Automated Medical Products Corp.
Care and Handling of Iron Intern

Product Description
Surgical instruments are designed to perform specific functions such as cutting, grasping, clamping, dissecting, probing, retracting, draining, aspirating, suturing, or legating. Surgical instruments may also be used to facilitate the insertion of surgical implants. The use of an instrument for tasks other than those for which they are indicated may result in damaged or broken instruments.

Proper cleaning, handling and sterilization will ensure that the surgical instruments perform as intended and extend their useful life.

How Supplied
Iron Intern is supplied non-sterile and must be cleaned and sterilized prior to use according to the procedures outlined in this document.

Inspection

Before use, inspect the instrument for possible damage, wear or non-functioning parts. Carefully inspect the critical, inaccessible areas, joints and all moveable parts. Damaged or defective instruments should not be used or processed. Contact your local sales representative or Automated Medical Products Corp. for repair or replacement.

Precautions

Delicate surgical instruments require special handling to prevent damaging the tips. Use caution during cleaning and sterilization. A non-fibrous sponge should be used to wipe off all blood and debris.

Do not apply excessive stress or strain at joints: misuse will result in misalignment or cracks at the box locks or jaws.

Rongeurs and bone cutting forceps should only be used to cut bone, never wire or pin. Do not twist or apply excessive stress during use.

Wear appropriate protective gloves, eyewear and clothing when handling biologically contaminated instruments.

Instruments manufactured of different metals should be processed separately to avoid electrolytic action between the different metals.

Care and Handling

The procedures outlined below should be followed to ensure safe handling of biologically contaminated surgical instruments. All instruments must be sterilized before use.

1. PRE-CLEANING

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments.

Remove gross contaminants with a steady stream of lukewarm/cool water (below110). Rinse each instrument thoroughly. Do not use saline or chlorinated solutions.

Open jaws of hinged instruments for cleaning. Give special attention to joints and serrations. Instruments having more than one part to piece must be disassembled to expose all surfaces to the cleaning process. Retain all parts facilitate reassembly.

Separate sharps and delicate surgical instruments. Avoid processing instruments of different metallic composition together.

Keep ionized instruments separate from other stainless steel instruments to avoid scratches to and removal of the ionized coating.

2. Cleaning

Cleaning Precautions:

If appropriate, disassemble surgical instruments prior to cleaning and sterilization.

Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed two hours soaking in any solution.

Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.

Microsurgical, plated and delicate instruments should be cleaned chemically or manually and should not be processed in an ultrasonic cleaner. Carefully protect the tips of delicate microsurgical instruments throughout the entire cleaning and sterilization process.

To preserve the surface coating of ionized instruments, keep ionized instrument separate from other instruments and avoid mechanical cleaning and abrasive cleaners as these processes can scratch the surface and remove the surface coating

Color anodized aluminum instruments may lose their color through the use of conventional, mechanical treatment processes.

a. Manual Cleaning

Hand wash using a low-sudsy protein dissolving detergent. Follow manufacturers' directions regarding concentration, temperature, contact time and reuse

Totally immerse instruments during cleaning to prevent aerosolization.

Use a large syringe or pulsating water jet to thoroughly flush all channels and lumens with cleaning solution to remove debris.

Use appropriate-sized, soft nylon brushes to clean the instruments and their parts.

b. Ultrasonic and Mechanical Cleaning

For ultrasonic cleaning, follow manufacturer's specification for water level, concentration levels of cleaning agent and temperature.

When using mechanical washer, make sure all instruments stay properly in place and do not touch or overlap each other. Do not ionize instruments to come in contact with each other or other instruments.

Always follow the manufacturer's specifications for automatic washer-sterilizers and use a free-rinsing, low sudsy detergent with a neutral pH (6.0-8.5). Due to variations in water quality, the type of detergent and its concentration may adjustment for optimal disinfections and cleaning.

Rinsing

Rinse all instruments thoroughly with water demonized or distilled water to remove all traces of debris and cleansing agents.

Make sure all internal lumens and ratchets are thoroughly rinsed.

3. Decontamination

Note: The decontamination procedure does not sterilize the instruments. Refer to and process the instruments as outlined in the STERILIZATION section.

Select a proper product for high-level disinfect ion such as the glutaraldehyde-family of disinfectant products. Follow the cleaning agent's recommended directions regarding concentration, temperature contact time and solution reuse.

Do not use high acid (pH 4 or lower) or high alkaline (pH 10 or higher) products for disinfection, such as bleach and bichloride or mercury.

Completely immerse the instruments in the disinfecting solution, including all lumens and shafts. Force solution into all areas and cavities.

Thoroughly rinse with distilled water to remove all traces of disinfecting solution.

USE STERILE WATER ON THE FINAL RINSE

4. DRYING

Instruments must be thoroughly dried and all residual moisture must be removed before they are stored. Use a soft, absorbent towel/cloth to dry external surfaces. Compressed air or a 70% alcohol rinse may be used to aid the drying process.

5. LUBRICATION / ASSEMBLY

See Cleaning Instructions.

6. STERILIZATION

Instruments may be packaged in rigid containers, woven or nonwoven materials. Packing should ensure sterility of instruments until opened for use at the sterile field and permit removal of contents without contamination.

Sterilization of instruments may be accomplished by steam or ethylene oxide (Et0) gas.

Flash sterilization should only be used in emergency situations.

Surgical instruments may also be placed within an rigid sterilization container for processing under generally accepted hospital in- use conditions

The recommended sterilization parameters are as follows:

		Minimum Exposure Time:	
Sterilization Method:	Temp:	Wrapped	In a SterilContainer™ System
Pre-Vacuum	270-275 F (133-135° C) 250-254 F (122-124° C)	4 minutes 15-30 min.	4 minutes 40 minutes
Gravity	270-275 F (133-135° C)	10-25 min.	30 minutes
Ethylene Oxide (Et0)	125-130 F (52-55° C)	105 minutes with 12%EO-88% FREON; aeration of 6 hours	

The cycle times for wrapped product are based on the recommendations of the AAMI Guidelines for steam and ethylene oxide sterilization. Instruments have also been validated for sterility at the above recommended cycle parameters.

7. STORAGE

Store sterile surgical instruments on carts or shelving in a storage area free of dust, insects, chemical vapors and extreme changes in temperature and humidity Do not store in plastic bags.

References:

ANSI/AAMI ST46:1993. Good Hospital Practice: Steam sterilization and sterility assurance.

ANSI/AAMI ST41:1992. Good Hospital Practice: Ethylene oxide sterilization and sterility assurance.