

The Essentials of Instrument Decontamination



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The Essentials of Instrument Decontamination Study Guide #06

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Description of Study Guide Topic

Today, healthcare professionals who are responsible for instrument preparation and processing are often confronted with a variety of issues involving infection control and decontamination. Complex instrument designs, virulent pathogenic microorganisms, guideline compliance and ongoing educational needs are challenging processing personnel. By understanding infection transmission and the importance of thorough decontamination and by adhering to the principles of infection control and processing practices, healthcare professionals can develop and implement policies and procedures that will minimize or prevent the spread of potentially infectious microorganisms.

Overall Purpose of the Study Guide

Review the essentials of disease transmission and decontamination to control or eliminate the transmission of infection.

Objectives

Upon completion of this study guide program, the participant should be able to:

1. Describe the decontamination environment necessary to prevent disease transmission.
2. Review critical steps of decontamination of reusable medical devices.

Intended Audience

This study guide is a self-study program intended for use by central service staff members, perioperative nurses, surgical technologists, endoscopy suite nurses, endoscopy staff members, infection prevention nurses and other healthcare professionals interested in this topic.

Infection Transmission

Healthcare-associated infections (HAI) are infections that are acquired during a healthcare experience, such as hospitalization, but may not be apparent until after the patient has been released from care or discharged. The source of these infections may be endogenous (from one's own tissues, self-infection) or exogenous (from objects or other persons, cross-contamination). HAI can proliferate in healthcare environments due to the population of susceptible hosts, presence of infective agents and the existence of various modes of transmission.

Healthcare professionals must understand the chain of infection so that practices can be implemented to control transmission of pathogens. The three main components in this chain of infection are the agent, the route of transmission and the host (AAMI, 2006).

The causative agent of infection can be a bacterium, virus, fungus, parasite, or prion. The pathogen must be virulent, invasive, infective and have the appropriate reservoir to survive and transmit disease.

- > **Virulent:** Virulence is the degree of pathogenicity or the ability of a microorganism to cause disease. As a microorganism becomes more virulent, the resulting disease becomes more severe and communicable
- > **Invasive:** The invading organism must be able to penetrate the host's defensive barriers (invasive) to cause disease
- > **Infective:** An infective dose is the number of pathogens of a specific organism needed to cause an infection. This number varies with the organism and the host

- > **Reservoir:** A reservoir is the place where the organisms metabolize and multiply. Different microorganisms require different reservoirs which may be animate or inanimate. Viruses, gram-positive bacteria and gram-negative bacteria survive best in a human reservoir while gram-negative bacteria can also survive in animals and on inanimate surfaces

The route of transmission of an organism can be through direct contact (blood transfusions, direct contact with body fluids, sexual contact), vectors (insects that can transmit disease), or indirect contact (exposure to contaminated food, water, air and inanimate objects, such as surgical instruments).

The host must be susceptible to the infective pathogen for disease to occur. Factors, such as age, physical condition and nutrition, can affect the host's susceptibility.

In summary, the chain of infection requires a causative agent that multiplies in a reservoir. A portal of exit allows the pathogen to escape and be transmitted to a susceptible host through a portal of entry. Therefore, disease is transmitted.

Definition of Decontamination

To minimize or prevent disease transmission, contaminated medical devices must be handled and prepared by destroying the causative agent or arresting its growth. The Association for the Advancement of Medical Instrumentation (AAMI) ST79 document "Safe Handling And Biological Decontamination Of Medical Devices In Healthcare Facilities And In Nonclinical Settings" (2006) defines decontamination as "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal." Stated more simply, "Decontamination is the physical or chemical process which renders an inanimate object that is potentially contaminated with harmful microbial life, safe for further handling" (AMSCO, 1989).

Decontamination is a two-step process involving thorough cleaning followed by a process, such as disinfection or sterilization, that will kill microorganisms to render items safe to handle. This study guide will focus on the cleaning aspect of the decontamination process. The AAMI document states that cleaning is the "removal, usually with detergent and water, of adherent visible soil from the surface, crevice, sensations, joints and lumens of instruments, devices and equipment by a manual or mechanical process that prepares items for safe handling or further decontamination" (AAMI, 2003). Earl Spaulding, Ph.D. once commented that "you can clean without disinfecting, but you cannot disinfect without cleaning" (Spaulding, 1972). Because a clean device is required before disinfection or sterilization can be achieved, great emphasis must be placed on thorough cleaning and rinsing.

Decontamination Environment

Usually the decontamination or cleaning area within the processing department is physically separated from the other areas either with walls or spatial separations. This physical layout prevents splashes and contamination onto clean items and work surfaces. Segregation of contaminated items from items being removed from mechanical processing equipment or clean items is necessary to protect processed items from recontamination. Also, the decontamination area supplies and equipment should be kept separate from those used in the clean preparation and pack area.

Traffic patterns should be monitored and controlled within the decontamination area. Only authorized personnel should be allowed access and should comply with the required attire when entering this area.

Lighting

Good general lighting is essential in a processing area. Direct or special lighting may be required for difficult or fine cleaning tasks, such as the inspection of instruments using magnified lighting. Overhead lighting should be recessed and sealed to prevent dust accumulation and facilitate their cleaning.

Ventilation

Proper ventilation within the decontamination area is extremely important to minimize or eliminate the potential for airborne contamination. Negative pressure is maintained in the decontamination area so that airborne contamination will not spread to clean areas.

There should be at least 10 complete air exchanges per hour. Fans should not be used in the decontamination area as this rapid air circulation can carry contaminants from the decontamination area to clean areas.

Temperature/Humidity

The decontamination environment should be controlled between 60-65°F (16-18°C) with a relative humidity of 30-60% for worker comfort and to inhibit microbial growth.

Housekeeping

Ceilings, floors and walls within the decontamination area should be made of materials that will withstand frequent cleaning. The surfaces should be nonporous, smooth and non-shedding without cracks and crevices that could harbor soil, dust, or airborne particulates that could contain disease-producing microorganisms. Horizontal surfaces should be cleaned and disinfected at least daily, but preferably at the end of each shift to control microbial contamination whenever they become visibly soiled. Any spills or splashes should be treated as soon as possible to contain the chemical or microbial spread.

Handwashing stations

Handwashing stations must be readily accessible in the decontamination area to encourage good handwashing practices. These stations should be separate from decontamination sinks that are used for cleaning or rinsing instruments and devices being reprocessed. Handwashing faucets should be designed so that hand contact is not necessary to turn them on and off, thus minimizing cross-contamination after the hands have been rinsed. Frequent handwashing should be encouraged, particularly after shoe covers or masks are changed, after gloves are removed, when soiled items are accidentally handled without gloves, or whenever the department policies recommend handwashing.

Emergency Eyewash/Shower Equipment

Since many chemicals and solutions are used in the decontamination area, AAMI recommendations state that emergency eyewash/shower equipment should be accessible within 10 seconds of the potential chemical exposure site (AAMI, 2003). The emergency equipment should be tested regularly and all employees should be instructed in the proper use and maintenance of this equipment. Immediate flushing of any exposed tissue is necessary to decrease the risk of serious injury when accidents occur.

Personal Attire

Since contaminated instruments are sources of disease-producing microorganisms that can invade personnel through skin nicks, cuts, or abrasions or through mucous membranes of the eyes, nose, or mouth, all personnel must wear appropriate attire when working in the decontamination area. It is important to recognize that no one should be working in the decontamination area with damaged/

broken skin. Consult the facility Infection Practitioner for guidance regarding wound coverage if working in this area is unavoidable. Clothing consisting of surgical pants and a shirt that is tucked in or a close fitting tunic top is recommended. This attire should be changed every day or whenever it becomes wet, is contaminated with blood or other infectious matter, or becomes grossly soiled. Head and facial hair should be covered with a surgical hood or cap and jewelry should not be worn. Fingernails should be kept short and clean and should not extend beyond the fingertips (AAMI ST79-2006). Acrylic, gel, or ceramic nails are discouraged as they can support the growth of pathogens.

Shoes or boots worn in the decontamination area should be durable enough to prevent injury if an item is dropped on the foot, while the bottom surfaces should be made of non-skid material or have a non-skid design. Often shoes or boots are liquid-proof to prevent soaking since solutions may be spilled or splashed on the footwear. Shoecovers may be worn, but should be changed if they become wet.

High filtration masks may be worn to protect the worker from potential airborne particulates. Eye protection is required to reduce the risk of eye injury from exposure to hazardous chemical agents or pathogenic microorganisms. Goggles, safety glasses with solid side shields, or glasses with a chin-length face shield are recommended for the best protection. Under OSHA regulations, face masks and eye protection are only required if aerosolization or splashing occur. Usually personnel working in the decontamination area will wear face masks and eye protection regularly as these potential problems can not be predicted (AAMI, 2003).

General purpose utility gloves that are heavy-duty, durable, cuffed and long are recommended to reduce the risk of cross-contamination to the hands and limit the potential for accidental punctures. Since gloves do not offer absolute protection, handwashing after removing the protective gloves must be practiced. A liquid-resistant covering with sleeves (i.e., jumpsuit or surgical gown) and a liquid-proof apron are worn to prevent contamination of the surgical clothing. Gloves, aprons and eyewear that are reusable should be cleaned at least daily and inspected regularly for evidence of deterioration (AAMI, 2003).

Decontamination Process

Decontamination begins at the site of the procedure when debris is wiped off surfaces and fluid is pulled through instrument channels. This preliminary cleaning should be ongoing because dried soil is more difficult to remove. A water-moistened sponge can be used to wipe the visible soil from the instruments. Saline must not be used as this salt solution can eventually cause damage to the instrument. Removing this debris will:

- > Reduce the number of microorganisms on the device
- > Reduce the nutrient material that might support pathogenic growth
- > Minimize the risk of environmental exposure from aerosolization or spillage
- > Decrease the possibility of device damage from such materials as blood, saline, iodine, or radiological dyes

There are some unique environmental conditions that may cause bioburden to be more of a challenge to thorough cleaning. For example, during laparoscopic procedures, instruments are used in a pressurized area within the abdomen. This pressurization can drive debris and liquid contaminants up into the endoscope and instrument channels, which can solidify during and after the procedure. Therefore, special attention to keeping the lumens flushed during the procedure becomes extremely important.

The initial decontamination process involves:

- > Sorting
- > Containment and transportation
- > Precleaning
- > Cleaning

Sorting

To begin the decontamination process, instruments and devices must be initially sorted following the procedure. The contaminated reusable instruments are kept separate from disposable devices that are discarded in an appropriate container, such as a puncture-resistant container for sharps as required by OSHA regulations. Separation of the soiled instruments from waste helps to minimize the potential injury and infection hazard from sharps. Heat, moisture-sensitive devices and delicate instruments are separated from the other devices since they require special attention during the reprocessing.

Containment and Transportation

Contaminated instruments and devices should be transported as soon as possible after use to the decontamination area in a covered or closed container with a tight-fitting lid. By covering or enclosing the contaminated items, the risk of contact or airborne pathogen transmission is minimized. A damp towel can be used to cover the contaminated instruments within a container so debris will not begin to dry on the surfaces. Containers, carts, or bags being used to transport contaminated devices should be marked with a biohazardous label or by other means to denote biohazardous (contaminated) contents. The type of items being transported will determine the most appropriate container or bin to be used for transportation.

If contaminated devices are soaked in an enzymatic cleaning solution or detergent immediately after use, ideally the liquid should be discarded before transporting the instruments to the reprocessing area. If the items must be transported in a solution, a tightly fitting lid that is secured to the container must be in place to prevent splashing or spilling during transport. Care must be taken when lifting heavy containers with solutions as workers can sustain back or other injuries. Gel and foam spray products are available to keep soil moist and eliminate the water weight hazard.

The containers used to transport soiled items must be made of durable materials that can be effectively decontaminated. If disposable containers are used, they must be made of materials that can be incinerated or disposed of appropriately. Environmental concerns must be considered if disposable containers are selected.

The transportation system used to move soiled instruments from the point of use to the decontamination area must be designed so that container, devices and other equipment will not roll around, or fall over or off the cart. The pick-up and transportation of contaminated items should be scheduled as soon after use as possible to minimize microbial reproduction or debris drying. High traffic areas should be avoided.

If contaminated devices must be transported between buildings or to an off-site facility, consideration must be given to the containment or packaging of the devices, temperature and humidity control in the transporting vehicle and loading procedures. Contaminated devices should not be transported in the same vehicle as clean or sterile items to prevent cross-contamination (AAMI, 2003). If only one vehicle is available, it must be decontaminated before using again to transport clean or sterile items.

Personnel who are transporting contaminated items need to receive education and training on basic infection containment principles. Personal protective attire and a biohazardous spill kit should be

available. When transporting to off-site facilities, the Department of Transportation (DOT) and state regulation requirements on containment, labeling and transporting need to be followed as certain contaminated products are considered to be infectious or biohazardous.

Precleaning

The next step in the decontamination cycle is precleaning. The instrument or device manufacturer is required to provide comprehensive written instructions for decontamination, along with a summary and interpretation of the research or tests that were conducted to validate that their products can be effectively and safely decontaminated. Commercial instrument transport gels are also available that allow staff to initiate the pre-cleaning process without having to handle contaminated instruments. Instrument transport gels prevent the drying of bioburden and soils on the instrumentation, thus decreasing the amount of time needed to manually clean the instruments at the sink.

Upon arrival in the decontamination area, the contaminated devices are removed from the transportation container. The instruments that are designed with more than one part or piece are disassembled to expose all of the surfaces to the cleaning processes. All small parts need to be kept together so that proper reassembly can be accomplished in a timely manner.

The design of complex instrumentation can provide quite a challenge during reprocessing. Some healthcare workers do not even realize that many of these devices can be taken apart. The manufacturer of the device will provide details for disassembly and reassembly.

Instruments with hinged joints must be completely disassembled whenever possible. A rigid grasper is a good example of a device with a hinged joint mechanism. One hinged joint may be at the control handle while the other hinged joint may be located at the working end. Ideally, the hinged joint instrument needs to be disassembled or taken down to its smallest parts. The design of this device often presents a challenge as the instrument must be carefully reassembled with the appropriate tension on the assembly screws so that the instrument works properly. Do not disassemble instruments without the manufacturer's instructions.

Stopcocks must also be disassembled completely for thorough reprocessing. Some manufacturers have designed stopcocks so that the inner part of the stopcock can be accessed for cleaning without being disassembled.

Formulated enzymatic cleaning products can be used to break down and loosen blood and other organic soil to facilitate cleaning. Enzymes are efficient catalysts that break down complex water insoluble organic molecules into smaller more water-soluble pieces that are more easily rinsed away.

Most enzymes are active at room temperature, but research has shown that enzyme activity generally increases as the temperature rises. There is a ceiling to this increase that occurs when the enzyme becomes denatured or dysfunctional. For example, the ceiling temperature for a particular enzyme may be 38-60° C or 100-140° F.

Manufacturers have developed single-use enzymatic cleaning products in packets for immediate use after a procedure is completed and before transporting the contaminated devices to the reprocessing area. Enzyme solutions facilitate the cleaning process, but do not necessarily clean the devices. After soaking in enzymatic cleaning product dilutions, the devices need to be thoroughly rinsed. Rinsing should not be performed under running water as aerosolization and splashing can occur. The proper PPE should be worn. Instruments need to be rinsed by immersing them under the water level in a sink or basin.

Cleaning

The most important step of decontamination is thorough cleaning. Cleaning fundamentally removes soil including bioburden rather than killing microorganisms. Thorough cleaning and rinsing depends on a variety of factors including:

- > correct preparation of the items to be processed (disassembly, etc.)
- > load configuration
- > water quality
- > detergent type and quality
- > acceptable washing method
- > proper rinsing and drying
- > time, temperature and load capacities of mechanical systems
- > worker or operator performance

Cleaning Methods

Cleaning can be performed manually, mechanically, or by using a combination of both methods. The mechanical friction involved in physically removing debris is accomplished through wiping, brushing, spraying, or flushing the devices. The cleaning method chosen should not damage the integrity of the instrument, should be effective and should be safe for the worker performing the task. The medical device manufacturer must provide recommendations for the cleaning method that is most appropriate depending on the device's size, fragility, immersibility, complexity, working parts, sensitivity to the cleaning agents and other properties.

Manual cleaning should be able to be performed on all instruments, but may be recommended as the preferred cleaning method for delicate or complex devices, such as air powered drills or saws, lensed instruments and endoscopes, or microsurgical instruments. Recommendations suggest that a three deep sink configuration be used for manual cleaning. The first sink is the wash sink that contains the cleaning solution to remove the soil from the instrument. All cleaning in the sink should be done under the water line to prevent exposure to microorganisms through aerosolization, especially when brushes are used to clean lumens. Brushes must be suitable in size to fit down channels so they will not damage the working ends or lenses of delicate instruments or devices. The cleaning detergent should be low-foaming so that the worker can see into the sink to identify all instruments and prevent injuries from sharp objects. The second sink is the rinse sink, designed to remove any detergent or remaining soil. Low-foaming or sudsing detergents rinse off more easily. Depending on the manufacturer's recommended practices or a facility's own practice, a third sink is needed for the final rinse with distilled or deionized water to prevent spotting on the instrumentation.

Mechanical cleaning of medical devices/equipment to remove soil and microorganisms is commonly accomplished using automated cleaning and rinsing processes.

Mechanical cleaning equipment includes utensil and/or cart washers, washer/sanitizers, washer/decontaminators, washer/disinfectors, washer/sterilizers and pasteurization equipment.

"Thermal sanitization and disinfection equipment employ hot water temperatures of 60°-95° C (140°-203° F). Thermal sanitization equipment generally operates at somewhat lower temperatures or for shorter exposure times than disinfection equipment does, but there is

no agreement on precisely when sanitization stops and disinfection begins" (AAMI, 2006).

Mechanical washers/decontaminators and washer/disinfectors cycle through various phases. These phases typically provide a prewash and/or enzymatic product treatment to remove or condition soil for easier removal during the wash phase. The wash phase generally contains either a neutral or alkaline detergent. After the wash phase, a rinse phase removes detergent and debris. Next, a thermal rinse treatment with a water temperature of 82°C-95°C (180°F-203°F) may be applied as a part of the thermal disinfection process. A heated pure water rinse can be added to best remove cleaning chemicals from surgical instruments. In addition, an instrument lubrication treatment can be used, followed by hot air drying.

Ultrasonic cleaners are another type of mechanical washer. They are designed for fine cleaning of medical devices to remove soil from hard to reach areas like crevices, joints, grooves, hinges, box locks, lumens, etc. Gross soil must be removed from instruments before processing in the ultrasonic cleaner because heavy soil can inhibit the cleaning activity.

Instruments that are constructed of dissimilar metals should be sorted and separated as there is an increased risk of etching and replating of metals, especially if brass, copper, or aluminum instruments are immersed with stainless steel instruments.

Ultrasonics could be detrimental to chrome-plated or previously damaged instruments because the cleaning activity may further damage already defective surfaces.

Ultrasonics works through cavitation as sonic waves are created that make tiny bubbles on the surfaces of the instruments. These bubbles expand until they become unstable and then collapse or implode. The resulting implosion produces very localized vacuum areas responsible for dislodging soil from surfaces. The soils are literally sucked off the instruments.

Flexible endoscopes, fiberoptic light cables and some rigid endoscopes must not be placed in the ultrasonic cleaner as the vibration can damage them. Some delicate fiberoptic, microsurgery and lensed devices can not be exposed to ultrasonic cleaning, automatic cleaning, or harsh chemicals. Device manufacturer's recommendations may require that these instruments be manually cleaned.

Typically, instruments are cleaned in the ultrasonic for five minutes in a warm 32-50° C or 90-122° F, mild detergent and water solution. The cleaning solution in an ultrasonic is instrumental in lifting the soils away from the instruments after cavitation has drawn them out. Additionally, the cleaning solution can sequester the water minerals, thus preventing the formation of hard water deposits on the instruments and equipment. Whenever a fresh solution of detergent and water is to be used, an empty cycle should be run first to "degas" or remove air from the solution, as excess air can hinder the cavitation process. Check with the manufacturer of the ultrasonic cleaner for instructions.

Any detergent used in an ultrasonic machine should have low and controlled foam so as not to interfere with the cavitation process. Enzymatic cleaners can be used in an ultrasonic provided they are low-foaming. After removal from the ultrasonic, instruments should be thoroughly rinsed with either deionized or softened water. Change the ultrasonic cleaning solution before it becomes heavily soiled for best cleaning results.

Cleaning Solutions

The most common types of soils found on instruments are blood, fat, peritoneal fluid, synovial fluid, or other body fluids. Regardless of whether the cleaning solution is used manually or in a machine, products labels must be read to determine the appropriateness of cleaning solutions for the specific type of soil encountered. The

medical device manufacturer's written instructions will provide details on acceptable solutions for cleaning various instruments.

A low-sudsing detergent should be used that can be completely rinsed off so that no detergent or debris is left on the instrument. Abrasives, such as steel wool, scouring powders, or scalpel blades, can damage the surface of a device and should never be used to remove soil. Contaminated instruments should never be exposed to alcohol because alcohol will dehydrate protein, making it even more difficult to remove during cleaning. The recommended water temperature for cleaning is usually warm 40-50° C or 104-122° F so protein coagulation will be prevented and protein can be more readily removed.

The life, function and appearance of instruments depend on the attributes and capabilities of the cleaning solutions used. Important attributes and capabilities to be considered are listed below:

- > **Effective soil removal of both organic and inorganic soils**
The cleaning chemistry chosen should be able to remove organic proteins and lipids as well as inorganic materials such as saline and ringer's solution. Surgical soils are complex mixtures of bodily fluids and tissues and broad spectrum cleaning effectiveness is necessary for complete soil removal.
- > **Ability to handle a variety of water types and qualities**
The cleaning chemistry should contain effective chelating and sequestering agents in order to prevent damage due to the presence of hard water and metal ions. Hard water ions can cause spotting and filming on instruments and equipment, potentially affecting both appearance and function. Metal ions in make-up water can deposit on surfaces, causing discoloration as well as triggering galvanic corrosion of instrument and washing equipment surfaces.
- > **Low and controlled foam for use in automated equipment**
High foam level in an ultrasonic and interfere with the cavitation mechanism necessary for cleaning. In a washer/disinfector high levels of foam can cause pump malfunctions and reduce pump pressure and spray arm movement. This reduction in spray arm movement can cause poor impingement (spray force), reducing both washer efficiency and ultimately pump life.
- > **Removal of corrosion**
Corrosion can occur in instrument lock boxes, on roughened handles and where there is minor instrument damage, such as nicks or scratches. Light corrosion should be removed on a continual basis so that it doesn't trap soil or microorganisms making them a more difficult challenge to reprocessing.
- > **Compatibility with materials of construction**
Cleaning agents should be safe on all stainless steel, gold and chrome-plated instruments. Understanding the compatibility profile of the cleaning chemistry allows it to be used on appropriate devices and in automated washing systems that may contain soft metal (brass or copper) or plastic fittings. Compatibility with aluminum tray and cart systems is also something to be considered when evaluating a cleaning chemistry.
- > **Instrument protection**
Water itself can be damaging to instrument surfaces. Cleaning chemistries should demonstrate the ability to

mitigate the damaging effects of water on expensive instrument and equipment surfaces.

- > **Free-Rinsing**
A free rinsing detergent can reduce the amount of residue left behind after washing. Detergent residues can cause impaired operation, corrosion and/or staining of instruments and equipment. Residues can potentially also have a negative impact on human tissue if transferred from the instrument to the patient during surgery. Inadequately cleaned instruments may retain soil which can also bind detergents, increasing residue retention. Thus improved cleaning performance will also positively impact rinsing.
- > **Liquid form**
A liquid cleaner (as opposed to a solid form) can be easily and accurately measured. Solid chemistry forms that rely on the force of water across a surface to reproducibly and accurately dissolve them can be negatively impacted by both water pressure and temperature. Liquid cleaning chemistries can be quickly and completely solubilized in water. Some powdered forms have difficulty with complete dissolution and can leave undissolved solids on both equipment and instrument surfaces.
- > **Biodegradable**
The cleaning solution should contain ingredients that are readily degraded in the environment. The ever increasing volume of surgical procedures combined with the volume of instruments needed for each surgical procedure is resulting in ever increasing effluent from the healthcare facilities due to reprocessing. Besides utilizing equipment with lower water usage rates, the most important impact a Central Processing Area can have is a choice of a cleaning chemistry designed to minimize environmental impact.
- > **Concentrated**
There is no reason to pay for more water than necessary to achieve appropriate cleaning efficiency. In addition to reducing water consumption, concentrated products also reduce packaging waste and are more ergonomically friendly, making them lighter and safer for staff to lift and move.
- > **Appropriate level of alkalinity**
Alkalinity can assist in the cleaning process by breaking down soils, but can also contribute to instrument degradation. A balanced amount of alkalinity is necessary and should be designed into products and choices. Enzymatic and Neutral based chemistries can contain little to no alkalinity and still be very effective at soil removal depending on the process and soil type/load.
- > **Designed for use both manually and in automated equipment**
A cleaner designed to be used in a variety of ways can achieve savings in cost by reducing the inventory required. Low foaming and free rinsing products that can be used across a spectrum of temperatures can enhance automated equipment efficiency while still allowing for manual cleaning applications.
- > **Other desired attributes**
Cost is a major consideration in the choice of a cleaning chemistry. However, cost should be evaluated not just in terms of price per gallon but in terms of cost per cycle and

cost per instrument. Concentrated detergents can cost less on a per cycle basis, while costing more per ounce. An aggressive cleaning chemistry can shorten instrument or equipment life, increasing refurbishment and replacement costs.

Combination of Cleaning Chemistries (Detergent) and Spray Force

When cleaning with automated decontamination equipment, soil removal is accomplished through a combination of cleaning chemistries and impingement (spray force). Cleaning chemistries contain various components in their formulations such as surfactants, chelating agents, enzymes (where appropriate), buffers, corrosion inhibitors and builders that both aid in soil removal and protect instruments and equipment from the damaging effects of water. Because soil removal is accomplished through the combination of both physical and chemical forces, it is important that they work well together to maximize the efficiencies of both.

Washer/disinfectors mechanically clean instruments by a spray action known as impingement. The washer arms move to distribute the chemistry and the level of impingement is determined by how strongly the water force contacts the surfaces. With a lower impingement force, a greater proportion of the cleaning performance is dictated by the chemistry. These types of washers will typically utilize a more aggressive chemistry (such as an Alkaline cleaning solution). For a piece of equipment designed to exert higher impingement, the spray force plays a greater role and the cleaning chemistry can be less aggressive. Chemistries that are less aggressive tend to have a greater spectrum of material of construction compatibility allowing for more processing flexibility. In either case, the cleaning chemistry can aid in penetrating the soil and lifting it from surfaces, preventing re-deposition, and breaking down proteins or fat molecules to make them more water soluble. Foam levels for cleaning chemistries designed for automated applications should be low and controlled as a higher level of foaming can negatively impact the impingement and thus decrease the effectiveness of the washer/disinfector. Chemistries and washers designed to maximize the efficiencies of each other will gain the greatest benefit to the user.

Rinsing

After manual or automatic cleaning, instruments must be thoroughly rinsed, especially the internal lumens, to remove any detergent residues that could effect disinfection or sterilization. Distilled, deionized water should be used for the final rinse because the chemicals and minerals (such as iron, calcium, or magnesium) present in most tap water can damage instruments. If distilled water is unavailable, then tap water can be filtered to remove these contaminants. Softened water is also a better alternative to tap water for rinsing if deionized is not available.

Final Steps

Instrumentation should be thoroughly dried after rinsing is complete. A soft, lint-free cloth or a pneumatic air gun can be used to dry surfaces and internal lumens. If devices are allowed to drip dry, spotting may occur.

Instrument lubrication may be performed after drying. An instrument lubricant can be used for instrument dipping (not soaking) to form a thin, protective film on the surfaces. Instrument lubricants should allow for sterilant contact and must be compatible with the method of sterilization chosen. Lubricant can also be applied during mechanical processing cycles.

Thorough cleaning removes 99% of the bioburden (Hanson, et al., 1990). If bioburden is left on a device, even if it is considered to be sterile, this soil can act as a foreign body if deposited in the

next patient. This "sterile dirt" can increase adhesion formation, increase the immune response and even delay healing (DesCoteaux, et al., 1995). Any organic debris or residual cleaning solutions can also inactivate chemical disinfectants or sterilants and can protect pathogens from destruction (AAMI, 2006).

Instruments must remain disassembled during the disinfection or sterilization phase of the decontamination process for appropriate processing to occur. When processing is complete and the instrument needs to be reassembled, staff members must understand the components of the instrument, how it is reassembled and how to check for proper working order of the device. If an instrument is reassembled incorrectly, the patient could sustain injury if the device fails during use. Remember, these same instruments may need to remain disassembled for terminal disinfection or sterilization.

Inspection

After the instrument has been thoroughly cleaned, rinsed and dried, inspection must be performed to ensure the integrity of the device. The person reprocessing the device must look for signs of rust, stains, corrosion, pitting, cracks, chips, nicks, or burrs. Crevices and seams must also be inspected because if they have weakened, then debris can enter the device causing damage, thus becoming a safety hazard. If damage is detected early, expensive repairs or replacement may be avoided.

If corrosion is present, then the outer layer of the instrument has probably been weakened. Most instruments are made of stainless steel that can corrode and become stained under certain circumstances.

When the parts of surgical instruments are first made, they do not have a well developed passive layer on the surface of the instrument to protect it. When these new parts are exposed to air, the chromium and iron present in the stainless steel are oxidized. This forms a very thin, passive layer (passivation) that is only molecules thick at the surface, but protects the instrument.

There are approximately 20 different grades of stainless steel that make up surgical instruments, which fall into two predominant groups: Austenitic (i.e., 300 series) and martensitic (i.e., 400 series).

Austenitic stainless steel has a greater chromium content and is more resistant to staining and corrosion; however, it is not as strong and durable. Austenitic stainless steel is used where cutting edges and strength are not required, such as retractors.

Martensitic stainless steel has a greater carbon content and is used where strength and cutting edges are needed. Martensitic stainless steel is not as corrosion-resistant as austenitic stainless steel; however, it is utilized in delicate eye instruments and other high quality surgical instruments (i.e., hemostats, surgical scissors). To prevent corrosion of the martensitic stainless steel devices, the surface of a newly produced instrument is treated with chemicals to remove any remaining metallic debris from the machining step, to remove some of the iron from the surface and to enrich the instrument surface with chromium. This process is repeated until the desired level of corrosion resistance is achieved. Surface polishing makes the surface of the instrument less rough, which also contributes to corrosion resistance (Cubberly et al., 1980).

To protect surgical stainless steel instruments, cleaning chemicals should be used that have data demonstrating the instrument's passive layer will not be harmed by the chemicals. Protection of the passivated surfaces of instruments can prolong the life of expensive surgical instruments and reduce refurbishing and replacement expenditures due to corrosion.

Foreign contaminants on an instrument's surface can cause poor performance and reduced instrument life. Below is a listing of the most common causes of instrument spotting, staining and corrosion,

along with suggestions for eliminating those causes:

- > **Poor cleaning:** Any soil residues remaining on the instrument may cause staining and promote corrosion if allowed to dry on the instrument's surface. Poor cleaning may be due to the improper or inappropriate use of a chemical cleaning agent. It also may be due to poorly functioning equipment or inappropriate processing steps
- > **Poor rinsing:** Mineral deposits, or cleaning compound residues, can appear as whitish spots or a dull coating on the instrument's surface. Deposits or residues may become chemically active under the heat and pressure of an autoclave and may accelerate corrosion. These deposits may be due to an insufficient rinse cycle that is caused by a malfunction of the equipment, by the spray jets becoming clogged, or by the use of tap water as the final rinse
- > **Improper use of disinfectant solution:** Most disinfecting solutions, (such as glutaraldehyde), can be corrosive to instruments, especially if exposure time is long or concentrations are high. Disinfectants should be selected that have corrosion inhibitors and are recommended for instruments. Additionally, iodine-based products can result in instrument staining
- > **Inadequate drying:** Moisture trapped in certain parts of surgical instruments, such as the box lock area, for a prolonged period of time can promote corrosion. Instruments must be properly dried before wrapping for sterilization
- > **Improperly cleaned textiles:** Laundered, reusable instrument wraps and other textiles may contain residual laundry compounds. These may be alkaline in nature from the detergents used. They may also be acidic in nature (a more serious problem) from the solutions used in the final rinse. These residual chemicals may be reactivated by the steam and heat in a steam sterilizer and could cause a corrosive environment on the instrument, thereby advancing corrosion rates and shortening instrument life. If this is a problem, laundry processing should be checked to ensure that appropriate chemical amounts and processing times are implemented to ensure removal of residues from the wraps
- > **Metal plating problems:** Metallic stains, which can appear as rust or brown stains on the instruments, can not be easily removed. For example, copper or gold ions can plate onto surgical instruments and cause these stains. This is commonly caused by different metals being in contact with each other during the washing process. Ideally, instruments of different metals should be washed separately
- > **Poor quality steam:** Poor boiler maintenance can cause foaming and/or "surging" of the boiler water into the steam line. This can lead to the carryover of boiler additives, sludge, iron, or other solids into the steam. These contaminants can be deposited on instruments and be dried in the sterilization process. Deposits due to poor quality steam can be distinguished from deposits due to poor cleaning and poor rinsing because the deposits due to poor quality steam will be apparent on both the wraps and the instruments

Some of the most common discolorations that may be found on instruments include: (Hales, 1998)

- > **Oxidation tints:** Iridescent discoloration from water that contains heavy metal ions or silicates

- > **Water spots:** Caused by hard water
- > **Water softeners:** Water softeners may contain salts; therefore, too much water softening may cause a white film or small, fine, "dust-like" particles to form on the instrument surface
- > **Surgical debris:** Yellow-brown to dark brown spots may be found on inaccessible areas, such as lock boxes and can lead to pitting and more visible damage. This is usually protein soil that can be identified by the application of a few drops of hydrogen peroxide. If it bubbles up, it is protein soil.

Different corrosion types along with their causes include:

- > **Surface corrosion:** Destruction of the protective chromium oxide layer of the instrument can be caused by contacts with strong acids or other caustics which can cause etching and corrosion
- > **Stress cracking:** Caused by wear and tear or abuse of the instrument. Corrosion can begin with residual debris left in the stress cracks
- > **Pitting:** When saline, bleach, iodine tinctures, protein residues, or cleaning agents are not immediately removed from an instrument's surface, then a localized and often rapid corrosion can occur
- > **Crevice corrosion:** Often found at juncture sites, known as a rust blister
- > **Contact corrosion:** Resulting from electrolytic contact with unlike metals. Must be removed by a device manufacturer or repair company
- > **Rust:** Can appear on surfaces, cracks, crevices, or juncture sites. May be transferred to other instruments

Decontamination Process

The next step in the decontamination process may involve a microbiocidal process to provide microbial kill. Basic terms that must be understood when determining the level of microbial destruction desired include:

- > **Static:** The term static means to inhibit the growth of microorganisms. Static is usually associated with preservatives of products. An antimicrobial ingredient is added to a product to keep the product from becoming contaminated with bacteria, viruses, or fungi. The static agent does not kill the microorganisms, but keeps them from multiplying within the product. When a product label makes a bacteriostatic claim, then the product has been properly preserved. A bacteriostatic product does not have the ability to disinfect, which is often thought to be the action of a static agent
- > **Cidal:** The suffix "cidal" means to kill. Disinfectants will claim bactericidal and virucidal properties, meaning that they are effective in their ability to kill bacteria and viruses. Organisms are killed when coming in contact with a cidal agent
- > **Disinfection:** Disinfection is the process that kills or destroys most disease-producing microorganisms, but not all spores
- > **Sterilization:** Sterilization is the process by which all forms of microbial life including bacteria, viruses, spores and fungi are completely destroyed

The final step of decontamination must be determined depending on the instrument use and risk of infection to the patient. Disinfection and sterilization methods provide different levels of microbial kill. No matter what level of microbial kill is desired, thorough cleaning, rinsing and drying must be performed first so that effective processing can be achieved.

There are different levels of disinfection including low-level, intermediate-level and high-level, that may be used in the decontamination process to render instruments safe to handle in the clean preparation and packaging areas (AAMI, 2006).

- > **Low-level disinfection:** Reduces the overall number of vegetative microorganisms, but does not destroy tubercle bacilli or bacterial spores. Low-level disinfectants are appropriate for non-critical medical devices and environmental surfaces
- > **Intermediate-level disinfection:** Kills tubercle bacilli, most viruses and some fungi but is not necessarily able to kill bacterial spores. Intermediate level disinfectants are appropriate for non critical medical devices, horizontal surfaces and floors
- > **High-level disinfection:** Kills most forms of microbial life, including tubercle bacilli, but not some of the bacterial spores. High-level disinfectants are often used for surgical devices that are semi critical, such as a flexible gastroscope used for diagnosis only. For years, glutaraldehyde has been an acceptable solution for reprocessing to achieve high-level disinfection for medical instrumentation and devices

Returning Devices for Repair

A malfunctioning device (in this section, device refers to any surgical instrument, powered equipment, or endoscope) can be sent to the original manufacturer or a reputable repair company for service. The criteria for selecting an appropriate repair company include the following:

- > Component inventory on hand
- > Technical skill of the repair persons
- > Types of repairs offered
- > Representatives in the field
- > Turn-around time
- > Tracking of repairs
- > Warranty return rate - should be less than 5%
- > Value-added services
- > Pricing
- > Reputation

The manufacturers of each medical device must provide the healthcare facility with instructions for preparing either decontaminated or contaminated items for return to them.

Before placing the defective device in the shipping package, it

must be decontaminated and dried thoroughly. The best packaging system includes the foam padding to stabilize and secure the device. A mailing label is placed on the outside of the outer container with the appropriate repair company address and the return address information.

If the device can not be cleaned before shipping, it must be sent as biohazardous material by being placed within two containers (with one container being leak and puncture resistant). The outer package needs to be labeled "biohazardous," so that the receiver knows that special handling is necessary when unpacking the contaminated device. The shipping company needs to be informed that the package contains biohazardous material and then asked if there are any further instructions required for shipping. The U.S. Postal Service and Federal Express are two carriers who will handle biohazardous packages, but their specific details must be followed. The cost to ship biohazardous material is much greater than normal shipping.

The specific steps for handling biohazardous materials are not recommendations, but are laws within the Department of Transportation (DOT) and Postal regulations. If contaminated materials are not handled according to these laws, then a hefty fine and even imprisonment can be levied. Other agencies that deal with the handling of biohazardous materials are OSHA, CDC, AAMI and the FDA. Some of their recommendations are mandated, while others are suggestions in handling biohazardous materials.

Documentation needs to accompany the device needing repair. Complete documentation is extremely valuable to the repair company. Documentation should include:

- > Date of cleaning or reprocessing
- > Level of decontamination performed
- > Name of the person who reprocessed the device
- > Procedure being performed when the device malfunctioned and any suspected damage to device

The healthcare worker sends the securely packed device with completed documentation to the shipping department or sends the defective device directly to the repair company. Some repair companies will contact the department owning the device to discuss any needed services and to obtain the repair purchase order. After the repair is completed, a warranty usually will be extended depending on the type of repair. When the device is returned from repair, it should be examined immediately to make sure no damage has occurred during shipping.

Summary

The practice of decontamination and instrument care requires the skill of qualified healthcare professionals, as instrumentation has become very complex and sophisticated. Proper reprocessing helps to ensure instrument integrity, patient safety and the control of infectious microorganisms. The importance of appropriate decontamination must never be minimized as it provides the practice and foundation of all surgical instrument care.

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Review Questions

1. A disease-causing microorganism must be virulent, invasive, infective and have the appropriate reservoir to survive and transmit disease.
 - A. True
 - B. False
2. _____ is the physical or chemical process which renders an inanimate object that is potentially contaminated with harmful microbial life, safe for further handling.
 - A. Sterilization
 - B. Disinfection
 - C. Reprocessing
 - D. Decontamination
3. In a reprocessing area, there should be at least _____ complete air exchanges per hour.
 - A. 25
 - B. 10
 - C. 5
 - D. 100
4. Instruments that are disassembled before cleaning must be reassembled before sterilization.
 - A. True
 - B. False
5. Enzyme ingredients are _____.
 - A. catalysts to speed reactions
 - B. compounds that can break down complete molecules into smaller more water-soluble ones
 - C. can be inactivated by too high of a temperature
 - D. All of the above
6. Available or free alkalinity is the concentration of alkalinity that is not tied up in formulation and is free and available to do work.
 - A. True
 - B. False
7. When cleaning with automated decontamination equipment, cleaning is accomplished through a combination of _____ and _____.
 - A. detergent and spray force
 - B. enzyme and detergent
 - C. impingement and spray force
 - D. mechanical cleaning and ultrasonics
8. Gross debris does not need to be removed from an instrument before immersing it in an ultrasonic cleaner.
 - A. True
 - B. False
9. High foaming/sudsing detergents are recommended because they are easy to rinse.
 - A. True
 - B. False
10. The final rinse cycle should be done with deionized, distilled, or filtered water that removes water minerals and impurities.
 - A. True
 - B. False

- Answers to Review Questions and section sources:
- | | | |
|-----|---|--|
| 1. | A | (Infection Transmission) |
| 2. | D | (Definition of Decontamination) |
| 3. | B | (Ventilation) |
| 4. | B | (Final Steps) |
| 5. | D | (Preliminary) |
| 6. | A | (Combination of Detergent and Spray Force) |
| 7. | A | (Combination of Detergent and Spray Force) |
| 8. | B | (Cleaning Methods) |
| 9. | B | (Cleaning Solutions) |
| 10. | A | (Rinsing) |

Evaluation Form

Study Guide #6: The Essentials of Instrument Decontamination

Last Name

First Name/M.I.

RN/LPN/LVN License Number (Circle one: RN - LPN - LVN)

Non-RN: License or Social Security Number

Health Care Facility

Health Care Facility Street Address City State ZIP Code

Current Home Street Address City State ZIP Code

For International Address: Country Province/Postal Code

Area Code /Telephone Number E-Mail Address

Please check here if you want the certificate to be mailed to the address above.

Please check here if you want the certificate e-mailed to you at the e-mail address above.

To receive continuing education credit, please complete the evaluation form and mail, fax or e-mail the completed form to STERIS Corporation.

Rate on a scale of: 1=low 5=high

To what extent did the study guide meet the 2 stated objectives below?

1. Describe the decontamination environment necessary to prevent disease transmission.

1 2 3 4 5

2. Review critical steps of decontamination of reusable medical devices.

1 2 3 4 5

3. The overall purpose of this educational activity was to review the essentials of disease transmission and decontamination to control or eliminate the transmission of infection. To what extent did the objectives relate to the overall purpose?

1 2 3 4 5

4. To what extent is this learning method easy-to-use?

1 2 3 4 5

5. How much time was required to read the content, take the test, compare your answers and complete the evaluation form?

_____ hours _____ minutes

6. Has the provider disclosed the conflict of interest or lack thereof declared by the planners and content specialist?

Yes _____ No _____ (Review inside cover page)

7. Was the content presented without bias of any commercial product or drug?

Yes _____ No _____

I have completed all the requirements for this entire activity (please sign and date).

Your signature is required to attest that you have completed the requirements for this activity.

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