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Standard Guide for Care and Handling of Stainless Steel Surgical Instruments [1]

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ε[1] NOTE—Warning statements were corrected throughout in November 2002.

1. Scope

1.1 This guide is intended to provide a better understanding of the care of stainless steel surgical instruments intended for reuse. This guide is not intended for use with electrical, pneumatic or other powered surgical instruments.

2. Referenced Documents

2.1 *ASTM Standards:*

F 899 Specification for Stainless Steels for Surgical Instruments[2]

F 921 Definitions of Terms Relating to Hemostatic Forceps[2]

F 1026 Specification for General Workmanship and Performance Measurements of Hemostatic Forceps[2]

F 1078 Terminology for Surgical Scissors—Inserted and Non-Inserted Blades[2]

F 1079 Specification for Inserted and Non-Inserted Surgical Scissors[2]

F 1089 Test Method for Corrosion of Surgical Instruments[2]

F 1325 Specification for Stainless Steel Suture Needle Holders—General Workmanship Requirements and Corresponding Test Methods[2]

3. General

3.1 *Stainless Steel Types*—The stainless steels most used are martensitic and austenitic types such as those in Specification F 899. Martensitic stainless steel contains iron, chromium, and sufficient carbon so that when it is hardened by heat treatment, a substantial martensitic structure is the result. Austenitic stainless steel has better corrosion resistance and contains iron, chromium, and nickel. It has a substantial austenitic structure and a lower carbon content. Although it cannot be hardened by heat treatment, it can be work-hardened.

3.2 *Passivation*—Stainless steel can spot, stain, and corrode. This is minimized by passivation which is a process used to create a protective chromium oxide surface layer while removing surface carbon and iron. This is accomplished in the atmosphere slowly or through immersion in oxidizing solution or through an electro-polish process. Through repeated processing the passivation layer will thicken until a good protective film is formed.

3.2.1 Never expose instruments to strong acids such as hydrochloric, aqua regia, dilute sulphuric, carbonic, and tartaric.

3.2.2 Avoid contact with salt solutions such as aluminum chloride, mercury salts, stannous chloride. Also avoid contact with potassium thiocyanate and potassium permanganate and limit contact with iodine solutions to periods less than 1 h.

3.2.3 Chloride-bearing solutions such as blood and saline can cause localized corrosion. Avoid prolonged exposure to or rinsing in saline solutions or corrosion and pitting will occur. Use demineralized or distilled water instead. Place instruments into water, enzymatic solution, or disinfectant bath immediately after use so the blood or other material will not dry on them prior to transport to designated cleaning/reprocessing area.

4. General Care of Instruments

4.1 *General*—Use instruments only for their intended purpose, such as cutting, holding, clamping, retracting, and so forth. Avoid undue stress or strain when handling and cleaning. Standard terminology relating to Hemostatic Forceps and Surgical Scissors are found in Definitions F 921 and Specification F 1078.

4.1.1 *Hemostatic Forceps*—These forceps are designed to clamp blood vessels. They should not be used to clamp towels, suction tubing, or as needle holders or pliers. Misuse generally results in misalignment and even cracked box locks.

4.1.2 *Needle Holders*—Although designed to withstand some force, they are not to be used as pliers, jaw misalignments being the result. Select a needle holder matching the size needle being used.

4.1.3 *Scissors*—Do not use scissors for the wrong job, otherwise, the tips will become misaligned and the blades will dull or chip. Delicate scissors should be particularly guarded against misuses. Use tissue scissors for tissue dissections only, not for cutting suture material or wires.

4.1.4 *Microsurgical Instruments*—Microsurgical instruments are most susceptible to damage through misuse or rough

[1] This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.33 on Medical/Surgical Instruments.

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[2] *Annual Book of ASTM Standards*, Vol 13.01.

handling. Consequently, extra care must be taken to avoid compromising their exacting performance. To minimize damage, the following should be done:

4.1.4.1 Inspect the instrument when purchased and after each use and cleaning, preferably under magnification.

4.1.4.2 Only use for its intended purpose.

4.1.4.3 After each use, remove blood and debris from instrument. A non-fibrous sponge may be used to eliminate snagging and breakage. (**Warning—**When handling sharp instruments, use extreme caution to avoid injury; Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.)

4.1.4.4 Clean and thoroughly dry before packaging or storing. Avoid using a washer decontaminator or an ultrasonic cleaner (see Appendix X.2).

4.1.4.5 Avoid metal-to-metal contact by using special racks designed to separate and protect.

4.1.4.6 Do routine preventive maintenance such as sharpening and realigning. Sterilization by dry heat or chemical vapor should be considered for these instruments.

4.1.5 *Instrument Kits*—Select an instrument tray which suits the size of the kit. Placing a large instrument kit in a small instrument tray may lead to broken instruments, bent tips, or dull scissors. Put heavier instruments such as retractors on the bottom and light weight instruments on the top. Ring-handled instruments should be kept open with a wire holder or pin. Curved clamps should all point in the same direction to protect the tips. Scissors should be kept separate. Cupped instruments should be placed so that water does not collect in them during sterilization. Separate instruments of dissimilar metals by separate processing, otherwise galvanic corrosion or electrolytic deposition may result.

4.1.6 *Other Sharp Instruments*—Rongeurs, bone cutting forceps, drill bits, reamers, and so forth should be used to cut bone, not wire or pins. Sometimes it is necessary to use rongeurs or osteotomes to chip bone away from bone plates and screws, which may nick or dull the blades. An alternate approach is to keep an older set of rongeurs or osteotomes for such orthopedic procedures. Instruments that are recommended to be sharpened by the manufacturer should be processed and verified by the manufacturer's specific instruction. Instruments should be used only for their identified purpose. Careful planning is necessary for selection of the proper amount and type of instruments needed for each surgical procedure.

4.2 *Care During Use*:

4.2.1 Handle instruments gently.

4.2.2 Avoid dropping instruments or covering them with heavier instruments.

4.2.3 Handle instruments individually or in small numbers.

4.2.4 Protect instrument tips, especially sharp ones. Do not place instruments down on their tips.

4.2.5 Do not drop delicate or sharp instruments into any cleaning receptacle. Such practice may cause damage to the instruments.

4.2.6 After a surgical procedure, an instrument count should be made to avoid sending any instruments to the laundry with the soiled linen. Although they eventually may be returned, they create a injury hazard to laundry workers and many are damaged beyond economical repair.

4.3 *Marking*—Do not use a vibrating or impact type marking devices on the box lock portion. If marking is necessary, do it on the shanks, otherwise the box locks may fail.

5. Cleaning

5.1 *General*—Clean instruments as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Wash all instruments whether or not they were used or were inadvertently contacted with blood or saline solution.

After surgery, open box locks and disassemble instruments with removable parts. Forceps and scissors should be cleaned and sterilized in the open position. This will limit blood drying on the instruments which may cause them to corrode. Delicate and sharp instruments should be cleaned separately. This is especially true for eye and microsurgery instruments. (**Warning—**When handling any sharp instruments, use extreme caution to avoid injury; Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact. Direct handling and cleaning of instruments should be done only when indirect methods, for example, tweezers, are not available or not possible.) Sort instruments by similar metal for subsequent processing so that electrolytic deposition due to contact between dissimilar metals will not occur.

Prior to regular cleaning, soak in enzyme solution or rinse instruments in demineralized or distilled water to remove blood and debris, especially those instruments with hollow tubes such as suction tubes and curettes.

Do not use abrasive pads or cleansers which will scratch the surface allowing dirt and water deposits to collect. Abrasive cleaning will remove the passive layer. Do not use chlorine bleach at a higher concentration than recommended by the manufacturer to clean or disinfect stainless steel instruments, as pitting will occur. High concentrations of chlorine-based solutions are not recommended as pitting and subsequent damage will occur. (See Appendix X3.)

5.2 *Detergents*—The detergent used should be in keeping with the cleaning equipment manufacturer's recommendations. Neutral pH detergents, between 7.0 and 8.5, which are low sudsing, free rinsing, and have good wetting are best over all for washer decontaminators and ultrasonic cleaners. High-sudsing detergents must be thoroughly rinsed or instruments will spot or stain. (See Appendix X2.)

5.3 *Washer Decontaminator*—Equipment of this type will wash and decontaminate instruments. Complete removal of soil from serrations and crevices depends on instrument construction, exposure time, pressure of delivered solution, and pH of the detergent solution, and thus may require prior brushing.

5.3.1 Be familiar with equipment manufacturers' use and operation instructions. Be aware that loading detergent water temperature and other external factors may change the effectiveness of the equipment. (See X4.5.)

5.3.2 Arrange heavier instruments on bottom, disassemble

instruments with removable parts, open box locks, and protect cutting edges.

5.3.3 Follow equipment manufacturers' recommendations for detergent, preferably a liquid one. Solid detergents may not disperse as completely. Concentrated detergents placed on the instruments may cause corrosion.

5.3.4 Install a water softener if the water is hard and the water supply is not already treated. This will minimize scum formation. Deionized water is recommended for rinsing to prevent spotting.

5.3.5 If instruments are dirty after decontamination, the ejector may be fouled. If fouled, foreign matter remains to deposit on the instruments. The ejector must be cleaned and extraneous matter removed.

5.3.6 Regularly cleaning decontaminator walls will remove rust and mineral deposits and avoid transfer of this type of debris to the instruments being cleaned. Follow the equipment manufacturer's instructions or descaling detergent manufacturers' instructions to clean decontaminator walls.

5.4 *Ultrasonic Cleaner*—Ultrasonic cleaners, when used with hot water per manufacturer's recommended temperature and specially formulated detergents, are very effective and thorough. Debris of all sizes can be removed even from crevices and corners in five minutes. After ultrasonic cleaning, the instruments cleaned still need to be sterilized.

5.4.1 Follow manufacturer's instructions when using an ultrasonic cleaner. Be aware that loading patterns, instrument cassettes, water temperature, and other external factors may change the effectiveness of the equipment. (See X4.5.)

5.4.2 Arrange instruments with box locks open and cutting edges protected. Do not clean delicate instruments in an ultrasonic cleaner since the vibrations can cause the tips to wear if they come in contact with other metal surfaces.

5.4.3 It is not recommended to clean plated instruments in an ultrasonic cleaner since the ultrasonic vibration and the presence of other sharp instrument edges may crack or rupture the plating. When the plating is ruptured ultrasonic energy will accelerate flaking. Any plated instrument with ruptured plating should be removed from use and refurbished or discarded.

5.4.4 Use hot water per manufacturer's recommended temperature (usually 90 to 140°F or 30 to 75°C).

5.4.5 Follow manufacturer's recommendations for proper cleaning solution, or use cleaning solution formulated specifically for ultrasonic cleaners. Neutral detergents or products with less than 2 % available alkalinity are suitable for ultrasonic cleaning. Acidic or alkaline products with more than 2 % available alkalinity are not recommended for ultrasonic systems because they cannot be properly neutralized.

5.4.6 Rinse instruments thoroughly after cleaning.

5.4.7 Check screws of instruments after cleaning to ensure that they have not loosened through vibration.

5.4.8 Keep cleaning solution particulate-free by changing often or changing the filter per manufacturer's recommendations.

5.5 *Lubrication*—To protect instruments during sterilization and storage from staining and rusting, they should be lubricated with a water-soluble, preserved lubricant after each cleaning. Since effective ultrasonic cleaning removes all lubricant, re-lubrication of the instruments is important. The lubricant should contain a chemical preservative to prevent bacterial growth in the lubricant bath. The bath solution should be made with demineralized water. A lubricant containing a rust inhibitor helps prevent electrolytic corrosion of points and edges. Immediately after cleaning, instruments should be immersed completely for 30 s and allowed to drain off, not wiped off. A lubricant film will remain through sterilization to protect them during storage. "Frozen" box locks can be immersed overnight and the joint then worked free.

5.6 *Inspection*—After lubricating, instruments should be inspected. Incompletely cleaned instruments should be re-cleaned, and those that need repair set aside. For complex instruments, the manufacturer's inspection and testing recommendations should be followed.

5.6.1 For hinged instruments such as clamps and forceps, lock stiffness, jaw alignment, and teeth should be checked.

5.6.2 For sharp instruments such as scissors, rongeurs, and curettes, sharpness should be tested per manufacturer's instructions.

5.6.3 Check plated instruments for chipped plating. These defects can tear rubber gloves, or cause the instruments to rust. Any plated instrument with ruptured plating should be removed from use and refurbished or discarded.

5.6.4 Pins and screws should be checked to see if they are intact.

6. Testing

6.1 Forceps and hemostats shall conform to performance characteristics stated in Specification F 1026.

6.2 Scissors shall conform to performance characteristics stated in Specification F 1079.

6.3 Suture needle holders shall conform to performance characteristics stated in Specification F 1325.

6.4 Scalpel handles should be checked for fit when the blade is attached to the scalpel handle. If fit is not snug, discard the handle.

NOTE 1—Test Method F 1089 contains test methods for corrosion of surgical instruments.

7. Repair and Restoration

7.1 When instruments wear through repeated use and sterilization, they should be sent to the manufacturer or a repair service knowledgeable in the function of surgical instruments.

7.1.1 Some manufacturers offer preventive maintenance programs that can be a cost effective alternatives to a repair service by limiting repairs. Routine maintenance by people familiar with instrument manufacture will limit costly repairs.

8. Sterilization

8.1 *Steam Sterilization*:

8.1.1 Staining and spotting may result if residual chemicals are not completely rinsed from instruments that are subjected to steam sterilization. Following proper drying cycles and the equipment manufacturer's recommendations are vital to preventing formation of excess moisture and the resultant water spotting.

8.1.2 Routine care and equipment maintenance instructions provided by the manufacturer, if followed, will help ensure

longer equipment life and minimize instrument processing difficulties. As a minimum, wiping the inner surfaces with the proper solution and servicing the traps regularly are two routine maintenance precautions to be taken.

8.1.3 High temperature steam filters may help reduce the incidence of staining and corrosion in cases where major systems changes may otherwise be needed to correct these problems.

8.2 *Dry Heat Sterilization*:

8.2.1 This sterilization method may be recommended for some heat stable microsurgical instruments as it is less prone to corrosion effects. Review manufacturer's specifications and recommendations before using this sterilization method.

8.3 *Chemical Vapor Sterilization (Alcohol, Formaldehyde, and anticorrosive with dry steam under pressure, made primarily for the dental industry)*:

8.3.1 This sterilization method may be recommended for some microsurgical instruments as it is less prone to corrosion effects. Review manufacturer's specifications and recommendations before using this sterilization method. (**Warning—** After sterilization, instruments must be kept dry; otherwise, corrosion may result.)

9. Trouble Shooting

9.1 A fully detailed written procedure which includes steps, equipment, and supplies should be drafted to assure proper instrument care. Include other departments such as maintenance so there is information on boiler water additives and piping changes and any other related details. Do not use short cuts in caring for the instruments or rusting or staining may result.

9.2 Specific recommendation according to cause and corrective action to be taken is found in Appendix X1, Appendix X2, and Appendix X3.

10. New Hospitals

10.1 For new washer decontaminators and autoclaves there is a break-in period, especially for the water and steam lines. Have a qualified instrument or equipment expert present during start-up and initial processing to identify and correct problems.

11. Keywords

11.1 care and handling; stainless steel surgical instrument; sterilization; surgical instruments

APPENDIXES

(Nonmandatory Information)

X1. CORROSION ON BLADES AND BOX LOCKS

X1.1 Corrosion on blades and box locks is an indication of one or more of the following situations:

X1.1.1 Inadequate cleaning and drying after use.

X1.1.2 Either corrosive sterilizing solutions or excess exposure to the sterilizing solutions, especially the cold soak solution process, or both.

X1.1.3 Incorrect detergent.

X1.1.4 Autoclave contaminated (steam).

X1.1.5 Course surfaces.

X1.1.5.1 Knurled or grooved surfaces may rust while polished surfaces may not be affected.

X1.1.5.2 Satin or matte surfaces may behave similarly to grooved and knurled surfaces.

X1.1.6 Minerals in the water.

X1.1.6.1 If the water used is hard, spotting from minerals containing calcium or magnesium will result.

X1.1.6.2 Soft water may also be corrosive due to dissolved salts.

X1.1.6.3 Deionized, distilled, or otherwise demineralized water should be used.

X2. SPOTTING/STAINING

X2.1 Spotting/Staining maybe an indication of one or more of the following situations. The effect of a specific situations may be lessened by the application of the listed solution. (See Appendix X1.)

X2.1.1 Light-colored spot after autoclaving.

X2.1.1.1 *Cause*—Water droplets evaporating from the instrument slowly, the water containing calcium, or magnesium.

X2.1.1.2 *Solution*—Follow autoclave manufacturer's instructions. Do not open autoclave door until steam has been exhausted.

X2.1.2 Dark-colored spot.

X2.1.2.1 *Cause*—Generally same as for light-colored spot.

X2.1.2.2 *Solution*—Prepare all solutions with chloride-free demineralized or distilled water where pH is 7.0.

X2.1.3 Rust-colored film after autoclaving.

X2.1.3.1 *Cause*—Foreign matter left in new installed steam pipes or water supply containing iron.

X2.1.3.2 *Solution*—If new steam pipes, the problem should subside in two to three months. If iron is in the water, consult the engineering staff for treating the water to remove the iron.

X2.1.4 Bluish-Gray stain after sterilization.

X2.1.4.1 *Cause*—This condition may be caused by some liquid chemical disinfection; germicidal solutions.

X2.1.4.2 *Solutions*—(*a*) If a liquid chemical disinfectant solution is used, it should be rinsed from the instruments before they are sterilized by heat. (*b*) Change the solution more

frequently; also use distilled water and a rust inhibitor. Follow manufacturer's directions.

X2.1.5 Brownish stain.

X2.1.5.1 *Causes*—(*a*) Chromium oxide film. This forms when stainless steel is excessively heated in the sterilizer. (*b*) Copper. Washing compounds containing polyphosphates can dissolve some copper from sterilizer components. The dissolved copper is deposited electrolytically on stainless steel.

X2.1.5.2 *Solutions*—(*a*) For chromium oxide, fill the sterilizer with the right amount of cold water. (*b*) For copper, use another instrument detergent which contains less polyphosphate or an instrument detergent that has been found to work.

X2.1.6 Purplish-Black stain.

X2.1.6.1 *Causes*—(*a*) Ammonia exposure. (*b*) Amines in steam lines. Amine chemicals are used to clean hard water scale from steam lines. This can contaminate the steam and react with stainless steel instruments.

X2.1.6.2 *Solutions*—(*a*) For ammonia exposure, identify and remove the source if possible or avoid exposure to these compounds. (*b*) For amines in steam lines, avoid descaling chemicals that use amines.

X2.1.7 Rust Deposit.

X2.1.7.1 *Causes*—(*a*) Sterilizing plated and stainless instruments together. If the plated instrument has plating missing, iron from where there is no plating will deposit on the stainless steel instrument. (*b*) Rinsing instruments in tap water with high concentrations of dissolved metals.

X2.1.7.2 *Solutions*—(*a*) For plated and stainless instruments, sterilize these instruments separately. When the plating on plated instruments starts to peel, replace them with stainless steel instruments or new plated instruments. (*b*) For dissolved metals in tap water, rinse with distilled or deionized water, especially in places where hard water is of concern.

X3. CORROSION/PITTING

X3.1 *Causes:*

X3.1.1 Ineffective rinsing of linens after washing with caustic chemicals by the laundry service.

X3.1.2 Dried blood in box locks, serrations, and ratchets which appears to be rust.

X3.1.3 Moisture left on instrument surfaces or crevices from end of autoclave cycle or from sterile warp packs.

X3.1.4 Hard water minerals deposited on the instruments.

X3.1.5 Chloride-bearing materials such as blood, saline, potassium chloride, chlorine based bleach solutions.

X3.1.6 Residue from acid-bearing detergents or detergents containing chloride.

X3.1.7 Unbuffered detergents that create a solution with a pH above 8.5 or detergents with more than 2 % available alkalinity can remove the chromic oxide passive layer.

X3.1.8 Dissimilar metals ultrasonically cleaned together.

X3.1.9 Exposure to chloride or halide containing solutions, or both, and high pressure steam from autoclaving in the presence of stress can promote stress corrosion cracking, which is difficult to detect until catastrophic failure occurs.

X3.2 *Solutions:*

X3.2.1 For ineffective rinsing of linens, rinse linens thoroughly with distilled or deionized water before using.

X3.2.2 For dried blood in box locks, clean instruments more thoroughly.

X3.2.3 For moisture left on surfaces, preheat autoclave. Do not rush drying time. Check valves for leakage.

X3.2.4 For hard water minerals, use distilled or deionized water during sterilization. To remove deposits on the autoclaving, wipe surfaces with acetic acid/water (50:50 mixture). If local water supply is used, wipe down weekly.

X3.2.5 For chloride-bearing materials, rinse instruments with running water as soon as possible after use and then clean as usual.

X3.2.6 For acid-bearing detergent residue, avoid acid-containing detergents capable of re-forming acid. For chloride containing residue, avoid detergents capable of leaving high concentrations of chloride in the residue.

X3.2.7 For high pH detergents, use a detergent that is buffered or creates a solution with pH ranging from neutral to 8.5. For cleaning solution with greater than 2 % alkalinity neutralize with mild acid rinse immediately after alkaline washing cycle is completed.

X3.2.8 Do not clean instruments made of dissimilar metals together: separate the instruments according to the metals for cleaning operations.

X3.2.9 Avoid exposure to chloride or halide containing solutions, or both, if possible. If instruments are sanitized in a solution containing chlorides or halides, or both, they should be rinsed thoroughly with distilled or deionized water before being autoclaved or sterilized by other methods.

X4. RATIONALE

X4.1 This guide was created to give a general understanding of the nature and concerns associated with the care and cleaning of surgical instruments. Attention has been paid to chemical and corrosion contacts that may inadvertently degrade, corrode, or otherwise shorten the expected useful life of hand held surgical instruments. This document is not meant to be complete or precise with regard to all the possible chemical contacts or reactions that may occur in a particular situation. The task group has attempted to identify those conditions that are most detrimental and pervasive.

X4.2 The term washer-sterilizer has been removed from this guide in favor of the term washer decontaminator. It is recognized that the term "washer sterilizer" is in common use

to describe types of equipment used to clean/disinfect instruments before high level sterilization by other methods such as dry heat, gas, chemical vapor, or steam. It is the consensus opinion of this task group to use the term washer decontaminator in place of washer-sterilizer.

X4.3 It is the consensus opinion of this task group that chloride ions in any concentration can be detrimental to the finish of hand held surgical instruments and should be avoided if and when possible. It is recognized that the use of bleach and other chlorine containing solutions are pervasive in current practice of care and handling of surgical instruments.

X4.4 Low foaming, free rinsing, detergents with good wetting ability and a neutral pH are compatible with most instrument metals including anodized aluminum. Detergents with greater than 2 % available alkalinity should not be utilized on stainless steel unless immediately neutralized with a mild acidic rinse after detergent cycles are completed.

X4.5 It is generally recognized that the best use of instruments and equipment fall within the guidance and specifications of the manufacturer. Please read and follow the manufacturer's instructions.