ST35:2003: Association for Advancement of Medical Instrumentation. "Safe handling and biological decontamination of reusable medical devices in health care facilities and in nonclinical settings". Approved 17 March 2003 by American National Standards Institute, Inc.

FDA, 1998: "Guidance Document For Washers And Washer-Disinfectors Intended For Processing Reusable Medical Devices," June 2, 1998, U.S. Department of Health and Human Services, FDA, Center

for Devices and Radiological Health, Infection Control Devices Branch, Division of Dental, Infection Control, and General Hospital Devices, Office of Device Evaluation.

FDA, 1998a: "Guidance on the Content and Format of Premarket Notification 510(k) Submissions of Washers and Washer-Disinfectors-Draft Guidance," U.S. Department of Health and Human Services, FDA, Center for Devices and Radiological Health, Infection Control Devices Branch, Division of Dental, Infection Control, and General Hospital Devices, Office of Device Evaluation.

Health InfoCom Network News, 1991: Nosocomial Infection and Pseudoinfection from Contaminated Endoscopes and Bronchoscopes -- Wisconsin and Missouri," Health InfoCom Network News, Vol. 4, No. 25, Page 6, December 25, 1991, Scottsdale, AZ.

CDC, 1993: "Recommended infection-control practices for dentistry," Centers for Disease Control and Prevention, MMWR 1993;42(No. RR-8).

BSG, 1997: "Cleaning and Disinfection of Equipment for Cleaning and Disinfection of Equipment for Gastrointestinal Endoscopy," British Society of Gastroenterology, Guidelines in Gastroenterology.

Forbes, 1999: "Blood Money," Neil Weinberg, Forbes, p. 123, March 22, 1999.

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About Charles Hughes

Charles Hughes is an educator and the general manager of SPS Medical Supply Corp. in Rush, N.Y. Certified as a Health Education teacher, Hughes has worked for more than 25 years in the manufacturing industry in areas of R&D, regulatory affairs, microbiology, marketing, and sterilization training. He is a corporate member of CSA, AAMI, IAHCSMM, ASHCSP, AORN, APIC and OSAP.