arthrosurface®

Technique Guide

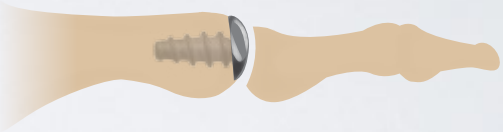
Toe Hemiarthroplasty

HemiCAP®

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

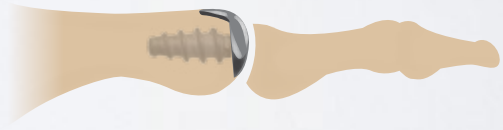
Chapter One

HemiCAP® Toe Classic



Chapter Two

HemiCAP® Toe DF

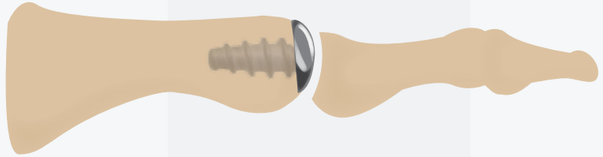


Chapter Guide *Toe Hemiarthroplasty*

Chapter One

HemiCAP®

Toe Classic



KEY FEATURES:

Anatomic "Inlay" with proven threaded fixation

Minimal bone removal maintains future options

Specifically designed for the metatarsals

Description

The HemiCAP® Contoured Articular Prosthetic incorporates an articular resurfacing component and a 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:	Titanium Alloy (Ti-6Al-4V)

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 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.

Patient selection factors to be considered include:

1) Need to obtain pain relief and improve function.
2) Patient age as a relative contraindiction to an arthrodesis procedure.
3) Patient overall well-being, including ability and willingness to follow instructions and comply with activity restrictions.

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 metal alloys typically used in prosthetic devices

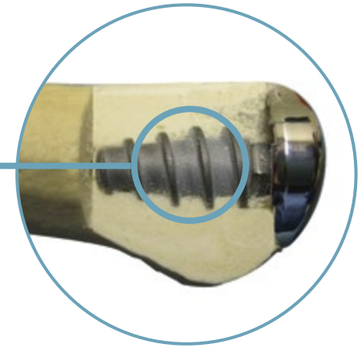
Relative contraindications include:

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

HemiCAP®

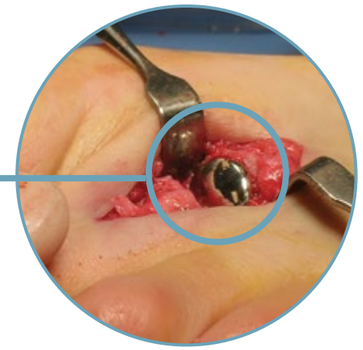
Proven Threaded Fixation versus “Push and Pray” Implants

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.



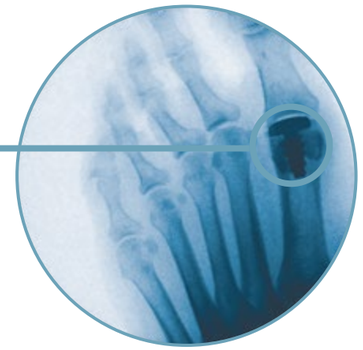
Restores a Smooth Joint and Sesamoid Articulation

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



Provides Improved Joint Decompression

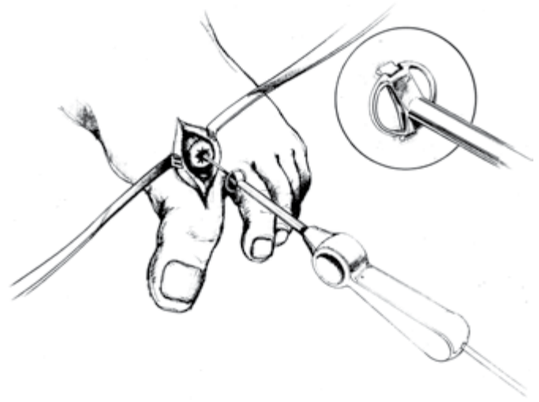
Metatarsal resurfacing combined with soft tissue mobilization, debridement and resetting the joint line provides improved joint decompression.



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 the **Step 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.

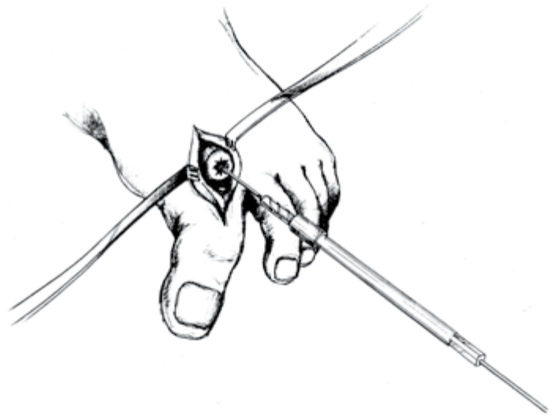
   *Note: It is important to verify that the **Drill Guide** is seated on the curved surface such that four points of contact are established on the articular surface. A normal axis and correct **Articular Component** diameter are necessary for proper implant fit.*



Drill Guide

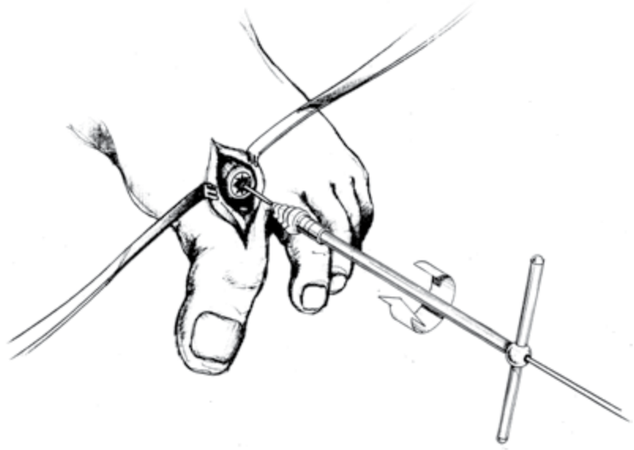
2. Place the **Step Drill** over the **Guide Pin** and drill until the proximal shoulder of the **Drill** is flush to the articular surface.

Step Drill

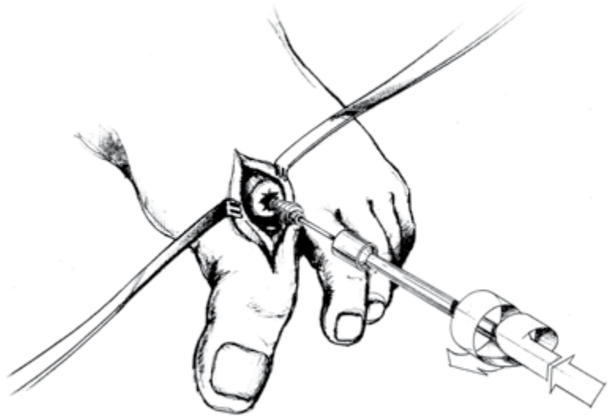


3. Tap hole to etched depth mark on the **Tap**. Insert bone cement into pilot hole.

Tap

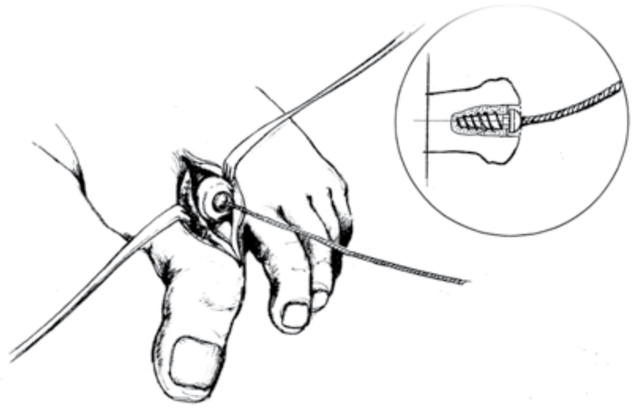


4. Place the **Driver** onto the **Taper Post** over the **Guide Pin** and advance the **Taper Post** until the line on the **Driver** is flush with the height of the original articular cartilage level.

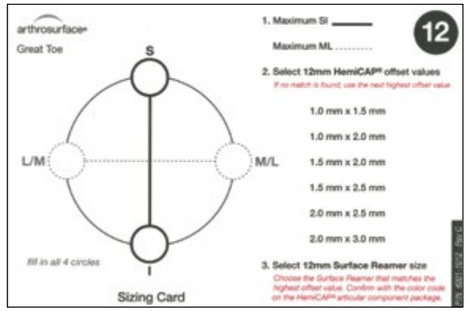


5. Remove the **Guide Pin**. Clean the taper in the **Taper Post** with the **Taper Cleaner**. Place the **Trial Cap** into the **Taper Post** to correct depth of the **Taper Post.** The peak height of the **Trial Cap** must be flush or slightly below the existing articular cartilage surface to avoid 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**.

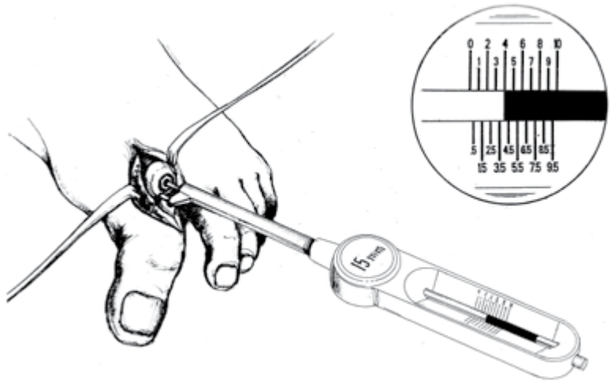
Trial Cap



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

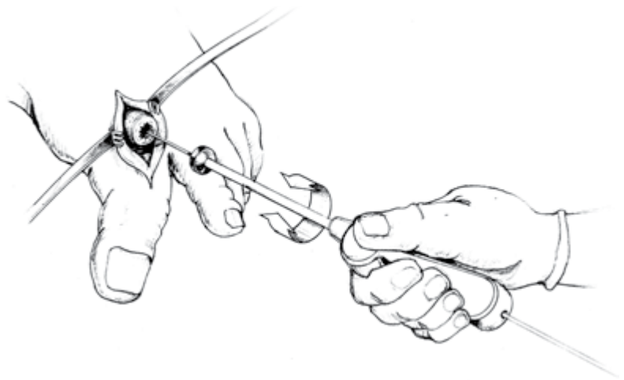


Centering Shaft (colored end up)


Contact Probe

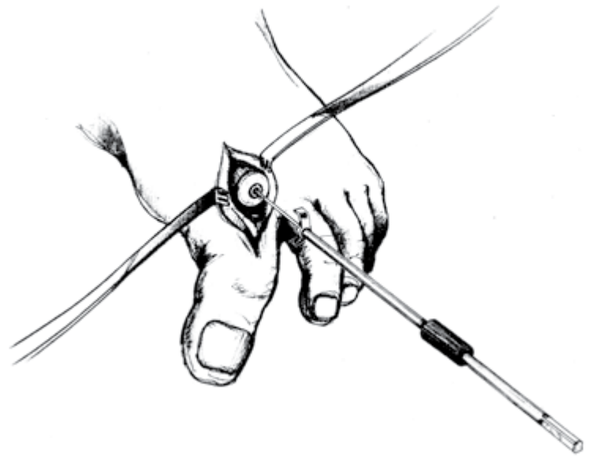
7. Remove the **Centering Shaft** and replace with the **Guide Pin**. Advance the **Circle Cutter** onto the articular surface by twisting the **Circle Cutter** back and forth avoiding any bending of the **Guide Pin**. Score articular cartilage down to subchondral bone.


Circle Cutter



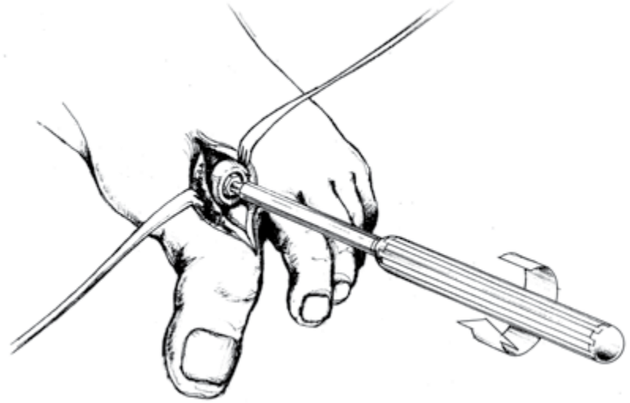
8. Choose the appropriate **Surface Reamer** based on the offsets. Confirm selection by matching the color code on the **Articular Component** package with the colored band on the **Surface Reamer** shaft. Drill the **Surface Reamer** over the **Guide Pin** until it contacts the top surface on the **Taper 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

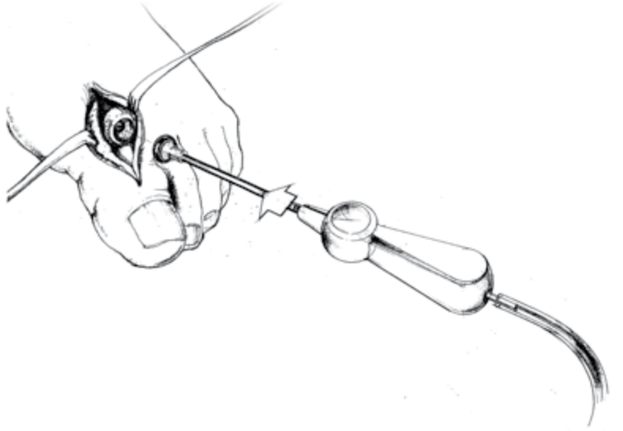


9. Remove the **Guide Pin**. Clean the taper in the **Taper Post** with the **Taper Cleaner** and remove any debris from the surrounding implant bed.


Taper Cleaner
✳ *Located in Disposable Kit*

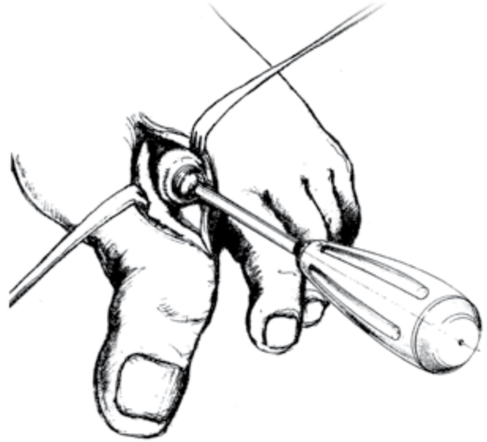


10. Place the **Sizing Trial** into the defect that matches the offset profile of the chosen **HemiCAP® Articular Component**. Confirm the fit of the **Sizing Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed. If the **Sizing Trial** is proud at the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



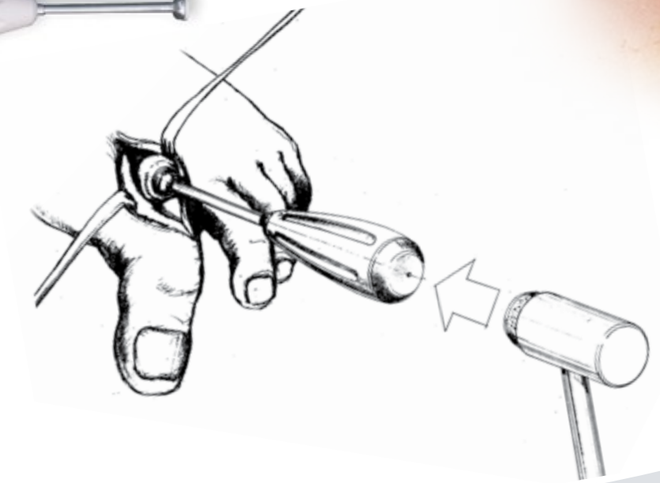
11. Before placing the **Articular Component** on the **Implant Holder,** make sure that sufficient suction is present to hold the device on the distal suction cup. Align the **Articular Component** on the **Implant Holder**. For non-spherical **Articular Components,** orient the etch marks on the back 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**.

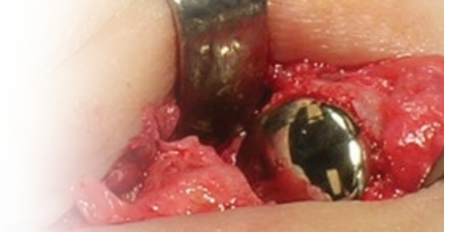

Implant holder



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 (HemiCAP® Toe Classic)

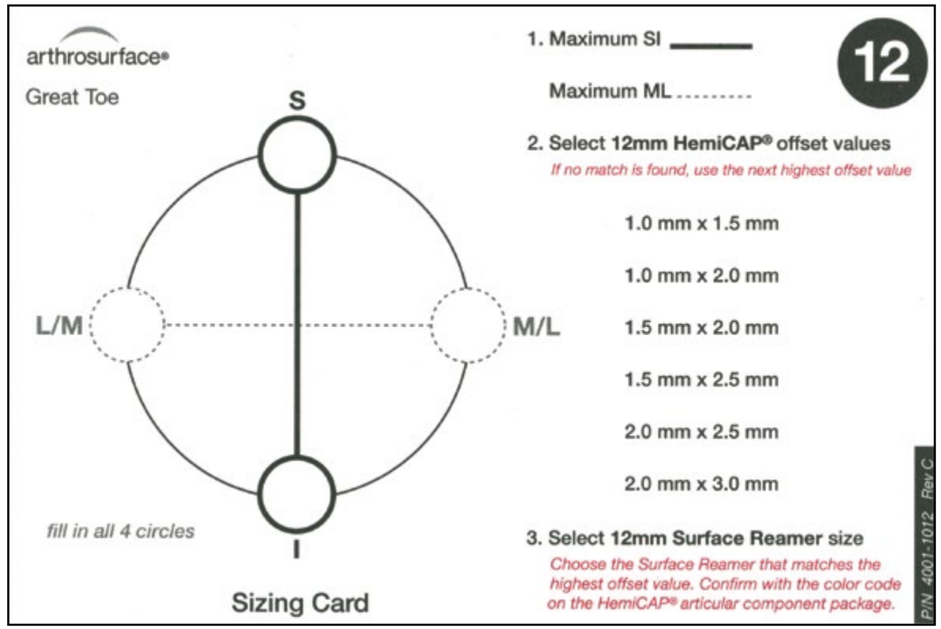
Instrumentation System	
9000-1200	Instrument Kit, 7mm
9000-3000	Instrument Kit, 12mm includes 12mm Sizing Trials
9000-3001	Instrument Kit, 15mm includes 15mm Sizing Trials
7007-1205	2.0 mm Guide Pin (5 PK) for 12 & 15 mm Implants

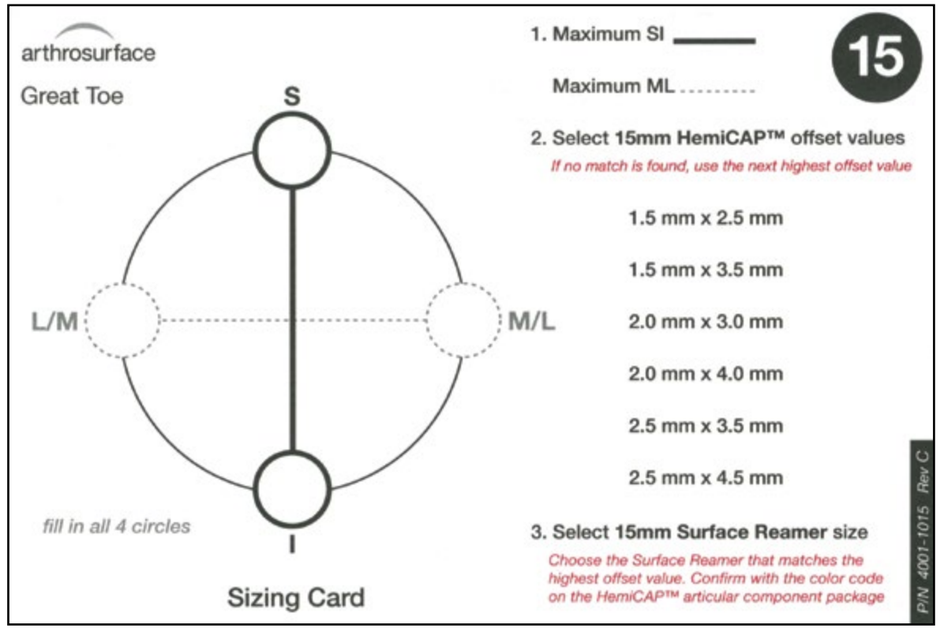
Taper Post (Fixation Components)	
9070-0013	Taper Post, 7.0mm x 13mm (for 12mm only)
9095-0018	Taper Post, 9.5mm x 18mm (for 15mm only)

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

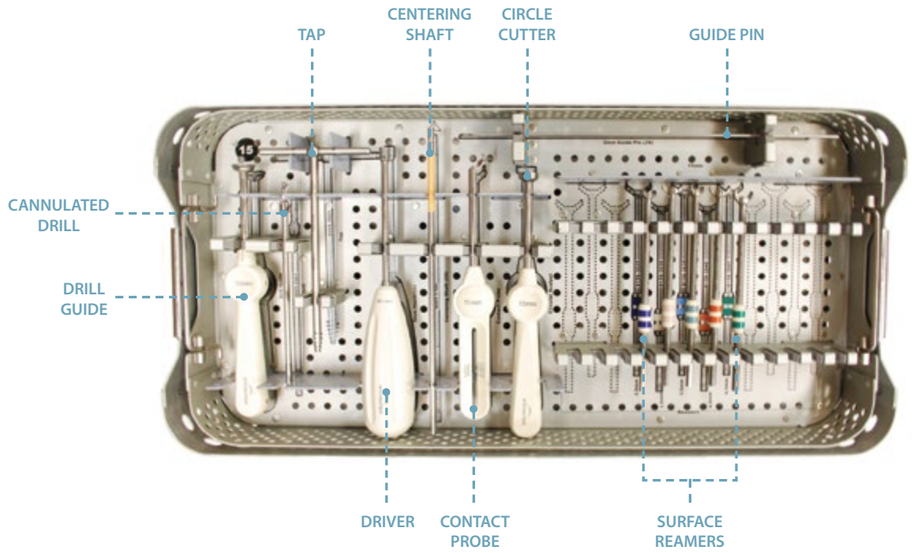
15mm Articular Components	
9152-1525	1.5mm x 2.5mm Offset
9152-1535	1.5mm x 3.5mm Offset
9152-2030	2.0mm x 3.0mm Offset
9152-2040	2.0mm x 4.0mm Offset
9152-2535	2.5mm x 3.5mm Offset
9152-2545	2.5mm x 4.5mm Offset

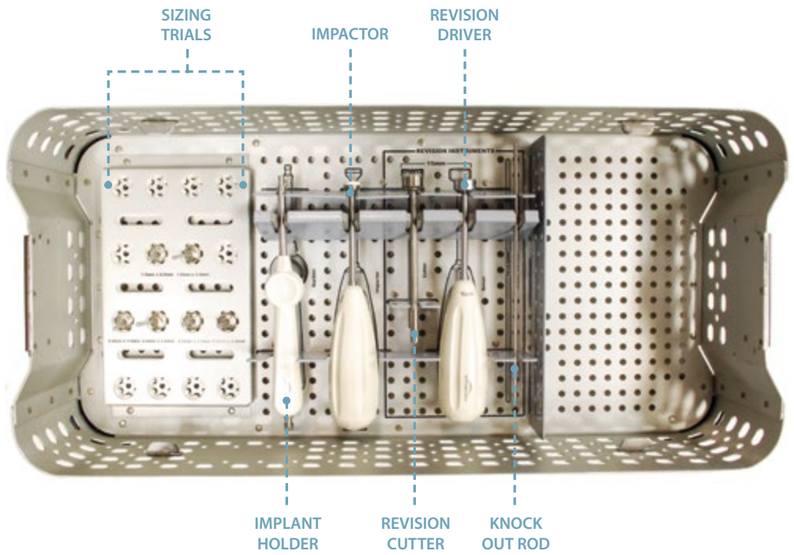
Sizing Cards (HemiCAP® Toe Classic)





Instrumentation (HemiCAP® Toe Classic)

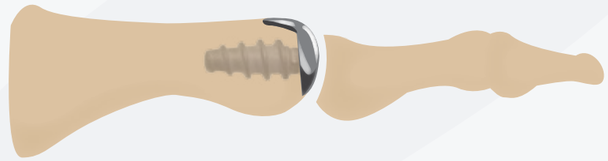




Chapter Two

HemiCAP®

Toe DF



KEY FEATURES:

Dual implant curvatures improve dorsal roll-off during dorsiflexion

Anatomic "Inlay" design for proper sesamoid articulation

Minimal bone removal maintains future options

Proven fixation provides a stable implant

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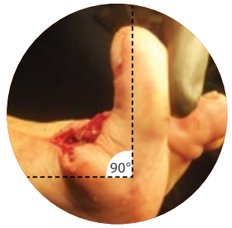
Maximizing Range of Motion through Implant Design, Intra- and Postoperative Management

Intraoperative Management:

- Soft Tissue Mobilization
  - Capsular release
  - Collateral ligament mobilization
  - Sesamoids mobilization
- Joint Decompression:
  - Advance screw by 2-3 mm
  - Re-ream implant bed and reshape metatarsal head
- Flexor Hallucis Brevis Tendon Release
  - Subperiosteal release at the bony insertion on the proximal phalanx

Intraoperative Goal:

- 90 degrees of passive dorsiflexion

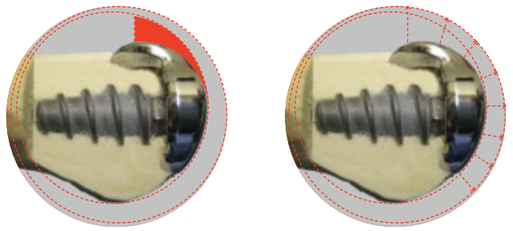


Postoperative Management:

- Patients are instructed in passive and active dorsi- and plantar-flexion preoperatively, and these instructions are repeated immediately postoperatively.
- Heel to toe gait and no walking on the side of the foot are encouraged.
- Patients without adjunct procedures are weight bearing immediately in a surgical boot or stiff-soled shoe for comfort and outside ambulation, but full weight bearing without a shoe in the household is encouraged immediately to prevent joint stiffness.
- Aggressive ROM therapy is initiated after healing of the integument.
- Return to normal shoe gear and activities after suture removal as tolerated.
- Early joint mobilization has not interfered with normal wound healing.
- No postoperative bracing is used to maintain alignment.
- No postoperative deformities have been reported in the literature.

Arthrosurface HemiCAP® DF Toe Resurfacing System:

Joint Decompression and improved DorsiFlexion through anatomic non-spherical implant design and re-establishment of multiple anatomic centers of rotation over the full arc of motion.



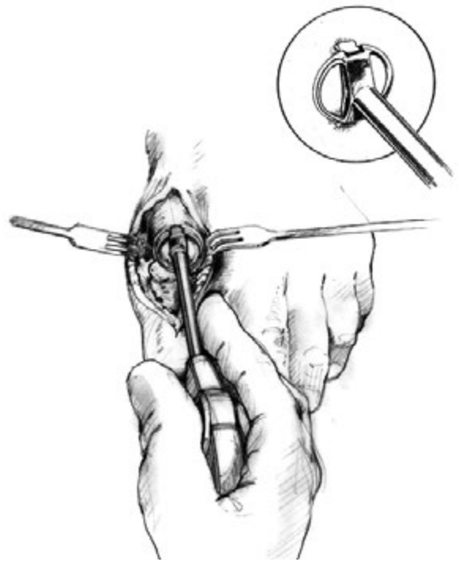
References:

1) Hasselman C, Shields N. Resurfacing of the First Metatarsal Head in the Treatment of Hallux Rigidus. Tech in Foot & Ankle Surgery 7(1):31–40, 2008
2) Carpenter B, Smith J, Motley T, Garrett A. Surgical Treatment of Hallux Rigidus Using a Metatarsal Head Resurfacing Implant: Mid-term Follow-up. J Foot Ankle Surg. 2010 July - Au gust;49(4):321-325.
3) Kinematics of the First Metatarsophalangeal Joint. MJ Shereff, FJ Bejjani, FJ Kummer. JBJS: Vol 68-A, No 3, 1986

Surgical Technique (HemiCAP® Toe DF)

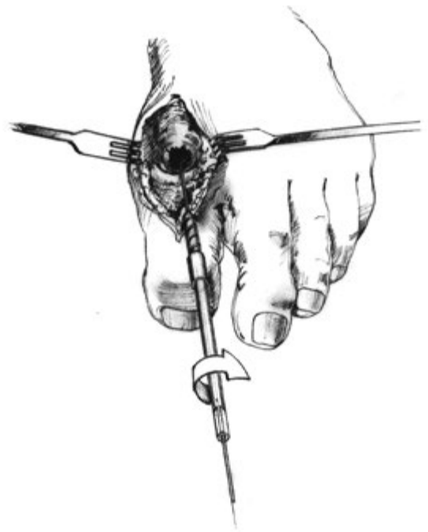
1. Use the **Drill Guide** to locate the axis normal to the articular surface and central to the defect. The plantar foot of the drill guide should be seated at or just below the crista. Place the **Guide Pin** into a **Cannulated Pin Driver** and secure at the etch marking on the **Guide Pin**. Advance the **Guide Pin** into the bone.

Drill Guide



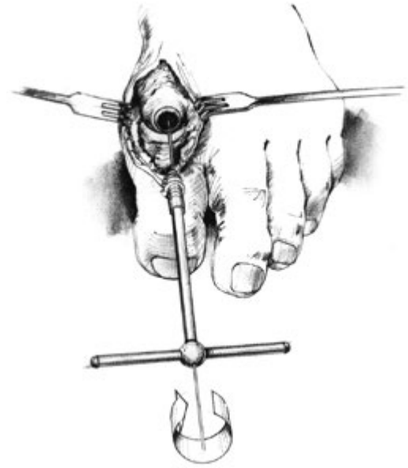
2. Place the cannulated **Step Drill** over the **Guide Pin** and drill until the proximal shoulder of the **Step Drill** is flush to the articular surface. Should the **Guide Pin** loosen, use the **Step Drill** to re-center the **Guide Pin** in the pilot hole and advance into the bone.

Step Drill



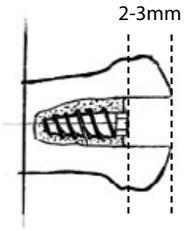
3. Tap hole to etched depth mark on the **Tap**. Insert bone cement into the pilot hole.

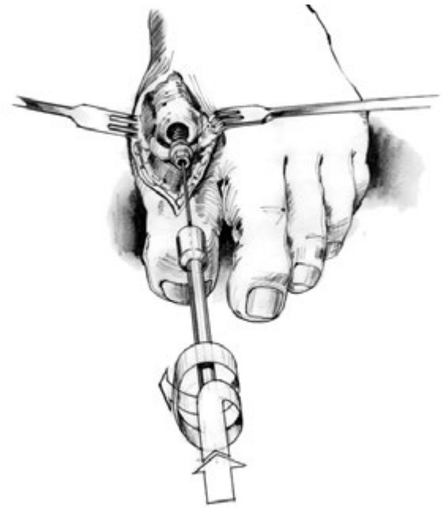
Tap



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: In a tight joint, you may decompress by advancing the **Driver** and **Taper Post** a 1/2 turn to decompress the joint by 2mm.*



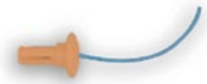


5. Clean the taper in the **Taper Post** with the **Taper Cleaner**. Place the **Trial Cap** into the **Taper Post** to confirm correct depth of the **Taper Post**. The height of the **Trial Cap** must be flush or slightly below the existing articular cartilage surface to avoid the **Articular Component** 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**.

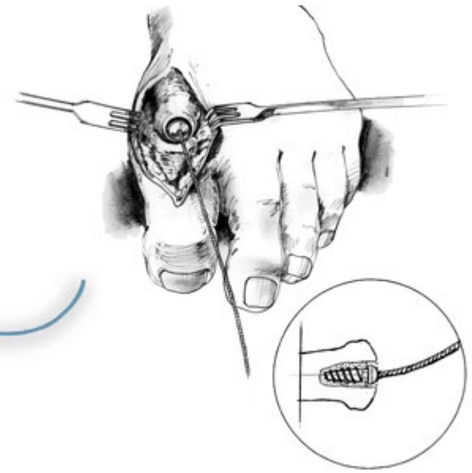
Note: If decompressing the joint, this step can be skipped.

Taper Cleaner

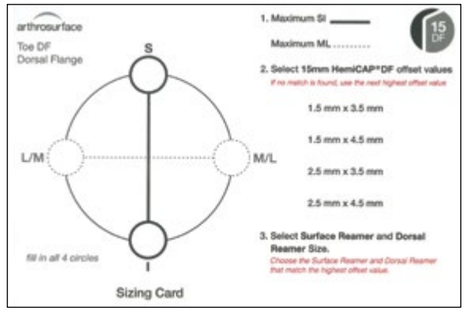
✳ *Located in Disposable Kit*



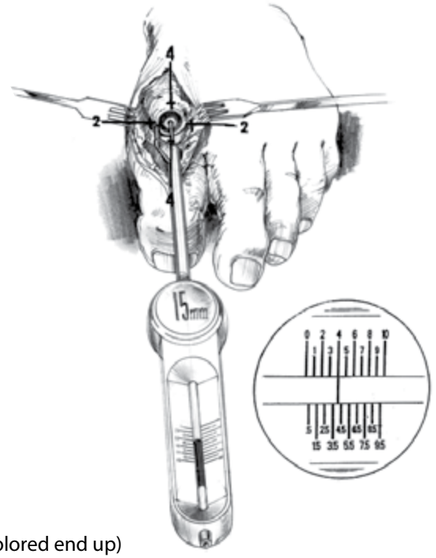
Trial Cap



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 **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 **Articular Component** using the **Sizing Card**.



Sizing Card



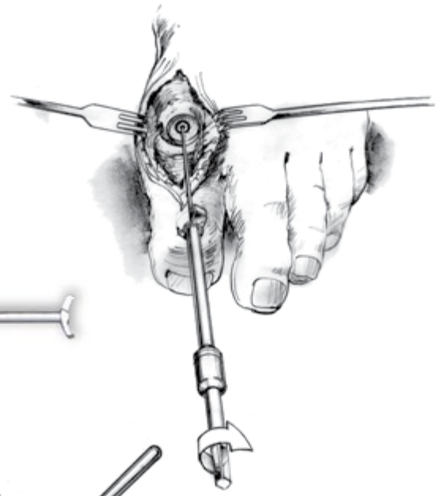
Centering Shaft (colored end up)

Contact Probe

7. Choose the appropriate **Surface Reamer** based on the offsets. Confirm selection by matching the color code on the **Articular Component** package with the colored band on the **Surface Reamer** shaft. Drive **Surface Reamer** over **Guide Pin** until it contacts the top surface on the **Taper Post**.

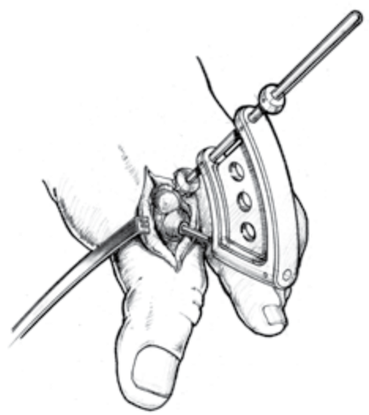
   *Note: If decompressing, start by reaming with the 3.5mm **Surface Reamer** and use the matching trial until satisfied with the fit.*

Surface Reamer

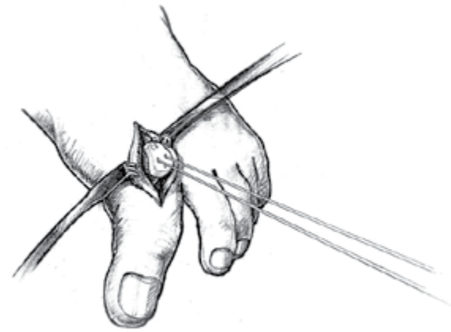


8. Place the appropriately sized **Dorsal Reamer Guide** into the taper of the **Taper Post**. The **Guide** should be oriented such that the dorsal ream is at the 12 o'clock position. Advance the **Dorsal Reamer** to the depth stop. Once the **Dorsal Reamer** has advanced to the handle, immediately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

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



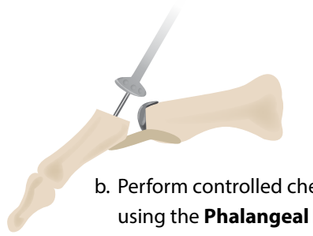
9. Place the **Sizing Trial** into the defect that matches the offset profile of the chosen **HemiCAP® DF Articular Component**. Confirm the fit of the **Sizing Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed. It is critical to ensure that the toe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



10. 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.

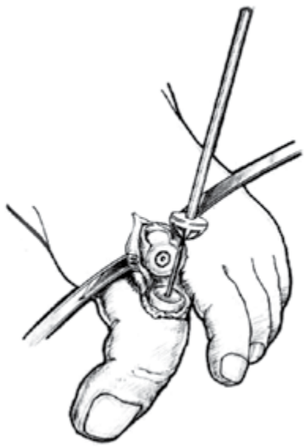
Phalangeal Reamer

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



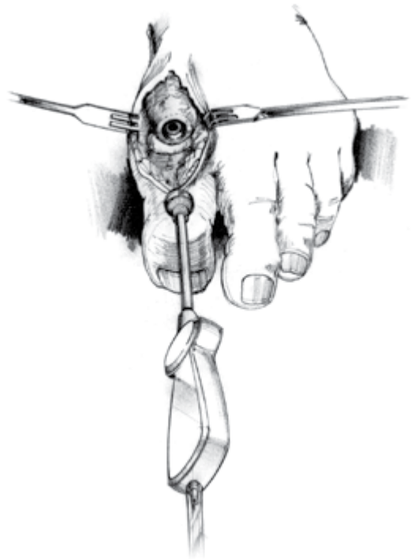
b. Perform controlled cheilectomy using the **Phalangeal Reamer**

c. Final phalangeal cheilectomy



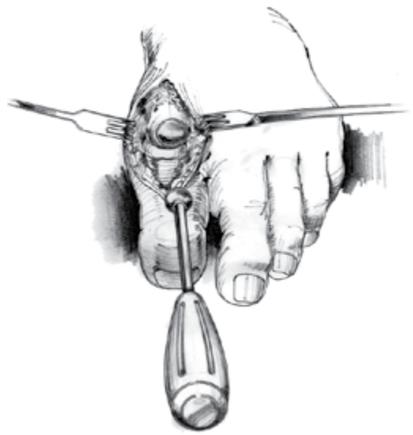
11. Before placing the **Articular Component** on the **Implant Holder** make sure that sufficient suction is present to hold the device on the distal suction cup. Align the **Articular Component** on the **Implant Holder**. Orient the etch marks on the back of the **Articular Component** with the etch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

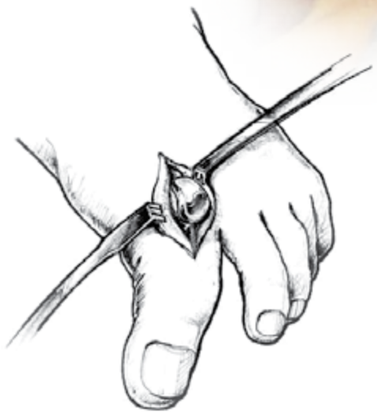
Implant holder

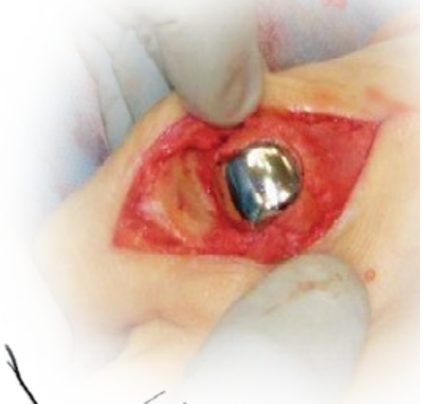


12. Use a slight tap on the **Impactor** to seat **Articular Component**. Progressively tap the **Impactor** until the **Articular Component** is firmly seated on the bone and into the **Taper Post**.

Impactor







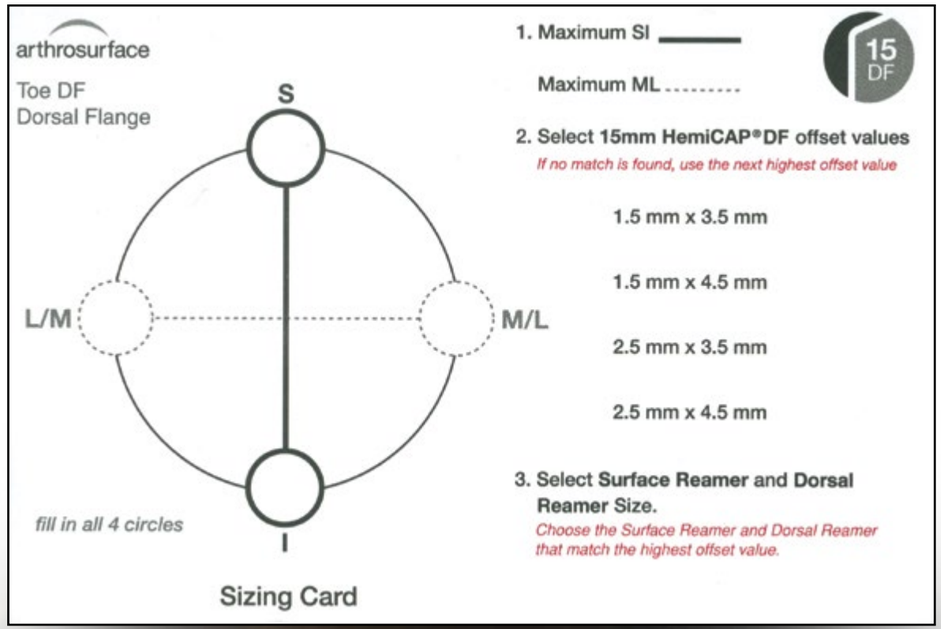
System Catalog (HemiCAP® Toe DF)

Instrumentation System	
9000-1510	Instrument Kit, Toe DF (must use with 9000-3001)
9000-3001	Instrument Kit, 15mm
7007-1205	2.0mm Guide Pin (5 Pk) for 12mm and DF Implants

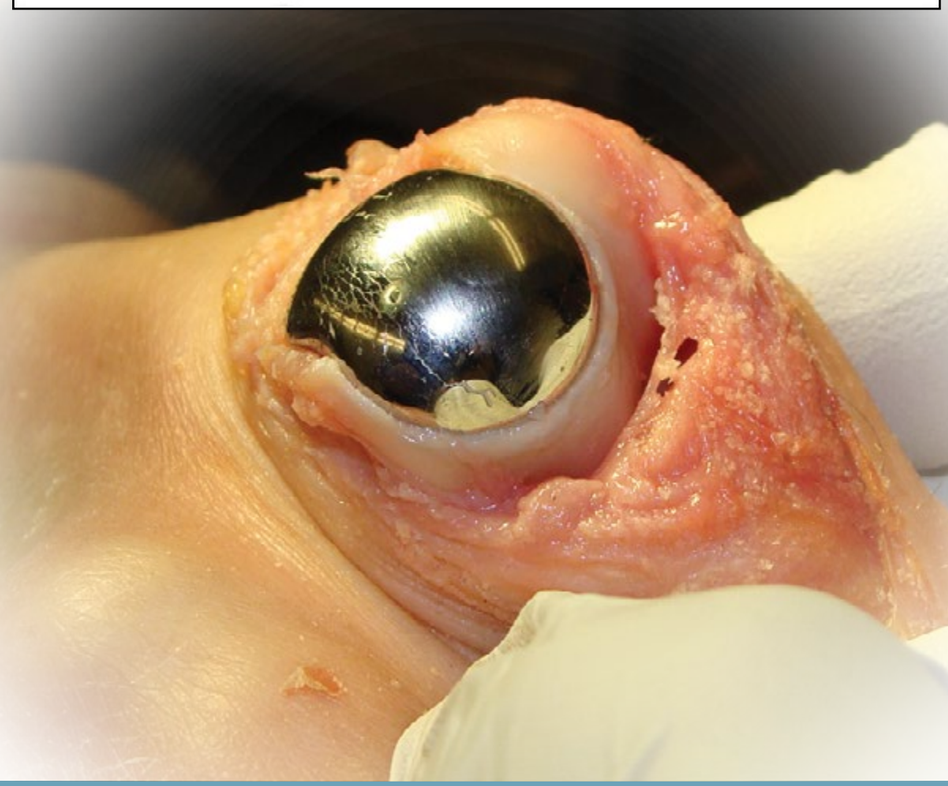
Taper Post (Fixation Components)	
9095-0018	Taper Post, 9.5mm x 18mm (for HemiCAP DF only)

DF 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

Sizing Card (HemiCAP® Toe DF)

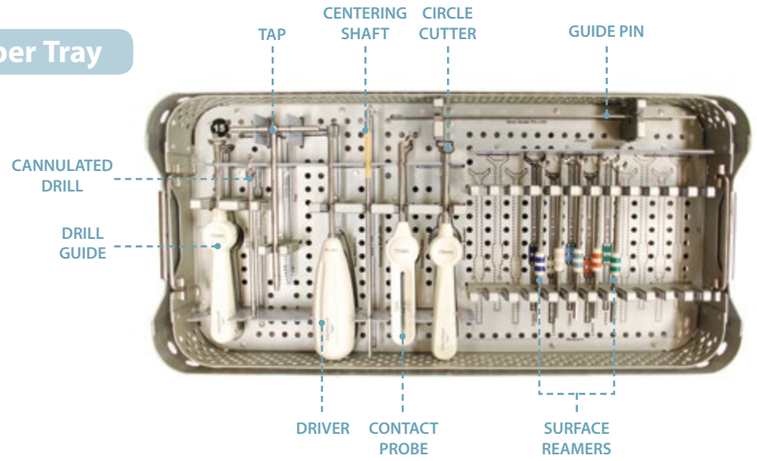


Sizing Card

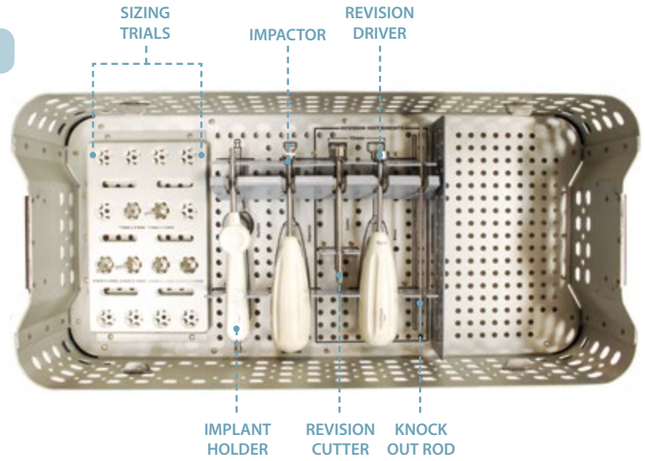


Instrumentation (HemiCAP® Toe DF)

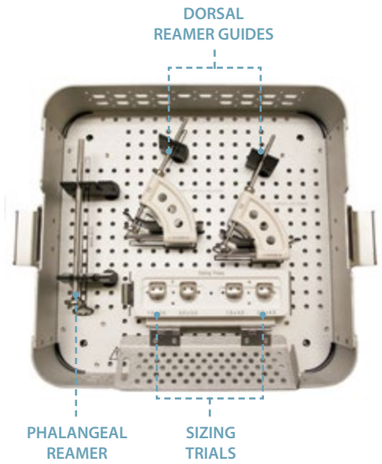
Upper Tray



Lower Tray



HemiCAP DF Tray



HemiCAP®

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 defining offsets of 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 offset point, ensuring that the selected implant will be flush or slightly recessed with the articular surface.

Prior to 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.

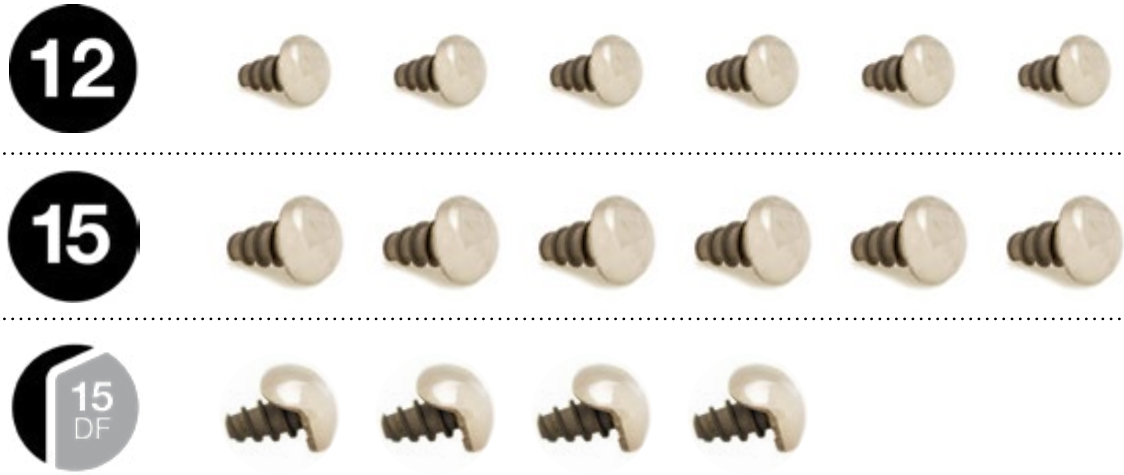
Precautions

HemiCAP® implants are intended to be fitted and installed with the HemiCAP® 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 HemiCAP® instrument set should be regularly inspected for any signs of wear or damage. Do not reuse implants or disposable instruments.

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.

HemiCAP Toe Classic & DF Implants



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

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

arthrosurface®

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

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

PN 4001-3001 REV A