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 One (Pages 3-12)

**HemiCAP Toe Classic**

“Metatarsal head resurfacing in combination with joint decompression, soft tissue mobilization, and debridement can **achieve excellent results in grade II and III hallux rigidus**.”


Chapter Two (Pages 13-22)

**HemiCAP Toe DF**

“Radiographic evaluation of the HemiCAP prosthesis in 56 patients demonstrated no significant evidence of loosening; it appeared to show **superior radiographic results** compared to those of other metallic implants using a stemmed design.”

Thomas San Giovanni, MD; *Arthrosurface HemiCAP Resurfacing. Chapter 21. Operative Techniques in Orthopaedic Surgery, 2010*
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**

<table>
<thead>
<tr>
<th>Component</th>
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<tbody>
<tr>
<td>Articular Resurfacing Component</td>
<td>Cobalt-Chromium Alloy (Co-Cr-Mo)</td>
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<tr>
<td>Surface Coating</td>
<td>Titanium (CPTi)</td>
</tr>
<tr>
<td>Taper Post</td>
<td>Titanium Alloy (Ti-6Al-4V)</td>
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</table>

**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 contraindication 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, musculontendinous 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
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.
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.*

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

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.

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.
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.

![](image1)

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.

![](image2)

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**.

![](image3)

Implant holder

**Chapter One: HemiCAP Toe Classic**
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.

**System Catalog**

**Instrumentation System**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>9000-1200</td>
<td>Instrument Kit, 7mm</td>
</tr>
<tr>
<td>9000-3000</td>
<td>Instrument Kit, 12mm includes 12mm Sizing Trials</td>
</tr>
<tr>
<td>9000-3001</td>
<td>Instrument Kit, 15mm includes 15mm Sizing Trials</td>
</tr>
<tr>
<td>7007-1205</td>
<td>2.0 mm Guide Pin (5 PK) for 12 &amp; 15 mm Implants</td>
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</table>

**Taper Post (Fixation Components)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>9070-0013</td>
<td>Taper Post, 7.0mm x 13mm (for 12mm only)</td>
</tr>
<tr>
<td>9095-0018</td>
<td>Taper Post, 9.5mm x 18mm (for 15mm only)</td>
</tr>
</tbody>
</table>

**12mm Articular Components**

<table>
<thead>
<tr>
<th>Code</th>
<th>Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>9122-1015</td>
<td>1.0mm x 1.5mm Offset</td>
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<tr>
<td>9122-1020</td>
<td>1.0mm x 2.0mm Offset</td>
</tr>
<tr>
<td>9122-1520</td>
<td>1.5mm x 2.0mm Offset</td>
</tr>
<tr>
<td>9122-1525</td>
<td>1.5mm x 2.5mm Offset</td>
</tr>
<tr>
<td>9122-2025</td>
<td>2.0mm x 2.5mm Offset</td>
</tr>
<tr>
<td>9122-2030</td>
<td>2.0mm x 3.0mm Offset</td>
</tr>
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**15mm Articular Components**

<table>
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<tbody>
<tr>
<td>9152-1525</td>
<td>1.5mm x 2.5mm Offset</td>
</tr>
<tr>
<td>9152-1535</td>
<td>1.5mm x 3.5mm Offset</td>
</tr>
<tr>
<td>9152-2030</td>
<td>2.0mm x 3.0mm Offset</td>
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<tr>
<td>9152-2040</td>
<td>2.0mm x 4.0mm Offset</td>
</tr>
<tr>
<td>9152-2535</td>
<td>2.5mm x 3.5mm Offset</td>
</tr>
<tr>
<td>9152-2545</td>
<td>2.5mm x 4.5mm Offset</td>
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Sizing Cards (HemiCAP® Toe Classic)

Chapter One: HemiCAP Toe Classic

1. Maximum Sl __________
   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.

1. Maximum Sl __________
   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.
Instrumentation (HemiCAP® Toe Classic)
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
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.

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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
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, musculontendinous 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
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:**


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.

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

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

![Centering Shaft (colored end up)](image)

![Contact Probe](image)

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 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 until satisfied with the fit.*

![Surface Reamer](image)

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 **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.

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**.
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.

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<td>9000-1510</td>
<td>Instrument Kit, Toe DF (must use with 9000-3001)</td>
</tr>
<tr>
<td>9000-3001</td>
<td>Instrument Kit, 15mm</td>
</tr>
<tr>
<td>7007-1205</td>
<td>2.0mm Guide Pin (5 Pk) for 12mm and DF Implants</td>
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<table>
<thead>
<tr>
<th>DF Articular Components</th>
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</tr>
</thead>
<tbody>
<tr>
<td>9M52-1535</td>
<td>1.5mm x 3.5mm Offset</td>
</tr>
<tr>
<td>9M52-1545</td>
<td>1.5mm x 4.5mm Offset</td>
</tr>
<tr>
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<th>Taper Post (Fixation Components)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>9095-0018</td>
<td>Taper Post, 9.5mm x 18mm (for HemiCAP DF only)</td>
</tr>
</tbody>
</table>
Sizing Card (HemiCAP® Toe DF)

1. Maximum SI
   - Maximum ML

2. Select 15mm HemiCAP®DF offset values
   - 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.

fill in all 4 circles
**Instrumentation** (HemiCAP® Toe DF)

**Upper Tray**
- TAP
- CENTERING SHAFT
- CIRCLE CUTTER
- GUIDE PIN
- STEP DRILL
- DRILL GUIDE
- DRIVER
- CONTACT PROBE
- SURFACE REAMERS

**Lower Tray**
- SIZING TRIALS
- IMPACTOR
- REVISION DRIVER
- IMPLANT HOLDER
- REVISION CUTTER
- KNOCK OUT ROD
- DORSAL REAMER GUIDES

**HemiCAP DF Tray**
- PHALANGEAL REAMER
- SIZING TRIALS
**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

12

15

15 DF

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.)

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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ISO 13485

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