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Cleaning & Sterilization Instructions

AMPCSI-US:030823

Important

CAUTION: Please read all the information contained in these instructions. Incorrect handling and care as well as misuse can lead to premature wear of surgical instruments. All persons using this device should be knowledgeable in the use and handling of surgical instruments, accessories, and related equipment. It is important to familiarize yourself with the Iron Intern® equipment and accessories, and the proper set-up and use of the system up before using in a clinical setting.



BEFORE INITIAL USE: Iron Intern® equipment and accessories are supplied non-sterile and must be cleaned, disinfected, and sterilized prior to initial use, and between each reuse, according to the processing instructions defined in this instruction sheet.



DO NOT USE SILICONE SPRAY, INSTRUMENT MILK, OR OTHER LUBRICANTS. Heating in a sterilizer makes lubricants coagulate, harden, and clog moving parts.



BEFORE EVERY USE, carefully inspect critical and inaccessible areas, joints, and all moveable parts for damage, wear, and proper functioning.

Do not use damaged or defective parts.

Do not perform repairs yourself. Contact your local sales representative or Automated Medical Products Corp. for repair or replacement.

Prior to any maintenance or processing, consult the Set-Up Instructions for Disassembly and Assembly procedures. Set-up videos are also available online on YouTube on the Iron Intern channel.

IN USE: Applying excessive pressure to the retractors during use may cause nerve and tissue damage to the patient.



Cleaning & Sterilization

The Cleaning Section of this instruction sheet applies to ALL instruments and sterilization trays from Automated Medical Products.

Limitations On Processing

Before every use, carefully inspect critical and inaccessible areas, joints, and all moveable parts for damage, wear, and proper functioning. Contact AMP for refurbishment.

Processing Instructions For Initial Use And Each Reuse

Initial Treatment at Point of Use

Hold the ARM and VERTICAL POLE firmly and loosen the WINGNUT on the 3/D SWINGER RAIL CLAMP.

Remove the Iron Intern® from the bedrail.



Remove the WINGNUTS, WRIST and ELBOW JOINTS.

NOTE: Removal of the WINGNUT exposes a WRIST CYLINDER. Keep this with the disassembled parts.



Rinse each part with water (below 110°F/43°C) to remove gross residue.

Keep all parts moist by soaking in warm water and commercially

available pre-soak product or enzymatic cleaner, compatible with stainless steel.

- Do not use saline or chlorinated solutions.
- Do not soak for more than two hours.

Preparation Before Cleaning: Disassembly

Disassemble all parts if not already done at Point of Use by loosening the WINGNUTS and separating each moveable part, including the WRIST CYLINDER that is exposed when the WINGNUT is removed.

Cleaning: Automated

When using a washer-disinfector, ensure all parts are secured in place and do not touch or overlap other parts.

Use a free-rinsing, low-suds detergent with a near neutral pH (7.0)

NOTE: Follow the washer-disinfector manufacturer's IFU for approved detergents, temperature, and cycle time.

Rinse all parts including channels with deionized or distilled water.

Cleaning: Manual

Immerse all parts in water during cleaning to prevent aerosolization.

Remove gross residue from all parts and channels using warm water, a pH neutral (7.0) enzymatic cleaning detergent, and a nylon bristled cleaning brush.

NOTE: Follow the detergent manufacturer's IFU for concentration, temperature, contact time, and reuse.

Flush all channels with water and cleaning solution.

Use a non-fibrous sponge to remove blood and debris.

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

Ultrasonic cleaners may be used for all disassembled parts.

NOTE: Follow the ultrasonic cleaner manufacturer's IFU for water level, concentration of cleaning agent, and temperature.

Visually inspect all parts for visible debris.

After cleaning, rinse all parts including channels with deionized or distilled water.

Disinfection: Washer-Disinfector

When using a washer-disinfector, ensure all parts are secured in place and do not touch or overlap other parts.

Use thermal disinfection.

Drying

Dry all Iron Intern® parts prior to packaging and storage.

Compressed air or a soft, non-linting, absorbent towel or cloth may be used on external surfaces.

Compressed air may be used for channels and holes.

Maintenance, Inspection and Testing

Visually inspect all parts for damage, discoloration, or rust.

Ensure all parts are visibly clean.

Assemble the ELBOW JOINTS with the WINGNUT and WRIST CYLINDER, leaving the assembly loose.

Do not apply excessive force or stress at the joints as this will result in misalignment or cracks.

Packaging

Package unassembled parts in rigid containers that may be wrapped or unwrapped, according to the rigid container manufacturer's IFU.

Sterilization: Steam Sterilization

US Recommended Sterilization Parameters

Sterilization Method	Temperature	Exposure Time
		Rigid Container
Pre-Vacuum	270-275°F	4 minutes
	250-254°F	40 minutes
Gravity	270-275°F	30 minutes

Storage

Store on carts or shelves in a clean, moisture-free area.

Liability

The instructions provided in this instruction sheet have been validated by Automated Medical Products, Corp., the manufacturer of the Iron Intern®, as being capable of preparing it for initial and subsequent reuse. It remains the responsibility of the processor to ensure that these processing steps, as actually performed using the processing facility's equipment, materials, and personnel, achieves the same result and results in a safely processed device. This requires verification, validation, or both, as well as routine monitoring of the process. Any deviation from these documented Cleaning & Sterilization Instructions is done at risk of the processing facility.

