The Arthrosurface® HemiCAP® Great 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.
Recreates articular surface curvatures • Maintains joint height & version angle
Preserves soft tissue tension • Restores a new load sharing surface
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.
Instructions for Use

1. Use 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 Guide Pin into a Cannulated Powered Drill and secure at the etch marking on the Guide Pin. Advance Guide Pin through the Drill Guide into bone making sure that it is central to the defect. (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.)

2. Place Cannulated Drill over Guide Pin and drill until the proximal shoulder of Drill is flush to the articular surface.
3. **Tap** hole to etched depth mark on **Tap**. Insert bone cement into pilot hole.

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 **Guide Pin**. Clean taper in **Taper Post** with **Taper Cleaner**. Place **Trial Cap** into **Taper Post** to confirm correct depth of **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 **Trial Cap**.

6. Place **Centering Shaft** into taper of **Taper Post**. Place **Contact Probe** over **Centering Shaft** and rotate around **Centering Shaft**. Read **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 appropriate **Articular Component** using Sizing Card.
7. Remove **Centering Shaft** and replace with **Guide Pin**. Advance **Circle Cutter** onto the articular surface by twisting the **Circle Cutter** back and forth avoiding any bending of the **Guide Pin**. Score articular cartilage down to subchondral bone.

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

9. Remove **Guide Pin**. Clean taper in **Taper Post** with **Taper Cleaner** and remove any debris from the surrounding implant bed.
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 matching Sizing Trial. Sizing Trials must match 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 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.
**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.
Step 6 Sizing Card 12mm

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.

Step 6 Sizing Card 15mm

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 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. Confirm with the color code on the HemiCAP® articular component package.
For all orders call +1-508-520-3003
Toll Free call +1-866-261-9294
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.

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<tr>
<th>Catalog Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>9000-1200</td>
<td>Instrument Kit, 12mm includes 12mm Sizing Trials</td>
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<tr>
<td>9000-1500</td>
<td>Instrument Kit, 15mm includes 15mm Sizing Trials</td>
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<tr>
<td>7007-1205</td>
<td>2.0mm Guide Pin (5 Pk) for 12 and 15mm implants</td>
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**Articular Component 12mm**

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<tr>
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<tbody>
<tr>
<td>9122-1015</td>
<td>1.0 x 1.5mm Offset</td>
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<tr>
<td>9122-1020</td>
<td>1.0 x 2.0mm Offset</td>
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**Articular Component 15mm**

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<td>9152-1535</td>
<td>1.5 x 3.5mm Offset</td>
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<td>9152-2030</td>
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<td>9152-2040</td>
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<td>9152-2545</td>
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**Taper Post**

<table>
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<th>Catalog Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>9080-0016</td>
<td>Taper Post, 8.0mm x 16mm (for 12mm only)</td>
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<tr>
<td>9095-0018</td>
<td>Taper Post, 9.5mm x 18mm (for 15mm only)</td>
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Arthrosurface’s HemiCAP® resurfacing system is also available for the following joints:

- Shoulder
- Hip
- Great Toe
- Knee (Available in most International markets via CE mark and as part of a IDE study in the US).