LEARNING OBJECTIVES

1. Discuss basic factors that influence cleaning and decontamination
2. Explain the importance of purified water in instrument cleaning processes
3. Identify common cleaning chemicals used for surgical instrumentation and review basic protocols for their use
4. Understand the difference between cleaning and decontamination
5. Understand manual and mechanical cleaning, and when to use each process

DECONTAMINATION

OBJECTIVE 1: DISCUSS BASIC FACTORS THAT INFLUENCE CLEANING AND DECONTAMINATION

POINT-OF-USE PREPARATION

Cleaning and decontamination should begin at the point-of-use. Dried-on soil is difficult to remove, requires more time to remove, and may damage the surface of some devices. Therefore, gross soil must be removed as soon as possible after use. IFU for each instrument explains point-of-use cleaning needs, and these must always be carefully followed. In general, gross soil must be removed, and instruments must be kept moist.

Point-of-use preparation involves several steps. Non-reusable components, if any, must be removed and properly disposed, and fluids must normally be emptied from all containers. However, if they are needed during transport, such as for soaking instruments, the devices and fluids should be kept in a closed container to avoid spillage during transport. Separate reusable sharps to help prevent injuries. Keep items that belong in a set together, and tag/identify items that must be repaired. After point-of-use preparation is completed, instruments can then be transported to the decontamination area for further processing.

SOILED ITEM TRANSPORT

Instruments must be contained during transport to minimize contact or airborne spread of microorganisms. Enclosed carts can be used, but if open carts are used they should have a solid bottom shelf and the items should be covered. Carts and all containers used for transporting soiled devices should be cleaned after each use.

If soiled items must be transported between buildings or campuses, one should consult US Department of Transportation (DOT) requirements for transportation of biohazardous materials. For example, clean and soiled items must be segregated if they are transported on the same truck at the same time. Applicable regulations are available from the DOT: Hazardous Materials.
Materials Regulation (HMR; 49 CFR Parts 100-180. Note: state and local requirements might also be applicable. Soiled items should be staged in a soiled holding area away from hallways or other high-traffic areas and locations, and away from cleaned items prior to transport. Personal protective equipment (PPE) must be worn when physically handling the soiled transport containers and carts, and transport personnel should properly wash their hands after completing this task.1

PRE-CLEANING
Prolonged cleaning delays can have detrimental effects on many medical devices, so it is important to keep instruments moist before they are cleaned. Devices should be sorted according to the cleaning process that will be used. Disposables should be discarded, and reusable sharps should be carefully removed from applicable instruments. Disassemble multi-part instruments to prepare them for cleaning. Open all items with box locks and hinges. Then inspect devices for gross tissue and bioburden, and rinse to remove these soils. Devices should be soaked in an enzyme or other detergent solution designed to release soil and remove it from device surfaces. Brush instrument surfaces, including ratchets, serrations and lumens to remove gross soil, and then thoroughly rinse them.

MANUFACTURER INSTRUCTIONS FOR USE (IFU)
IFU must always be followed when cleaning all devices. Manufacturers of reusable medical devices are responsible for ensuring that their devices can be effectively cleaned and disinfected or sterilized, if necessary. Device labeling should identify specific methods of cleaning that have been validated by the manufacturer. These instructions are reviewed by the US Food and Drug Administration (FDA) and are approved as part of the device 510(k) or pre-market approval process.

OBJECTIVE 2: EXPLAIN THE IMPORTANCE OF PURIFIED WATER IN INSTRUMENT CLEANING PROCESSES
Purified water should be used for instrument cleaning to ensure that no minerals, dissolved solids, particles, gases, or organic and non-organic chemicals are present. Purified water also reduces other problems that impact water quality, including those related to conductivity, acidity or alkalinity, and the presence or chlorides or other particles. Some water sources might also contain bacteria, algae and parasites. These contaminants could impede the cleaning and decontamination processes, and might have detrimental effects on the instruments’ finishes. Water sample tests using chemical test strips should be made at each site where water is used as a final rinse.

Common processes to purify water include:
• Granular activated charcoal – a form of carbon riddled with small, low-volume pores that increase the surface area and allows water to be purified by adsorption
• Filters – Filter manufacturers should be consulted to learn when filters should be replaced. For example, a drop in pressure on the water line might indicate the need for filter replacement.
• Softened water requires less detergent to accomplish the same level of cleanliness.
• Distillation removes dissolved solids, gases and organic materials, along with particles, bacteria, pyrogens (substances in bacteria that produce fever when they are in blood) and endotoxins (poisons in bacteria that are released when the cell is destroyed).
• Deionization systems remove ionic-charged elements in water, along with dissolved solids and gases. However, they do not remove organics, particles, bacteria, pyrogens, or endotoxins.
• Reverse osmosis removes a large percentage of dissolved solids and organics, and can remove all particles, bacteria, pyrogens, and endotoxins. However, reverse osmosis removes little, if any dissolved gases.

OBJECTIVE 3: IDENTIFY COMMON CLEANING CHEMICALS USED FOR CLEANING SURGICAL INSTRUMENTATION AND REVIEW THE BASIC PROTOCOLS FOR THEIR USE
Different types of chemicals are used in the cleaning process. Each has a specific purpose and must be used in accordance with the IFU for the device being cleaned. Enzymes are catalysts that can accelerate chemical reactions. Different enzymes are useful in removing specific types of organic matter. For example, protease breaks down blood, mucous and feces, and albumin and lipase helps to remove fats. Removing or dissolving fats helps to loosen bone chips, which can be bound together by fat. Amylase is useful in removing starch.

Temperature is a special concern using enzyme-based cleaning products. If water temperature is too low (usually below 90°F; 32°C) the enzyme will not activate and will be ineffective. If water temperature is too high (above 140°F; 68°C), the enzyme can break down.

Detergents enhance water’s ability to remove soil. Emulsifiers and chelating agents in detergents help minimize formulation of insoluble deposits and prevent water spots. Alkaline detergents (pH 10-11.5) can effectively remove organic soils. An alkaline detergent may need to be neutralized with an acidic detergent rinse. Acidic detergents work well on inorganic soils and make stainless steel shine. Acidic scalers are used to remove mineral scale.
Cleaning refers to the removal of all visible and non-visible soil and any other foreign material.

In contrast, decontamination relates to removing or reducing contamination by infectious organisms or other harmful substances.

**OBJECTIVE 4: UNDERSTAND THE DIFFERENCE BETWEEN CLEANING AND DECONTAMINATION**

Cleaning refers to the removal of all visible and non-visible soil and any other foreign material. It is the first and most important step in the disinfection or sterilization process. One can clean without sterilizing or disinfecting, but one cannot sterilize or disinfect without cleaning. Bioburden left on medical devices can cause pyrogenic or foreign body reactions and create a breeding site for infections (even if the bioburden is microscopic).

In contrast, decontamination relates to removing or reducing contamination by infectious organisms or other harmful substances. The purpose of decontamination is to make the device safe for handling without PPE. Some devices are safe for handling after thorough cleaning, while others require exposure to a microbiocidal process.

**OBJECTIVE 5: UNDERSTAND MANUAL AND MECHANICAL CLEANING, AND WHEN TO USE EACH PROCESS**

Manufacturer’s IFU indicate whether a device should be manually or mechanically cleaned, and how specific devices should be cleaned. In general, mechanical cleaning is more effective and consistent than manual cleaning; however, many devices cannot be cleaned mechanically because the device cannot be immersed or a mechanical process may damage the device.

**MANUAL CLEANING**

Manual cleaning is used to physically remove deposits not removed or only softened during pre-soaking. It is also used prior to mechanical cleaning to remove heavy, gross debris and soil, and can be used when a mechanical process is not available. Some delicate or complex instruments require manual cleaning because a mechanical process may damage them or be ineffective on some or all surfaces that must be cleaned. Some instruments (example: power equipment) cannot be immersed and, therefore, must be manually cleaned. Instruments with lumens may also require manual cleaning if special mechanical attachments are not available to clean the lumens.

Accessories, including cleaning brushes, are typically needed for manual cleaning. Brushes used to clean lumens must be the correct diameter. One that is too small will not effectively remove soil from lumen walls, and a brush that is too large will flatten backwards and not effectively remove the soil. The brushing action (direction) used on aluminum or stainless steel devices should be with the grain of the metal, not against or across the grain, which may damage the metal surface.

Brushing should be performed under the surface of the detergent solution to prevent forming aerosols that could spread contaminants. Vertical soaking cylinders can be used for devices with lumens. The cylinder is filled with detergent solution, and the instrument is then hung in the cylinder with the lumen hanging down. This will help to soften anything still in the lumen and be drawn by gravity down and out of the lumen.

**MECHANICAL CLEANING**

A variety of mechanical cleaning equipment is available for cleaning medical devices.

**Ultrasonic Cleaners.** Ultrasonic cleaners remove light soil from hard-to-reach places, such as hinges and box locks on some instruments. Heavy, gross soil must be removed from devices before placing them in an ultrasonic cleaner. Ultrasonic vibrations create tiny air bubbles that grow larger until they implode or collapse. This process, called cavitation, dislodges soil that is present, and the process is superior to manual cleaning because it can reach parts of the device that are inaccessible with manual brushing or rinsing procedures. Pre-cleaning to remove gross soil is critical before using an ultrasonic cleaner.

Detergent solution ultrasonic cleaners must be changed whenever the solution appears visibly soiled, or is cloudy or turbid in appearance. The sink drain should be checked, and any debris present should be removed every time the water is changed. The cleaning solution will also need to be degassed each time the water is changed. This is done by running the ultrasonic cleaner for 5-10 minutes before placing any devices in the cleaning solution.

Although ultrasonic cleaning processes are very effective, there are some devic-
es on which they should not be used. For example, ultrasonic cleaning could remove the plating on chrome, ebon-ized (black chrome), or other types of plated instruments. Instruments made of plastic, cork, glass, chrome, and rubber can absorb sonic waves and render the process ineffective. Needles, some delicate instruments, and endoscopes might also be damaged by ultrasonic waves. Different metals should not be processed at the same time as this can damage and discolor the metals.

The cleaning chamber of an ultrasonic cleaner should not be overloaded because attempting to process too many devices at the same time may dilute the process and cause it to be ineffective.

Automated Instrument Washers. A variety of automated instrument washers is available. Some perform all cleaning, disinfecting and drying processes within one chamber, while others use a tunnel configuration with separate chambers for each process.

Most automated instrument washers use impingement: the spray force action of pressurized water against instruments being processed to physically remove bioburden. These washers rely on a combination of water temperature, special detergent, and spray force action to remove soil from instruments during processing.

Automated instrument washers use several steps in the wash process, including: 1) pre-rinse to wet the instruments; 2) detergent cycle with higher temperature water; 3) lubrication cycle; 4) rinse cycle(s); and 5) dry cycle. Most automated instrument washers are sold with pre-set factory installed cycles.

Instruments must be properly prepared before being placed in the washer. Multi-part instruments must be disassembled. Generally, if an instrument can be taken apart without any tools it should be taken apart for cleaning. All box locks and hinges must be opened, and instruments should be placed in the cleaning basket with the box lock or hinge facing upward. Multi-level trays must be separated, trays should not be stacked in the washer, and all lids and covers must be removed from the tray. Special hold-down covers can be used to hold small or delicate instruments in place, and delicate instruments should be contained.

Automated Cart Washers. These carts are used to wash large items, such as carts, basins and instrument containers. Their use has automated the cleaning of surgical case carts, rigid sterilization containers, basins, and other types of carts. Cart washers operate in a manner similar to automated instrument washers, but on a larger scale. High temperature water and detergent are delivered under high pressure, followed by rinse and drying cycles.

IN CONCLUSION
Reusable medical devices must be adequately cleaned and decontaminated before being prepared for packaging and subsequent sterilization. This can be a simple process for some devices, but a very complex and time-consuming process for others. Manufacturer’s IFU for a particular device must always be followed exactly. Failure to do so may yield a device that is not adequately cleaned and, therefore, cannot be disinfected or sterilized. As well, the device may not be safe to handle without protection.

REFERENCE

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