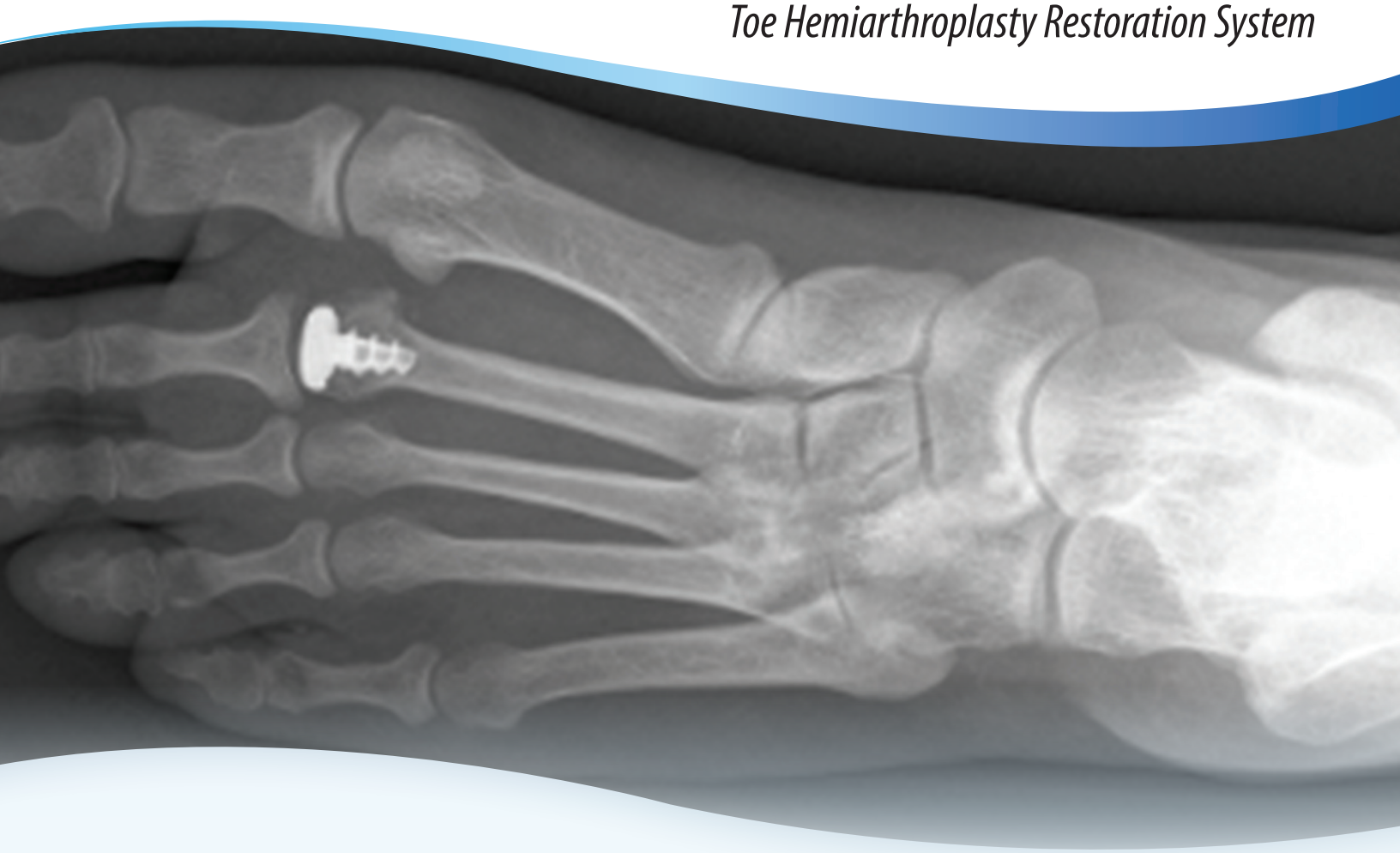
arthrosurface®
#STAYACTIVE

Technique Guide

Toe Hemiarthroplasty Restoration System



The Toe HemiCAP® Classic

The Toe HemiCAP® Restoration Systems restore the surface geometry of the metatarsal head and preserve functional structures using an innovative 3 dimensional mapping system and a contoured articular implant.

- *Anatomic "Inlay" with proven threaded fixation*
- *Minimal bone removal maintains future options*
- *Specifically designed for the lesser metatarsals*

HemiCAP®

Description

The Toe HemiCAP® 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-Chronium Alloy (Co-Cr-Mo)
Surface Coating:	Titanium (CPTi)
Taper Post 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:

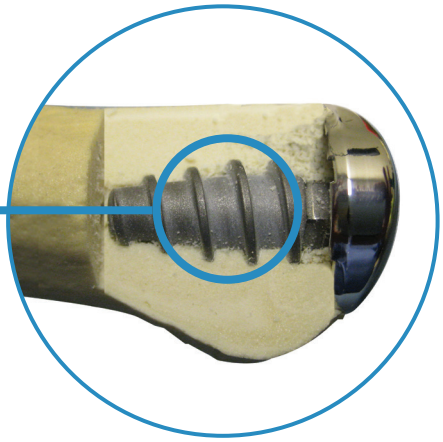
1) Significant bone demineralization or inadequate bone stock
2) Inadequate skin, musculontendinus or neurovascular system status
3) Inflammatory or rheumatoid arthritis, infection, sepsis, and osteomyelitis
4) Patients that have a known sensitivity to cobalt-chrome alloys typically used in prosthetic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

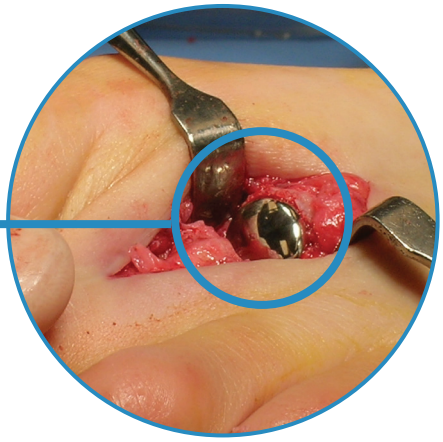
Proven Threaded Fixation versus "Push and Pray" Implants

The threaded taper post, morse taper interlock and inlay design provides optimal fixation in the metatarsal bone and reduces shear forces that may cause loosening.



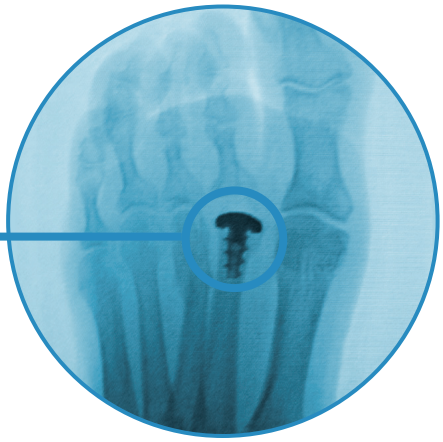
Restores a Smooth Joint and Sesamoid Articulation

Resurfacing the metatarsal head with a HemiCAP provides a smooth articulating surface.

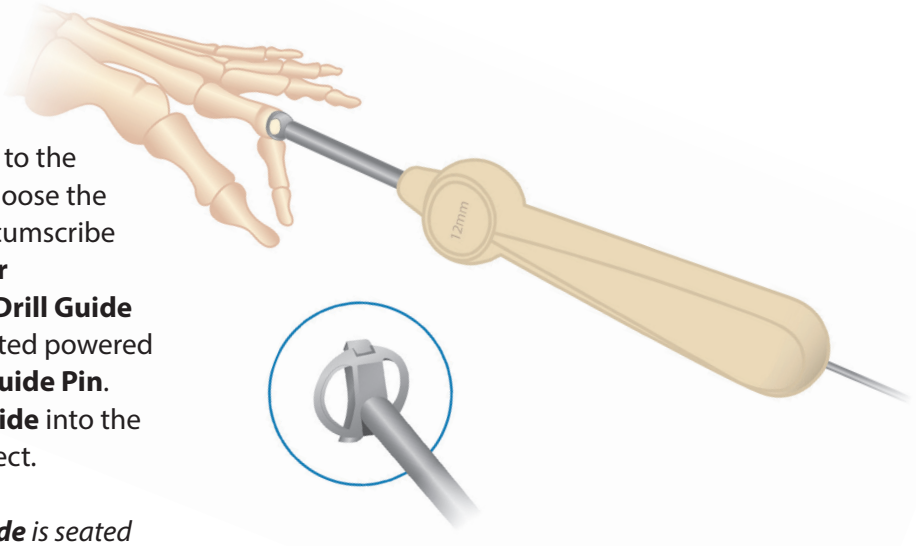


Provides Improved Joint Decompression

Metatarsal resurfacing combined with soft tissue mobilization, debridement and resetting the joint line provides improved joint decompression.



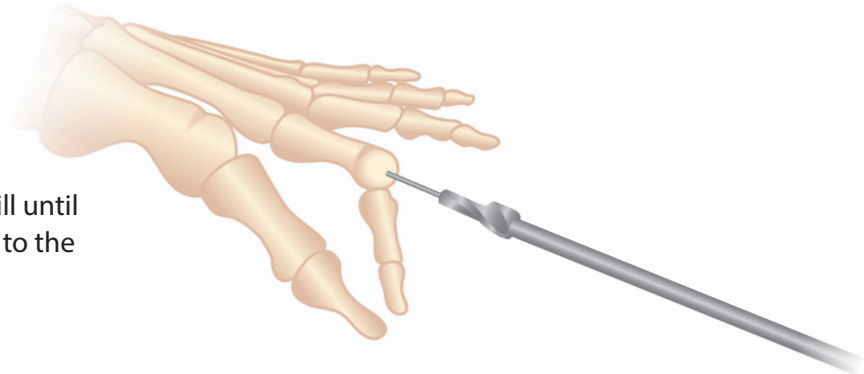
Surgical Technique (HemiCAP® Toe Classic)



1. Use the **Drill Guide** to locate the axis normal to the articular surface and central to the defect. Choose the correct **Drill Guide** diameter sufficient to circumscribe the defect. Confirm the appropriate **Articular Component** diameter by matching it to the **Drill Guide** diameter. Place the **Guide Pin** into a cannulated powered drill and secure at the etch marking on the **Guide Pin**. Advance the **Guide Pin** through the **Drill Guide** into the bone making sure that it is central to the defect.

   *Note: It is important to verify that the **Drill Guide** is seated on the curved surface such that four points of contact are established on the articular surface. A normal axis and correct **Articular Component** diameter are necessary for proper implant fit.*

Drill Guide

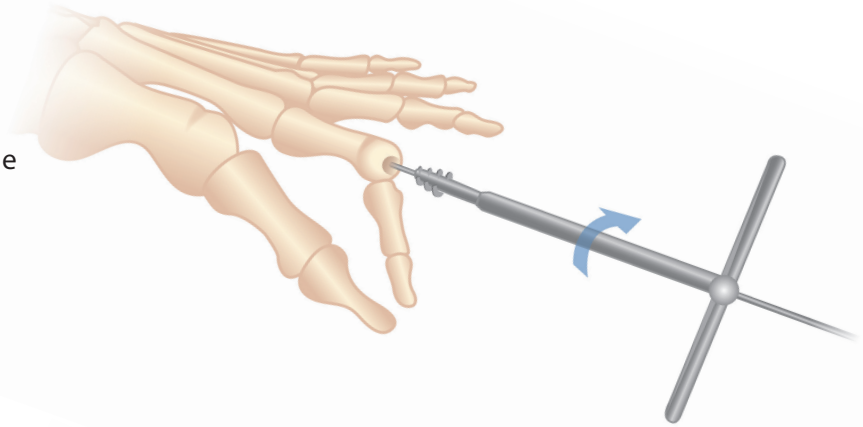


2. Place the **Step Drill** over the **Guide Pin** and drill until the proximal shoulder of the **Step Drill** is flush to the articular surface.

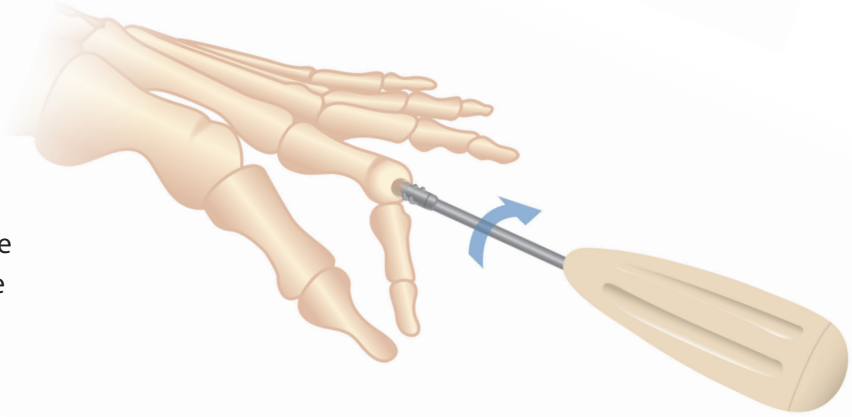
Step Drill

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

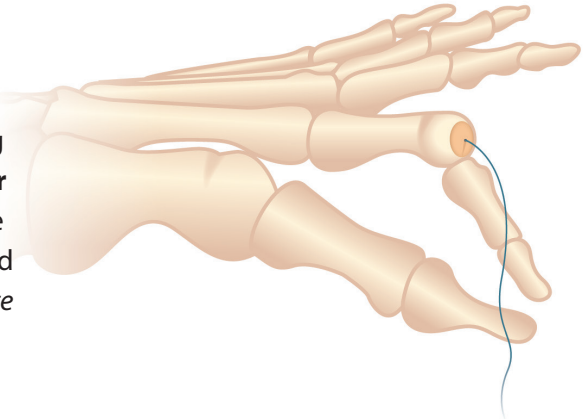
Tap

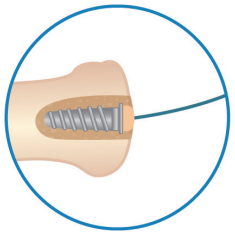


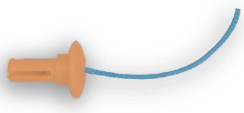
4. Place the **Driver** onto the **Taper Post** over the **Guide Pin** and advance the **Taper Post** until the line on the **Driver** is flush with the height of the original articular cartilage level.



5. Remove the **Guide Pin**. Clean the taper in the **Taper Post** with the **Taper Cleaner**. Place the **Trial Cap** into the **Taper Post** to correct depth of the **Taper Post.** The peak 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 defect. Adjust depth if needed using the **Driver** to rotate the **Taper Post** *(rotate clockwise to advance and counterclockwise to retract)*. Remove the **Trial Cap**.

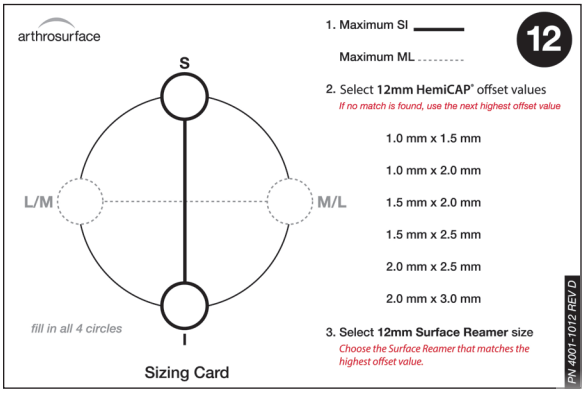




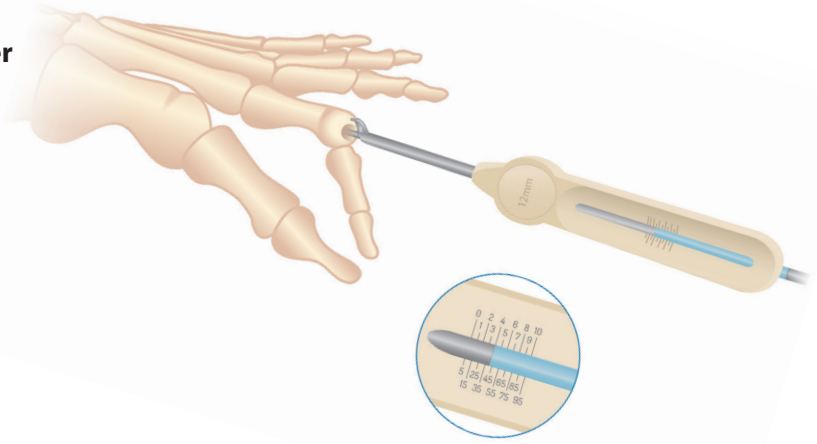


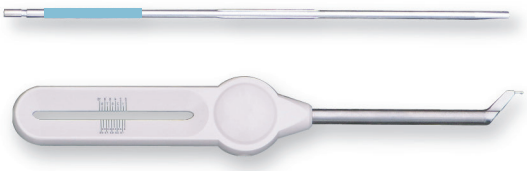
Trial Cap

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**. Read the **Contact Probe** to obtain offsets at four indexing points *(superior/inferior and medial/lateral)* and mark each of the identified offsets on the appropriate **Sizing Card**. Select the appropriate **Articular Component** using the **Sizing Card**.

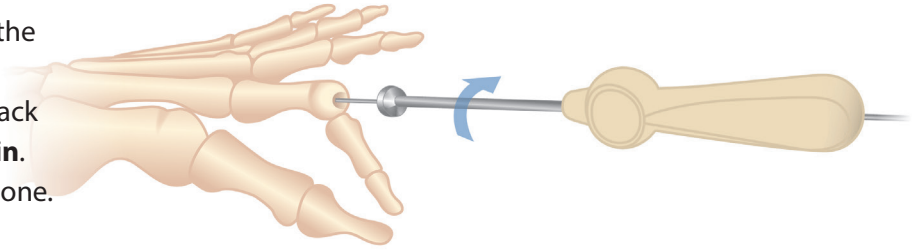


Sizing Card


Centering Shaft (colored end up)

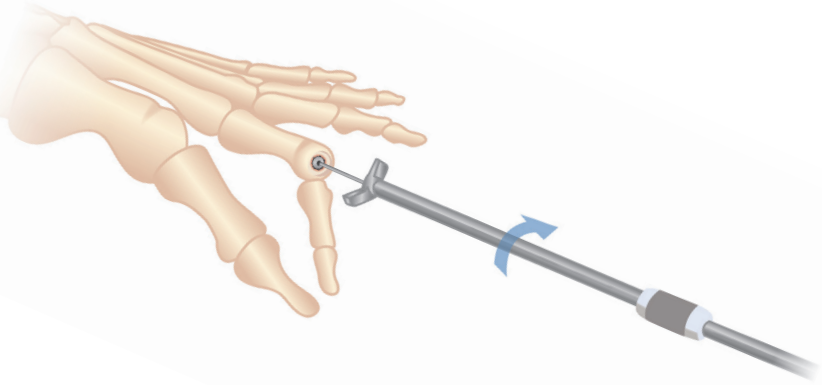

Contact Probe

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




Circle Cutter

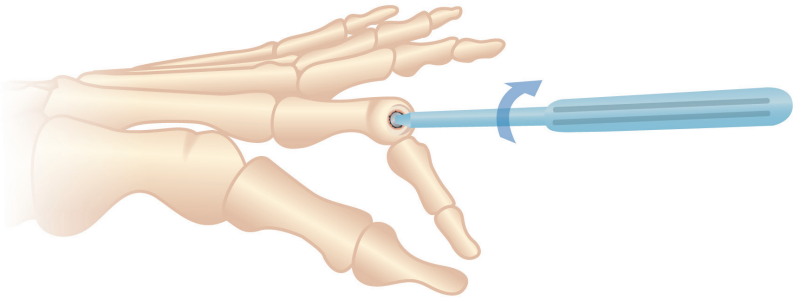
8. Choose the appropriate **Surface Reamer** based on the offsets. Drill the **Surface Reamer** over the **Guide Pin** until it contacts the top surface on the **Taper Post**. Make sure not to bend the **Guide Pin** during drilling as it may result in **Articular Component** malalignment. Begin rotation of the **Surface Reamer** prior to contact with bone to prevent chipping of the articular rim.



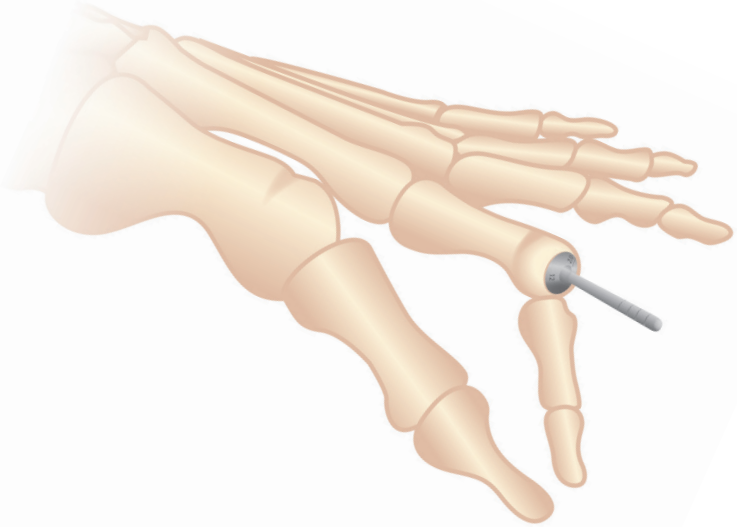

Surface Reamer

9. Remove the **Guide Pin**. Clean the taper in the **Taper Post** with the **Taper Cleaner** and remove any debris from the surrounding implant bed.

Taper Cleaner
✳ *Located in Disposable Kit*

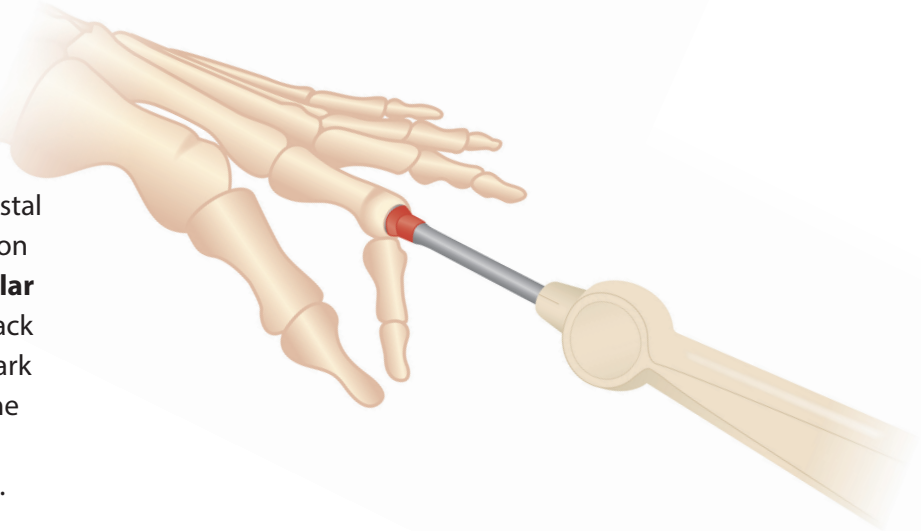


10. Place the **Sizing Trial** into the defect that matches the offset profile of the chosen **HemiCAP® Articular Component**. Confirm the fit of the **Sizing Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed. If the **Sizing Trial** is proud at the edge of the articular cartilage, ream with the next appropriate sized reamer and use the matching **Sizing Trial**. **Sizing Trials** must match the **Surface Reamer's** offset size.



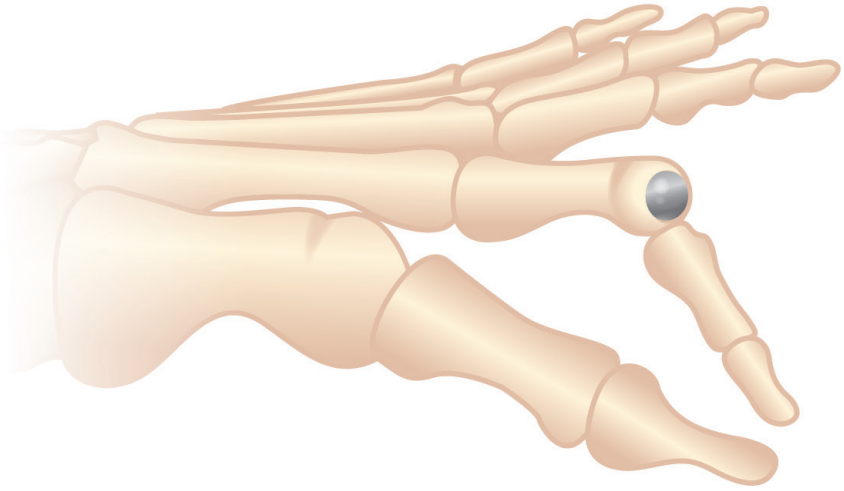
11. Before placing the **Articular Component** on the **Implant Holder,** make sure that sufficient suction is present to hold the device on the distal suction cup. Align the **Articular Component** on the **Implant Holder**. For non-spherical **Articular Components,** orient the etch marks on the back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

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.

Impactor



System Catalog

Instrumentation System	
9000-1200	Instrument Kit, 7mm
9000-3000	Instrument Kit, 12mm includes 12mm Sizing Trials
9000-3001	Instrument Kit, 15mm includes 15mm Sizing Trials
7007-1205	2.0 mm Guide Pin (5 PK) for 12 & 15 mm Implants

Taper Post (Fixation Components)	
9070-0013	Taper Post, 7.0mm x 13mm (for 12mm only)
9095-0018	Taper Post, 9.5mm x 18mm (for 15mm only)

12mm Articular Components	
9122-1015	1.0mm x 1.5mm Offset
9122-1020	1.0mm x 2.0mm Offset
9122-1520	1.5mm x 2.0mm Offset
9122-1525	1.5mm x 2.5mm Offset
9122-2025	2.0mm x 2.5mm Offset
9122-2030	2.0mm x 3.0mm Offset

15mm Articular Components	
9152-1525	1.5mm x 2.5mm Offset
9152-1535	1.5mm x 3.5mm Offset
9152-2030	2.0mm x 3.0mm Offset
9152-2040	2.0mm x 4.0mm Offset
9152-2535	2.5mm x 3.5mm Offset
9152-2545	2.5mm x 4.5mm Offset

Sizing Cards (HemiCAP® Toe Classic)

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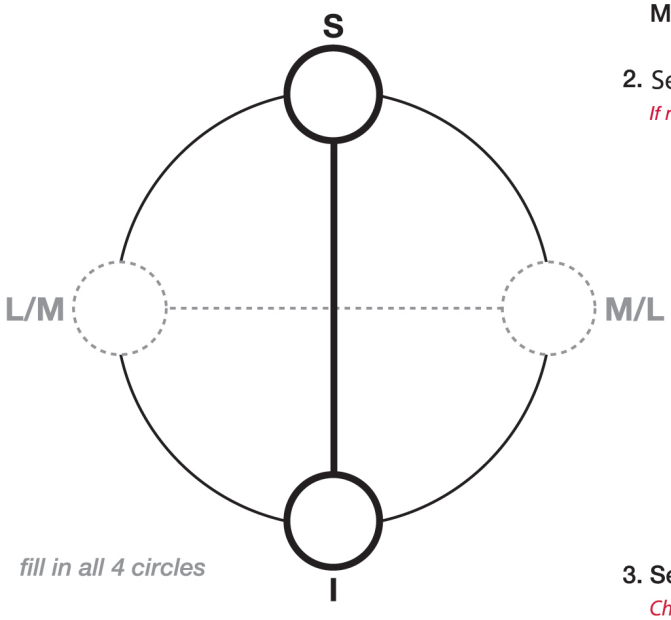


fill in all 4 circles

Sizing Card

1. Maximum SI ——
   Maximum ML - - - - - -

12

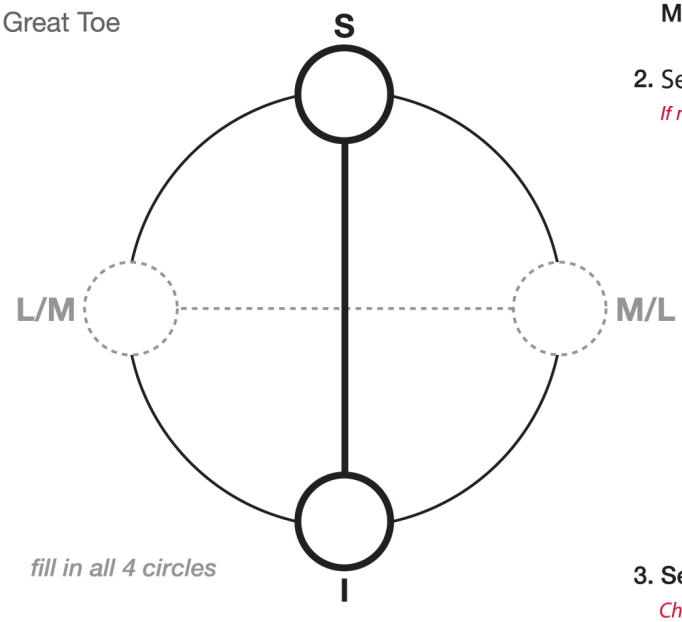
2. Select **12mm HemiCAP®** offset values
   If no match is found, use the next highest offset value

1.0 mm x 1.5 mm
1.0 mm x 2.0 mm
1.5 mm x 2.0 mm
1.5 mm x 2.5 mm
2.0 mm x 2.5 mm
2.0 mm x 3.0 mm

3. Select **12mm Surface Reamer** size
   Choose the Surface Reamer that matches the highest offset value.

PN 4001-1012 REV D

arthrosurface
Great Toe



fill in all 4 circles

Sizing Card

1. Maximum SI ——
   Maximum ML - - - - - -

15

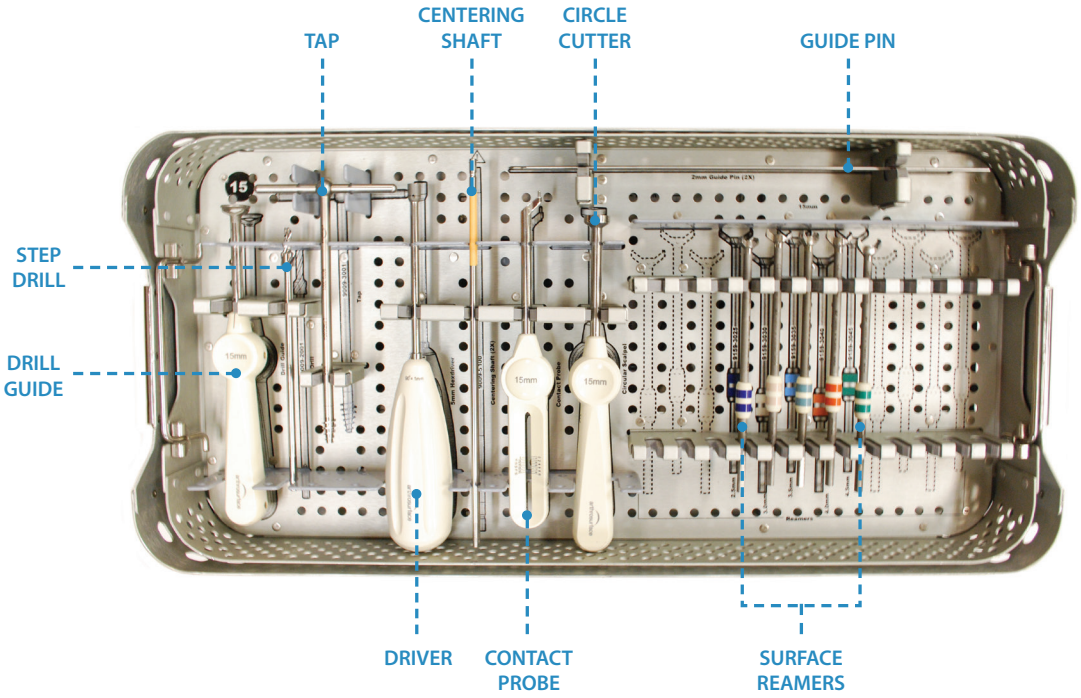
2. Select **15mm HemiCAP®** offset values
   If no match is found, use the next highest offset value

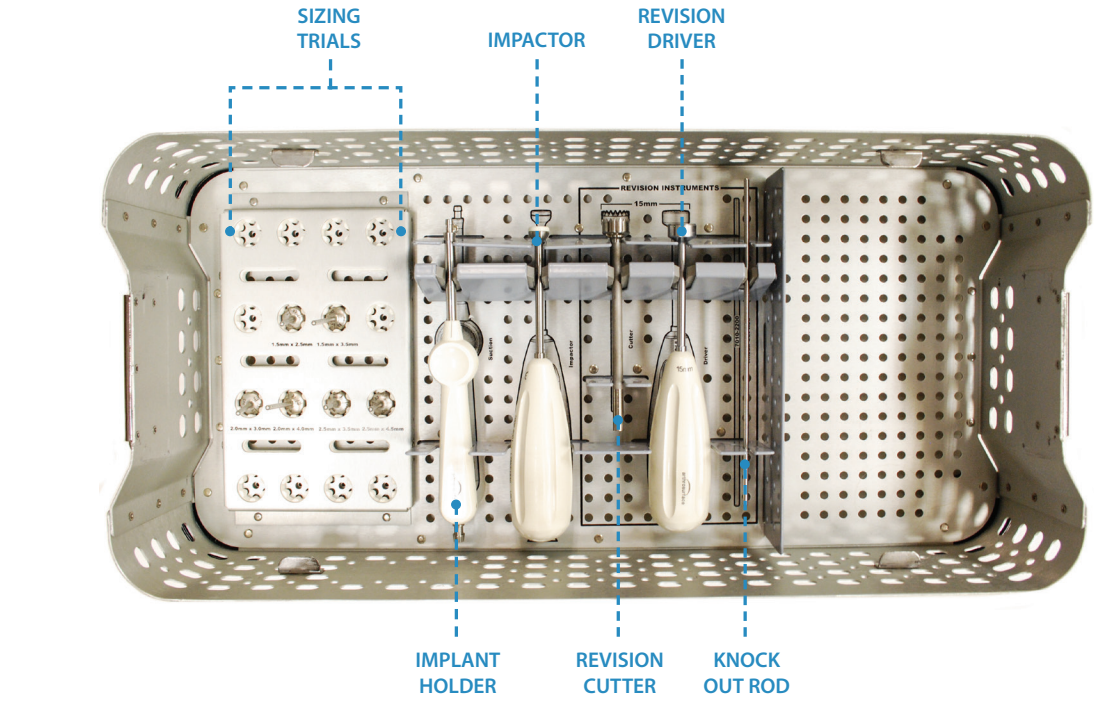
1.5 mm x 2.5 mm
1.5 mm x 3.5 mm
2.0 mm x 3.0 mm
2.0 mm x 4.0 mm
2.5 mm x 3.5 mm
2.5 mm x 4.5 mm

3. Select **15mm Surface Reamer** size
   Choose the Surface Reamer that matches the highest offset value.

PN 4001-1015 REV E

Instrumentation (HemiCAP® Toe Classic)





Warnings

Improper selection, placement, positioning, alignment, and fixation ofthe implant components may reduce the service life of the prostheticcomponents. Inadequate preparation and cleaning of the implantcomponents 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 jointsurfaces. 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 prepared margin. 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 with vigorous lavage to minimize heat effects to adjacent bone and cartilage tissues.

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.

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 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

- 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 material. 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.

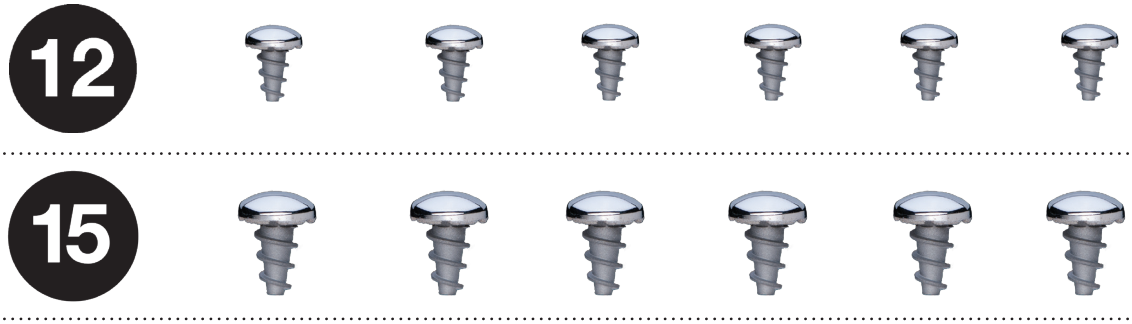
Sterility

Implants and single-use disposable instruments are provided STERILE. Metallic implant components are sterilized by exposure to gamma radiation. 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.

HemiCAP Toe Classic



The Arthrosurface HemiCAP System is also available for the following joints:

- Shoulder
- Patello-Femoral
- Unicompartmental
- Talus *(Available in most International markets via CE mark)*
- Hip
- Femoral Condyle *(Available in most International markets via CE mark and as a part of a IDE study in the U.S.)*

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For more information, visit our website:
www.arthrosurface.com

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ISO 13485

This pamphlet and information is intended for markets where regulatory approval has been granted.