EXTREMITY® MEDICAL

ADVANCED JOINT PREPARATION INSTRUMENTATION
PACKAGE INSERT

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

DESCRIPTION AND INTENDED USE:

Advanced Joint Preparation Instruments are designed to facilitate joint preparation and deformity correction prior to fusion. They are intended to improve the speed and efficiency for preparation of curved and straight joints in the forefoot, midfoot, hindfoot, and ankle.

MATERIAL

The Advanced Joint Preparation Instruments are made primarily of surgical grade stainless steel (ASTM F138, F899, A564), Aluminum Alloy, Radel (ASTM D6394), and Delrin (ASTM D6778).

HOW SUPPLIED

Advanced Joint Preparation instruments are provided **non-sterile** and must be cleaned and sterilized prior to use according to the procedures outlined in this document.

CONTRAINDICATIONS

The Advanced Joint Preparation instruments should not be used in a patient who has currently, or who has a history of:

- Local or Systemic acute or chronic inflammation;
- Active infection or inflammation;
- Suspected or documented metal allergy or intolerance.

WARNINGS

For safe and effective use of the device, the surgeon should be familiar with the appropriate surgical technique for the device. In every case, accepted surgical practices should be followed in postoperative care. Patient sensitivity to device materials should be considered and assessed prior to surgery.

PRECAUTIONS

Joint preparation using the Advanced Joint Preparation Instruments should only be performed by experienced surgeons with specific training in the use of this System because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The following instruments are intended for single patient use: Guidewires, Wire Tacks, Saw Rasps, Distraction Guide, Seeker Tab, Joint Prep Cup Curette, Joint Prep Rasp and Fenestrating Drill. Single use devices should not be re-used. Possible risks associated with re-use of single use devices include:

- Mechanical malfunction
- Transmission of infectious agents

Handle sharp instruments with care.

IMPORTANT: The Guidewires included in the Advanced Joint Preparation Instrument System are not intended as implants. The Guidewires are only intended for use as instruments to hold other instruments/guides in place.

POSSIBLE ADVERSE EFFECTS

Pre-operatively, the patient should be made aware of the possible adverse effects of orthopedic surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:

- Pain or discomfort;
- Nerve or soft tissue damage;
- Necrosis, resorption, or fracture of the bone;
- Necrosis of the tissue or inadequate healing

These do not include all adverse effects, which can occur with surgery in general. General surgical risks should be explained to the patient prior to surgery.

CARE AND HANDLING

Advanced Joint Preparation 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 for instruments is normally determined by wear and damage due to use.

Point of Use

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 devices.

Reprocessing begins at the point of use, which includes initial cleaning measures to prevent drying of the soil and contaminants in and on the devices.

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:

- Thoroughly rinse instruments under running tap water to remove gross contamination
- 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.

Maintenance and Repair

Warning: The use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.

Warning: Do not attempt to repair any Extremity Medical instrument.

If your Extremity Medical instrument requires repair or maintenance, return the instrument in the Extremity Medical box or other sturdy box with adequate packaging material to protect the instrument. Send the packaged instrument to:

Extremity Medical, LLC
300 Interpace Parkway
Building A, 2nd Floor
Parsippany, NJ 07054
Attn: Extremity Medical Technical Services

Note: Instruments returned to Extremity Medical must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

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.

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

In conformity with the requirements of standards ISO 17664, ISO 17665 and AAMI TIR12 the following sterilization procedures have been validated:

	U.S. Cycle	EU Cycle
Sterilizer Type	Pre-Vacuum	Pre-Vacuum
Minimum Temp.	132˚C	134˚C
Exposure*	4 min	3 min
Dry Time	30 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 Advanced Joint Preparation Instruments or a copy of the Surgical Technique Manual, please contact Extremity Medical, LLC or your local Extremity Medical Distributor.

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