arthrosurface

Instructions for Use

BaseCAP® MTP Hemiarthroplasty System

Description

The BaseCAP® MTP Hemiarthroplasty System incorporates an articular component and a cancellous taper post fixation component that mate together via a taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface.

The enclosed BaseCAP® Phalangeal Base implant is intended for hemiarthroplasty only. Do not use in conjunction with metallic metatarsal implant.

Materials

Phalangeal Base Implant:
Cobalt-Chromium Alloy (Co-Cr-Mo)
Taper Post Component:
Titanium Alloy (Ti-6Al-4V)

Indications

Hemiarthroplasty implant for the metatarsophalangeal joint for use in the treatment of patients with degenerative and post-traumatic arthritis in the metatarsal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus or hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is a single use implant intended to be used with bone cement.

Patient selection factors to be considered include:

1. Need to obtain pain relief and improve function.
2. Patient age as a potential for early-age-revision of total joint arthroplasty.
3. Patient overall well-being, including ability and willingness to follow instructions and comply with activity restrictions.
4. Failure of previous conservative treatment options in correcting deformity and achieving pain relief.

Contraindications

Absolute contraindications include:

1. Significant bone demineralization or inadequate bone stock.
2. Inadequate skin, musculotendinus or neurovascular system status
3. Inflammatory or rheumatoid arthritis, infection, sepsis, and osteomyelitis.
4. Patients that have a known sensitivity to Cobalt-Chrome alloys typically used in prosthetic devices.

Relative contraindications include:

1. Uncooperative patient or patient incapable of following preoperative and postoperative instructions.
2. Metabolic disorders which may impair the formation or healing of bone.
3. Infections at remote sites which may spread to the implant site.
4. Rapid joint destruction or bone resorption visible on roentgenogram.
5. Chronic instability or deficient soft tissues and other support structures.
6. 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. 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.

When placing implant, carefully trim articular cartilage debris around margin of implant. Remove bone particles and lavage thoroughly.

To ensure mechanical interlock of the Taper Post and implant, carefully clean Taper Post taper with provided instruments. All drilling or reaming should be done at slowest speeds possible with vigorous lavage to minimize heat effects to adjacent bone and cartilage tissues.

Excessive activity, impact, and weight gain have been implicated in the reduction of the benefit and service life of prosthetic devices.

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.

These implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. Their safety in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Possible Adverse Effects

These implants are intended to be fitted and installed with the associated instruments. 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 instruments should be regularly inspected for any signs of wear or damage.

Surgeon or Physician should discuss general risks and potential complications associated with this and any

surgical procedure with the patient prior to patient consent.

Possible Adverse Effects

1. 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.
2. Infection or allergic reaction.
3. Loosening, migration or loss of fixation of implant.
4. Fretting and crevice corrosion can occur at the interface between the implant components.
5. Fatigue fracture of the implants as a result of bone resorption around the implant components.
6. Wear and damage to the implant articulating surface.
7. Wear and damage to the adjacent and opposed articular cartilage surfaces or soft tissue support structures.
8. Intraoperative or postoperative bone fracture.
9. Postoperative pain or incomplete resolution of preoperative symptoms.
10. Periarticular calcification or ossification, with or without impediment of joint mobility.
11. Incomplete range of motion due to improper selection or positioning of components.
12. Transient nerve palsy.
13. Embolism.

Sterility

Implants and single-use disposable instruments are provided STERILE. Metallic implant components are sterilized by exposure to gamma radiation. Do not resterilize. Do not use components if packaging is

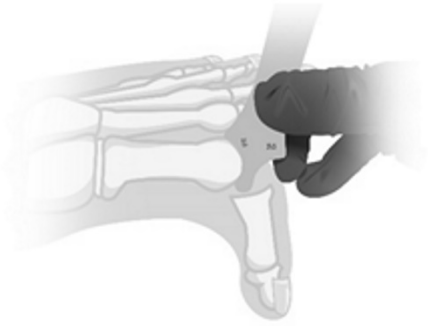
opened or damaged. Do not use components if beyond expiration date. Do not reuse implants or single-use disposable instruments. Reuse of these devices can increase the risk of patient infection and can compromise service life and other performance attributes of the device(s).

Caution

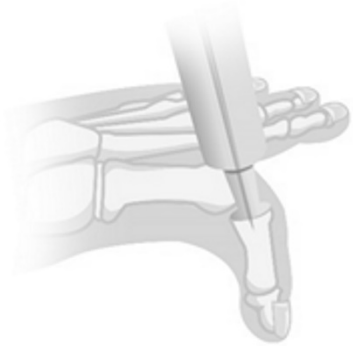
United States Federal Law restricts this device to sale by or on the order of a physician.

Instructions for Use

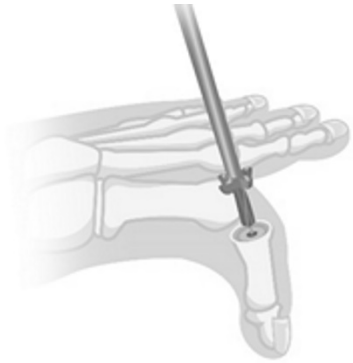
1. Measure the metatarsal head curvature using the **Measuring Template**. Use a matched curve **Phalangeal Base Implant** for final placement. Note: The implants are available in four different curvatures.



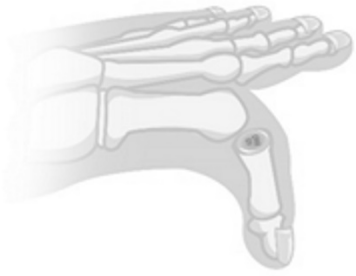
2. Using the **Pin Drill Guide**, place the **1.5 mm Guide Pin** central to the Phalangeal surface, in-line with the axis of the bone. Confirm correct Pin placement radiographically before proceeding.



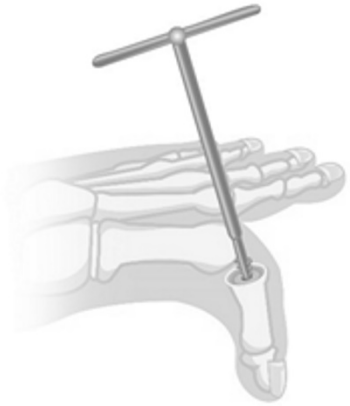
3. Introduce the **Reamer** over the **1.5 mm Guide Pin** and advance under power until the **Reamer** proximal surface is flush with the phalangeal articular surface.



4. Place the **Fixation Trial** component in the reamed bone. Ream deeper if joint decompression is desired and check with the **Fixation Trial** to determine final position of implant placement.

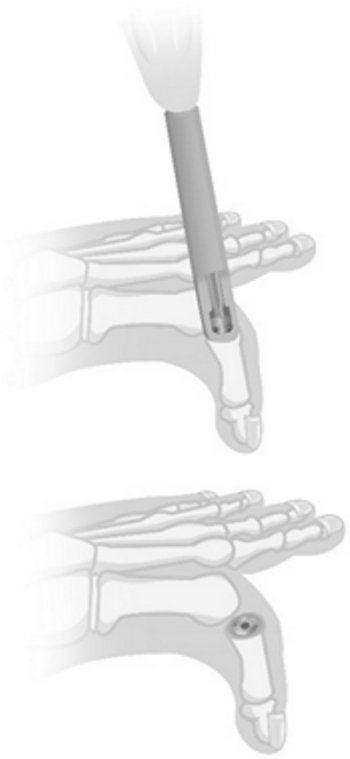


5. Introduce the **Tap** over the **1.5 mm Guide Pin** and advance by hand until the Tap depth indicator (laser line) is flush with the phalangeal articular surface. Insert bone cement into pilot hole in a retrograde fashion.

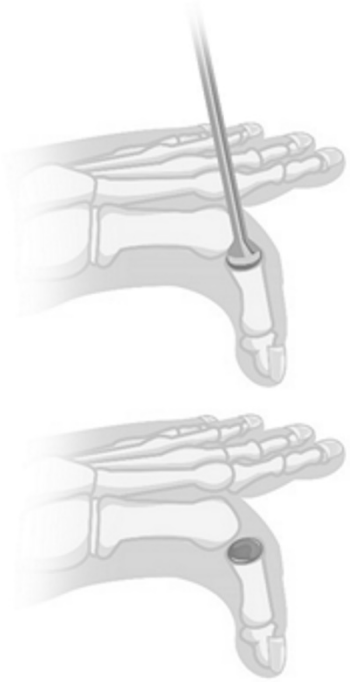


6. Introduce the **Taper Post** component with the aid of the **Screw Guide** over the **1.5 mm Guide Pin**, and advance using the **Hexdriver** until the driver handle contacts the proximal end of the **Screw**

Guide. Ensure that the taper of the **Taper Post** component is clean all around prior to proceeding.



7. Select the **Phalangeal Base Implant** based on Step 1 above and align the dorsal marking on the same with the dorsal surface of the phalangeal bone. Using the **Impactor** seat the **Phalangeal Base Implant** onto the **Taper Post** component. Perform final range of motion evaluation.



Provided by: Arthrosurface, Inc.
28 Forge Parkway, Franklin, MA 02038
tel +1 508 520 3003 ● fax +1 508 528 4604

arthrosurface®

www.arthrosurface.com

℞ ONLY

PN 4001-2008 REV B