

IFU

INSTRUCTIONS FOR USE



Cleaning Guidelines for API Reusable Stainless Steel Surgical Instruments

1. RINSING

Immediately after surgery, rinse instruments with distilled water. Rinsing should remove all blood, body fluids and tissue. If distilled water is not available, rinse under warm (not hot) running water.

2. CLEANING

If not done immediately after rinsing, instruments should be submerged in a solution of water and neutral PH (7) detergent.

A. Ultrasonic Cleaning

- For micro and eye instruments, use manual cleaning (*See Step C Manual Cleaning*).
- Instruments should be processed in the cleaner for the full recommended cycle time (usually 5-10 minutes).
- Place instruments in open position into the ultrasonic cleaner. Make sure that "Sharps" (scissors, knives, osteotomes, etc.) blades do not touch other instruments.
- All instruments have to be fully submerged.
- Do not place dissimilar metals (stainless, copper, chrome plated, etc.) in the same cleaning cycle.
- Change solution frequently (at least as often as manufacturer recommends).
- Rinse instruments after ultrasonic cleaning with water to remove ultrasonic cleaning solution.

B. Automatic Washer Sterilizers

Follow manufacturer recommendations but make sure instruments are lubricated after last rinse cycle and before sterilization cycle.

C. Manual Cleaning

Most instrument manufacturers recommend ultrasonic cleaning as the best and most effective way to clean surgical instruments, particularly those with hinges, locks and other moving parts. If ultrasonic cleaning is not available, observe the following steps:

- C1.** Use stiff plastic cleaning brushes (nylon, etc.). **DO NOT** use steel wool or wire brushes except specially recommended stainless steel wire brushes for instruments such as bone files or on stained areas in knurled handles.
- C2.** Use only neutral PH (7) detergents because, if not rinsed off properly, low PH detergents will cause breakdown of stainless protective surface and black staining. High PH detergents will cause surface deposit of brown stain, which will also interfere with smooth operation of the instrument.
- C3.** Brush delicate instruments carefully and, if possible, handle them totally separate from general instruments.
- C4.** Make sure all instrument surfaces are visibly clean and free from stains and tissue. This is also a good time to inspect each instrument for proper function and condition. Check and make sure that:
 - Scissor blades glide smoothly all the way (they must not be loose when in closed position).
 - Test scissors by cutting into thin gauze. Three quarter of length of blade should cut all the way to the scissors tips and not hang up.
 - Forceps have properly aligned tips.
 - Hemostats and needle holders do not show light between the jaws, lock and unlock easily, and joints are not too loose. Check needle holders for wear on jaw surfaces.
 - Suction tubes are clean inside.
 - Retractors function properly.
 - Osteotomes and knives have sharp undamaged blades.
 - Test biopsy punches by cutting tissue paper. Punches should produce a clean cut-out without hanging or tearing.
- C5.** After scrubbing, rinse instruments thoroughly under running water. While rinsing, open and close scissors, hemostats, needle holders and other hinged instruments to make sure the hinge areas are rinsed out, as well as the outside of the instruments.

3. AFTER CLEANING

If instruments are to be stored, let them air dry and store them in a clean and dry environment.

4. AUTOCLAVING

If instruments are to be reused or autoclaved:

- A. Lubricate all instruments which have any “metal to metal” action such as scissors, hemostats, needle holders, self retaining retractors, etc. Recommended surgical lubricants such as Miltex Spray Lube No. MX-SL are best. **DO NOT** use WD-40 oil or other industrial lubricants.
- B. Put instruments up for autoclaving either individually or in sets.
 - **Individual instruments:** Disposable paper or plastic pouches are ideal. Make sure you use a wide enough pouch (4” or wider) for instruments with ratchet locks such as needle holders and hemostats so the instrument can be sterilized in an open (unlocked) position.
 - **Instrument Sets:** Unlock all instruments and sterilize them in an open position. Place heavy instruments on bottom of set (when two layers are required). **NEVER lock an instrument during autoclaving.** It will not be sterile as steam cannot reach the metal to metal surfaces. The instrument will develop cracks in hinge areas because of heat expansion during autoclaving cycle.

DO NOT overload autoclave chamber, as pockets may form that do not permit steam penetration. Place towel on bottom of pan to absorb excess moisture during autoclaving. This will reduce the chances of getting “wet packs”. Make sure the towels used in sterilization of instruments have no detergent residue and are neutral PH (7) if immersed in water. This can be a real problem as laundries frequently use inexpensive but high PH (9-13) detergents and do not properly rinse out or neutralize those detergents in the final wash/rinse cycle. Also, sometimes bleaches such as Clorox are added and are not neutralized.

CAUTION: At the end of the autoclave cycle (before the drying cycle) unlock autoclave door and open it no more than a crack (about $\frac{3}{4}$ ”). Then run dry cycle for the period recommended by the autoclave manufacture. Hospital grade autoclaves do not require the door to be open during the drying cycle and may remain closed.*

If the autoclave door is opened fully before the drying cycle, cold room air will rush into the chamber, causing condensation on the instruments. This will result in water stains on instruments and also cause wet packs.

PREVACUUM/SFPP STERILIZATION <i>(Recommended)</i>		GRAVITY STERILIZATION	
Unwrapped	132° C (270° F) 3 minutes 135° C (275° F) 3 minutes	Unwrapped	132° C (270° F) 3 minutes 135° C (275° F) 3 minutes
Wrapped	132° C (270° F) 4 minutes 135° C (275° F) 3 minutes	Wrapped	132° C (270° F) 15 minutes 135° C (275° F) 10 minutes

5. COLD STERILIZATION

Most cold sterilization solutions render instruments sterile only after a 10 hour immersion. This prolonged chemical action can be more detrimental to surgical instruments than the usual 20 minute autoclave cycle. If the instruments need to be “disinfected” only, cold sterilization is okay as disinfection will take place in only 10 minutes.

Be sure to keep in mind the difference between sterile and disinfected:

STERILE: An absolute term (no living organism survives) • **DISINFECTED:** Basically clean

Always use the proper sterilization/cleaning technique to render the instrument in the required condition for use.

WARNING: For instruments with Tungsten Carbide inserts (needle holders, scissors, tissue forceps), we **DO NOT** recommend use of solutions containing Benzyl Ammonium Chloride which will destroy the Tungsten Carbide inserts.

**Please refer to the manual of your sterilizer for complete instructions.*

6. SPOTS & STAINS

Following proper cleaning procedures will prevent most instruments from staining. Below is a list of possible stain causes and solutions. It is important to act quickly should a problem arise. Delay will only add to the problem and irreparable harm may result to the instruments.

A. Black Stains: The result of contact with ammonia. Many cleaning compounds contain ammonia that remain on the instruments unless they are rinsed well. Black stains may also be the result of amine deposits traced to the steam in autoclaves. Cleaning solutions often contain amines.

Solution: It is important to follow steam line cleaning procedures with a cycle of distilled water to remove all traces of amines from the autoclave system.

B. Blue Stains: Usually the result of cold sterilization techniques. It is important to prepare the solution according to exact proportions and to change the solution as recommended. Exceeding the manufacturer's time limit could result in serious instrument corrosion.

Solution: Use distilled water and a rust inhibitor in the solution to help slow discoloration.

C. Brown Stains: Detergents containing polyphosphates may dissolve copper elements in the sterilizer. This results in copper being deposited on the instruments by an electrolytic reaction. A dull brown stain is usually a build-up of oxidation on the surface.

Solution: Try a different detergent or check the quantities being used. The oxidation build-up will not harm the instrument and will protect it from serious corrosion.

D. Light or Dark Spots: The result of slow evaporation of water condensation on the instruments. What remains is a mineral deposit which is related to the mineral content of the water.

Solution: Try using distilled water for sterilizing procedures to help eliminate the formation of these residual spots. Also, it is very important to follow the autoclave operating instructions supplied by the manufacturer. Spots may result if the autoclave doors are opened before the steam is completely vented. Another cause of spotting can be traced to instrument wraps. During laundering procedures it is vital that detergents are thoroughly rinsed out and that the final rinse is prepared so that the wraps are left with a PH between 6.8 and 7.0.

E. Rust Deposits: Surgical grade stainless steel usually does not rust. What appears to be rust is usually residual organic matter in box locks or mineral deposits which have been baked onto the surface of the instrument. In localities where the water has a high iron content, an iron deposit will result in a metallic film on the instrument.

Solution: This is not the fault of the instrument and can be prevented with the use of distilled or demineralized water during the cleaning procedures.

WARNING

Note that certain compounds are highly corrosive to stainless steel and will severely damage instruments if they are exposed to them. ***Below is a list of substances that your instruments should never be exposed to if possible.***

CORROSIVE COMPOUNDS THAT DAMAGE STAINLESS STEEL

• Aqua Regia	• Calcium Chloride	• Ferrous Chloride	• Potassium Permanganate
• Aluminum Chloride	• Chlorinated Lime	• Hydrochloric Acid	• Sodium Hypochlorite
• Barium Chloride	• Dakin's Solution	• Iodine	• Stannous Chloride
• Bichloride of Mercury	• Dilute Sulphuric Acid	• Mercury Chloride	
• Carbolic Acid	• Ferric Chloride	• Potassium Thiocyanate	

Rinse instruments **IMMEDIATELY** if they have been exposed to any of these substances