Introduction

Medical devices can be as simple as a disposable tongue depressor or as complicated as a flexible endoscope. Since disposable items are meant to be used only once, this article will focus on the care and handling of medical devices that must be reprocessed to use repeatedly. If medical devices are not reprocessed correctly, there is a high risk of passing infection from patient to patient, from patient to staff and from the patient to the community at large. In addition, medical devices are costly and it is the job of the sterile processing department to handle them carefully to reduce the risk of breakage or chemical damage.

Learning Objectives

- Review Spaulding’s classification for reprocessing decision making.
- Learn how to identify and avoid instrument damage.
- Understand how corrosion can affect the functionality of surgical devices.
- Review handling and transport procedures for staff in instrument processing.

Reduce the Transmission of Infection to Patients

In the Mid 1960s, Dr. Earl Spalding developed a framework to guide reprocessing decision making. The system is based on the patient’s risk of infection from contact with instruments and equipment.

- **Noncritical Equipment/Devices** – These devices have low risk of transmitting infection. They come into contact with normal and intact skin or do not touch the patient directly. Noncritical equipment may include but not be limited to stethoscopes, BP cuffs, ECG machines, baby scales, electric thermometers, and environmental surfaces. In such cases, cleaning with a detergent and drying is usually adequate. However, if common sense dictates, further disinfection may be needed.
- **Semi-critical Equipment/Devices** – These devices do come into contact with non intact skin or mucous membranes but do not penetrate them. Examples include laryngoscopes,
endotrachial tubes, anaesthesia equipment, specula, ultrasound probes, ear cleaning equipment and breast pump accessories. Cleaning followed by HLD – High Level Disinfection or sterilization is required. Three types of HLD are disinfection by boiling, moist heat at 70-100°C and chemical disinfection. These will be discussed later.

- Critical Equipment/Devices – These devices penetrate sterile tissues such as body cavities and the vascular system. With these devices there is a high risk of passing on infection from one patient to another. It is imperative that the devices are cleaned and sterilized properly. Examples include surgical instruments, intrauterine devices, vascular catheters and implants.

The first step in any decontamination process is cleaning. Gross soil must be removed as close to the point of use as possible. After surgery, the OR staff should wipe down instruments to remove gross soil and then place the instruments in a multi-enzymatic solution or spray them with an enzyme product prior to transport to the decontamination area. Enzymes are catalysts that facilitate the breakdown of organic matter. Enzymes work on specific types of matter, substrates. Protease breaks down proteins such as blood, mucous, feces, and albumin. Lipase breaks down fats such as bone marrow and adipose tissue. Amylase breaks down starches. Cellulase breaks down cellulose, carbohydrates and is believed to break down biofilm. If a soak is used, the solution should be emptied prior to transport to prevent spills. It is important to keep the instruments moist during transport. A closed system should be used to transport instruments from the OR or point of use to the Sterile Processing Department (SPD) for cleaning and further sterilization or disinfection, as required.

When the instruments reach the SPD, they may be washed manually or mechanically in sonic cleaners and automated washers. Each cleaning step should be followed by a thorough rinse to remove soil and detergent residue from the previous cleaning step. If manually washing, brushes with nylon bristles are recommended and the brush should be of the correct size to fit the lumen of the instrument. All medical devices should be disassembled so all surfaces can be cleaned. The detergent should be pH balanced and the final rinse should always be with high quality water. High quality water is pH neutral water that has been purified and contaminants have been removed. Water soluble lubricant should only be used on parts that have first been cleaned and rinsed completely. Otherwise, the lubricant will trap the bioburden. The instructions for use should be followed exactly so the device is cleaned the way the medical device manufacturer intended. Instrument chemistries such as detergents and enzymatic cleaners also have instructions for use that must be followed. The package label includes the correct use parameters including temperature, dilution ratio and soak time, as well as rinsing and drying requirements. Cleaning correctly is essential. Neither decontamination nor
sterilization can be effective if all soil has not been removed. Devices must be dried completely before sterilization or disinfection. Moisture may promote the colonization of waterborne microorganisms and the growth of biofilms. Moisture will also interfere with the sterilization process.

HLD or High Level Disinfection may be used after cleaning if the device falls under the semi-critical category. High level disinfection will destroy all vegetative microorganisms, tubercle bacilli, most fungi, non-lipid and small viruses with the exception of high numbers of bacterial spores. Chemicals that provide HLD include Glutaraldehyde, Ortho-Phthalaldehyde, Peracetic acid and Hydrogen peroxide. Instruments must be soaked in the chemical solutions for a specified period, rinsed and dried completely. Thermal disinfection takes place by applying heat to the device and is accomplished with machines such as automatic washer-sanitizers/disinfectors, pasteurisation equipment and automatic endoscope reprocessors.

Critical equipment or devices must be sterilized. Sterilization is the process by which all forms of microbial life including bacteria, viruses, spores and fungi are completely destroyed. There are several methods of sterilization in use today. Steam sterilization is the most prevalent. Effective sterilization takes place when there is adequate contact of the steam to the objects being sterilized, the objects are exposed to the steam for the correct amount of time, the temperature is set correctly and moisture content of the steam is correct. Low temperature methods of sterilization include Ethylene Oxide, Hydrogen Peroxide (or Plasma) and Ozone. Low Temperature sterilization may be required for devices that are heat and moisture sensitive. The manufacturer test and validate the sterilization systems and include Instructions for Use with the sale of the unit. The Instructions for Use also include the process required to clean the sterilization chambers. It needs to be stressed that devices MUST be clean before they can be sterilized. The sterilant needs to be able to come in contact with all surface areas and if bioburden remains on the instruments it forms a barrier to effective sterilization.

Reduce Risk of Breakage and Chemical Damage to Medical Devices

Surface damage to medical devices may result from improper reprocessing. If surface changes do occur, it is important to proceed in a logical manner. The first thing to do is to determine the origin and cause of the surface change. Next assess the risk. Will the surface change affect the care of the patient or is it only aesthetic? Next, process and treat items in accordance with manufacturer’s recommendations. Sometimes the surface change can be removed or corrected. In other instances, the device must be discarded. Finally, take appropriate measures to prevent
recurrence. Sometimes small changes such as performing a final rinse with demineralised water can prevent damage to devices in the future.

Corrosion is the destructive attack on a metal through interaction with its environment. Water is corrosive because the oxygen in the water reacts with iron in the metals and forms rust in a process called oxidation. Steel that has not been treated is especially vulnerable to rusting and rust spreads. The rust particles from a rusty instrument can be transferred to non rusty instruments causing secondary rusting. Rusty instruments, therefore, should be removed to avoid further contamination of non affected devices. Rust looks orange or red and has a flaky appearance.

Devices made out of stainless steel or anodized aluminum are resistant to wear and have maximum corrosion resistance. However, both these metals can become corroded and stained if not cared for effectively. Stainless steel is composed of iron, carbon, chromium, nickel, manganese, silica and many other metals. The more chromium in the stainless steel, the higher the resistance to corrosion. A layer of chromium oxide forms during a process called passivation and creates a barrier to corrosion. Damage to this protective layer can be physical or chemical. If this layer is scratched, exposed to highly acidic or highly alkaline cleaners or if soil remains on the device, damage may occur. Halogen salts (halides) especially chlorides can cause pitting corrosion which may appear as black dots or in the worst case large deep holes. Chlorides can also cause stress corrosion cracking. Chlorides can be present in water, organic residues, physiological salt solutions, etchants and drug residues. The danger of chloride induced pitting rise with an increase in chloride content, increase in temperature, decreased PH value, increased exposure time and insufficient drying. As discussed, organic residue (blood has chloride ions) left on medical devices can cause pitting. It can also cause discoloration and the formation of biofilm, which becomes difficult to remove. In order to reduce organic residue, cleaning should occur as quickly as possible after use and gross contamination should be removed immediately. Soil should never be allowed to dry on instruments.

The misuse of disinfectants can also cause damage. It is essential that staff follow the manufacturer’s instructions for use so the correct concentration and exposure times of disinfectants are followed. Both saline solutions and chlorine compounds such as bleach can harm stainless steel instruments and instruments should never be allowed to soak in these solutions. Water, especially hard water, can leave deposits on instruments and act as seed points for corrosion. The final rinse water needs to be demineralized and of high quality. Instruments should be dried thoroughly after cleaning. Even “flash” sterilization can damage passive layers of stainless steel, because of the rapid temperature change.
Anodized aluminum is lighter than stainless steel and has greater thermo conductivity making it the ideal choice in the manufacture of cases for instrument sterilization. In order to make the aluminum harder and more durable, the metal must undergo an oxidation process followed by a seal, anodization, which reduces the porosity of the metal and results in the formation of a strong, durable, corrosion resistant, passive surface. Anodized aluminum must be washed with pH balanced detergents to prevent corrosion and preserve the useful life of the device. A sterilization container that is neither properly anodized nor processed will become degraded over time and corrosion may result. Medical devices that are subject to corrosion should be removed from service as an affected item will subject other devices to corrosion and may be harmful to patients during surgery.

Corrosion on surgical instruments can result in instrument malfunction. In many cases, they will need to be removed from service and replaced. With the high price of medical devices, it is imperative that the SPD staff have the training to know how to protect these crucial medical instruments. Instruments with joints or moving parts are especially subject to fretting and stress corrosion cracking. Fretting corrosion becomes apparent around the area that has been chafed. This appears as brown stains or rust formation. Organic matter and humidity can be trapped and precipitate corrosion. Also the friction of moving parts can erode the passive layer of the metal. With these types of instruments, a water soluble lubricant is recommended and lubrication is performed after cleaning. Lubricants must be vapor permeable and sterilizable. Again the manufacturer’s Instructions for Use should always be reviewed and followed. Stress corrosion cracking can lead to visible cracks and to hidden fractures. This occurs in areas of instruments that have high tensile stress. To prevent stress corrosion cracking, clean instruments in the open position and sterilize them with the ratchet locked in the first tooth at the farthest. Also use only high quality water for cleaning, final rinse and sterilization. If a crack is detected, remove the item from use.

Physical damage to medical devices can occur when instruments are packed in loaded baskets and move against each other during the cleaning and sterilization process. When possible, brackets and other means of securing instruments should be used to prevent surface abrasions. Delicate instruments should be confined in small perforated baskets with lids. Instruments should be processed in the open position. The instructions for use should be followed carefully for items that need to be disassembled prior to cleaning and reassembled after sterilization. All instruments should be visually inspected for damage.
Reducing the Risk to Staff Handling Medical Devices

Personal Protection Equipment (PPE) refers to the attire required by medical staff in the Central Processing Department. These should include full face protection, utility gloves, a fluid resistant covering with sleeves, and shoe covers. This clothing was mandated by the Occupational Safety and Health Administration and is for the safety of staff so that they are protected from harmful pathogens. Remember that infectious agents can be microscopic and therefore, may not be seen. Care must be taken at all times to dress correctly when handling medical devices. Hand washing is a simple means of avoiding infection. Hands must be washed with soap and water or rubbed with an alcohol based hand rub upon entering and leaving the work area. If a person has an open wound, they should not handle patient care equipment. Food and drink should not be allowed in work areas.

Personnel that transport contaminated items to the decontamination site should receive special training. They must learn methods to avoid spillage and to ensure that items are securely contained. If staff members use manual methods of cleaning, they must learn to clean devices by immersing the items and cleaning with minimal splashing. Dirty water can carry infectious material. Those personnel that operate the sterilizers should receive special training. There is a risk of burns from steam sterilizers that work at high temperatures. Ethylene Oxide, used in some low temperature sterilizers, is particularly toxic and personnel that use Ethylene Oxide sterilizers require special guidelines and training.

Personnel that work in the Central Processing Department are crucial to the safety of all patients and staff. They must not relax in their roles, but be constantly vigilant of the dangers around them.

Summary

Implementing proper protocols in your hospital can go a long way toward protecting your instruments from unnecessary damage and keeping your environment safe. With everyone on the team working together to ensure that all instruments are adequately cleaned, decontaminated, inspected, repaired, packaged and sterilized, your patients will receive the quality of care they expect and deserve. By paying attention to detail during each step, you can help make sure that your instruments function properly, patients receive the best care and you remain safe.
Works Cited Page


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