arthrosurface

Instructions for Use

Total Toe – Proximal Phalanx Articular Component

DESCRIPTION

The Arthrosurface Total Toe System consists of a metatarsal component and a phalangeal component designed for resurfacing the 1st metatarsal head and the base of the proximal phalanx. These two implants replace the metatarso-phalangeal joint by complete functional preservation of the joint and maintaining of the sesamoid complex.

The enclosed Phalangeal Fixation Component is to be used with an appropriate HemiCAP MTP metatarsal head resurfacing articular implant (sold separately).

MATERIALS

Proximal Phalanx Fixation Component:
Titanium Alloy (Ti-6AI-4V)
Proximal Phalanx Articular Inlay:
Ultra High Molecular Weight Polyethylene (UHMWPE)

Sold Separately
Metatarsal Head Articular Component:
Cobalt-Chromium Alloy (Co-Cr-Mo)
CP Ti Plasma Spray Coating applied

INDICATIONS FOR USE

The Arthrosurface Total Toe Resurfacing System is a two-piece implant that is intended to be used as prosthesis for the metatarso-phalangeal joint (MTP). The device is intended for cemented use only. Indications for use include:

- Painful degenerative metatarso-phalangeal joint change
- Hallus rigidus stage 3 and 4
- Hallux valgus and hallux rigidus
- Hallux limitus with painful arthrofibrosis
- Revisions after moderate proximal phalanx resection

Patient selection factors to be considered include:

- Need to obtain pain relief and improve function
- Patient age as a relative contraindication to an arthrodesis procedure and
- Patient's overall well-being, including ability and willingness to follow instructions and comply with activity restrictions

CONTRAINDICATIONS

Absolute contraindications include:

- Significant bone demineralization or inadequate bone stock
- Inadequate skin, musculotendinus or neurovascular system status
- Inflammatory or rheumatoid arthritis, infection, sepsis, and osteomyelitis
- Patients that have a known sensitivity to UHMWPE plymers typically used in prosthetic devices

Relative contraindications include:

- Uncooperative patient or patient incapable of following preoperative and postoperative instructions
- Osteoporosis
- Metabolic disorders which may impair the formation or healing of bone
- Infections at remote sites which may spread to the implant site
- Rapid joint destruction or bone resorption visible on roentgenogram
- Chronic instability or deficient soft tissues and other support structures
- Vascular or muscular insufficiency

WARNINGS AND PRECAUTIONS

- Improper selection, placement, positioning, alignment, and fixation of the implant components may reduce the service life of the prosthetic components.
- Incorrect sizing of the Proximal Phalanx implant could result in excessive loading of the affected toe joint.
- Inadequate preparation and cleaning of the implant components mating surfaces may result in improper

fixation of the device. Improper handling of the implants can produce scratches, nicks or dents that may have adverse clinical effects on mating joint surfaces. Do not modify implants. The surgeon shall be thoroughly familiar with the implants, instruments, and surgical technique prior to performing surgery.

- Accepted practices in post operative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to post operative instructions and activity restrictions.
- Excessive activity, impact, and weight gain have been implicated in the reduction of the benefit and service life of prosthetic devices.
- Arthrosurface implants are intended to be fitted and installed with the appropriate Arthrosurface instrument set. Use of instruments from other systems may result in improper implant selection, fitting, and placement, which could result in implant failure or poor clinical outcome. The Arthrosurface Total Toe instrument sets should be regularly inspected for any signs of wear or damage.
- Do not reuse implants. Reuse of single use devices can increase the risk of patient infection and can compromise service life and other performance attributes of the device.
- The Arthrosurface Total Toe Implants have not been evaluated for safety and compatibility in the MR environment nor have they been tested for heating or migration in the MR environment.

POSSIBLE ADVERSE EFFECTS

- Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions. Particulate wear debris and mild tissue discoloration from metallic components have been noted in other prosthetic devices constructed of similar materials. Some types of wear debris have been associated with osteolysis and implant loosening.
- Infection or allergic reaction.
- Loosening, migration or loss of fixation of implant.

- Fatigue fracture of the implants as a result of bone resorption around the implant components.
- Wear and damage to the implant articulating surface.
- Intraoperative or postoperative bone fracture.
- Postoperative pain or incomplete resolution of peroperative symptoms.

STERILITY

The Arthrosurface Total Toe Proximal Phalanx components are provided STERILE. The Titanium Proximal Phalanx Fixation component is sterilized by exposure to gamma irradiation. The UHMWPE Articular Inlay component is H2O2 Gas Plasma Sterilized. Do not resterilize. Do not use if packaging is opened or damaged. Do not use if beyond expiration date. For Single Use Only.

The accompanying Proximal Phalanx Delivery Tool is provided STERILE. The device is sterilized by exposure to Ethylene Oxide gas. Do not resterilize. Do not use if packaging is opened or damaged. Do not use if beyond expiration date. For Single Use Only.

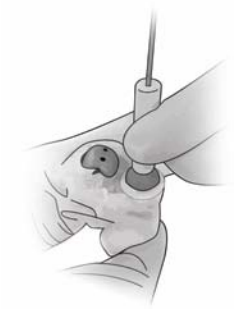
CAUTION

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

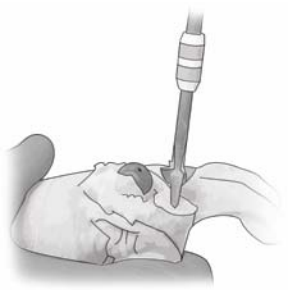
INSTRUCTIONS FOR USE

Implant Arthrosurface metatarsal head articular component according to Instructions for Use for that device.

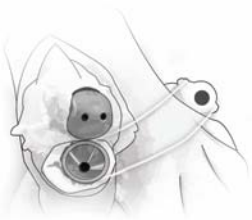
1. Using the Pin Drill Guide, place the 1.5mm Guide Pin central to the Phalangeal surface, in- line with the axis of the bone. Confirm correct Pin placement radiographically before proceeding.



2. Introduce the Reamer over the 1.5mm Guide Pin and advance under power until the Reamer depth indicator is flush to the phalangeal articular surface.



3. Introduce the Tap over the 1.5mm Guide Pin and advance by hand until the Tap depth indicator is flush to the phalangeal articular surface.
4. Place the 2 loops of the Retention Suture around the proximal end of the Fixation Component. Apply tension to the proximal end of the suture to mount the Fixation Post onto the Delivery Tool. Introduce over the 1.5mm Guide Pin, and advance using the Hexdriver until the distal surface of the Fixation component is fully seated in the prepared bone socket.



5. Use the Insert Trials to determine the most appropriate Phalangeal Insert for seating into the Fixation Component. Perform range of motion evaluation before proceeding.

6. Pass the proximal knotted end of the Retention Loop through the slot in the Hexdriver shaft. Rotate the Hexdriver to tension the sutures and apply force through the Delivery Tool to seat the Phalangeal Insert. Perform final range of motion evaluation.

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