The Care and Handling of Medical Devices

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.

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 and used repeatedly. If medical devices are not reprocessed correctly, there is an increased risk of passing infection from patient to patient, from patient to staff, from staff to patients and from the patient to the community at large. In addition, medical devices are expensive, and it is the job of the sterile processing department to handle them carefully to reduce the risk of breakage or chemical damage.

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.
- **Non-critical Equipment/Devices** – These devices have minimal 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 are not limited to stethoscopes, BP cuffs, ECG machines, 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 come into contact with non-intact skin or mucous membranes but do not penetrate tissues. Examples include laryngoscopes, endotracheal tubes, anesthesia equipment, specula, ultrasound probes, ear cleaning equipment and breast pump accessories. Cleaning followed by High Level Disinfection (HDL) or sterilization is required. There are three types of HLD. They are disinfection by boiling, moist heat at 70-100°C and chemical disinfection.

- **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 through inappropriately cleaned instruments. It is imperative that the devices are cleaned and sterilized properly. Examples include surgical instruments, intrauterine devices, vascular catheters and implants.

The first, and most important, 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 transportation to the decontamination area. Enzymes are catalysts that facilitate the breakdown of organic matter. Enzymes work on specific types of matter and 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 must 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 disinfection or sterilization, as required.

When the instruments reach the SPD, they may be washed manually and mechanically, utilizing 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 neutral 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 disinfection or sterilization. Moisture may promote the colonization of waterborne microorganisms and the growth of biofilms. Moisture will also interfere with the sterilization process.
High level disinfection may be used after cleaning if the device falls under the semi-critical category. HLD 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-Phthaldehyde, 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-disinfectors, pasteurization 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 appropriately and moisture content of the steam is correct. Low temperature methods of sterilization include Ethylene Oxide, Hydrogen Peroxide Gas Plasma and Ozone. Low temperature sterilization may be required for devices that are heat and moisture sensitive. The manufacturer tests and validates the sterilization systems and include Instructions for Use (IFU) with the sale of the unit. 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, minor 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 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 properly. 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 rises 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. 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 IFUs 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. 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 IUSS 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. To make the aluminum harder and more
durable, the metal must undergo an oxidation process followed by sealing, 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 neutral detergents to prevent corrosion and preserve the useful life of the device. A sterilization container that is neither properly anodized nor processed properly 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 this lubrication should be performed after cleaning. Lubricants must be vapor permeable and sterilizable. Again, the manufacturer’s IFU 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 point. 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 a mask, face shield, head cover, utility gloves, a fluid-resistant covering with sleeves, and shoe covers. This clothing was mandated by the Occupational Safety and Health Administration (OSHA) and is for the safety of staff, so they are protected from harmful pathogens. Remember that infectious agents can be microscopic and therefore, may not be seen. 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. 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. Instruments must be kept moist but transporting liquid is not acceptable practice. Fluids should be suctioned prior to transporting the tray to the Decontamination area.

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. Precautions should also be taken when unloading Hydrogen Peroxide sterilizers. PPE should always be worn to protect from exposure and burns from residual hydrogen peroxide.

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.
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