Description

The BOSS™ Toe Fixation System incorporates a cancellous taper post component that mates via a morse taper interlock with an articular component to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface. This system is intended to improve stabilization in a first metatarsal bone that presents with a distal bone void when used in conjunction with the HemiCAP® Toe DF or as part of the Arthrosurface ToeMotion® total toe system.

Materials

Taper Post Component: Titanium Alloy (Ti-6Al-4V)

Sold Seperately

Metatarsal Articular Component: Cobalt-Chromium Alloy (Co-Cr-Mo)
Surface Coating: Titanium (CP Ti)

Indications

Hemiarthroplasty implant for the first metatarsophalangeal joint for use in the treatment of patients with degenerative and post-traumatic arthritis in the first 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 or without bone cement.

Patient selection factors to be considered include:

1. Need to obtain pain relief and improve function.
2. Patient age as a relative contraindication to an arthrodesis procedure.
3. Patient overall well-being, including ability and willingness to follow instructions and comply with activity restrictions.
4. Failure of previous conservative or other surgical treatment options in correcting deformity and achieving pain relief.

Contraindications

Absolute contraindications include:

1. Significant bone demineralization or inadequate bone stock.
2. Inadequate skin, musculotendinous or neurovascular system status.
3. Inflammatory or rheumatoid arthritis, infection, sepsis, and osteomyelitis.
4. Previous or current infection at or near the implantation site.

5. Patients that have a known allergy or sensititvity to titanium alloy, cobalt-chrome alloys, and/or stainless steel typically used in prosthetic devices.

Relative contraindications include:

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

Warnings

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 mapping articular surfaces, care should be taken to ensure that instruments are properly aligned and mated with taper in Taper Post. Visually confirm distal tip of contact probe is making contact on articular surfaces and free from any soft tissue structures to ensure accuracy. Use light pressure on contact probe to slightly indent articular surface at each measurement point, ensuring that the selected implant will be flush or slightly recessed with the articular surface.

When placing implant, carefully trim articular cartilage debris around margin of implant. Remove bone particles and lavage thoroughly. After seating the implant, avoid additional rotations of the Driver as the bone socket threads may strip.

To ensure mechanical interlock of the taper post and articular component, carefully clean the taper post's 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.

Accepted practices in postoperative care should be used. The patient is to be instructed and monitored to ensure compliance to postoperative 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.

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.

Precautions

These implants are intended to be fitted and installed with the appropriate 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 peroperative 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 irradiation. 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 single-use 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

As the manufacturer of this system, Arthrosurface, Inc. does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

It is the surgeon's responsibility to become familiar with this system's implant and instrument components. The basic technique steps describing the use of the instruments to implant the prosthetic components of this system are provided below:

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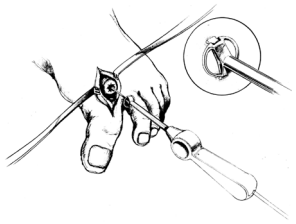
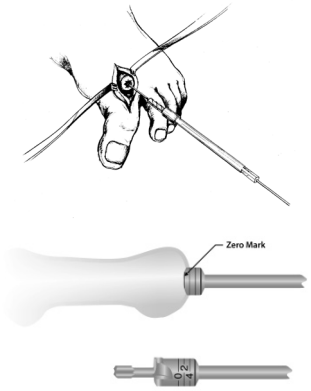
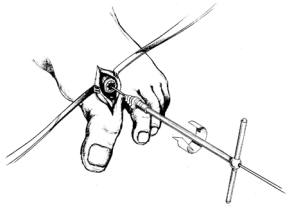
1. Use the **Drill Guide** to locate the axis normal to the articular surface and central to the metatarsal head. Place **Guide Pin** into a Cannulated Powered Drill and secure at the etch marking on the **Guide Pin**.
Advance **Guide Pin** into bone making sure that it is central to the metatarsal canal. Using fluoroscopy, confirm **Guide Pin** placement in line with the axis of the metatarsal.



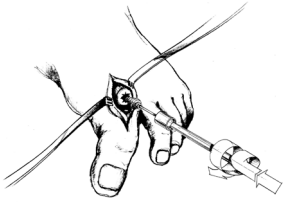
2. Place **BOSS Disposable Drill** over **Guide Pin** and drive until the depth indicator on the shoulder of the **BOSS Disposable Drill** is flush to the articular surface when viewed dorsally. (Use lavage during drilling to prevent possible tissue damage from heat effects.) Should the guide pin loosen, use the **BOSS Disposable Drill** to re-center the **Guide Pin** in the pilot hole and advance into bone.



3. Tap hole to etched depth mark on **Tap**. Insert bone cement into pilot hole if required.

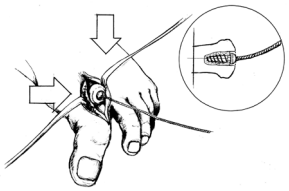


4. Place the **Driver** onto the **Taper Post** and advance the **Taper Post** until it is fully seated. ***Use caution to not overtighten and strip threads.***

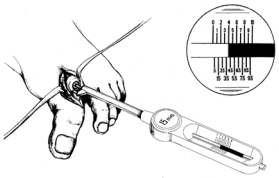


5. Clean taper in **Taper Post** with **Taper Cleaner**.

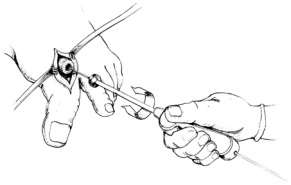
Place **Trial Cap** into **Taper Post** to confirm correct depth of **Taper Post**. The height of the **Trial Cap** must be flush or slightly below the existing articular cartilage surface to avoid the **Articular Component** from being placed proud or above the surface of the metatarsal head. Adjust depth if needed using the Driver to rotate the **Taper Post** (rotate clockwise to advance and counterclockwise to retract). Remove **Trial Cap**.



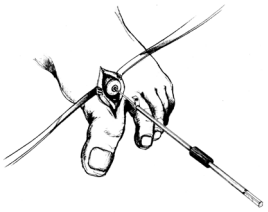
6. Place **Centering Shaft** into taper of **Taper Post**. Place **Contact Probe** over **Centering Shaft** and rotate around shaft. Use light pressure on the Contact Probe to ensure proper contact with the articular surface. Read **Contact Probe** to obtain offsets at indexing points and mark each of the identified offsets on the appropriate Sizing Card. Select appropriate **Articular Component** using Sizing Card.



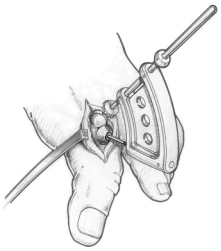
7. Remove **Centering Shaft** and replace with **Guide Pin**. Advance **Circle Cutter** onto the articular surface by twisting the **Circle Cutter** back and forth avoiding any bending of the **Guide Pin**.



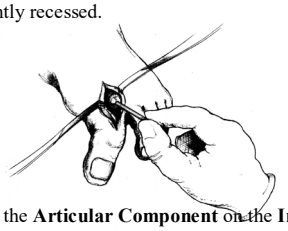
8. Choose the appropriate **Surface Reamer** based on the offsets. Drive **Surface Reamer** over **Guide Pin** until it contacts the top surface on **Taper Post**. (Use lavage during drilling to prevent possible tissue damage from heat effects.) Make sure not to bend the **Guide Pin** during drilling as it may result in **Articular Component** malalignment.



9. Place the appropriately sized **Dorsal Reamer Guide** into the taper of the **Taper Post**. Advance **Dorsal Reamer** to the depth stop.

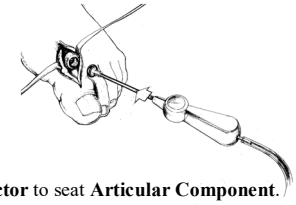


10. Place the **Sizing Trial** into the defect that matches the offset profile of the chosen **Articular Component**. Confirm the fit of the **Sizing Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed.

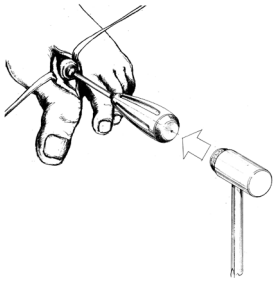


11. Before placing the **Articular Component** on the **Implant Holder** make sure that sufficient suction is present to hold the device on the

distal suction cup. Align the **Articular Component** on the **Implant Holder**.



12. Use a slight tap on the **Impactor** to seat **Articular Component**. Progressively tap the **Impactor** until the **Articular Component** is firmly seated on the bone.



Revision Procedure

In the event that the BOSS™ Toe Fixation System requires removal, please follow these steps.

1. Remove any tissue directly on and up to the outer edge of the device. Choose the appropriate diameter **Revision Cutter** and place into a Cannulated Powered Drill. Advance the **Revision Cutter** counterclockwise through the tissue surrounding the outer edge of the device until all the tissue is removed and the full depth of the outer rim of the device is completely exposed.
2. Place the appropriate diameter **Revision Driver** over the device and then impact the **Revision Driver** until it locks around the edge of the implant. Twist the **Revision Driver** in a counterclockwise rotation until the implant is removed.
3. If necessary, use an osteotome or rongeur to remove the tissue surrounding the head of the Taper Post until sufficient space is available to insert the **Female Hex Driver**. Insert the Driver onto the Taper Post and then rotate counterclockwise to remove the Taper Post from the bone.

Manufacturer

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Gamma Irradiated

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Great Toe BOSS Instructions for Use