

CARE FOR INSTRUMENTS

SURGERY INSTRUMENTS

DESCRIPTION/INTENDED USE

Surgery Instruments are provided in a reusable, non-sterile state. Cleaning and sterilizing should be done before the first use. These instruments are used in general surgical procedures.

REUSE

When sterilized in line with these proven recommendations, we guarantee that our items will last at least 50 sterilization cycles. Instrument life can be improved by handling instruments with caution.

CONTRAINDICATIONS

The instrument, if used other than the intended use may cause damage, lacerations or hemorrhage.

SAFETY TIPS

It is very important to check each surgical instrument for visible damage and wear, such as cracks, breaks or insulation defects, before each use.

Never use the instruments in the presence of flammable or explosive substances.

CLEANING & REPROCESSING INSTRUCTIONS

1) Holding/Presoak

It is important never to hold instruments in a dry container, which allows blood and debris to dry onto instrument surfaces and makes cleaning more difficult. If rinsing and decontamination processes are not immediately available, pre-treat instruments or hold them in a neutral pH (7) holding/presoak enzymatic solution after use but before actual cleaning. As soon as possible, rinse, disinfect and clean as follows:

2) Rinsing

Immediately after surgery, remove organic materials by rinsing instruments under warm (not hot) running water. Rinse should remove most blood, fluids and tissue. Do not process dissimilar metals (stainless steel, copper, chrome plated etc.) together. Always wear safety protection gear.

3) Cleaning

All blood, dried body fluids and tissue should be completely removed from the instruments prior to sterilization. Following cleaning methods should be utilized.

A) Soak: An enzymatic cleaner bath (soak), a solution of water and a neutral pH (7) detergent are effective in removing organic material from instruments. Use distilled (deminerIALIZED) water, if possible. Instruments should be fully submerged for at least 3-5 minutes. Do not let sharps instruments (scissors, knives, osteotomes, etc.) touch each other and also make sure dissimilar metal instruments are separated. Rinse instruments under running water to remove solutions. Change solutions frequently.

B) Ultrasonic Cleaning: 6-15 minutes, depending upon the complexity of the instrument. We recommend ultrasonic cleaning as the most effective way to clean surgical instruments, particularly those with hinges, box locks, and other moving parts. When selecting detergents or enzymatic cleaners, make sure they are compatible with the metal and other materials of the surgical instrument. The type of organic material you are trying to remove should also be considered. Proteases may be added to neutral pH (7) solutions to assist in removing organic material. Enzymes in these formulations attack proteins that make up a large portion of common soil (e.g., blood, pus). Cleaning solutions may also contain lipases (enzymes active on fats) and amylases (enzymes active on starches). Enzymatic cleaners are not disinfectants, and proteinaceous enzymes can be inactivated by germicides. No matter which cleaning solution you use, rinse thoroughly after cleaning. Adequate rinsing of the surgical instrument is required to remove cleaning residues to levels that will not interfere with the disinfection and sterilization processes.

After your instruments are cleaned, unlock or open to allow the instruments to air dry, prior to sterilization.

C) Manual Cleaning: If ultrasonic cleaning is not available, observe the following steps:

- Use stiff nylon cleaning brushes. Do not use steel wool or wire brushes except specially recommended stainless steel wire brushes for instrument serrated areas, bone files, burs or on stained areas of knurled handles.
- Use only neutral pH (7) detergents. If not rinsed off properly, low pH (acidic - less than 6) detergents break down the stainless protective surface resulting in pitting and/or black staining. High pH detergents (alkaline - more than 8) can cause brown stains (phosphate surface deposit) which can also interfere with the smooth operation of instruments. Most brown stains are not rust and are easily removed.
- Brush delicate instruments carefully, and if possible, separate them from general instruments.
- Make sure 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.

D) Automated Cleaning and Disinfection:

- Use only validated washer-disinfector machines with approved efficacy (e.g. CE mark or FDA clearance and validation according to ISO 15883). Follow the instructions of the washer/disinfector manufacturer.
- Use only low-foaming, free rinsing, neutral pH (7) cleaning solutions.
- Use only cleaning solutions that are labeled for use with medical devices or surgical instruments.
- If gross soiling is evident on the instrument, manual pre-cleaning with a neutral pH (7) cleaning solution may be necessary.
- Connect instruments with lumens/cannulations to irrigation ports, if available. Ensure lumens/cannulations are not horizontal, and blind holes incline downward to assist in cleaning and drainage.
- Open all hinged surgical instruments with handles, such as scissors, hemostats, and forceps to full extension.
- Place instruments with curved surfaces facing down to prevent pooling of water.
- Place the instruments in suitable carriers such that they are not subject to excessive movement or contact with other instruments.
- Place heavy instruments on the bottom of containers, taking care not to place delicate instruments or overload wash baskets.

Following processing, carefully inspect the instruments for cleanliness, any evidence of damage, and proper operation. If visible soil remains on the instrument following processing, the cleaning process should be repeated.

Use only *DELICATE* or *GENTLE* cycle when processing microsurgical instruments in automated washer.

For Washer-Disinfectors

- Pre-Rinsing: Conduct two cold rinses at <95°F (<35°C) to remove visible debris and prevent coagulation of residues.
- Detergent Cycle: Run a detergent cycle at 147.2°F -150.8°F (64°C-66°C) for up to 13 minutes using a lowfoaming, non-ionizing spray wash detergent cleaner (pH ≤ 12) to remove organic and inorganic residues.
- Rinse Cycle: Perform a rinse cycle at 122°F (50°C) using a neutral pH (7) low foaming, non-ionic surfactant with isopropyl alcohol to ensure complete detergent removal.
- Disinfection Cycle: Operate a disinfection cycle at a temperature between 140°F (60°C) and 212°F (100°C) for at least 1 minute to kill microorganisms. The disinfection cycle's duration may vary (typically 5-30 minutes) based on equipment type and disinfection requirements.
- Drying Cycle: Activate a 20 minutes drying cycle to remove residual moisture.

STERILIZATION

To prevent instruments from touching each other or other instruments, wrap each instrument in its own wrapper or place them in a container.

Steam: 30 minutes in a steam autoclave at 250°F (121°C). If a wrapping method is used, make certain that the instruments are individually wrapped or sealed in a sterile pack. Other metal objects should never come in contact with the insulating material of forceps and handles. Such points of contact may cause melting of the insulation. It is important that the longest drying cycle possible is employed to prevent buildup of moisture inside the instrument. We recommend a drying cycle of 30-45 minutes.

Flash: For 10 minutes, steam autoclave at 275°F (134°C). Minimum exposure time is 4 minutes. Average drying time is 8-15 minutes. Flash autoclaving will reduce the useful life of the instrument, particularly when it is constructed of various materials encompassing different expansion rates.

Pre-Vac: Use a steam autoclave at 270°F-273°F (132°C-135°C) for 4 minutes of exposure time and 20 minutes of drying time.

Chemical/Cold Sterilization: Most chemical/cold sterilization solutions render instruments sterile only after 10 hours immersion. This prolonged chemical action can be more detrimental than the usual 20 minutes autoclave cycle. If the instruments need to be "disinfected" only, a chemical/cold sterilization soak is acceptable, as disinfection will take approximately 10 minutes or more.

INSPECTION

Before and after each usage, the instrument should be inspected visually for evident physical damage such as discoloration, strange lumps, cuts, punctures, and nicks. Also inspect tips for damage, corrosion or misalignment condition.

STORAGE & HANDLING

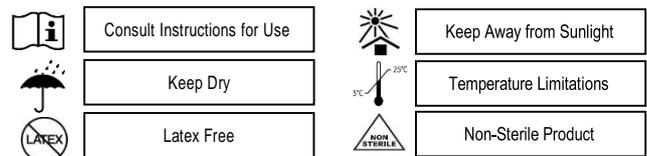
Surgery Instruments must be stored until use in a suitable sterilization container for steam sterilization according to the standards. The storage room must be dust-free with low microbiological contamination, dark and free of temperature fluctuations.

WARRANTY

These instruments come with a material and workmanship warranty. Should damage arise as a result of poor handling or usage, the guarantee is invalid. The use and reprocessing of these goods must be done with caution.

PRECAUTIONS

- Avoid using abrasives to scratch or scrub coated surfaces.
- In the sterilization tray, avoid overlapping the instruments.
- Do not use bleach.



The above is given as a guideline only.

Alira Medical Devices LLC accepts no responsibility or liability whatsoever relating to these guidelines.

