

Instructions for Use

Dev4 TrapEZ™

Description

The Dev4 TrapEZ™ is provided as a sterile single use kit in one configuration. Each kit contains a sterile TrapEZ™ small bone extraction tool.

Intended Use

The Dev4 TrapEZ™ is intended for use in removal of the small bones in the hand.

Indications for Use

The Dev4 TrapEZ™ is indicated for:

- Thumb CMC arthroplasty
- Limited wrist fusions
- Proximal Row Carpectomy
- Pisiform excision
- Distal scaphoid excision

Contraindications

- Active infection
- Conditions that limit the patient's ability or willingness to follow postoperative instructions

Instructions for Use

- Apply downward pressure allowing the TrapEZ™ tool tip to create a pilot hole in the bone you are removing.
- While applying downward pressure rotate tool clockwise until adequate thread insertion depth has secured the TrapEZ™ tool.
- With the TrapEZ™ tool secure within the bone you are removing, TrapEZ™ can be used as a fulcrum or joystick allowing safer access to key structures aiding in bone removal.

Warnings

- TrapEZ™ is a sterile single use device. Do not reuse.
- Do not sterilize or cold soak devices for reuse.
- Do not expose to excessive heat.
- Knowledge of surgical techniques is extremely important.
- Pre- and intra-operative planning are always suggested.
- Patients should strictly follow post operative instructions.
- TrapEZ™ has not been evaluated for safety and compatibility in the MRI environment.
- TrapEZ™ is designed for single use only and must never be reprocessed for additional use. Risks of reuse or reprocessing include contamination and mechanical failure of components.

Packaging and Sterility

- The device supplied is sterile. Method of sterilization is Gamma irradiation.
- The device is intended for single (one time) use only.
- Do not use the device if packaging has been previously opened or damaged.

Material Specifications

- TrapEZ™, 17-4 S.S. and ABS



Catalog number



Batch code



Consult electronic instructions for use at www.dev-4.com

www.dev-4.com



Caution



Sterilized using Irradiation



Unique device identifier



Manufacturer



Prescription Use Only



Do not use if package is damaged and consult instructions for use



Do not re-use



Single sterile barrier system



Use by date



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