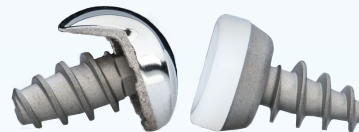




HemiCAP® Toe DF & ToeMotion® Implant Systems



Both **The ToeMotion® Total Toe Restoration System** & **The HemiCAP Toe DF System** restore mobility and maintains native biomechanics. Fourth generation fixation components provide stable constructs on both sides of the joint.

Description

The Toe HemiCAP® DF Contoured Articular Prosthetic incorporates an articular component and a cancellous taper post component that mate together via a morse taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface.

Materials

Articular Resurfacing Component:	Cobalt-Chromium Alloy (Co-Cr-Mo)
Surface Coating:	Titanium (CPTi)
Taper Post:	Titanium Alloy (Ti-6Al-4V)
BOSS Fixation Component:	Titanium Alloy (Ti-6Al-4V)

Indications - US Only

Hemiarthroplasty implant for the 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 critical conditions: hallux valgus or hallux limitus, 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.

Indications – CE and Outside US

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:

- Need to obtain pain relief and improve function
- Patient age as a potential for early-age revision of total joint arthroplasty
- Patient overall well-being, including ability and willingness to follow instructions and comply with activity restrictions
- 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, musculotendinous 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

Description

The **Arthrosurface® ToeMotion® System** consists of a metatarsal component and a phalangeal component designed for arthroplasty of 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 DF MTP metatarsal head articular implant (sold separately).

Materials

Proximal Phalanx Fixation Component:	Titanium Alloy (Ti-6Al-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
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Indications

The **Arthrosurface ToeMotion® - Proximal Phalanx Implant** 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
- Hallux 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:

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, musculotendinous or neurovascular system status
3. Inflammatory or rheumatoid arthritis, infection, sepsis, and osteomyelitis
4. Patients that have a known sensitivity to UHMWPE polymers 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

Soft Tissue Dissection

The biomechanics of the toe joint are similar in some ways to the knee. The sesamoid bones, which are under the metatarsal head, are comparable to the patella. Due to this, care must be taken to address proper sesamoid function when performing a modular toe restoration arthroplasty.

The three keys to success are:

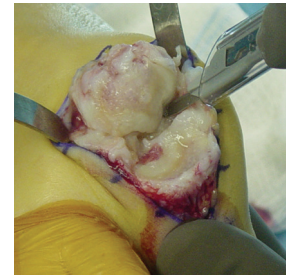
1. Proper joint alignment
2. Immediate rigid fixation of the components
3. Appropriate soft tissue releases

The soft tissue releases and proper component placement are performed by the surgeon while the rigid fixation is provided by the HemiCAP® implants.

The soft tissue contractures determine which releases need to be performed. In hallux rigidus, the majority of the contractures are on the plantar surface. For this reason, few patients if any, have an unstable first MTP joint after hemiarthroplasty. In fact, the opposite is usually true. Patients are more often stiff and contracted after receiving a hemi. One of the theories to explain hallux rigidus is that it begins with plantar contractures. The shortening of the soft tissues under the toe decreases the joint space and this leads to dorsal impaction of the joint, osteophyte development, loss of cartilage and finally arthritis. This is why in hallux rigidus, the cartilage loss starts on the metatarsal head and proceeds from superior to anterior. If the primary plantar contracture is not addressed then future outcomes may be compromised.

The soft tissue releases of the first met include the sesamoidal ligaments, collateral ligaments and plantar plate (fig 1). Essentially, all soft tissues are released to include the distal 3 cm of the metatarsal head (fig 2). The dissection is similar to the release of the medial structures when doing a total knee replacement for a varus knee. A curved osteotome or similar device is placed just proximal to the sesamoid articulation and the plantar plate is released from its insertion into the metatarsal (fig 3). Since the blood supply within the bone is not disrupted with an osteotomy, the risk of avascular necrosis should not been an issue with this technique. Based on almost 500 cases, Carl Hasselman, MD, reports that instability after the procedure has not been an issue as long as subperiosteal stripping is performed.

The soft tissues of the proximal phalangeal base are released similar to the sesamoid dissection, with the collateral ligaments being freed directly off the periosteum. The plantar plate and flexor hallucis brevis are released by sharp periosteal dissection. This can be done with a knife or curved osteotome (fig 4). The key is that the release should NOT cut the flexor hallucis brevis but rather dissect it sharply off the bone. In the knee, this would be the very much like the release of the hamstrings for a flexion contracture of the knee during TKR (fig 5). By dissecting the flexor brevis off the bone rather than transecting the tendon, flexion strength can be maintained and range of motion improved.



(Fig. 1) Soft tissue release of the metatarsal head to include the sesamoidal ligaments and collateral ligaments.



(Fig. 2) Complete release of all soft tissues off the metatarsal head from the joint to 3 cm proximal to the joint line.



(Fig. 3) Use of a curved osteotome to release the plantar plate proximal to the sesamoid articulation with the metatarsal head.

Rigid fixation of the device into bone is another key to success. The immediate fixation of ToeMotion® allows for aggressive early range of motion, a key advantage in any arthroplasty procedure, no matter which joint. There are several metatarsal head resurfacing implants on the market but most are pressfit and rely on bony ingrowth to support fixation which requires approximately six to ten weeks. If excessive forces are transmitted across the implant during this time, a fibrous fixation will occur rather than a bony incorporation of the implant. This may lead to early component failure and migration, which is why the threaded fixation is so important.

Although implant arthroplasty of the first MTP is still in its infancy, there was a time not long ago when hip, knee and ankle arthroplasties were considered experimental. As fusions are not without complications, it presents a need to find options that allow pain relief without sacrificing joint motion. A stepwise approach, proper soft tissue releases, immediate implant fixation, surface restoration and early rehabilitation are all key to long term implant survival and patient satisfaction.

Surgical Approach

The patient is placed supine on the operating table, with the operative extremity in a well-padded position. The procedure can be done with either a regional popliteal block and a calf tourniquet or an ankle block with an Esmarch bandage wrapped around the ankle. A dorsal incision is made centered over the MTP joint and slightly medial to the extensor hallucis tendon. The subcutaneous tissues are spread gently to expose the dorsal joint capsule, with care being taken to protect the dorsomedial cutaneous nerve. The extensor hallucis longus tendon is freed from the capsule and retracted laterally to keep the tendon within its sheath. A longitudinal arthrotomy is made along the medial border of the joint, and the capsule is elevated off the bone. A complete release of the collateral ligaments, sesamoid suspension ligaments, and capsule should be made so that the entire joint, including the sesamoids, is easily visualized. It is very important to visualize the articular edge of the sesamoid Christi on the metatarsal head because this is the landmark for placement and sizing of the implant. In advanced hallux rigidus, the sesamoids and flexor hallucis brevis will have fibrotic adhesions to the metatarsal head that will limit dorsiflexion postoperatively. A curved osteotome, freer or McGlammary elevator can be used to release these plantar adhesions. Care should be taken to avoid damage to the metatarsal-sesamoid articulation. A cheilectomy is not performed at this time to avoid overresection of bone.



(Fig. 4) Subperiosteal dissection of the flexor digitorum brevis and plantar plate from the proximal phalangeal base using a knife.



(Fig. 5) Further dissection of the flexor digitorum brevis and plantar plate from the proximal phalangeal base using a curved osteotome.

Hasselman C, Shields N. Resurfacing of the First Metatarsal Head in the Treatment of Hallux Rigidus. Techniques in Foot & Ankle Surgery 7(1):31–40, 2008

Surgical Technique

HemiCAP DF® Articular Component

1. Use the **Drill Guide** to locate the axis normal to the articular surface and central to the defect. The plantar foot of the **Drill Guide** should be seated at or just below the crista. Place the **Guide Pin** into a cannulated pin driver and secure at the etch marking on the **Guide Pin**. Advance the **Guide Pin** into the bone. Confirm correct **Guide Pin** placement radiographically before proceeding.



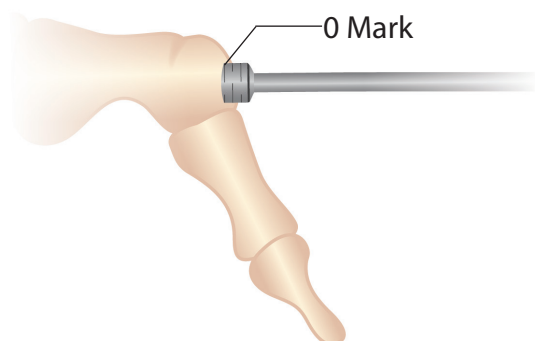
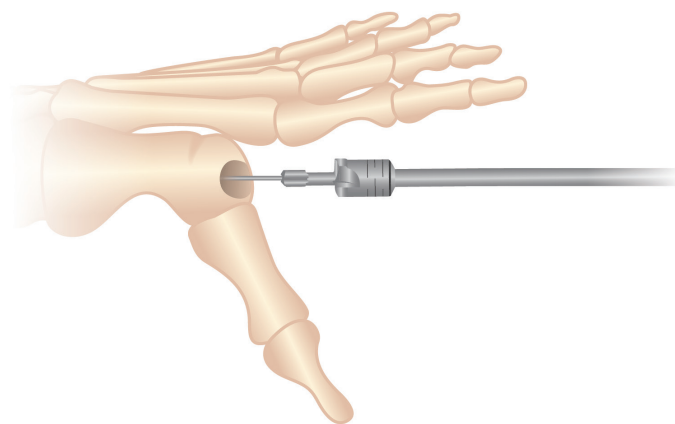
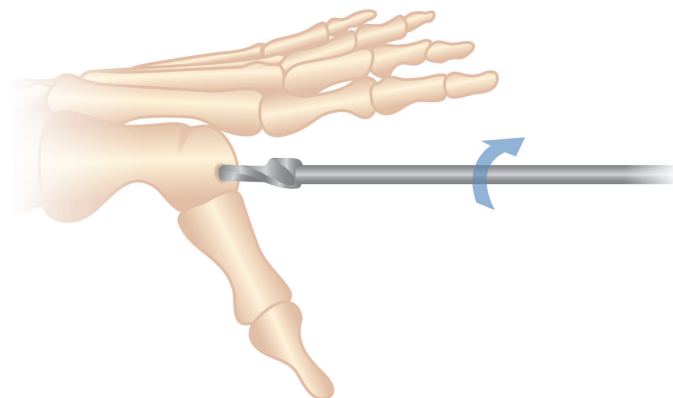
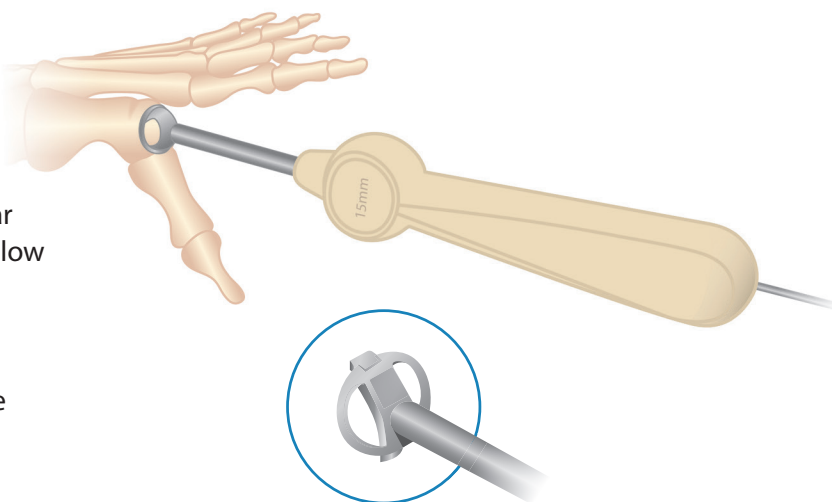
Drill Guide

2. Place the **Step Drill** over the **Guide Pin** and drill until the proximal shoulder of the **Step Drill** is flush to the articular surface. Should the **Guide Pin** loosen, use the **Step Drill** to re-center the **Guide Pin** in the pilot hole and advance into the bone.

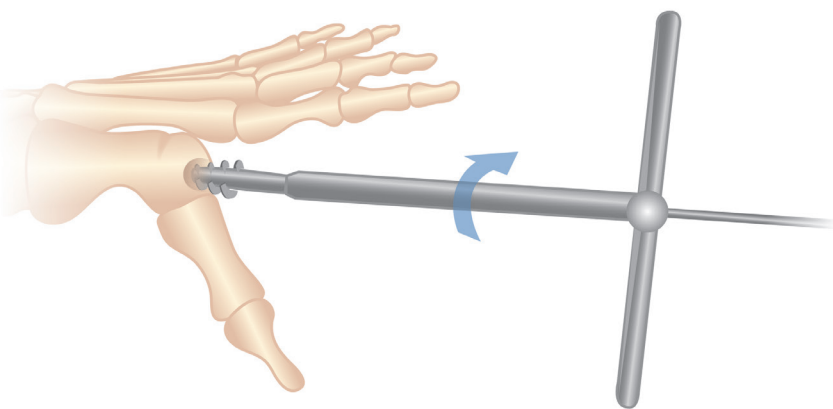


Step Drill

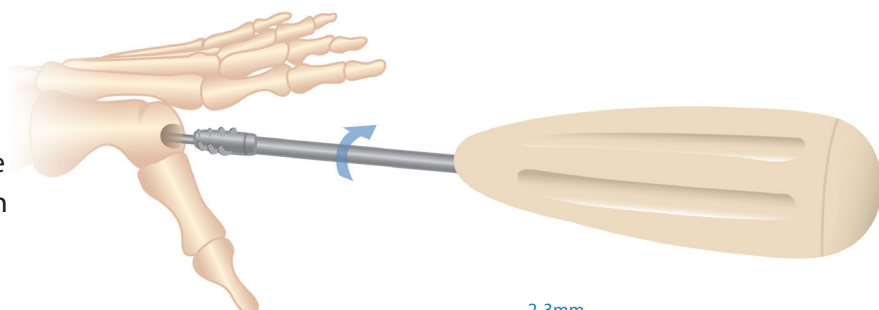
- 2.5 If addressing a distal bone void and utilizing the **BOSS™ Fixation Component**, Place **BOSS™ Disposable Drill** over **Guide Pin** and drive until the depth indicator on the shoulder of the **BOSS™ Disposable Drill** is flush to the articular surface when viewed dorsally. (Use lavage during drilling 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.



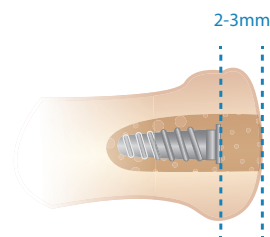
3. Tap the hole to the etched depth mark on the **Tap**. Based on the resistance felt during tapping, a decision can be reached as to whether or not bone cement will be needed.



4. Place the **Driver** into the **Taper Post** and advance the **Taper Post** until the line on the **Driver** is flush with the cartilage surface making sure that it is central to the defect.



*Note: It may be necessary to decompress the joint by advancing the **Driver** and **Taper Post** an additional 1/2 to 3/4 turn to create an additional 2 to 3mm of joint space, respectively. This will also compensate for the functional thickness of the **Proximal Phalynx Implant**.*

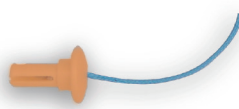


5. Clean the taper in the **Taper Post** with the **Taper Cleaner**. Place the **Trial Cap** into the **Taper Post** to confirm correct depth of the **Taper Post**. The height of the **Trial Cap** must be flush or slightly below the existing articular cartilage surface to avoid the **HemiCAP DF Articular Component** from being placed proud or above the surface of the defect. Adjust depth if needed using the **Driver** to rotate the **Taper Post**. Remove the **Trial Cap**.

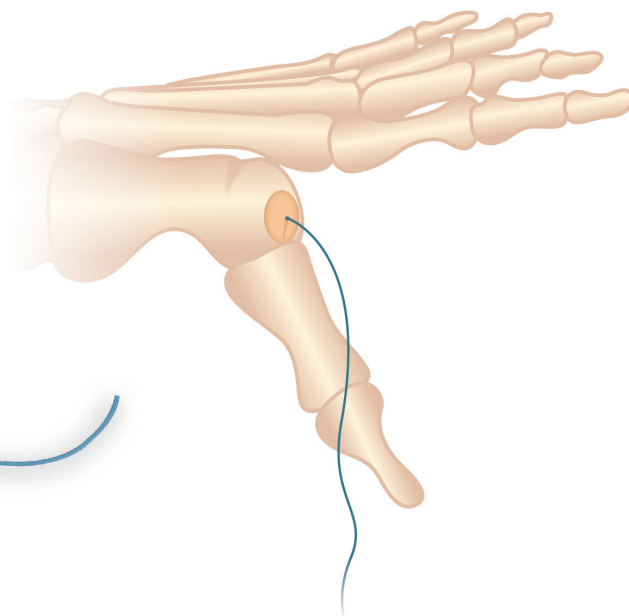
Note: If decompressing the joint, the next step can be skipped.



Taper Cleaner
(Located in Disposable Kit)



Trial Cap



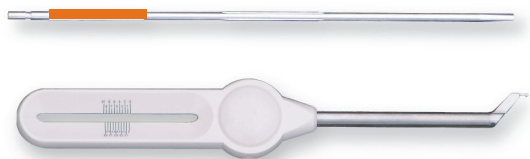
6. Place the **Centering Shaft** into the taper of the **Taper Post**. Place the **Contact Probe** over the **Centering Shaft** and rotate around the **Centering Shaft**. Use light pressure on the **Contact Probe** to ensure proper contact with the articular surface. Read the **Contact Probe** to obtain offsets at four indexing points and mark each of the identified offsets on the appropriate **Sizing Card**. The plantar offsets are best determined by placing the **Contact Probe** on either side of the crista – within the sesamoid grooves. Select the appropriate **DF Articular Component** using the **Sizing Card**.

arthrosurface
Toe DF

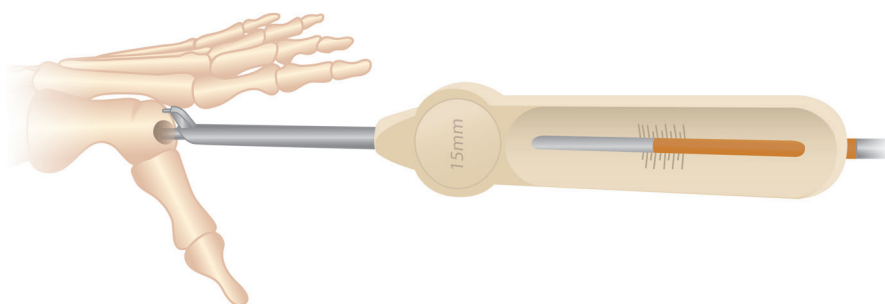
Sizing Card

1. Maximum SI _____
Maximum ML _____
2. Select 15mm HemiCAP® offset values
If no match is found, use the next highest offset value
 - 1.5 mm x 3.5 mm
 - 1.5 mm x 4.5 mm
 - 2.5 mm x 3.5 mm
 - 2.5 mm x 4.5 mm
3. Select Surface Reamer and Dorsal Reamer Size.
Choose the Surface Reamer and Dorsal Reamer that match the highest offset value.

Centering Shaft (colored end up)



Contact Probe

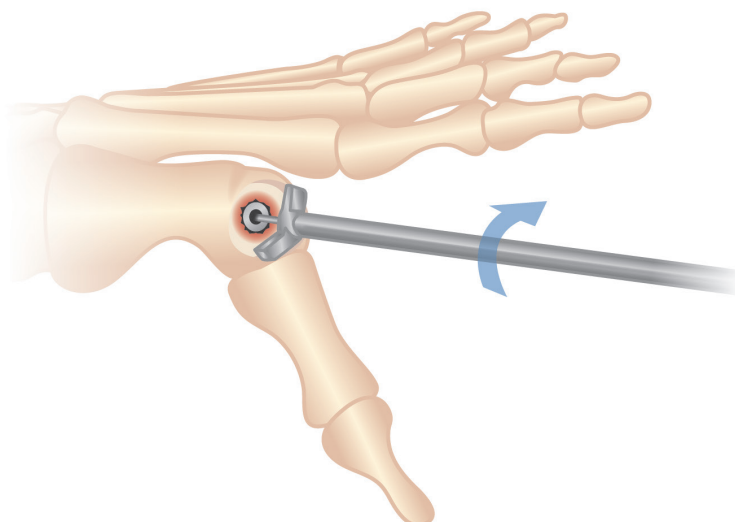


7. Choose the appropriate **Surface Reamer** based on the offsets. Drive the **Surface Reamer** over the **Guide Pin** until it contacts the top surface on the **Taper Post**.

*Note: If decompressing, start by reaming with the **3.5mm Surface Reamer** and use the matching **Trial** to confirm fit and range of motion. If greater range of motion is needed, advance to the **4.5mm Surface Reamer** and matching **Trial**.*

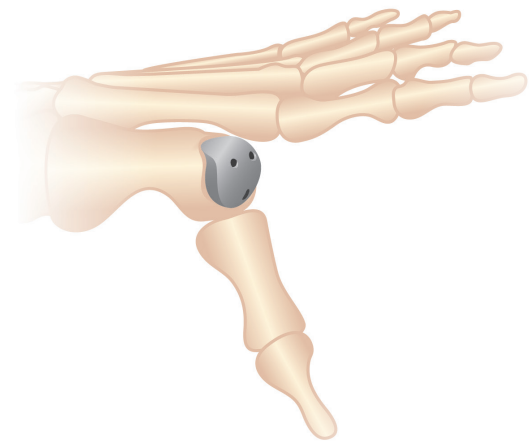
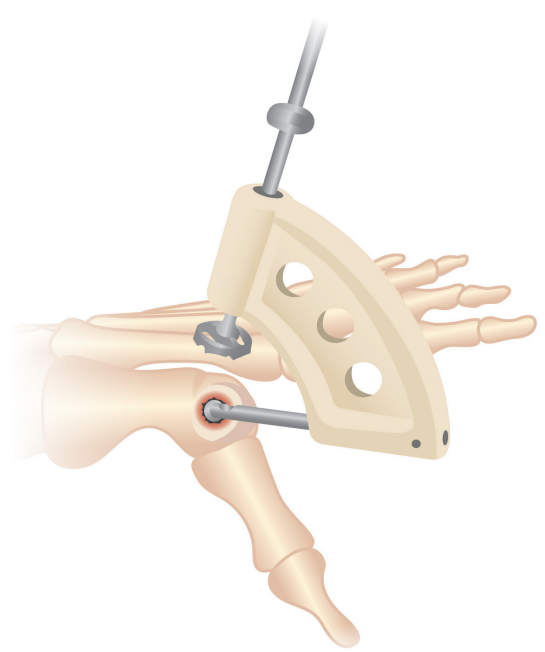


Surface Reamer



8. Place the appropriately sized **Dorsal Reamer Guide** into the taper of the **Taper Post**. The **Guide** should be oriented such that the **Dorsal Reamer** is at the 12 o'clock position. Advance the **Dorsal Reamer** to the depth stop. Once the **Dorsal Reamer** has advanced to the handle, immediately stop the cannulated powered drill and remove the **Dorsal Reamer Guide**.

Note: The 3.5mm Dorsal Reamer will provide a flatter curvature and the 4.5mm Dorsal Reamer will provide more curvature over the dorsal flange.

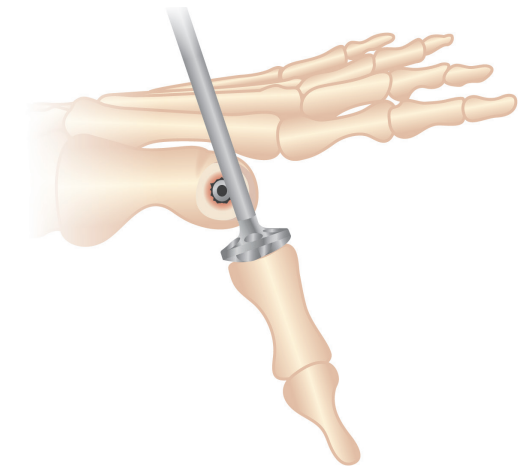


9. Place the **Sizing Trial** into the defect that matches the offset profile of the chosen **DF Articular Component**. Confirm the fit of the **Sizing Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed. It is critical to ensure that the toe can be articulated to 90 degrees dorsiflexion. Removal of all osteophytes and non-essential bone on the metatarsal head with adequate soft tissue and sesamoid releases will increase ROM.

IF PERFORMING THE TOEMOTION:

Proceed to Step 1 on page 11

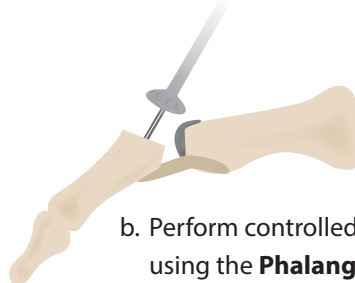
10. If using the **DF Articular Component** as hemi-arthroplasty, all osteophytes should be removed from the dorsal phalanx to maximize ROM. The **Phalangeal Reamer** can be utilized or a standard cheilectomy cut can be performed. If using the **DF Articular Component** and **Phalangeal Component** as a total joint replacement, defer osteophyte removal until **Phalangeal Component** is positioned.



Phalangeal Reamer



a. Place the **Guide Pin** into phalanx



b. Perform controlled cheilectomy using the **Phalangeal Reamer**

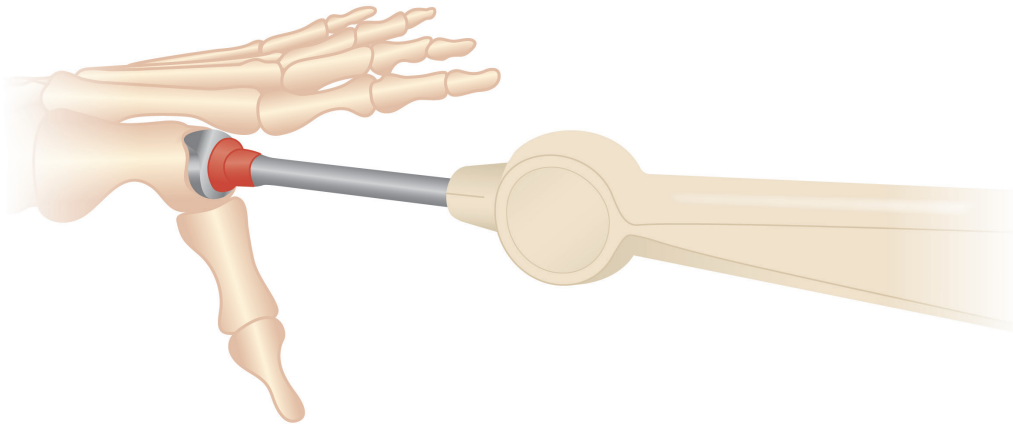


c. Final phalangeal cheilectomy

11. Before placing the **DF Articular Component** on the **Implant Holder**, make sure that sufficient suction is present to hold the device on the distal suction cup. Align the **DF Articular Component** on the **Implant Holder**. Orient the etch marks on the back of the **DF Articular Component** with the etch mark on the handle of the **Implant Holder**. Align the **DF Articular Component** with the appropriate offsets. Insert into taper of the **Taper Post**.



Implant Holder



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



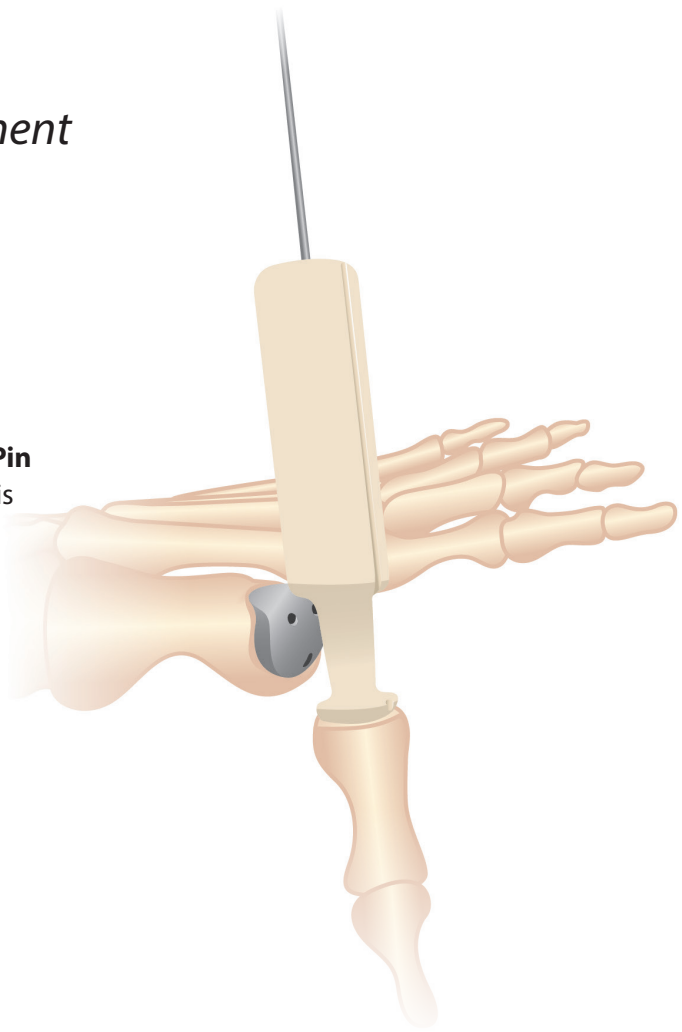
Impactor



Surgical Technique

Proximal Phalanx Articular Component

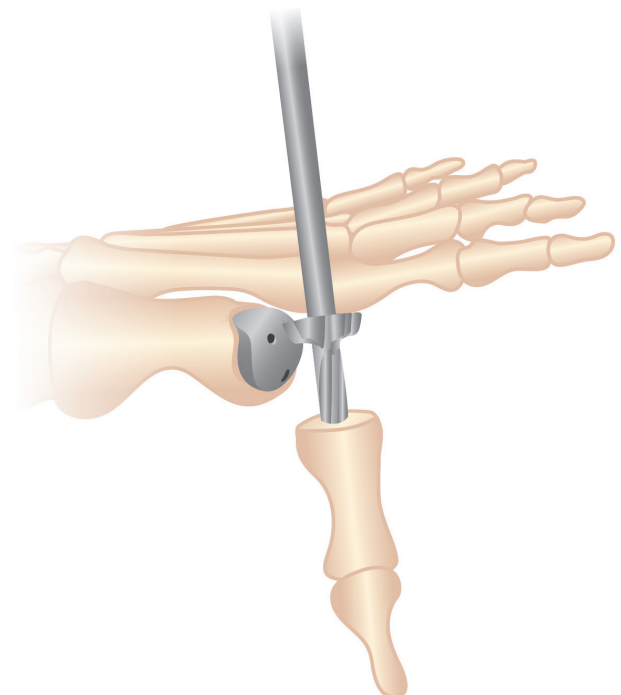
1. Using the **Pin Drill Guide**, place the **1.5mm Guide Pin** central to the phalangeal surface, in line with the axis of the bone. Confirm **1.5mm Guide Pin** placement radiographically before proceeding.



2. Introduce the **Reamer** over the **1.5mm Guide Pin** and advance under power until the **Reamer** depth indicator is flush to the *medial*, *lateral*, and *plantar* phalangeal articular surfaces. Do not use the *dorsal* surface as a reference as the **Reamer** may cut beyond its margin making proper depth determination difficult.

*Note: It may be necessary to decompress the joint by advancing the **Reamer** an additional 1mm to 2mm deeper to create an additional 1mm to 2mm of joint space. This will also compensate for the functional thickness of the **Proximal Phalynx Implant**.*

3. Introduce the **Tap** over the **1.5mm Guide Pin** and advance by hand. Advance **Tap** by 2 rotations then reverse 1 rotation, repating until the **Tap** depth indicator is flush to the level of the original (before reaming) phalangeal articular surface.



4. Remove the **1.5mm Guide Pin**, and place the **Fixation Component** into the tapped pilot hole. Using the **Hex Driver**, turn the **Fixation Component** counter clockwise to align threads of **Fixation Component** to the tapped pilot hole. Advance the **Fixation Component** clockwise until the distal surface of the **Fixation Component** is fully seated in the prepared bone socket.

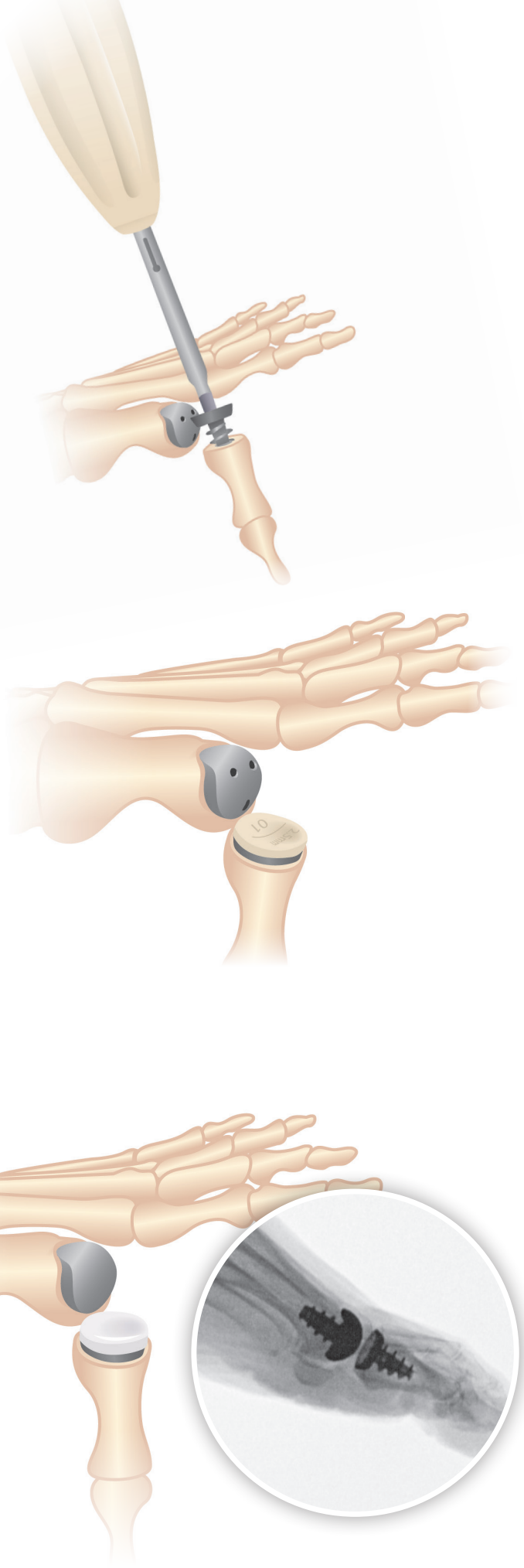
*Note: Prior to inserting the **Fixation Component**, thoroughly cleanse the pilot hole of any debris and then inject the cement in a retrograde fashion from the end of the hole upwards*

Confirm screw position radiographically before proceeding to next step.

5. Use the **Insert Trials** to determine the most appropriate **Phalangeal Insert** for seating into the **Fixation Component**. The medial lateral offset dimensions of the **Trial** and **Phalangeal Insert** should match the medial lateral offset dimensions of the **DF Articular Component**. Perform range of motion evaluation before proceeding.

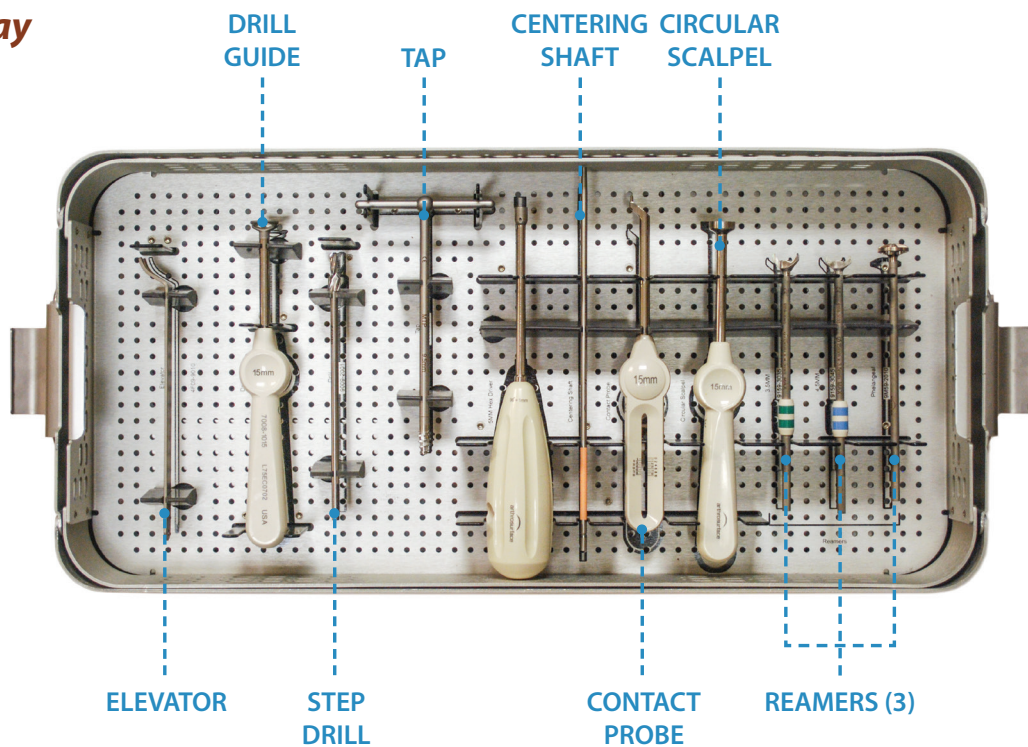
*Note: In joints that have required decompression, pay particular attention to the plantar flexion of the **Phalangeal Component** over the sesamoid complex. Trimming of the tissue around the plantar aspect of the **DF Articular Component** may be necessary.*

6. Pass the proximal knotted end of the **Suture** from the **Delivery Tool** through the slot in the **Hex Driver** shaft. Rotate the **Hex Driver** to tension the sutures and apply force through the **Delivery Tool** to seat the **Phalangeal Insert**. Perform final range of motion evaluation.

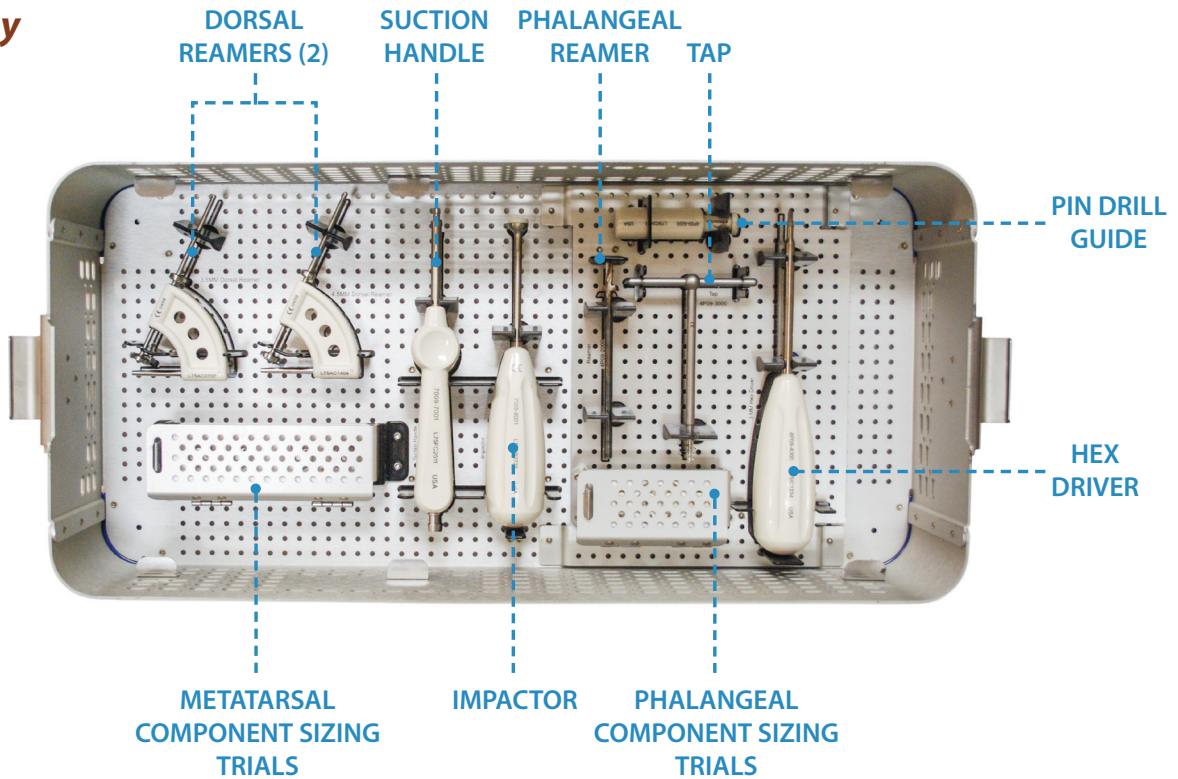


Instrumentation

Upper Tray



Lower Tray



Sizing Card

arthrosurface
Toe DF

S

I

Sizing Card

- Maximum SI _____
Maximum ML _____
- Select 15mm HemiCAP® offset values
If no match is found, use the next highest offset value
 - 1.5 mm x 3.5 mm
 - 1.5 mm x 4.5 mm
 - 2.5 mm x 3.5 mm
 - 2.5 mm x 4.5 mm
- Select **Surface Reamer** and **Dorsal Reamer** Size.
Choose the Surface Reamer and Dorsal Reamer that match the highest offset value.

System Catalog

Instrumentation System

9000-3002	Instrument Kit, ToeMotion
6007-1200	2.0mm Guide Pin for Metatarsal Implants
9P07-1002	1.5mm Guide Pin Kit, ToeMotion
9CR9-2100	10.0mm BOSS Disposable Drill

Metatarsal Articular Components

9M52-1535	1.5mm x 3.5mm Offset
9M52-1545	1.5mm x 4.5mm Offset
9M52-2535	2.5mm x 3.5mm Offset
9M52-2545	2.5mm x 4.5mm Offset
9095-0018	Taper Post, 9.5mm x 18mm (for Metatarsal only)
9CRS-D100	Taper Post, BOSS, 10.0mm x 20.0mm
9CRS-D200	Taper Post, BOSS, 10.0mm x 18.5mm

Proximal Phalanx Articular Components

9P15-0100	Insert Delivery Tool, Phalangeal
9P15-PA01	Modular Insert, 1.5 mm Offset - 01 (3.6 mm Thick)
9P15-PA02	Modular Insert, 1.5 mm Offset - 02 (4.6 mm Thick)
9P15-PB01	Modular Insert, 2.5 mm Offset - 01 (3.6 mm Thick)
9P15-PB02	Modular Insert, 2.5 mm Offset - 02 (4.6 mm Thick)
9P15-S180	Fixation Component, DF-P

Warnings & 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.
- Incorrect sizing of the Proximal Phalanx implant could result in excessive loading of the affected toe joint.
- 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.
- Arthroscopic implants are intended to be fitted and installed with the appropriate Arthroscopic 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 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.
- 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

- 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.

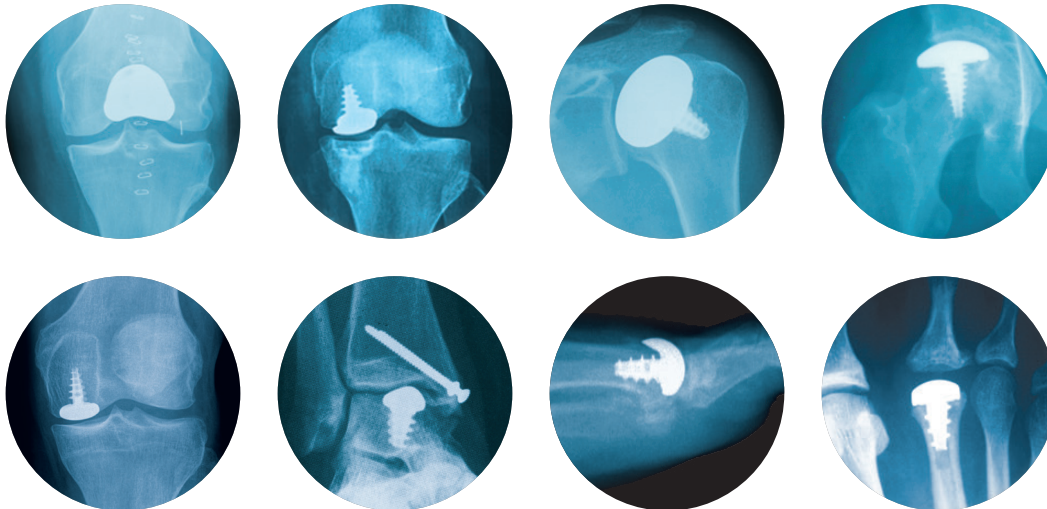
- Some types of wear debris have been associated with osteolysis and implant loosening.
- Infection or allergic reaction.
- Loosening, migration or loss of fixation of implant.
- Fretting and crevice corrosion can occur at the interface between the implant components.
- Fatigue fracture of the implants as a result of bone resorption around the implant components.
- Wear and damage to the implant articulating surface.
- Wear and damage to the adjacent and opposed articular cartilage surfaces or soft tissue support structures
- Intraoperative or postoperative bone fracture.
- Post-operative pain or incomplete resolution of pre-operative symptoms.
- Periarticular calcification or ossification, with or without impediment of joint mobility.
- Incomplete range of motion due to improper selection or positioning of components.
- Transient nerve palsy.
- Embolism.

Sterility

Implants and single-use disposable instruments are provided STERILE. Metallic implant components are sterilized by exposure to gamma radiation. Nonmetallic implant components are sterilized by gas plasma sterilization. The single-use disposable delivery tool instrument is sterilized by exposure to EtO Gas. All other single-use disposable instruments 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.



The Arthrosurface® HemiCAP® Systems are available for the following joints:

- Patello-Femoral
- Unicompartmental
- Femoral Condyle (*Available in most International markets via CE mark*)
- Shoulder
- 1st & 2nd MTP
- Hip
- Talus (*Available in most International markets via CE mark*)

This product is covered by one or more of U.S. Patent Nos. 6,520,964; 6,610,067; 6,679,917 and other patents pending.
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This pamphlet and information is intended for markets where regulatory approval has been granted.