ADVANCED JOINT PREPARATION INSTRUMENTATION (STERILE)
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 of surgical grade stainless steel (ASTM F899, A564).

HOW SUPPLIED

Advanced Joint Preparation instruments are provided sterile. **Do not resterilize.**

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.

Joint preparation instruments are intended for single patient use. 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.

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.

DIRECTIONS FOR USE

Before using the Extremity Medical Advanced Joint Preparation Instrumentation System for the first time, the surgeon should be thoroughly familiar with the System specific Surgical Technique. Pre-operative planning by the surgeon should determine the type of instrument(s) required.

For complete instructions regarding the proper use and application of all Extremity Medical instruments, please refer to the System specific Surgical Technique Manual.

CARE, HANDLING, AND STORAGE

Advanced Joint Preparation instruments are provided sterile and should be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

Do not use if the box is ripped or damaged. Report and return any damaged or opened instruments to the Extremity Medical Sales representative.

Discard if open but unused. Do not use after expiration date.

DISPOSAL

The disposal of sharp or cutting instruments must be carried out with care to prevent all risks of physical harm to users. Devices should be disposed of according to hospital protocol.

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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