

“Approximately 5%-18% of all hip arthroplasties are completed on patients with a primary diagnosis of osteonecrosis. Patients are generally younger adults age 35 years to 45 years, and risk factors for 75%-90% of cases include chronic steroid use, alcoholism, smoking, hip trauma including femoral neck fractures and hip dislocations, and prior hip surgery.”

*Anjan P Kaushik, Anusuya Das and Qunjun Cui.
World J Orthop. 2012 May 18; 3(5): 49-57.*



The Arthrosurface® HemiCAP® Hip Hemiarthroplasty System restores the unique articular surface geometry of the femoral head and preserves functional structures by using an intraoperative 3 dimensional mapping system and a contoured articular resurfacing implant.

Description

The HemiCAP® Contoured Articular Prosthetic incorporates an articular resurfacing component and a cancellous fixation component that mate together via taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/ prosthetic interface. The device is a single use implant intended to be used with bone cement.

Materials

Articular Component:	Cobalt-Chromium Alloy (Co-Cr-Mo)
Surface Coating:	Titanium (CPTi)
Taper Post:	Titanium Alloy (Ti-6Al-4V)

Indications

Relief of pain, disability, and restoration of hip function within patients who have radiographic evidence of good bone stock in the femoral head and acetabulum, with the bearing surface and supportive bone structure of the acetabulum being normal. The device is a single use implant intended to be used for cemented hemi-hip resurfacing applications only.

Patient selection factors to be considered include:

- 1) Need to obtain pain relief and improve function
- 2) Patient age as a potential for early-age-revision of total joint arthroplasty
- 3) Patient overall well-being, including ability and willingness to follow instructions and comply with activity restrictions

Contraindications

Absolute contraindications include:

- 1) Defects that are not localized
- 2) Defects that are located on joint surfaces that are discontinuous
- 3) Inflammatory degenerative joint disease, rheumatoid arthritis, infection, sepsis, and osteomyelitis

Relative contraindications include:

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

Surgical Technique

Please Note: Before the case begins, ensure the correct icon is displayed both on the side of the tray as well as inside the top tray above the Drill Guide.



1. Use the **Drill Guide** to locate the axis normal to the articular surface and central to the defect. Place the **Guide Pin** into a cannulated powered drill and secure at the etch marking on the Guide Pin. Advance the **Guide Pin** into 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 is necessary for proper implant fit.*

2. Place the **Step Drill** over the **Guide Pin** and drive until the proximal shoulder of the **Step Drill** is flush with the articular surface. (Use lavage during drilling to prevent possible tissue damage from heat effects).



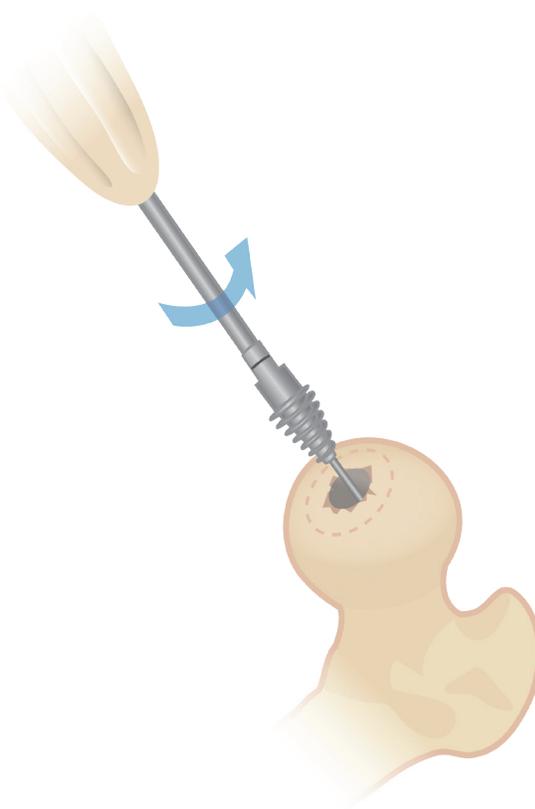
3. Tap the hole to the etched depth mark on the **Tap**.



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** onto the **Taper Post** and advance the **Taper Post** until the line on the **Driver** is flush with the height of the original articular cartilage levels.



6. Remove the **Guide Pin**. Clean the taper of the **Taper Post** with the **Taper Cleaner**. Place the **Trial Cap** onto the **Taper Post** to confirm 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 **Hex Driver** to rotate the **Taper Post** (rotate clockwise to advance and counterclockwise to retract). Remove **Trial Cap**.



7. 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**.

arthrosurface®
Femoral Head

Sizing Card

1. Maximum SI _____ **35**
Maximum ML

2. Select 35mm HemiCAP® offset values
If no match is found, use the next highest offset value

- 6.0 mm x 6.0 mm
- 6.5 mm x 6.5 mm
- 7.0 mm x 7.0 mm
- 7.5 mm x 7.5 mm
- 8.0 mm x 8.0 mm
- 8.5 mm x 8.5 mm
- 9.0 mm x 9.0 mm

3. Select 35mm Surface Reamer size
Choose the Surface Reamer that matches the highest offset value.

PN 1001-1535 REV B



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



9. Choose the appropriate **Surface Reamer** based on the offsets. 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 articular rim.



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



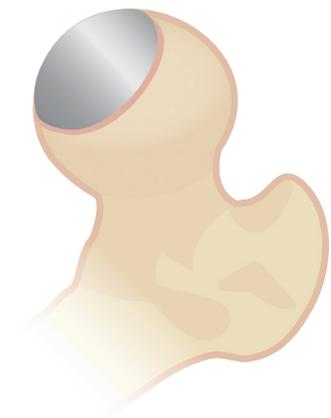
11. Place the **Sizing Trial** into the defect that matches the offset profile of the chosen **Articular Component**. Confirm the fit of the **Sizing Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed. If the **Sizing Trial** is proud at the edge of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



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**. Insert onto the taper of the **Taper Post**.

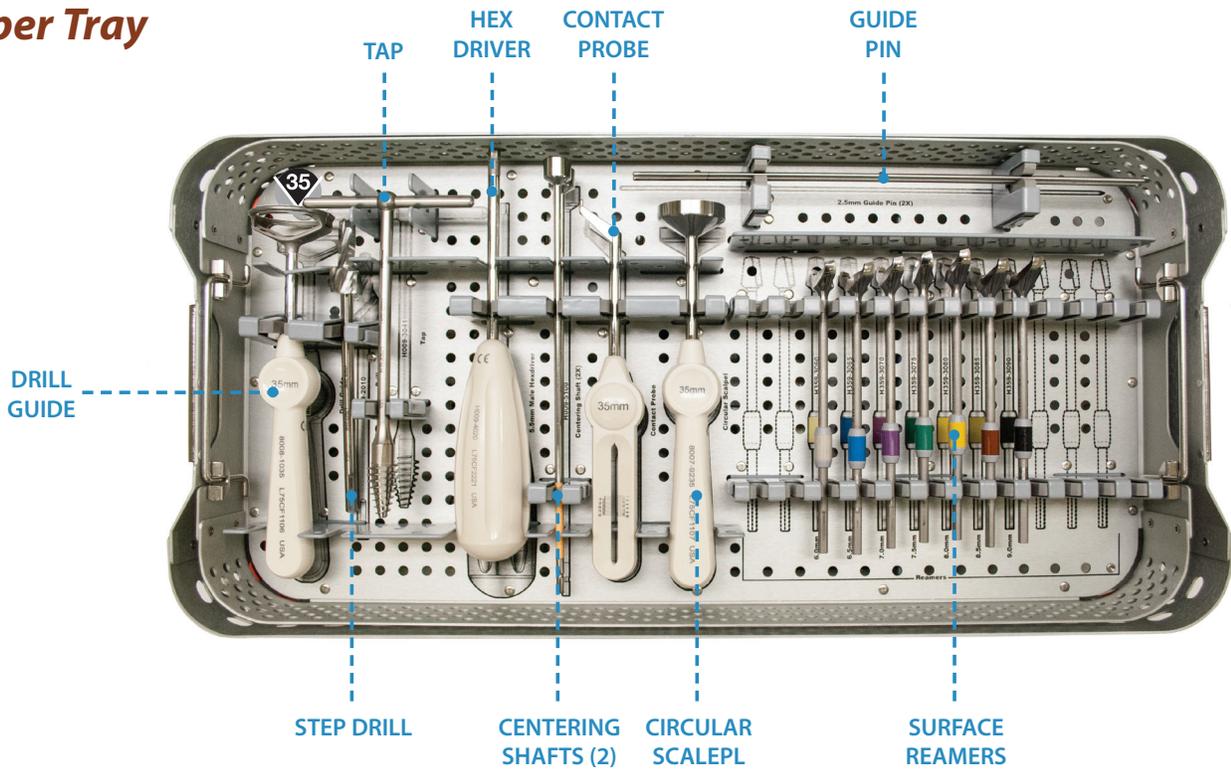


13. Use a slight tap on the Impactor to seat the **Articular Component**. Progressively tap the **Impactor** until the **Articular Component** is firmly seated on the bone.

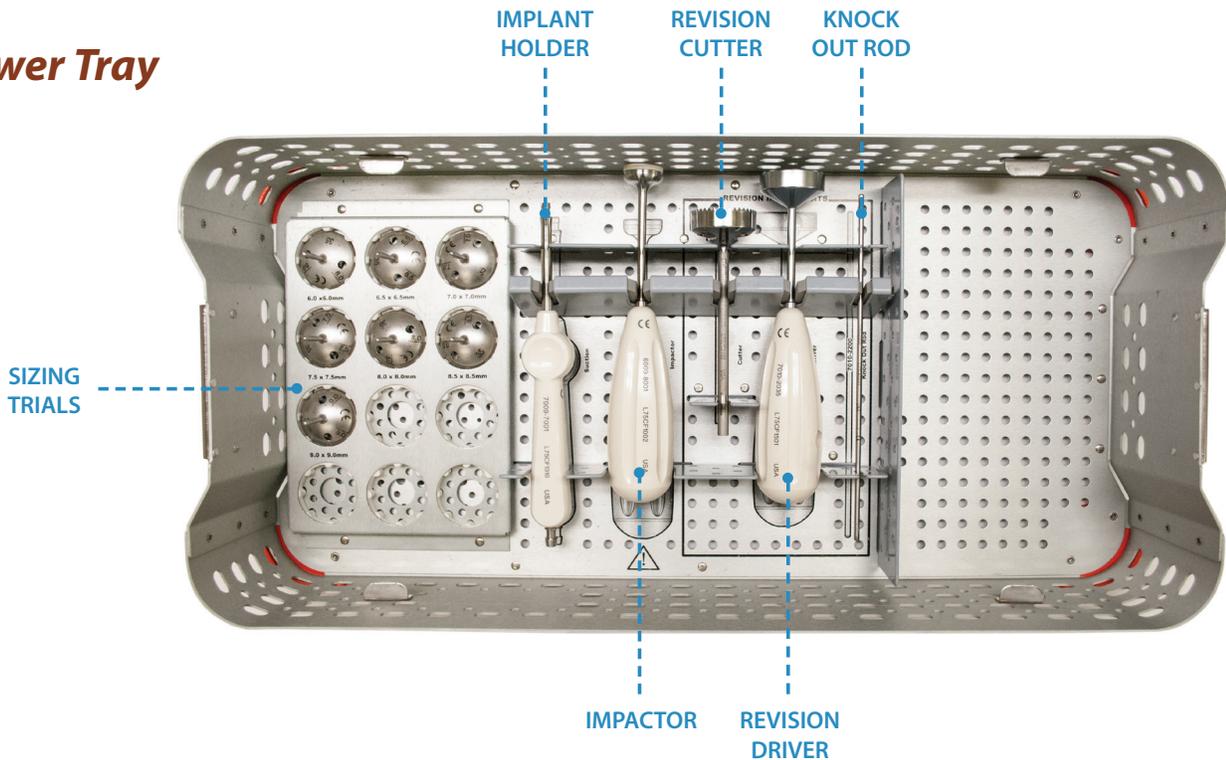


Instrumentation

Upper Tray



Lower Tray



Sizing Card

arthrosurface®
Femoral Head

S

L/M M/L

fill in all 4 circles

Sizing Card

1. Maximum SI _____
- Maximum ML

2. Select 35mm HemiCAP® offset values
If no match is found, use the next highest offset value

- 6.0 mm x 6.0 mm
- 6.5 mm x 6.5 mm
- 7.0 mm x 7.0 mm
- 7.5 mm x 7.5 mm
- 8.0 mm x 8.0 mm
- 8.5 mm x 8.5 mm
- 9.0 mm x 9.0 mm

3. Select 35mm Surface Reamer size
Choose the Surface Reamer that matches the highest offset value.

PN R001-1135 REV B

System Catalog

Instrumentation System

H000-3500	Instrument Kit, 35mm, Hip
8007-1205	2.5mm Guide Pin (5 pk), Hip

Articular Component 35mm

H352-0060	6.0mm x 6.0mm Offset
H352-0065	6.5mm x 6.5mm Offset
H352-0070	7.0mm x 7.0mm Offset
H352-0075	7.5mm x 7.5mm Offset
H352-0080	8.0mm x 8.0mm Offset
H352-0085	8.5mm x 8.5mm Offset
H352-0090	9.0mm x 9.0mm Offset

Taper Post

H156-0032	Taper Post, 15.6mm x 32mm
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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

These implants are intended to be fitted and installed with the matched 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 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.



The Arthrosurface Resurfacing Systems are also available for the following joints:

- Shoulder
- Great Toe
- 2nd MTP
- Talus (*Available in most International markets via CE mark*)
- Unicompartmental
- Patello Femoral
- Femoral Condyle (*Available in most International markets via CE mark*)

This product is covered by one or more of U.S. Patent Nos. 6,520,964; 6,610,067; 6,679,917; 7,163,541; 7,029,479 and other patents pending.

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