

Designation: F1744 – 96(Reapproved 2008)^{ε1}

Standard Guide for Care and Handling of Stainless Steel Surgical Instruments¹

This standard is issued under the fixed designation F1744; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

ε¹ NOTE—Editorial changes were made throughout in June 2008.

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:²

F899 Specification for Wrought Stainless Steels for Surgical Instruments

F921 Terminology Relating to Hemostatic Forceps

F1026 Specification for General Workmanship and Performance Measurements of Hemostatic Forceps

F1078 Terminology for Surgical Scissors—Inserted and Non-Inserted Blades

F1079 Specification for Inserted and Noninserted Surgical Scissors

F1089 Test Method for Corrosion of Surgical Instruments

F1325 Specification for Stainless Steel Suture Needle Holders-General Workmanship Requirements and Corresponding Test Methods

3. General

3.1 Stainless Steel Types—The stainless steels most used are martensitic and austenitic types such as those in Specification F899. 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, and stannous chloride. Also avoid contact with potassium thiocyanate and potassium permanganate and limit contact with iodine solutions to periods of 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 the 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 Terminology F921 and Terminology F1078.
- 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

¹ This guide 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.

Current edition approved Feb. 1, 2008. Published March 2008. Originally approved in 1997. Last previous edition approved in 2002 as $F1744 - 96 (2002)^{e1}$ DOI: 10.1520/F1744 - 96R08E01.

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

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 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 lightweight 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 device 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 overall 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, the pressure of the delivered solution, and the pH of the detergent solution, and thus may require prior brushing.

- 5.3.1 Be familiar with equipment manufacturers' use and operating 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 the 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 the 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 Plated instruments should not be cleaned 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 $140^\circ F$ or 30 to $75^\circ C).$
- 5.4.5 Follow the 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 the 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, 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 lubrication, instruments should be inspected. Incompletely cleaned instruments should be recleaned, 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 the 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 F1026.
- 6.2 Scissors shall conform to the performance requirements in Specification F1079.
- 6.3 Suture needle holders shall conform to performance characteristics stated in Specification F1325.
- 6.4 Scalpel handles should be checked for fit when the blade is attached to the scalpel handle. If the fit is not snug, discard the handle.

Note 1—Test Method F1089 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 cost effective by limiting repairs. Routine maintenance by people familiar with instrument manufacture will limit costly repairs.