Talar Dome System
Surgical Technique
CAP™ TALAR DOME RESURFACING HEMIARTROPLASTY IMPLANT

Surgical Technique Guide

Description
The HemiCAP® Contoured Articular Prosthetic incorporates an articular resurfacing component and a cancellous taper post component that mates 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-Molybdenum alloy (Co-Cr-Mo)
- **Surface Coating:** Titanium (CP Ti)
- **Taper Post Component:** Titanium alloy (Ti-6Al-4V)
Indications for Use:
Partial resurfacing of the talar dome of the ankle for use in the treatment of patients with localized post-traumatic degenerative disease, necrosis associated with large unstable osteochondral fractures, or osteochondritis dessicans. Soft tissues and other structures contributing to joint stability should be intact or reconstructable. The intended use of the device is part of an interim clinical strategy for patients who have not responded to other treatments and who will likely receive a joint replacement or fusion in the future. The device is a single use implant.

Patient selection factors to be considered include:
1) Patient has localized disease of the ankle and talar dome
2) Patient’s need to obtain pain relief and improve function;
3) Patient’s age as relative contraindication to an arthrodesis or joint replacement procedure; and
4) Patient’s overall well-being, including ability and willingness to follow instructions and comply with activity restrictions.
Contraindications:

**Absolute contraindications include:**
1) Extensive talar necrosis, significant bone demineralization or inadequate bone stock;
2) Inadequate skin, musculotendinous or neurovascular compromise;
3) Inflammatory or rheumatoid arthritis, infection, sepsis, and osteomyelitis; and
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 pre-operative and post-operative 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; rapid joint destruction or bone resection visible on roentgenogram
5) Loss of lateral ligaments, chronic instability or deficient soft tissues and other support structures; and
6) Vascular or muscular insufficiency.
7) Diffuse tibiotalar degeneration
8) Severe malalignment of the ankle

**Pre-operative Considerations and Assessments:**
1) Extent of the lesion and radiographic alignment;
2) Neurovascular status and soft tissue coverage;
3) Location of the lesion to be resurfaced and approach that will be required for exposure
History and Challenges of Talar Defects

- Why?
- Where the occur?
- Challenge to reproduce anatomic fit
- Why HemiCAP® is suitable to address these lesions
- Other thoughts?
Surgical Exposure
as described by Prof. C. Niek van Dijk,
Chair, AMC, Netherlands

Exposure Pictures used here are representative and not final
1. Use **Drill Guide** to locate the axis normal to the articular surface and central to the defect. Place **Guide Pin** into a Cannulated Powered Drill and secure at the etch marking on the **Guide Pin**. Advance **Guide Pin** into bone making sure that it is central to the defect. (It is important to verify the **Drill Guide** is seated on the curved surface such that four points of contact are established. A normal axis is necessary for proper implant fit.)
2. Place **Cannulated Drill** over **Guide Pin** and drive until the proximal shoulder of the **Drill** is flush with the articular surface. (Use lavage during drilling to prevent possible tissue damage from heat effects.)
3. Tap hole to etched depth mark on Tap.
4. Before inserting the Taper Post, thoroughly cleanse the pilot hole of any debris and then inject the cement in a retrograde fashion from the end of the hole upwards.
5. Place the **Driver** into the **Taper Post** and advance the **Taper Post** until the line on the **Driver** is flush with the cartilage surface.
6. Clean taper in **Taper Post** with **Taper Cleaner**.

7. 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** (rotate clockwise to advance and counterclockwise to retract). Remove **Trial Cap**.
8. 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 the 4 indexing points and mark each of the identified offsets on the appropriate **Sizing Card**. Select appropriate **Articular Component** using **Sizing Card**.
1. Maximum SI

Maximum AP

2. Select 15mm HemiCAP® offset values
   If no match is found, use the next highest offset value
   - 0.5 mm x 4.0 mm
   - 0.5 mm x 4.5 mm
   - 1.0 mm x 4.0 mm
   - 1.0 mm x 4.5 mm
   - 1.0 mm x 5.0 mm
   - 1.0 mm x 5.5 mm
   - 1.5 mm x 4.0 mm
   - 1.5 mm x 4.5 mm
   - 1.5 mm x 5.0 mm
   - 1.5 mm x 5.5 mm
   - 2.0 mm x 4.0 mm
   - 2.0 mm x 4.5 mm
   - 2.0 mm x 5.0 mm
   - 2.0 mm x 5.5 mm

3. Select 15mm Surface Reamer size
   Choose the Surface Reamer that matches the highest offset value. Confirm with the color coda on the HemiCAP® articular component package.

fill in all 4 circles
9. 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**.
10. 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**. (Use lavage during drilling to prevent possible tissue damage from heat effects.) Make sure not to bend the **Guide Pin** during drilling as it may result in **Articular Component** malalignment.
11. 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.
12. 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**.
13. Use a slight tap on the **Impactor** to seat the **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 mapping articular surfaces, care should be taken to ensure that instrument taper surfaces 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 mapping points, ensuring that the selected implant will be flush or slightly recessed just below articular surface at margins of implant. Prior to placing implant, carefully trim articular cartilage debris around margin of implant. 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 at slowest speeds possible 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
The HemiCAP® Contoured Articular Prosthetic Talar Dome implant is intended to be fitted and installed with the HemiCAP® Contoured Articular Prosthetic Talar Dome 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 instrument set should be regularly inspected for any signs of wear or damage. Do not reuse implants.

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 materials. 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
Postoperative pain or incomplete resolution of preoperative symptoms.

Sterility
Prosthetic components are sterilized by exposure to gamma irradiation. Do not resterilize. Do not use components if packaging is opened or damaged. Do not use components if beyond expiration date.
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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>T000-1500</td>
<td>Kit, Instrument, 15mm, Talus</td>
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<tr>
<td>9007-1300</td>
<td>2mm Guide Pin, Talus</td>
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<td>T103-0020</td>
<td>Taper Post, 10.3mm</td>
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<td>T152-0540</td>
<td>15mm Talus Art. Comp., 0.5 x 4.0mm</td>
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