accufix SURGICAL
RESTORING ANATOMICAL FUNCTION

IFU INSERT FOR THE ACCU-JOINT HEMI IMPLANT SYSTEM

Please read these instructions for use and the corresponding surgical technique carefully before use. Ensure that you are familiar with the appropriate surgical technique.

DECRIPTION OF THE DEVICE

The Accu-Joint Hemi Implant consists of a hemi-arthroplasty metatarsal head or phalangeal base intended to resurface the metatarsophalangeal joint. These components are used for hemi-arthroplasty and are not used together to create a joint. The Accu-Joint Hemi Implant is designed with a self-tapping, self-drilling threaded shaft for intramedullary insertion. The implant has a driver pocket on the articular surface axially aligned with the threaded shaft. To accommodate a wide range of patient anatomies, various sizes are offered. The surface of the implants is highly polished for enhanced articulation.

MATERIAL

The device is made of Ti 6AL-4V ELI per ASTM F136. The instrumentation is made from various grades of stainless steel, titanium, and aluminum.

INDICATIONS

The Accu-Joint Hemi Implant, a hemi-arthroplasty metatarsal head or phalangeal base implant for the metatarsophalangeal (MTP) joint, is indicated for use in the treatment of patients with degenerative and post-traumatic arthritis in the MTP joint in the presence of good bone stock, along with the following clinical conditions: Hallux Limitus, Hallux Valgus, Hallux Rigidus, and an unstable or painful MTP joint. The Accu-Joint Hemi Implant is intended to be used with bone cement.

The metatarsal head and phalangeal base may not be used together at the same joint.

CONTRAINDICATIONS

- A general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure
- An active infection or a previous infection of the lower extremity that has not been quiescent for at least six months
- A local or systemic infection
- Significant deficiency in the vascular supply to the extremity
- Severe structural deficiency of the sub-chondral bone that may result in insufficient support for the prosthesis
- A condition of the toe which may lend itself to a more conservation procedure
- Severe compromise of the supporting muscles or ligaments about the toe
- Use of metatarsal head and phalangeal base together at the same joint
- Abnormal joint alignment beyond 8˚.

POSSIBLE COMPLICATIONS

Possible complications specific to the device may include:

- Implant breakage, failure, or loosening
- Bone fracture
- Allergic reaction to implant materials

OTHER GENERAL COMPLICATIONS ASSOCIATED WITH ORTHOPEDIC SURGERY MAY INCLUDE

- Pain
- Revision surgery
- Bleeding
- Infection, early or late
- Tissue or nerve damage
- Scar formation

WARNINGS

- The metatarsal head and phalangeal base may not be used together at the same joint.
- Use of an inappropriately sized device in an area of high functional stresses may lead to implant fracture and failure.
- Evaluating the safety and compatibility of the device in the MR environment, the following concerns were determined: magnetically induced displacement force and torque, radio frequency (RF) heating and image artifacts.
- Prior to use, make sure that the instruments are in a perfect technical condition and sterile damaged instruments should not be reused. Systematically check the cutting edges of drilling and cutting tools for damage.
- Excessive contact pressure has to be avoided.
- It can lead to damage of the instruments' working part as well as blade breakouts. At the same time extreme heat is generated which increases the risk of thermal necrosis.
- Components of this system should not be used with components of any other system or manufacturer.
- Never use the instruments for other than their intended use.
- During the use of the rotary instruments, ensure a sufficient cooling and always respect the maximal rotation speed indication on the label. An insufficient cooling or an excessive rotation speed lead to the fouling of blades with fragments which leads to increased heat generation and at worst to irreversible damage to the bone (thermal necrosis). Moreover, the service life of the instruments will be reused.

MAINTAINING DEVICE EFFECTIVENESS

- The surgeon must exercise reasonable judgment when deciding which implant sizes to use for specific indications.
- The Accu-Joint Hemi Implant is not intended to endure excessive abnormal functional stresses.
- Failure to use dedicated, unique Accu-Joint Hemi Implant instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect Accu-Joint Hemi Implant instruments before and after each procedure to ensure they are in proper operating condition. Instruments which are faulty, damaged, or suspect should not be used. They should be replaced or sent to Accufix Surgical for disposition and repair.

Attention: Instructions for Use are in the Accu-Joint Hemi Implant Surgical Technique Guide

INSTRUCTIONS FOR USE, ACCU-JOINT HEMI IMPLANT – METATARSAL HEAD

1. Make a longitudinal incision at the dorsal aspect of the MTP joint cutting in the proximal direction from the proximal aspect of the metatarsal head extending the incision to the diaphysis of the proximal phalanx. Deepen the incision to the level of the MTP joint with a sharp and blunt dissection while avoiding the extensor tendon and retracting neurovascular structures. Perform a longitudinal capsulotomy to expose the joint. Resect all hypertrophic bone from both the metatarsal and phalangeal base. Free the metatarsal head from its attachments on the medial and lateral aspects.
2. After the head is resected, various sized trials will be placed over the exposed head surface until the appropriate size trial/implant is determined.
3. Hold the trial in place on the metatarsal head and inset the guide wire. Remove the trial and drive the guide wire into the bone.
4. Place the Reamer over the guide wire and ream off the damaged cartilage to prepare the bone end for the implant.
5. Drill the appropriately sized pilot hole. The Ø1.7mm Drill is used for the Ø9mm x 15mm, Ø10mm x 15mm, and Ø11mm x 15mm implants; the Ø2.7mm Drill is used for the Ø12mm x 20mm, Ø14mm x 20mm, Ø16mm x 20mm, Ø18mm x 20mm, and Ø20mm x 20mm implants.
6. Insert trial to ensure seating, alignment, and range of motion for the implant. Continue reaming if more decompression of joint is necessary. Remove guide wire. Initially drive the implant into the pilot hole by hand. Drive the implant into the bone until fully seated with the T6 driver.

INSTRUCTIONS FOR USE, ACCU-JOINT HEMI IMPLANT – PHALANGEAL BASE

1. Make a longitudinal incision at the dorsal aspect of the MTP joint cutting in the proximal direction from the proximal aspect of the metatarsal head extending the incision to the diaphysis of the proximal phalanx. Deepen the incision to the level of the MTP joint with a sharp and blunt dissection while avoiding the extensor tendon and retracting neurovascular structures. Perform a longitudinal capsulotomy to expose the joint. Resect all hypertrophic bone from both the metatarsal and phalangeal base. Free the phalangeal base from its attachments on the medial and lateral aspects.
2. After the base is resected, various sized trials will be placed over the exposed base surface until the appropriate size trial/implant is determined.
3. Hold the trial in place on the phalangeal base and inset the guide wire. Remove the trial and drive the guide wire into the bone.
4. Place the Reamer over the guide wire and ream off the damaged cartilage to prepare the bone end for the implant.
5. Drill the appropriately sized pilot hole. The Ø1.7mm Drill is used for the Ø8mm x 12mm, Ø9mm x 12mm, and Ø10mm x 12mm implants; the Ø2.7mm Drill is used for the Ø11mm x 15mm, Ø13mm x 15mm, Ø15mm x 15mm, Ø17mm x 15mm, and Ø19mm x 15mm implants.
6. Insert trial to ensure seating, alignment, and range of motion for the implant. Continue reaming if more decompression of joint is necessary. Remove guide wire. Initially drive the implant into the pilot hole by hand. Drive the implant into the bone until fully seated with the T6 driver.

CLEANING, CARE AND STERILIZATION OF NON- STERILE INSTRUMENTS

Devices supplied non-sterile must undergo an appropriate cleaning process before use (disassembled if necessary) and sterilized using a validated steam sterilization procedure.

CLEANING PROCEDURE

In accordance with AAMI TIR12, AAMI TIR30, ANSI/AAMI ST81 and ISO 17664 the following cleaning procedure has been validated:

MANUAL CLEANING PROCEDURE

STEP	INSTRUCTIONS
1	In case of cannulated instrument, using a cleaning tool, remove gross soil from the device lumen by inserting the wire and moving it back and forth a minimum of three (3) times.
2	Rinse soiled device under running, purified water (from one or any combination of the following processes: ultra-filter, RO, DI, and/or distilled) for a minimum of (1) minute. Use a syringe, pipette, or water jet to flush a minimum of 10 ml of water through the lumen in case of cannulated instruments. During rinsing, remove gross soil from the outer surfaces using a soft-bristled or clean, soft, lint-free cloth.
3	Prepare a neutral pH enzymatic cleaning solution per the manufacturer's instructions.
4	Fully immerse the device in the fresh, newly prepared enzymatic cleaning solution for a minimum of five (5) minutes.
5	Manually clean the device for a minimum of (1) minute in the freshly prepared neutral pH enzymatic solution. Use a syringe or pipette to flush the lumen with a minimum of 10 ml of the solution in case of cannulated instrument. Use a soft-bristled brush to remove soil and debris from the outer surfaces of the device.
6	Prepare a neutral pH enzymatic cleaning solution per the manufacturer's instructions.
7	Using an ultrasonic cleaner and the fresh, newly prepared enzymatic cleaning solution, fully immerse the device and sonicate the device for a minimum of ten (10) minutes.
8	Rinse device under deionized or distilled water for a minimum of (1) minute. Use a syringe, pipette, or water jet to flush the lumen with a minimum of 10 ml of water in case of cannulated instrument.
9	Gently wipe down the device components with a soft lint-free cloth. Remove residual water from the lumen using filtered compressed air or a syringe in case of cannulated instrument. Visually inspect the device, including the lumen of the in a well-lite area; it should be clean, dry, and residue-free.

STERILIZATION PROCEDURE

1. Implants and instruments are supplied non-sterile.
2. Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
3. The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
4. Instruments and implants may be loaded into dedicated trays or general-purpose sterilization trays for sterilization. Use standard medical grade FDA cleared steam sterilization wrap following AAMI double wrap method (AAMI ST79-2006).
5. Non-sterile devices should be sterilized by steam sterilization (autoclaving). For sterilization of Accu-Joint Hemi Implants and instruments, the following parameters should be used.

Tray System	
Pre-Vacuum Steam Sterilization	
Minimum Temperature:	270˚F (132˚C)
Time:	4 minutes
Dry Time:	20 minutes

CAUTION

- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged, or suspect Invasive instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.

MRI SAFTEY INFORMATION

The Accu-Joint Hemi Implant has NOT been evaluated for safety and compatibility in the MR environment. It has NOT been tested for heating migration or image artifact in the MR environment. The safety of the Accu-Joint Hemi Implant in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

KEY TO SYMBOLS AND ABREVATIONS THAT MAY BE MENTIONED ON THE DEVICE LABELING

SYMBOL	MEANING
REF	REFERENCE NUMBER
LOT	BATCH NUMBER
	DATE OF MANUFACTURE
	NON- STERILE
	CAUTION: SEE INSTRUCTIONS FOR USE

SYMBOL	MEANING
2	SINGLE USE ONLY; DO NOT REUSE
	NO NOT USE IF PACKING IS DAMAGED
	MANUFACTURE
Rx Only	USE IN ACCORDANCE WITH MEDICAL PRESCRIPTION ONLY

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