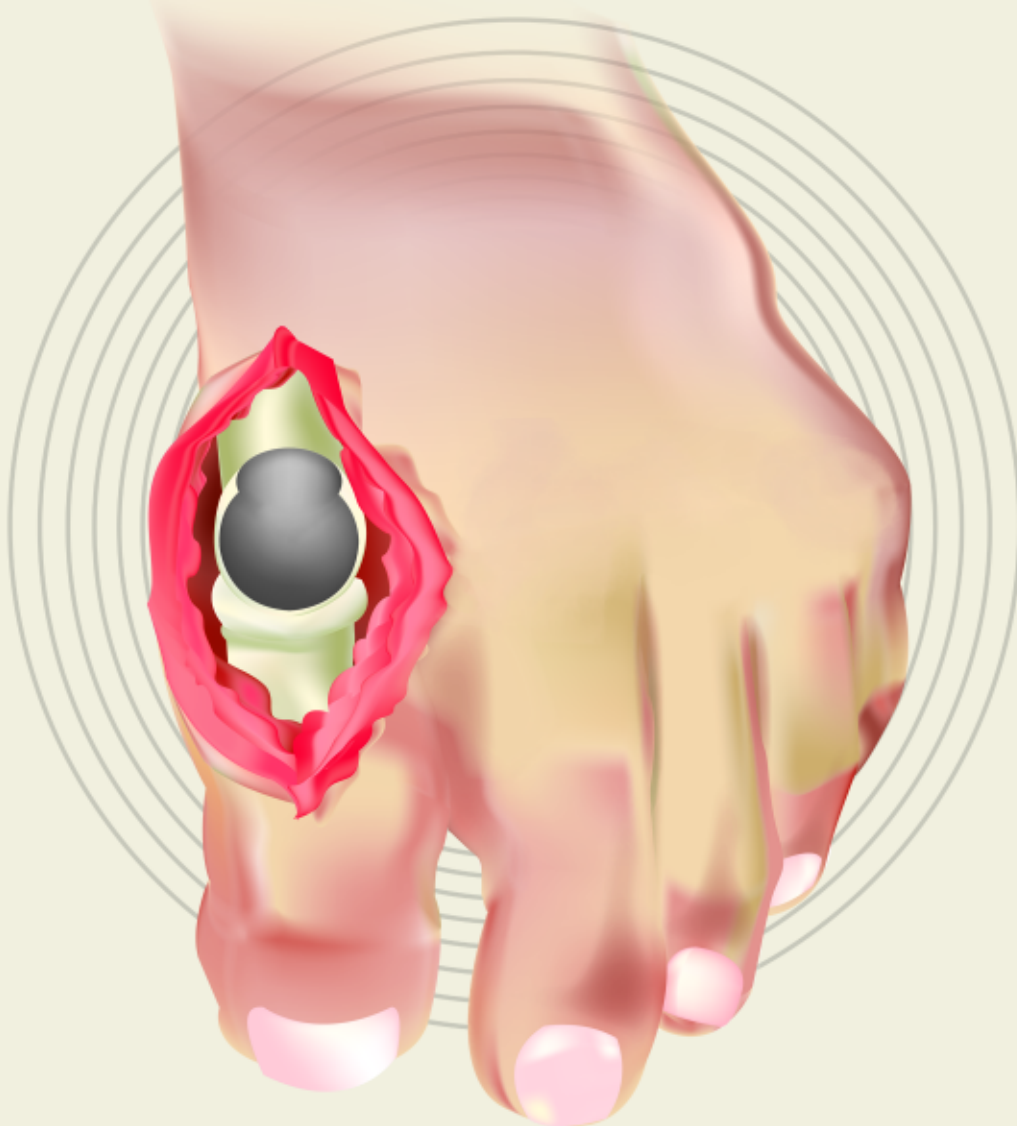




**HemiCAP**®<sup>DF</sup> Toe Resurfacing System

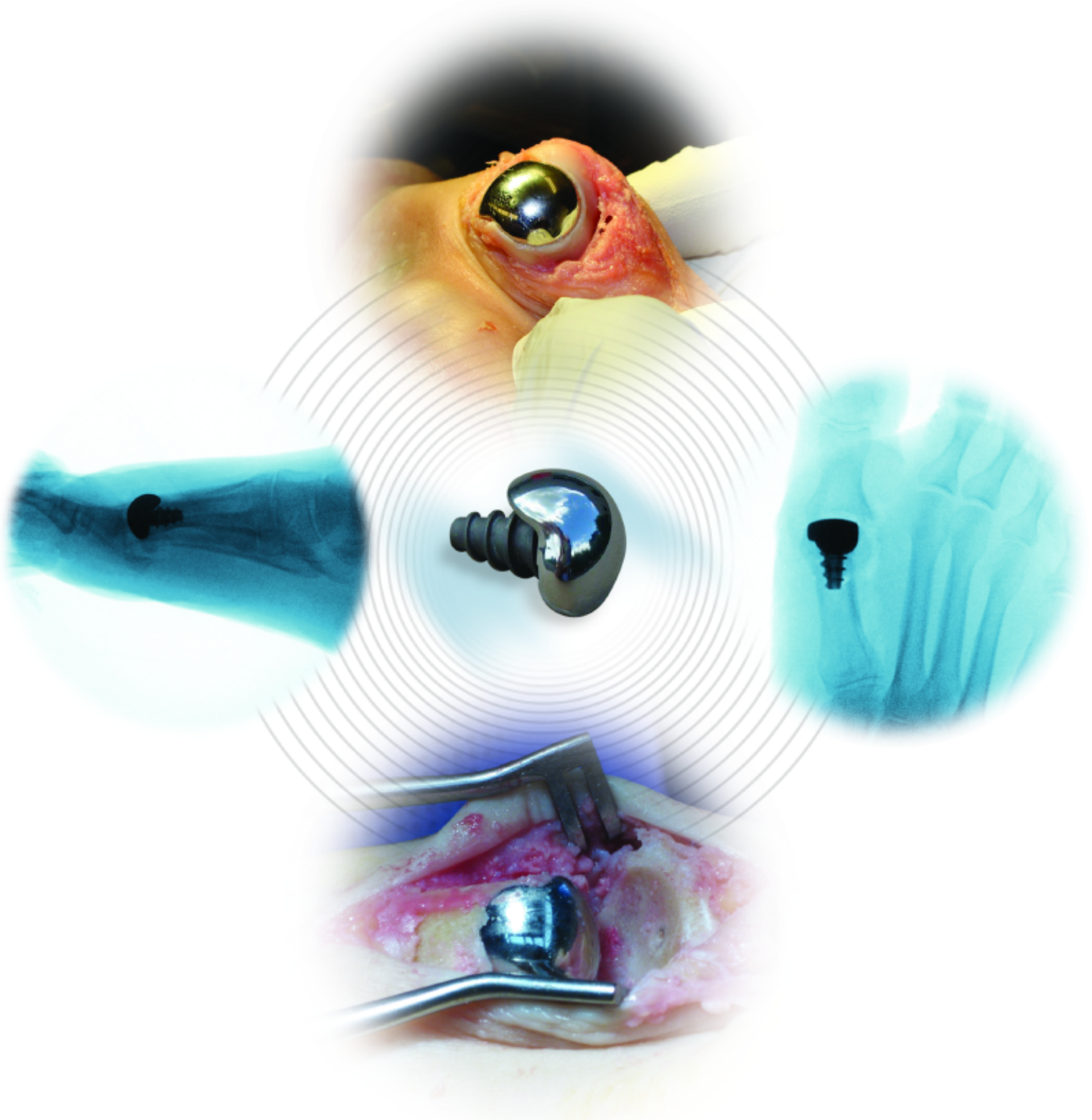


The Arthrosurface® HemiCAP® DF Toe Resurfacing System restores the cartilage surface geometry of the metatarsal head and preserves functional structures using an innovative 3 dimensional mapping system and a contoured articular resurfacing implant.



# **HemiCAP<sup>DF</sup>** Toe Resurfacing System

- Dual implant curvatures increase joint space during dorsiflexion
- Proven fixation provides a stable implant
- Anatomic “Inlay” design for proper sesamoid articulation
- Minimal bone removal maintains future options





## Description

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

### Materials:

Articular Resurfacing Component:

Cobalt-Chromium Alloy (Co-Cr-Mo)

Surface Coating: Titanium (CP Ti)

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

## Indications

Hemiarthroplasty implant for first metatarso-phalangeal 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 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 contraindication to an arthrodesis procedure and
3. Patient's overall well-being, including ability and willingness to follow instructions and comply with activity restrictions.

## Contraindications

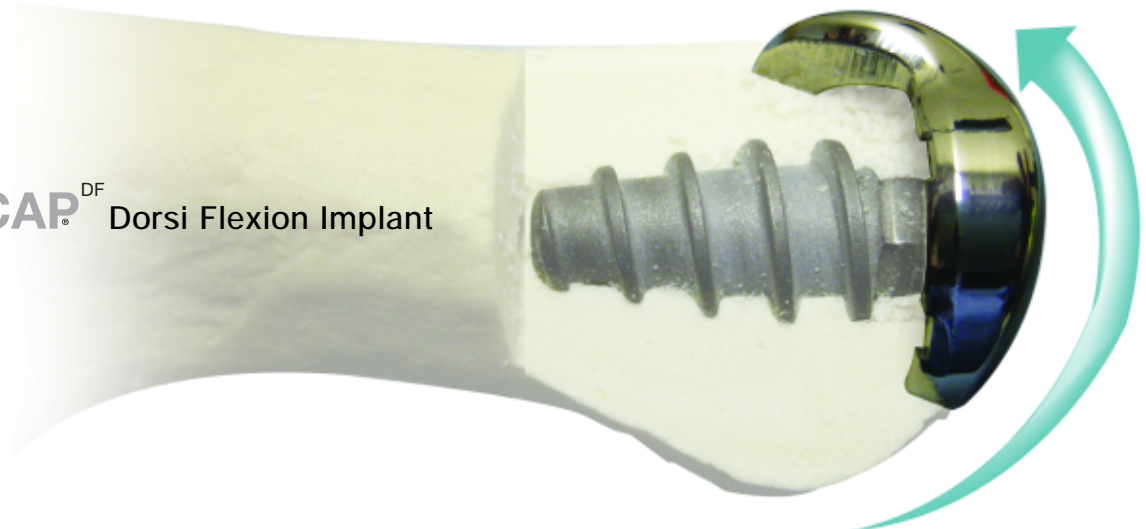
Absolute contraindications include:

1. Significant bone demineralization or inadequate bone stock
2. Inadequate skin, musculotendinous 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:

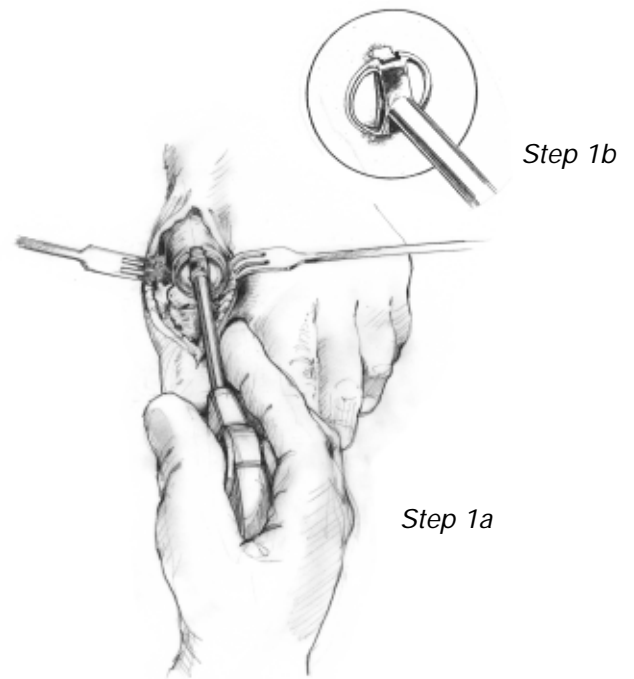
1. Uncooperative patient or patient incapable of following preoperative and postoperative instructions
2. Osteoporosis
3. Metabolic disorders which may impair the formation or healing of bone
4. Infections at remote sites which may spread to the implant site
5. Rapid joint destruction or bone resorption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

 **HemiCAP**<sup>DF</sup> Dorsi Flexion Implant



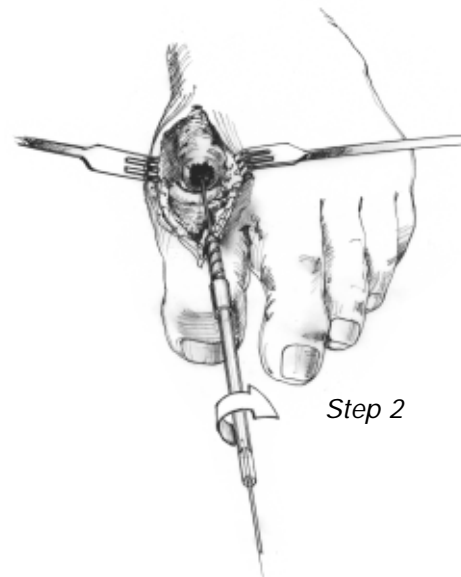
## Instructions for Use

1. Use **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 **Guide Pin** into a **Cannulated Pin Driver** and secure at the etch marking on the **Guide Pin**. Advance **Guide Pin** into bone.

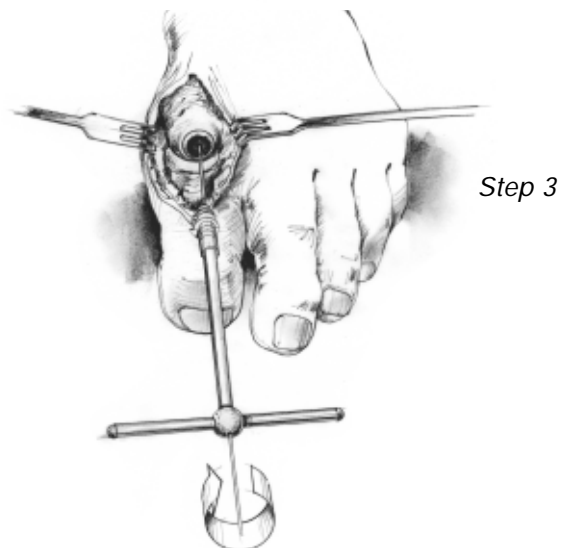


4

2. Place cannulated **Step Drill** over **Guide Pin** and drive until the proximal shoulder of **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 bone.



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

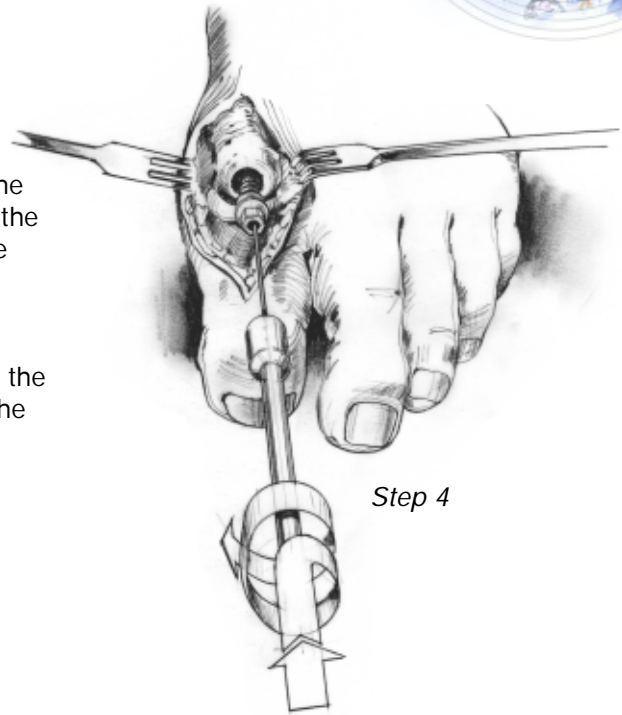






4. Place the **Driver** into the **Taper Post** and advance the **Taper Post** until the line on the **Driver** is flush with the cartilage surface making sure that it is central to the defect.

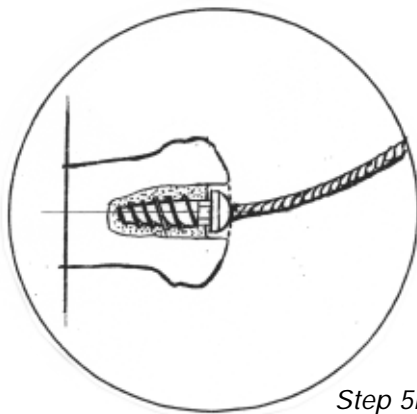
\*In a tight joint, you may decompress by advancing the **Driver** and **Taper Post** a 1/2 turn to decompress the joint by 2mm.



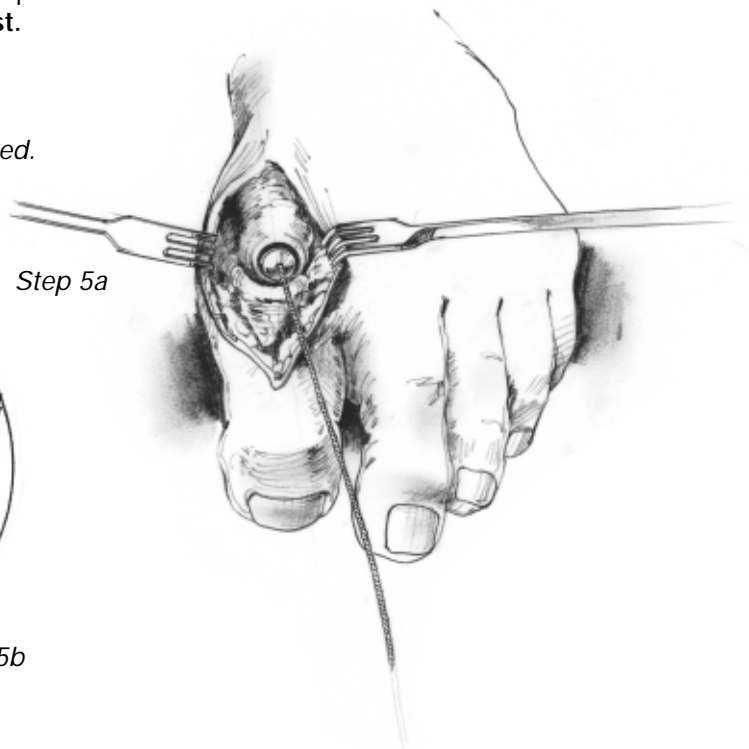
Step 4

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 defect. Adjust depth if needed using the **Driver** to rotate the **Taper Post**. Remove **Trial Cap**.

*\*If decompressing the joint, this step can be skipped.*



Step 5b



Step 5a

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**. The plantar offsets are best determined by placing the **Contact Probe** on either side of the crista – within the sesamoid grooves. Select appropriate **Articular Component** using **Sizing Card**.

arthrosurface  
Toe DF

Sizing Card

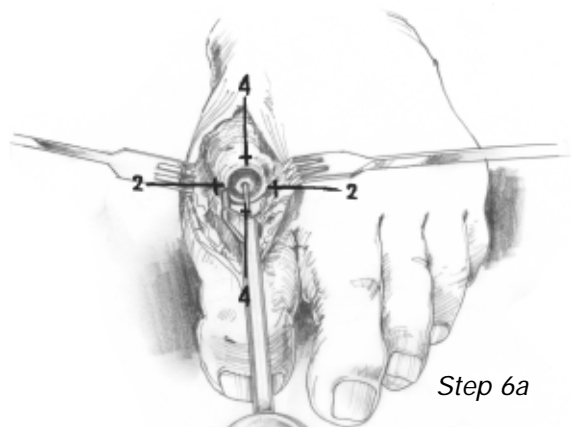
1. Maximum SI \_\_\_\_\_  
Maximum ML .....

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

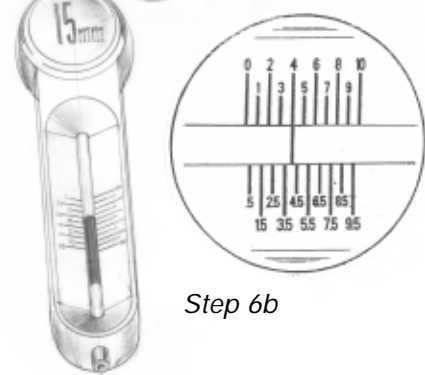
- 1,5 mm x 3,5 mm
- 1,5 mm x 4,5 mm
- 2,5 mm x 3,5 mm
- 2,5 mm x 4,5 mm

3. Select Surface Reamer and Flange Reamer Size.  
*Choose the Surface Reamer and Flange Reamer that match the highest offset value.*

Step 6c Sizing Card



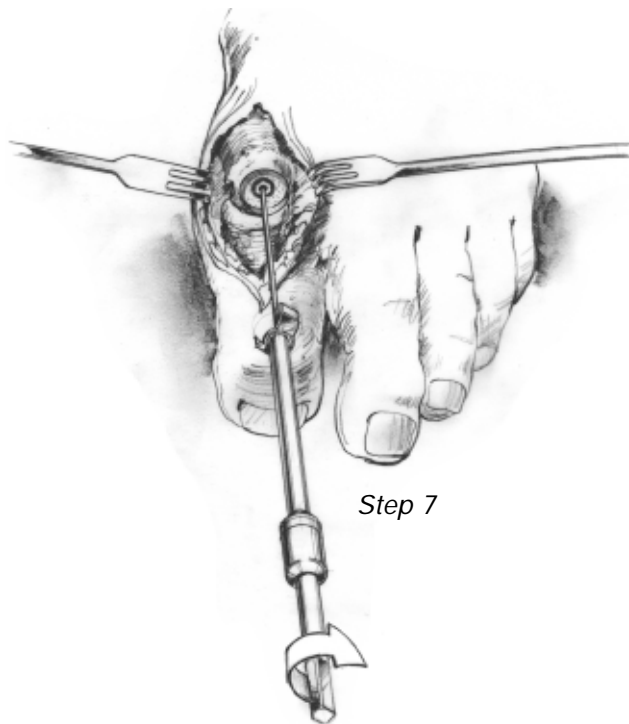
Step 6a



Step 6b

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 **Taper Post**.

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

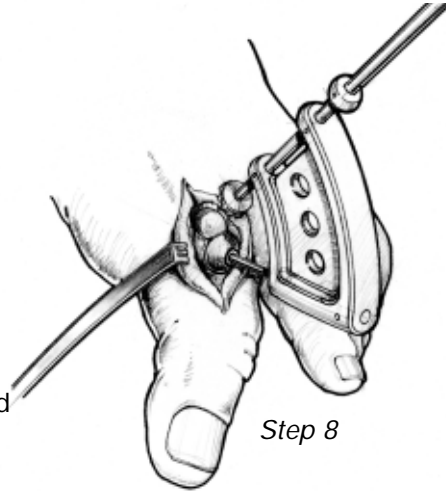


Step 7



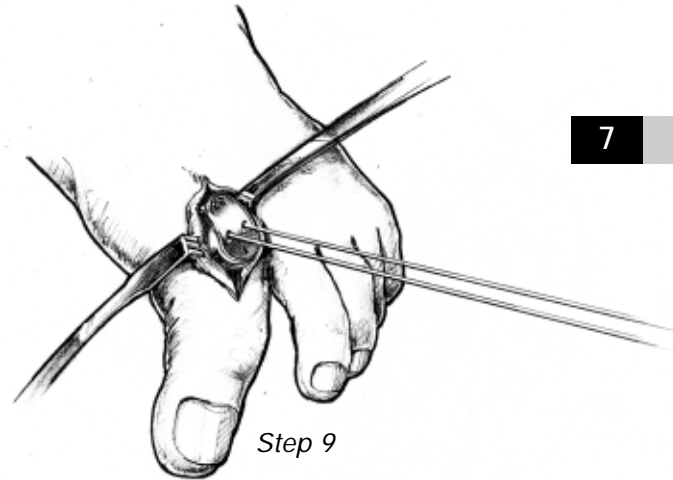
8. Place the appropriately sized **Dorsal Reamer Guide** into the taper of the **Taper Post**. The **Guide** should be oriented such that the dorsal ream is at the 12 o'clock position. Advance **Dorsal Reamer** to the depth stop. Once the **Dorsal Reamer** has advanced to the handle, immediately stop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

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



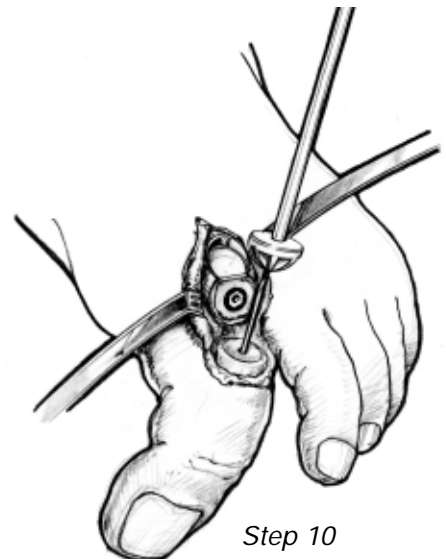
Step 8

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.



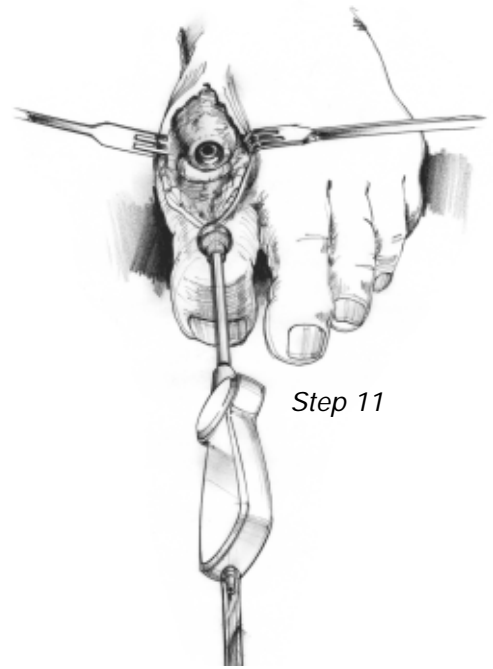
Step 9

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.

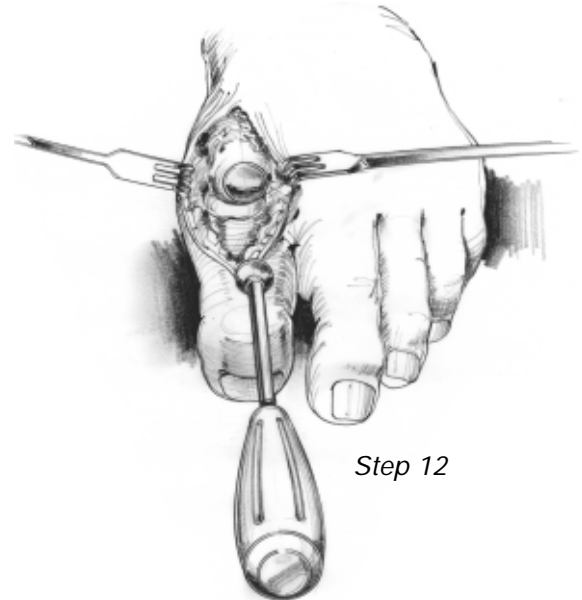


Step 10

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 **Taper Post**.



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**.







## 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

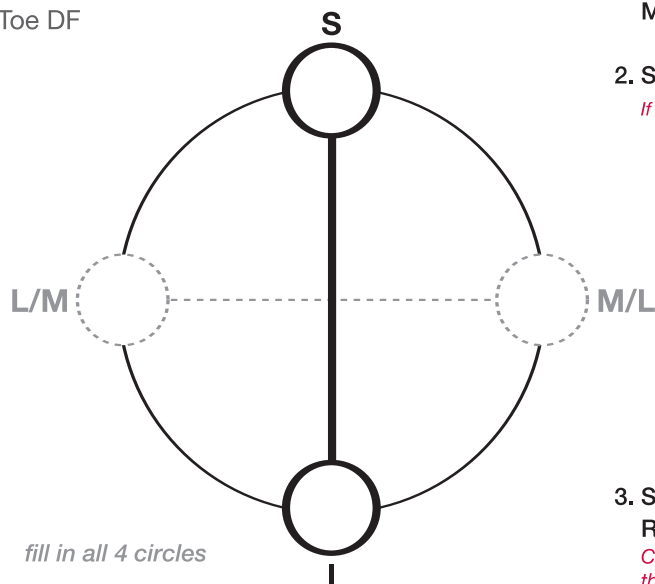
HemiCAP® implants are intended to be fitted and installed with the HemiCAP® instrument set. Use of instruments from other systems may result in improper implant selection, fitting, and placement which could result in implant failure or poor clinical outcome. The HemiCAP® instrument set should be regularly inspected for any signs of wear or damage. Do not reuse implants or disposable instruments. Reuse of single use devices can increase the risk of patient infection and can compromise service life and other performance attributes of the device.

## 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.

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

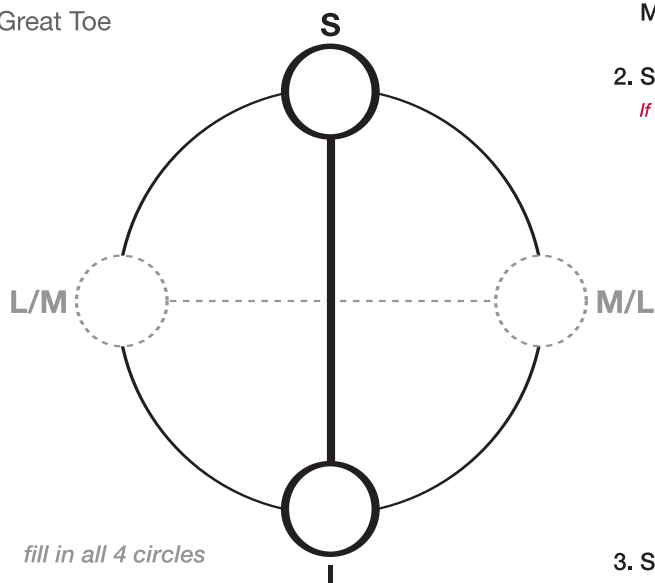
3. Select Surface Reamer and Flange Reamer Size.

*Choose the Surface Reamer and Flange Reamer that match the highest offset value.*

Step 6 Sizing Card DF Toe

arthrosurface®

Great Toe



Sizing Card

1. Maximum SI \_\_\_\_\_

Maximum ML \_\_\_\_\_



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

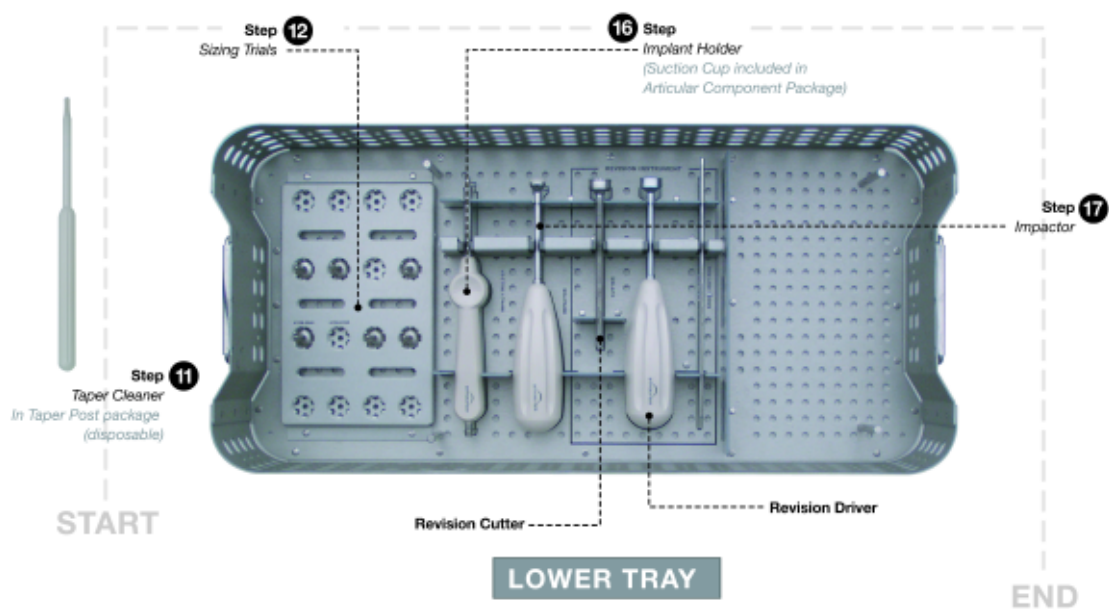
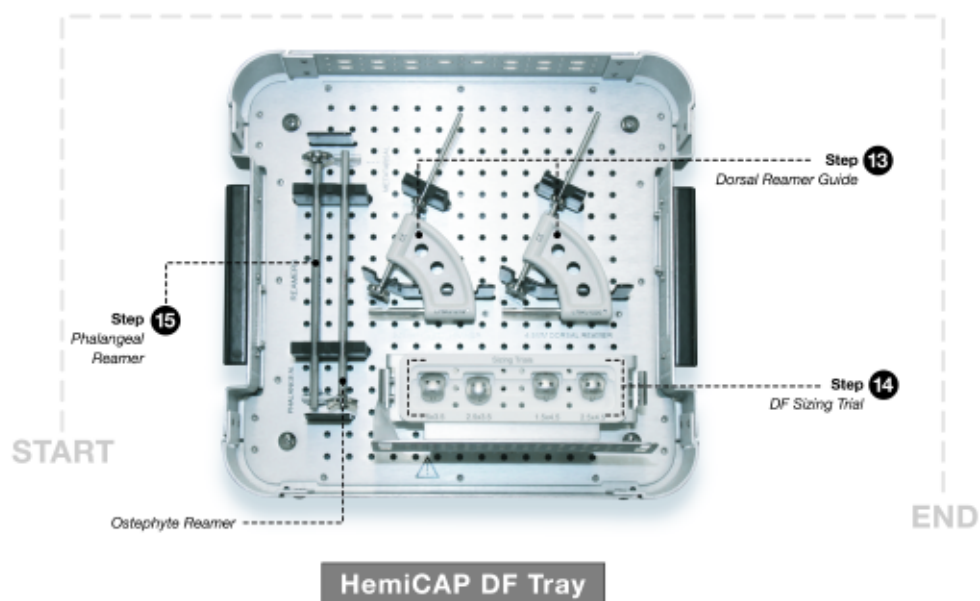
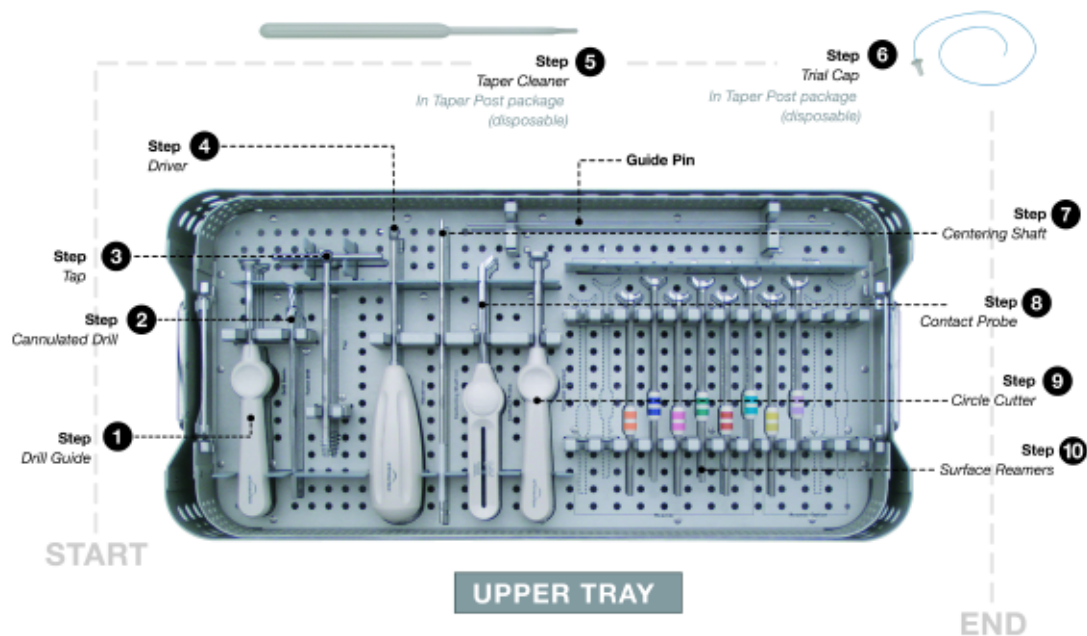
2.0 mm x 2.5 mm

2.0 mm x 3.0 mm

3. Select 12mm Surface Reamer size

*Choose the Surface Reamer that matches the highest offset value. Confirm with the color code on the HemiCAP® articular component package.*

Sizing Card Lesser MTP



**Manufactured by:**  
 Arthrosurface®, Inc., 28 Forge Parkway, Franklin, MA 02038  
 tel +1 508 520 3003 • fax +1 508 528 4604



Catalog Number	Description
9000-1200	Instrument Kit, 12mm
9000-1510	Instrument Kit, Toe DF (must use with 9000-1500)
9000-1500	Instrument Kit, 15mm
7007-1205	2.0mm Guide Pin (5 Pk) for 12 and DF Implants
<b>Articular Component DF</b>	
9M52-1535	1.5 x 3.5mm Offset
9M52-1545	1.5 x 4.5mm Offset
9M52-2535	2.5 x 3.5mm Offset
9M52-2545	2.5 x 4.5mm Offset
<b>Articular Component 12mm</b>	
9122-1015	1.0 x 1.5mm Offset
9122-1020	1.0 x 2.0mm Offset
9122-1520	1.5 x 2.0mm Offset
9122-1525	1.5 x 2.5mm Offset
9122-2025	2.0 x 2.5mm Offset
9122-2030	2.0 x 3.0mm Offset
<b>Taper Post</b>	
9080-0016	Taper Post, 8.0mm x 16mm (for 12mm only)
9095-0018	Taper Post, 9.5mm x 18mm (for HemiCAP DF only)

Arthrosurface's HemiCAP® resurfacing system is also available for the following joints:

- Shoulder
- Hip
- Great Toe
- Condyle
- Patello-Femoral

For all orders call +1-508-520-3003  
 Toll Free call +1-866-261-9294



**R<sub>x</sub> ONLY**

[www.arthrosurface.com](http://www.arthrosurface.com)

This product is covered by one or more of US Patent Nos. 6,520,964; 6,610,067; 6,679,917 and other patents pending.  
 HemiCAP™ is a trademark of Arthrosurface, Inc.