EXTREMITY® MEDICAL

HAMMERFIX IP FUSION SYSTEM
NON-STERILE INSTRUMENT
PACKAGE INSERT

Extremity Medical instruments are designed to be used in surgical procedures in association with Extremity Medical implants.

INDICATIONS FOR USE
Surgical instruments for orthopedic use.

DESCRIPTION OF THE MEDICAL DEVICE:
NON-STERILE INSTRUMENTS – TO BE CLEANED AND STERILIZED BEFORE USE.

COMPOSITION
Surgical grade stainless steel (ASTM F899)
Radel® polyphenylsulfone (ASTM D6394)

LABEL SYMBOLS

	Catalog Number
	Lot Number
QTY	Quantity
	Consult instructions for use
	Non-Sterile
	Do Not Re-Use
	Manufacturer
	Date of Manufacture
	Prescription Use Only
	European Conformity Mark

CARE AND HANDLING
HammerFiX instruments are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be sterilized according to the standard hospital procedure. Refer to the STERILIZATION section for recommended parameters.

Limitations on Processing
Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

PRECAUTIONS
Warning: The following Extremity Medical instruments are intended for single use: Guidewires, cannulated drills, and cleaning brushes.

Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure safe handling of biologically contaminated instruments.

Single use instruments should not be re-used. Possible risks associated with re-use of single use devices include:

- Mechanical malfunction
- Transmission of infectious agents

Preparation for Cleaning
- If possible, it is recommended that devices be reprocessed promptly after use.
- Where instruments interface with other devices, disassemble prior to cleaning.
- Remove gross soil with a clean, disposable, absorbent Kimwipe or equivalent.
- Soak and/or rinse cannulated and multi-component assemblies with neutral or mild alkaline cleaning agent solution. Follow the cleaning agent manufacturer's instructions for correct exposure time, temperature, water quality, and concentration.
- Ensure debris are cleared from cannulations/lumens via cleaning brush or equivalent, where applicable.
- Repeat soak/rinse step followed by cleaning via cleaning brush or equivalent until visibly clean
- Extremity Medical devices must be cleaned separately from Extremity Medical instrument trays/cases.
- Instruments must be thoroughly cleaned.

Cleaning (Automated)
- Ensure all gross soil is removed from the device and that all preparation for cleaning steps are complete.
- For devices that have cannulations/lumens or present complexity, a preliminary manual cleaning may be required.
- Use a validated, properly maintained, and calibrated washer disinfector.
    - Equipment: Washer Disinfectant/ Decontaminator (Hydrim L110W) and detergent (HIP Cleaning Solution L110W) or equivalent.
- Place the device(s) in a washer basket or equivalent for loading into washer disinfector
    - Ensure that the devices are oriented in a way that allows devices to drain
    - Ensure device orientation aligns with manufacturer's orientation recommendations.
- It is recommended that a pH-neutral enzymatic solution is used. If using an alkaline solution, a neutralizer must be added. Please follow manufacturer's datasheet for concentration of solution, time of use, and temperature.
- Rinse devices using sterile or freshly prepared purified water
- Use automated drying cycle to dry devices or hand dry using absorbent, non-shedding cloth.
- The following cycle will be selected (at a minimum):

Prewash	Cold Water + Hot Water for 2 minutes (tap water)
Pulsed Enzyme	Hot water for 11 minutes (tap water) with Prolystica 2x Concentrate Enzymatic Pre-Soak and Cleaner (1/8oz of detergent/gallon of water)
Rinse	Purified water for 2 minutes
Thermal Disinfection	90°C for 5 minutes
Dry	High Temperature for 30 minutes

- Inspection: When unloading, visually inspect the devices for complete removal of any debris. If the device is not visually clean, repeat the automated cleaning cycle or use manual cleaning.
- Remove instruments from the Washer/Disinfector and wrap devices with sterilization wrap or place instrument in a sterilization pouch.

Cleaning (Manual)
Warning: Movable components and blind holes require particular attention during cleaning.

All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.

Manual Cleaning Instructions:

- Alcohol wipe the instruments.
- Bathe the instruments in an enzymatic solution for 20 minutes; where appropriate, the instrument shall be rotated and briskly moved in bath to promote flushing. Where appropriate, a large syringe or pulsating water jet may be used to thoroughly flush all channels and lumens with the solution.
- Scrub the instruments with a soft brush.
- Rinse the instruments in cold water.
- Submerge the samples in cleaning/disinfection solution and sonicate for 15 min at 40˚C (104˚F).
- Scrub the instruments with a soft brush.
- Rinse the instruments in deionized water until all traces of cleaning solution are removed.
- Pat dry the instruments with a clean, disposable, absorbent Kimwipe or equivalent.
- Visually inspect the instruments for complete removal of any debris. If the device is not visually clean, repeat manual cleaning.

Disinfection
Disinfection solution may be used in accordance with the label instructions.

If automated cleaning is employed, a final rinse at 60 ˚ C for 20 minutes may be used to affect thermal disinfection.

Inspection and Function Testing
All instruments: Visually inspect for damage and wear. Where instruments interface with other devices, inspect to ensure that the interface is not damaged.

Check for misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored or damaged instruments.

Packaging
Instruments may be loaded into dedicated instrument trays, or in general-purpose trays. Wrap the trays using an appropriate method.

Storage
Extremity Medical instruments must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

STERILIZATION/RESTERILIZATION PROCEDURE
In conformity with the requirements of standards ISO 17664, ISO 17665 and AAMI TIR12 the following sterilization procedures has been validated:

EU Cycle: pre-vacuumed autoclave
- Temperature : 134 °C
- Time : 3 minutes exposure
- Drying : 20 minutes

Cycle: pre-vacuumed autoclave (Use an FDA cleared wrap for sterilization)
- Temperature : 132 °C
- Time : 4 minutes exposure
- Drying : 20 minutes

Note: Only FDA-cleared sterilization barriers (e.g., wraps, pouches, or containers) should be used by the end-user for packaging terminally sterilized devices.

LIABILITY
Extremity Medical declines all responsibility in case of deviation from the above mentioned directions.

CUSTOMER SERVICE

For further information regarding the HammerFiX System or a copy of the HammerFiX System Surgical Technique Manual, please contact Extremity Medical, LLC or your local Extremity Medical Distributor.

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