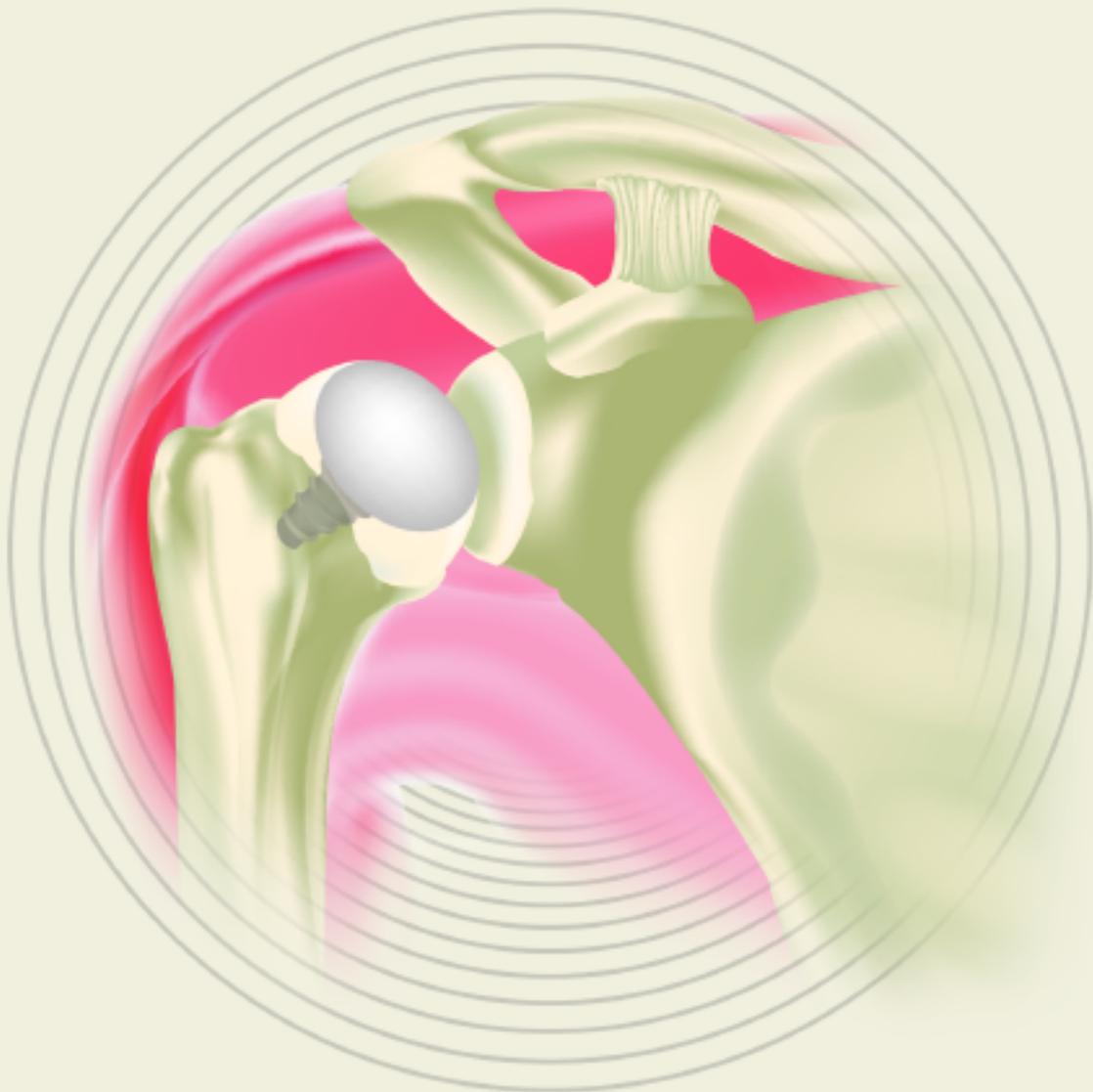


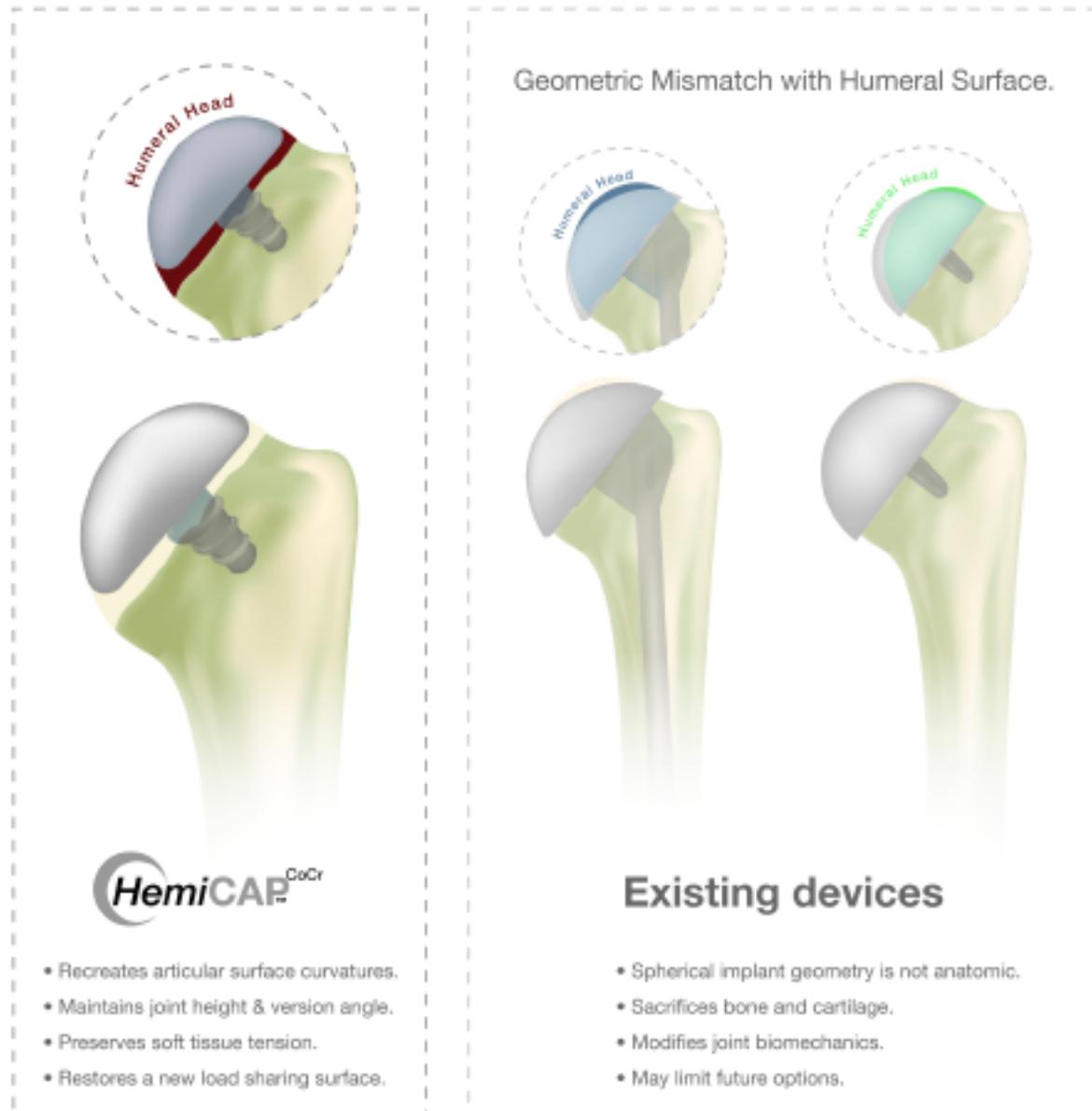


HemiCAP™^{CoCr} Shoulder Resurfacing System



The Arthrosurface HemiCAP™ Shoulder Hemiarthroplasty System restores the articular surface geometry of the humeral head and preserves functional structures using an innovative 3 dimensional mapping system and a contoured articular resurfacing implant.

Congruency is the key

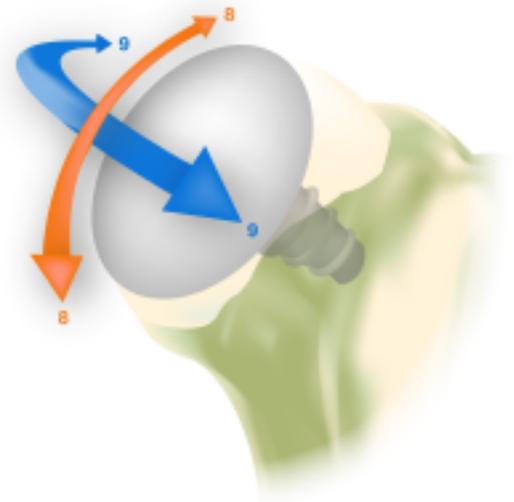


2

The spherical geometry and instrumentation of existing hemiarthroplasty devices limit the surgeons' ability to recreate the patient's original articular surface geometry and joint biomechanics. The HemiCAP™ system allows the surgeon to map the patient's articular surface intraoperatively and restore a new load sharing surface that is congruent and bone sparing.

"History has shown that hemiarthroplasty can be an appropriate treatment for glenohumeral arthrosis, yet it has failed to address the issue of true restoration of articular congruity. The humeral head is spherical in its central portion but becomes less so at the edges. Having an implant which allows different radii of curvature in two planes gives us options to more closely approximate true humeral anatomy. This will improve joint biomechanics resulting in decreased wear and perhaps improved range of motion."

– Anthony Miniaci, M.D., FRCS, Cleveland Clinic, OH



The humeral head isn't spherical; why should your implants be?

The Science behind the new Arthrosurface 35mm HemiCAP™ Hemiarthroplasty system



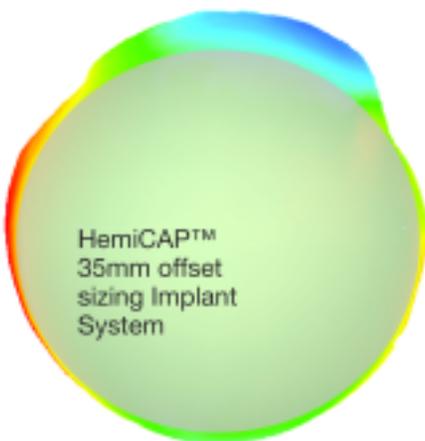
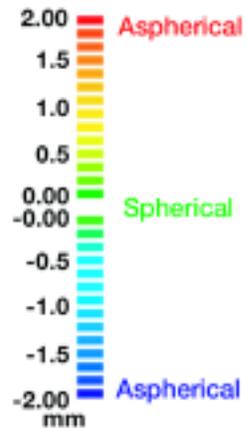
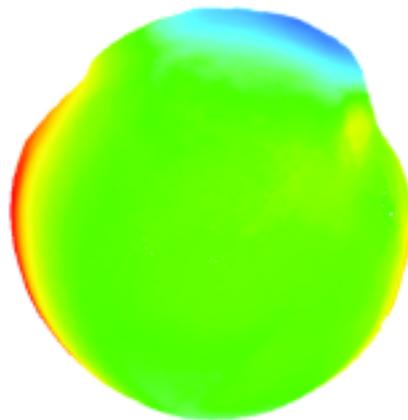
3-D mapped Humeral Head.



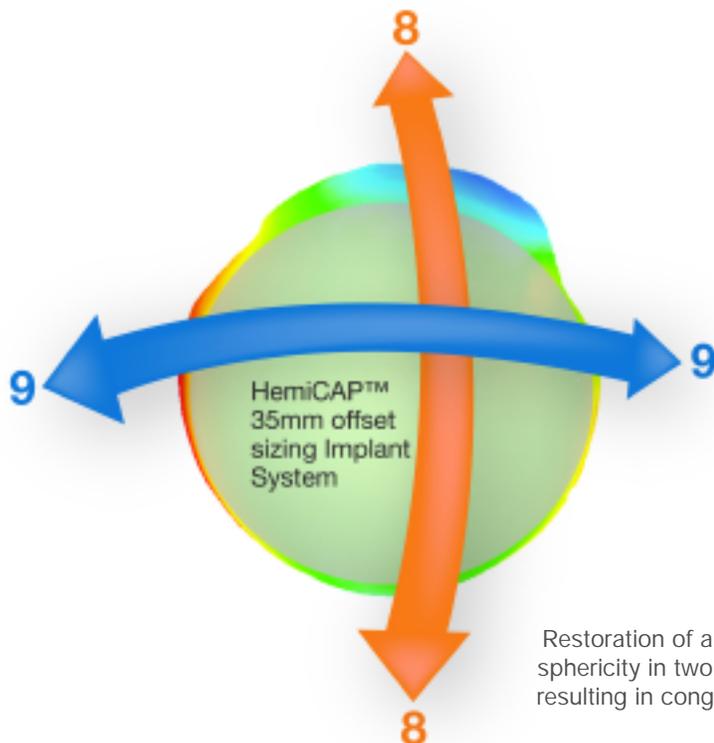
Bird's eye of the Humeral Head.

Mapped graphic showing nonspherical nature of humeral articular cartilage at its outer margins.

Superior/Inferior plane has an offset of up to 1mm as compared to the Medial/Lateral plane.



Effective coverage area of the Arthrosurface HemiCAP™ 35mm implant.



Restoration of articular sphericity in two planes resulting in congruency.

Anterior Deltopectoral Approach

as described by Dr. Thomas F. Holovac, Massachusetts General Hospital,
Harvard Shoulder Service



4

1. Beachchair position (tilt back to 45 degree angle).
2. Short deltopectoral incision (from coracoid tip to pectoralis major insertion).
3. This incision is utilitarian and can be converted to an extensile approach if necessary.
4. Develop skin flaps over pectoralis & deltoid.
5. Develop deltopectoral interval.
 - a. The cephalic vein may go either medially or laterally. Lateral retraction of the cephalic vein can be beneficial because it preserves the venous outflow from the deltoid.
 - b. Identify coracoid tip.
 - c. Identify pectoralis major insertion.
6. Release subdeltoid and subacromial adhesions. Abducting the shoulder in order to relax the deltoid facilitates this step.
7. Retract the deltoid and pectoralis major muscles. This step is facilitated by the use of a blunt, multi-pronged self-retaining retractor.
8. Identify and develop the lateral border of the conjoined tendon. This step is assisted by flexion of the shoulder, which relaxes the conjoined tendon & facilitates exposure.
9. Retract the conjoined tendon medially. Take care to not injure the musculocutaneous nerve. A blunt, non self-retaining retractor under the conjoined tendon facilitates exposure while minimizing risk to the nerve.
10. Remove bursa from atop the subscapularis insertion.
11. Identify the anterior humeral circumflex vessels, which define the inferior aspect of the subscapularis. As needed, a 90 degree pediatric clamp is a useful tool to isolate the vessels. If necessary, a suture can be used to ligate the vessels.
12. Identify and protect axillary nerve. The axillary nerve lies deep to the anterior humeral circumflex vessels and superficial to the subscapularis muscle at the level of the glenoid. A rubber vessel loop can be used to protect/isolate the axillary nerve, if necessary.
13. Incise the subscapularis. Use of a needle tip electrocautery 1 cm lateral to the musculotendinous junction facilitates this step.

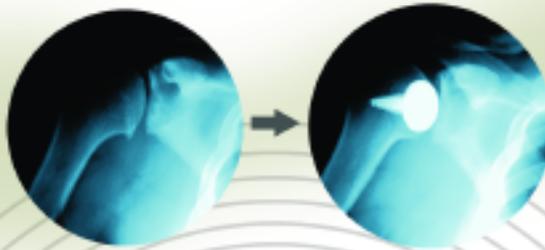


- a. Patients with anterior-inferior instability may be candidates for capsular shift and/or Bankart repair. In such cases, begin the subscapularis incision inferiorly and proceed superiorly in order to best differentiate the tendon from the underlying capsule.
 - b. Alternatively, the subscapularis and capsule can be incised in one layer.
 - c. Alternatively, the lesser tuberosity may be osteotomized with a sharp, 1-inch straight osteotome. This will allow bone to bone healing at the conclusion of the procedure.
14. Place #2 sutures using a Mason-Allen configuration into the edge of the subscapularis to help retract the tendon and for definitive repair at the conclusion of the procedure.
- a. A medium Cobb elevator and/or Metzenbaum scissors help to bluntly develop the layer between the subscapularis and the joint capsule. It is important to separate the subscapularis and the capsule medial to the joint line in order to address (if necessary) a Bankart lesion.
15. Release the rotator interval capsule between the upper border of the subscapularis and the anterior edge of the supraspinatus.
16. Incise the glenohumeral joint capsule along the anatomic neck with electrocautery.
17. If necessary, place a blunt “Cobra” or Hohman retractor between the axillary nerve and subscapularis/capsule in order to protect the axillary nerve.
18. Release the glenohumeral capsule from its insertion on the anatomic neck of the humerus anteriorly and inferiorly. External rotation and flexion of the shoulder facilitates capsular release and improves humeral head exposure.
19. Release the capsule completely off the anatomic neck until adequate exposure of the humeral head defect is achieved.
- a. Posterior humeral head defects can be successfully addressed with the Arthrosurface HemiCAP™ implant using an anterior deltopectoral exposure. Inferior capsular release from the anatomic neck of the humerus is an important step. Take care to release the capsule directly off the bone in order to minimize risk to the axillary nerve. Blunt retractors (i.e. Cobra or Hohman) placed between the inferior capsule and the axillary nerve can also minimize neurological injury.
20. Place a humeral head retractor (i.e. Fukuda) to evaluate the glenoid and check for a Bankart lesion.
21. Address any glenoid pathology as indicated.
22. Insert Arthrosurface HemiCAP™ implant as indicated.
23. Repair glenohumeral joint capsule and subscapularis as indicated.
24. Closure utilizing accepted practices.

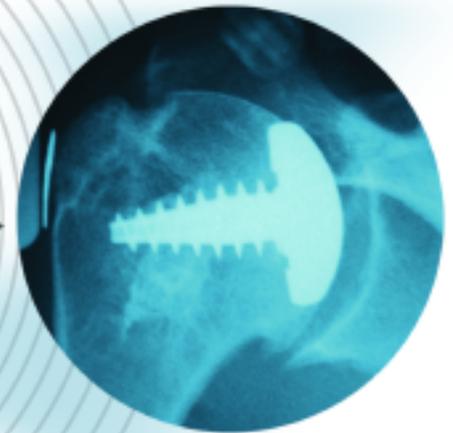
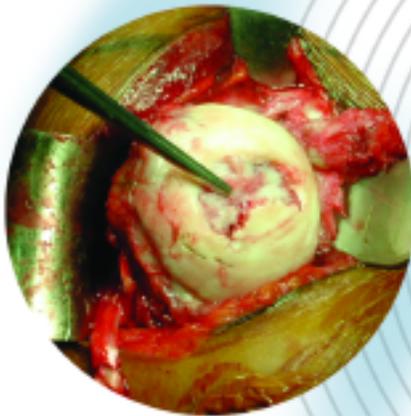
HemiCAP^{CoCr}_{TM}

Recreates articular surface curvatures • Maintains joint height & version angle
Preserves soft tissue tension • Restores a new load sharing surface

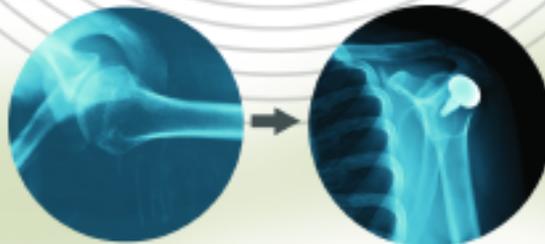
Patient:
35 y/o Male
auto mechanic
with a traumatic
lesion



Follow-up:
20 months Patient
returned to full strength
and off disability



Patient:
36 y/o Male waiter
with Focal Traumatic
Osteochondral defect



Follow-up:
10 months
Pain free with
full active ROM
and normal
strength



Description

The HemiCAP™ Contoured Articular Prosthetic incorporates an articular resurfacing component and a 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)

Undersurface Coating: Titanium (CP Ti)

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

Indications

For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. 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 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.

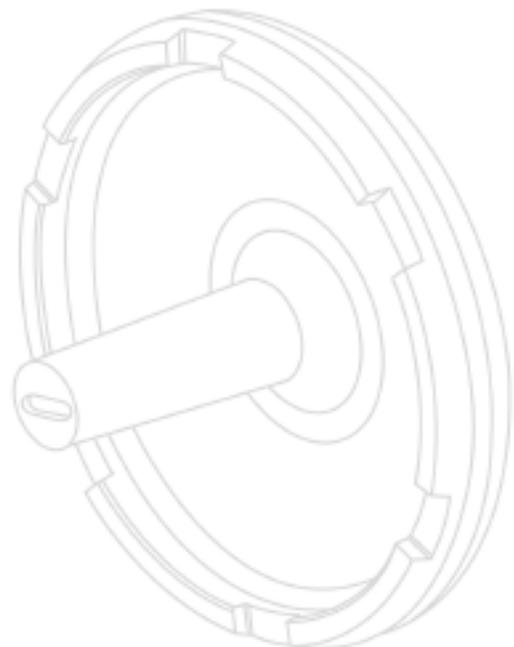
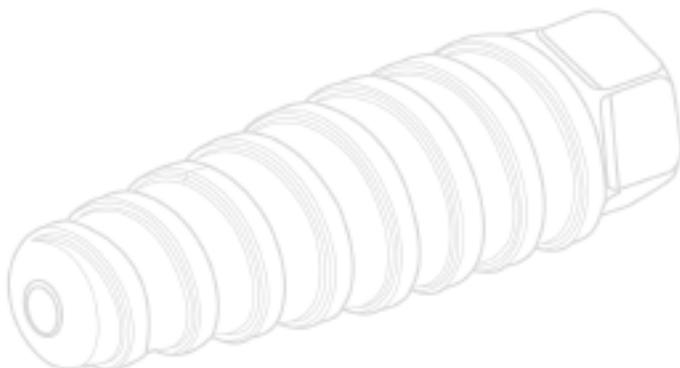
Contraindications

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
4. Patients that have a known sensitivity to metal alloys typically used in prosthetic devices.

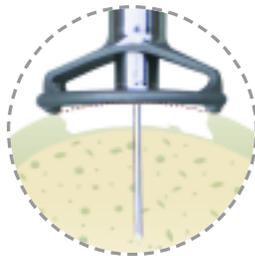
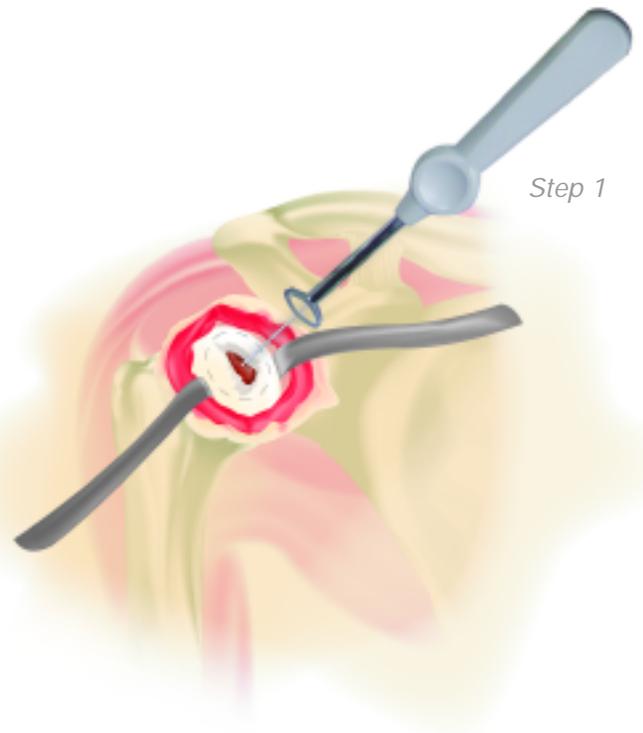
Relative contraindications include:

1. Uncooperative patient or patient incapable of following preoperative and postoperative instructions
2. 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.



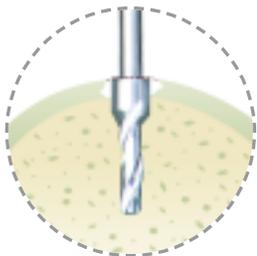
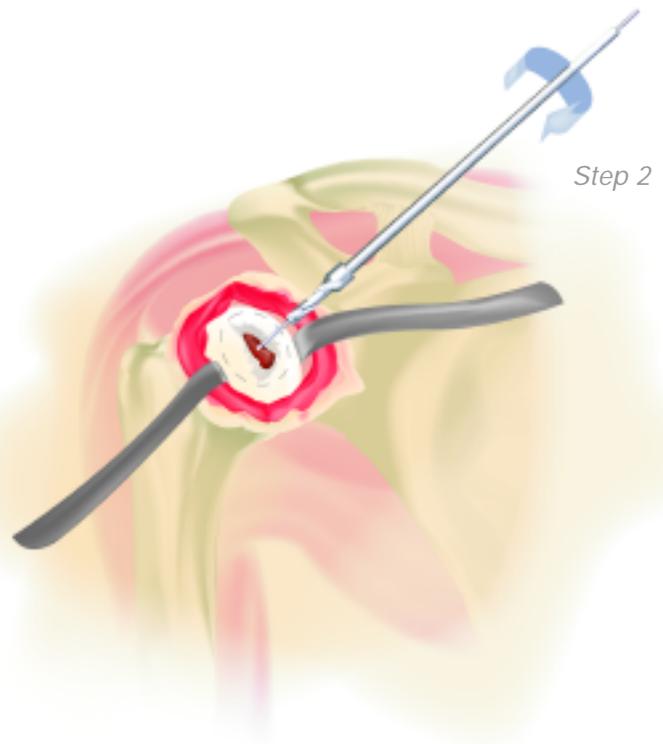
Instructions for Use

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.)*

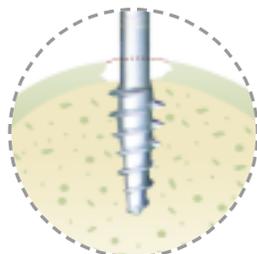


Step 1a

2. Place **Cannulated Drill** over **Guide Pin** and drill until the proximal shoulder of the **Drill** is flush with the articular surface. Tap hole to etched depth mark on **Tap**.



Step 2a: Drill to proximal shoulder of drill.



Step 2b: Tap laser mark to the height of original articular cartilage level.

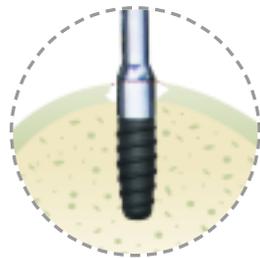


3. Prior to inserting the **Taper Post**, thoroughly cleanse the pilot hole of any debris and then inject the cement in a retrograde fashion from the end of the hole upwards.

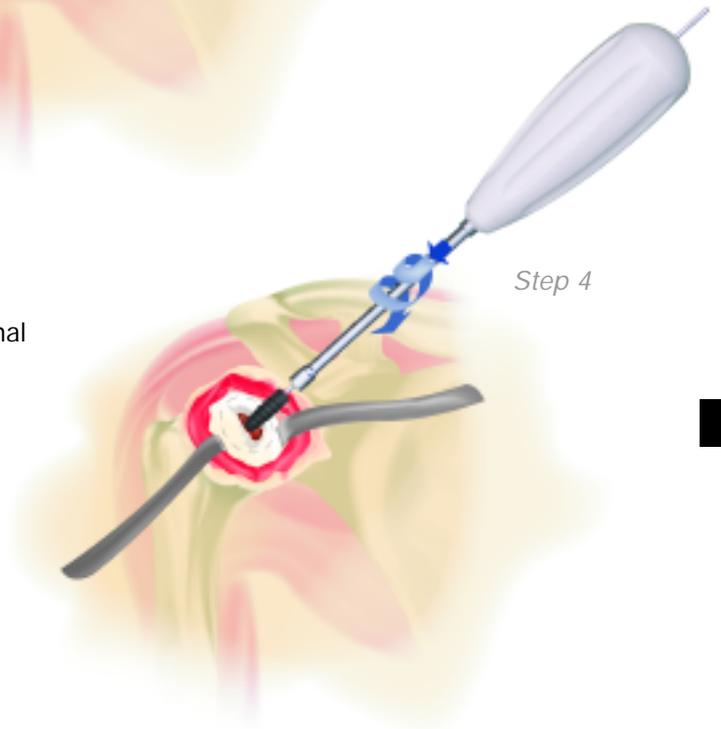


Step 3

4. Place the **Driver** onto the **Taper Post** over the **Guide Pin** advance the **Taper Post** until the line on the **Driver** is flush with the height of the original articular cartilage level.

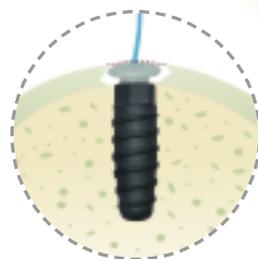


Step 4a

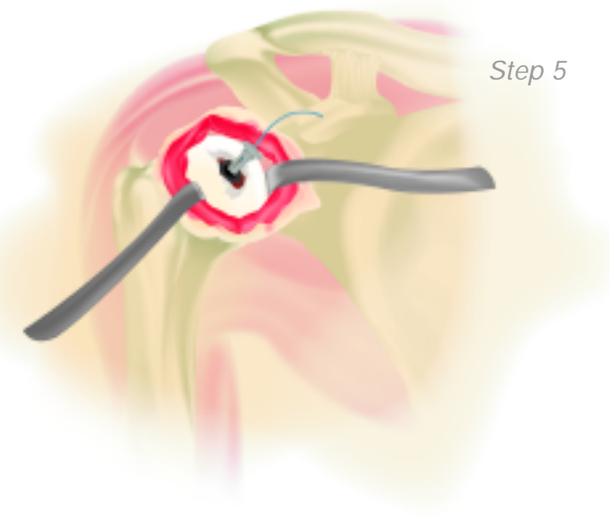


Step 4

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

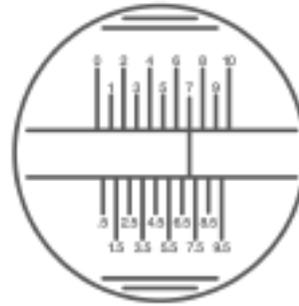


Step 5a

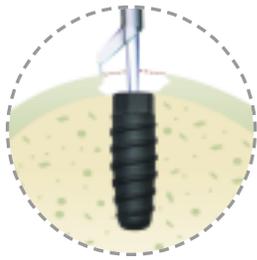


Step 5

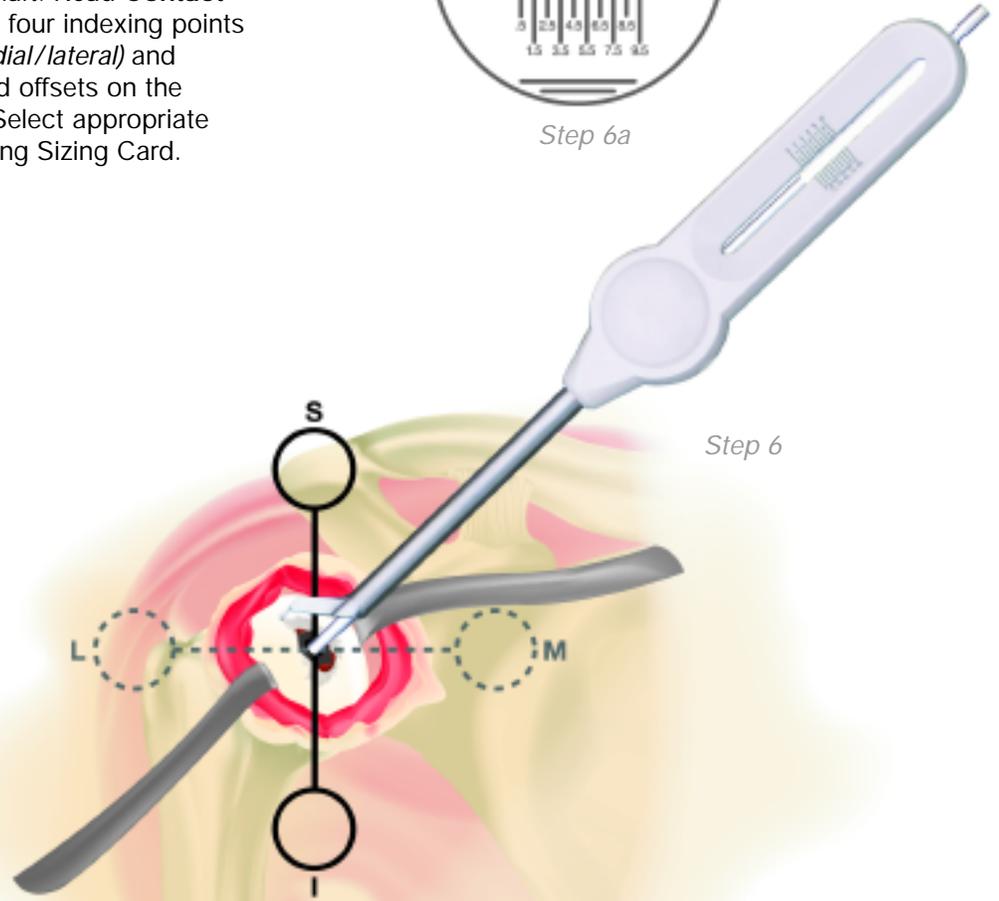
6. Place **Centering Shaft** into taper of **Taper Post**. Place **Contact Probe** over **Centering Shaft** and rotate around centering shaft. Read **Contact Probe** to obtain offsets at four indexing points (*superior/interior and medial/lateral*) and mark each of the identified offsets on the appropriate Sizing Card. Select appropriate **Articular Component** using Sizing Card.



Step 6a



Step 6b



Step 6

arthrosurface

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

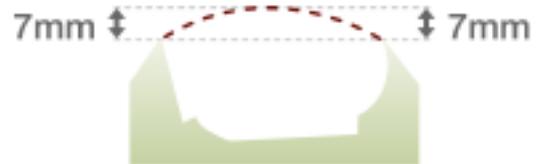
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- 8.0 mm x 9.0 mm
- 8.5 mm x 8.5 mm
- 9.0 mm x 9.0 mm
- 9.0 mm x 10.0 mm
- 9.5 mm x 9.5 mm

3. Select **35mm Surface Reamer** size

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

35

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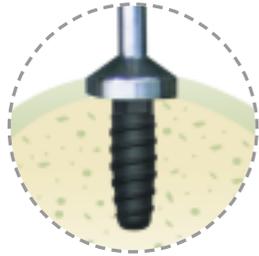


Step 6d

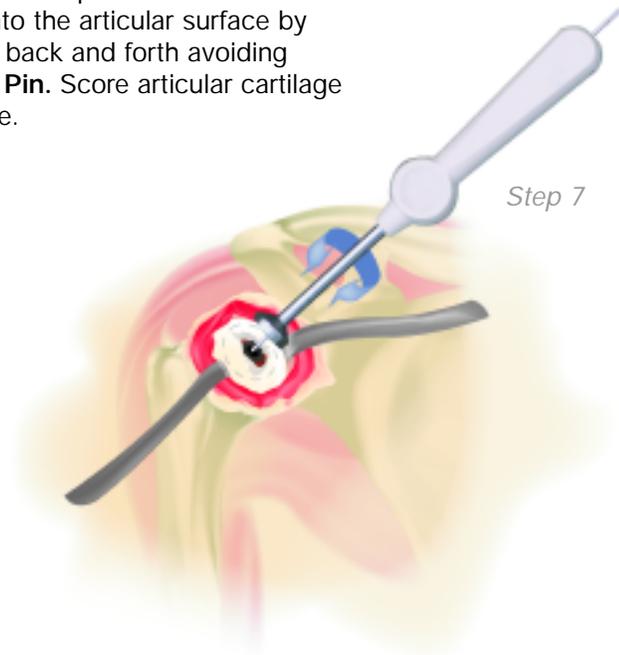
Step 6c Sizing Card



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.



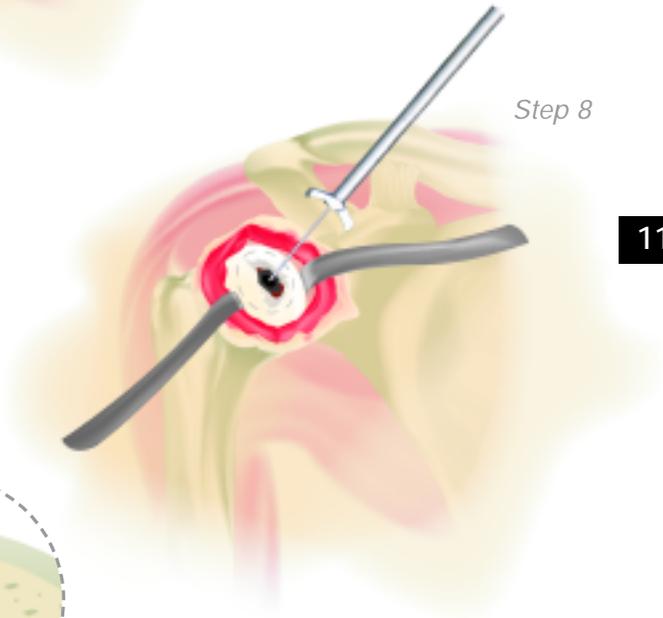
Step 7a



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** malalignment. Begin rotation of **Surface Reamer** prior to contact with bone to prevent chipping of articular rim.



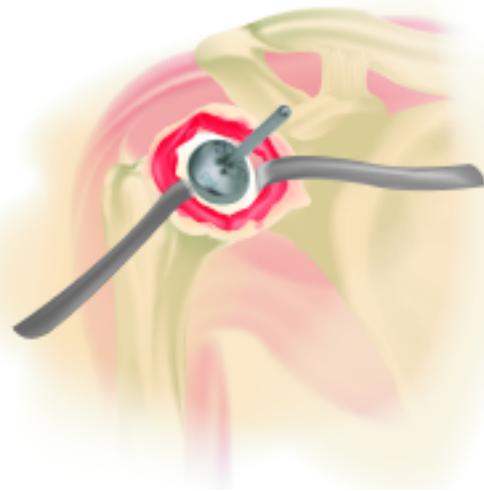
Step 8a



9. Clean taper in **Taper Post** with **Taper Cleaner** and remove any debris from the surrounding implant bed.

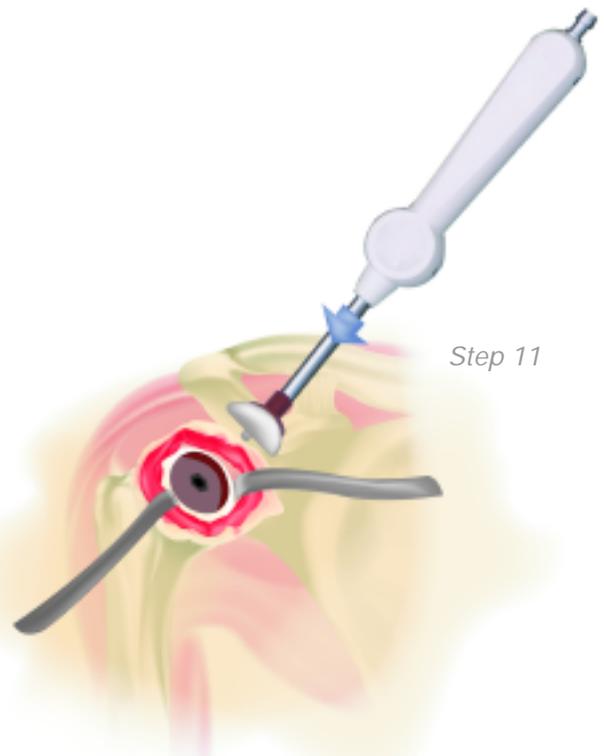


10. Place the **Sizing Trial** into the defect that matches the offset profile of the chosen **HemiCAP™ Articular Component**. Confirm the fit of the **Sizing Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed. If the **Sizing Trial** is proud at the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



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**. 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**.

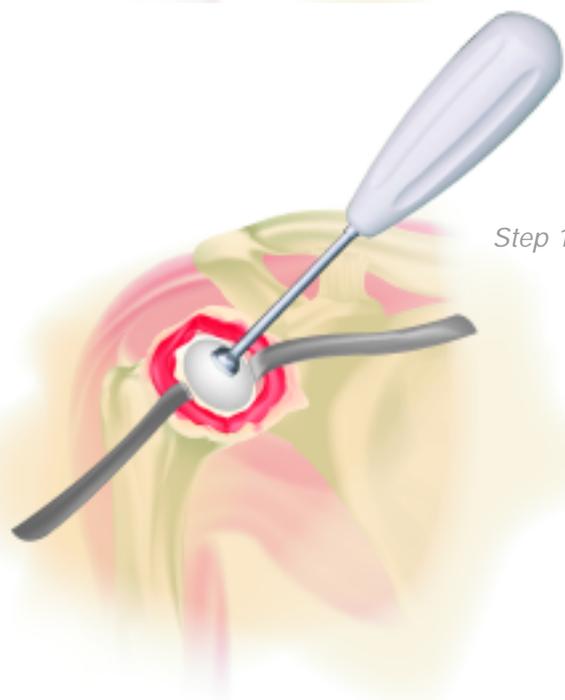


Step 11

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.



Step 12a



Step 12



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.

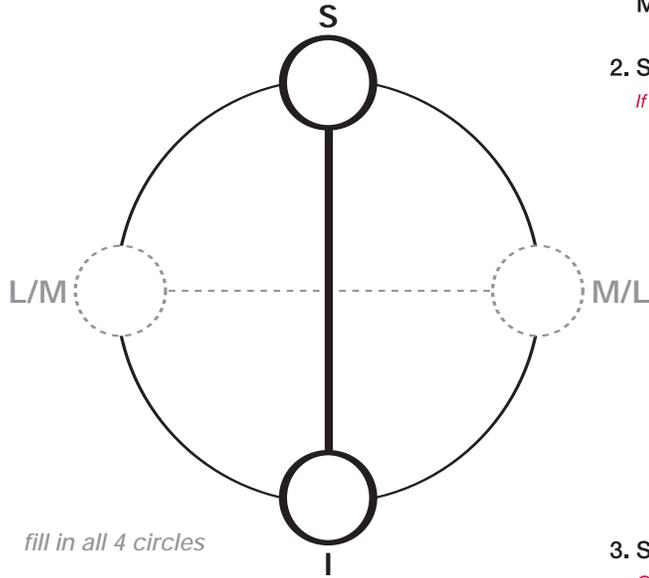
Accepted practices in post operative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to post operative instructions and activity restrictions. Excessive activity, impact, and weight gain have been implicated in the reduction of the benefit 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.



Sizing Card

1. Maximum SI _____

Maximum ML _____

35

2. Select **35mm HemiCAP™** offset values

If no match is found, use the next highest offset value

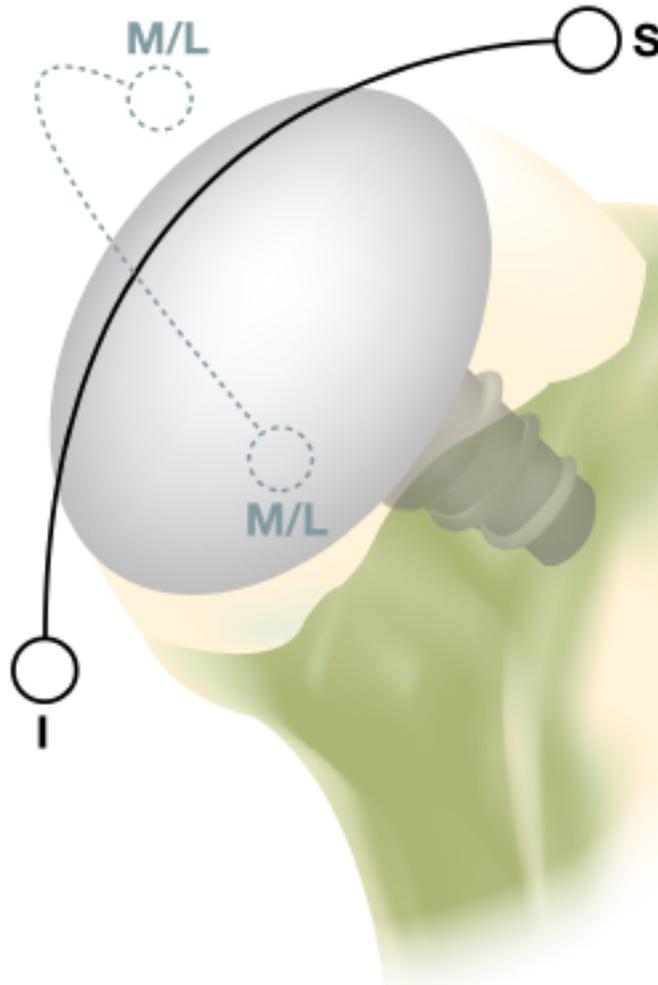
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- 9.0 mm x 10.0 mm
- 9.5 mm x 9.5 mm

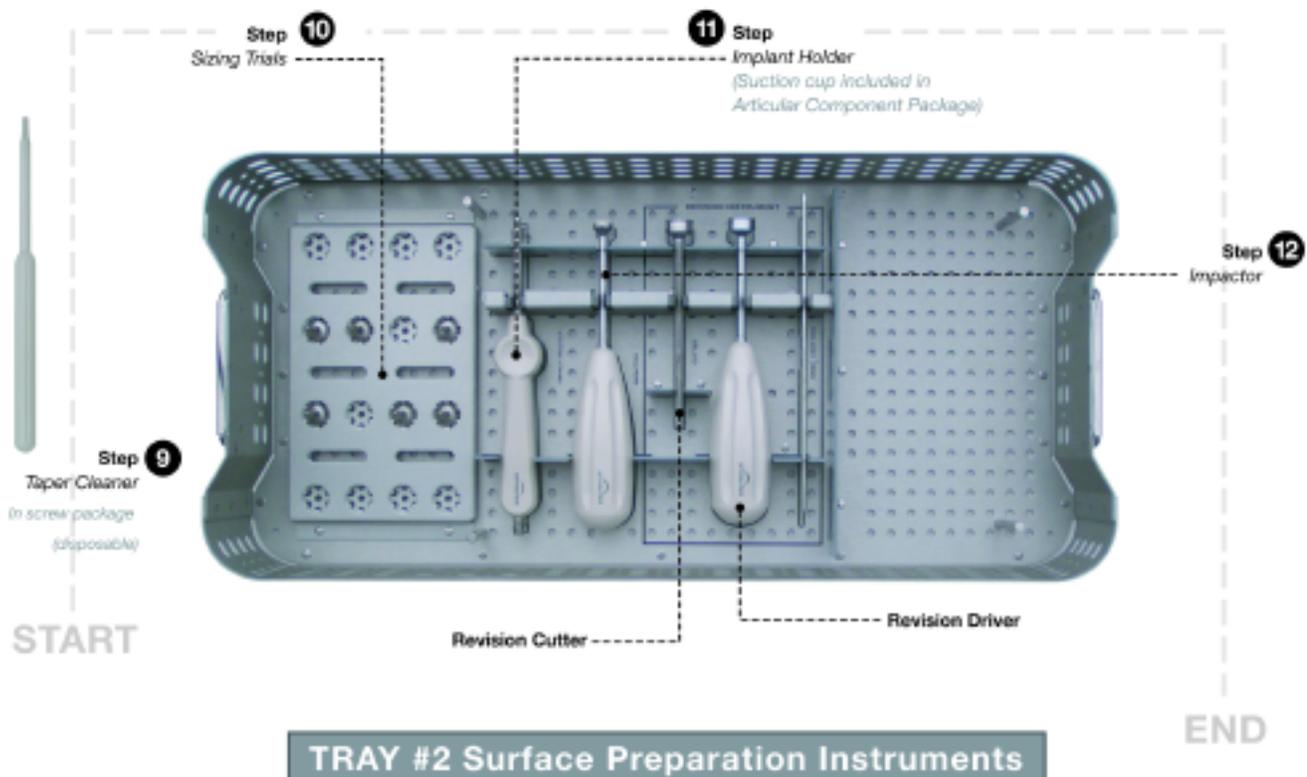
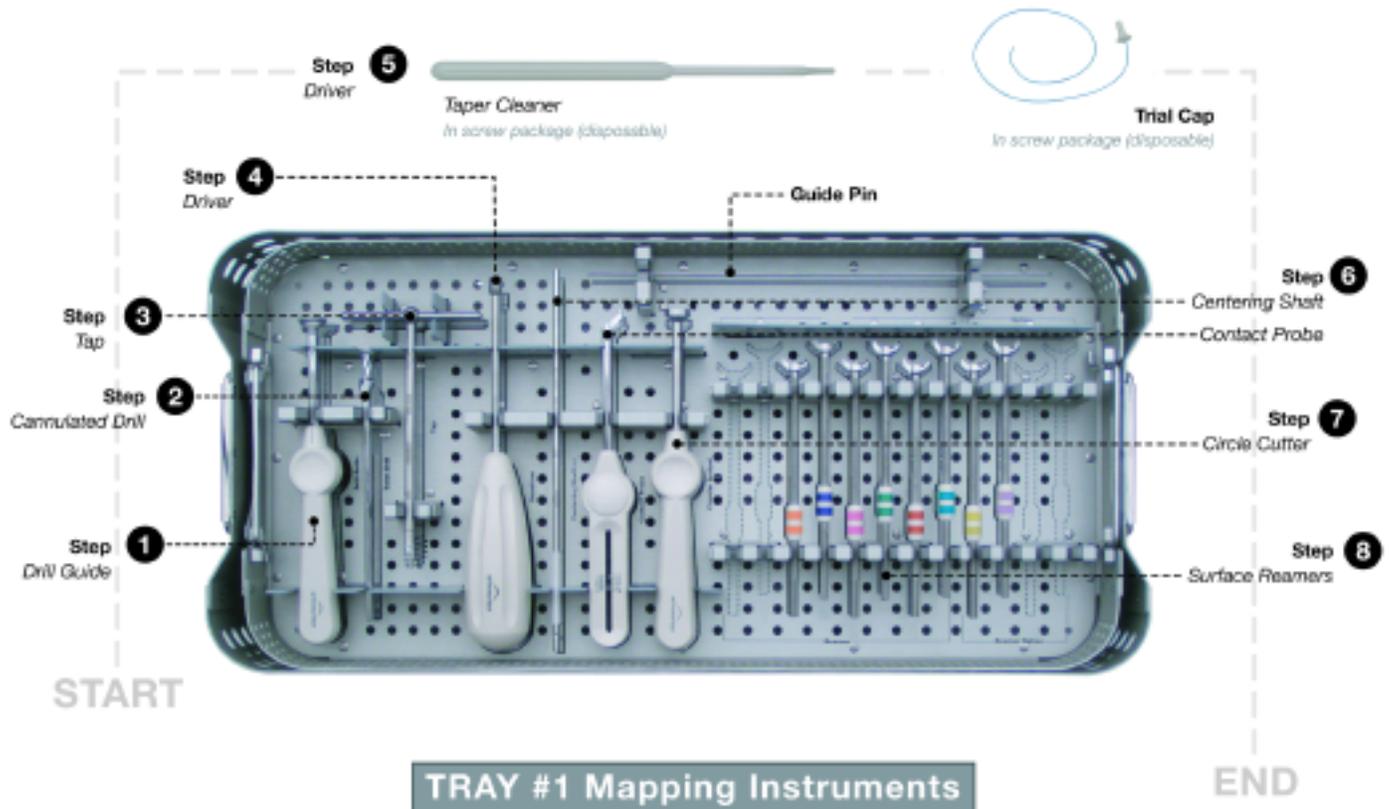
3. Select **35mm Surface Reamer** size

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

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Step 6 Sizing Card 35mm





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



Catalog Number	Description
8000-3500	Instrument Kit, 35mm includes 35mm Sizing Trials
8007-1205	2.5mm Guide Pin (5 pk) for 35mm Implants
Articular Component 35mm	
8352-6565	6.5 x 6.5mm Offset
8352-7070	7.0 x 7.0mm Offset
8352-7080	7.0 x 8.0mm Offset
8352-7575	7.5 x 7.5mm Offset
8352-8080	8.0 x 8.0mm Offset
8352-8090	8.0 x 9.0mm Offset
8352-8585	8.5 x 8.5mm Offset
8352-9090	9.0 x 9.0mm Offset
8352-9010	9.0 x 10.0mm Offset
8352-9595	9.5 x 9.5mm Offset
Taper Post	
8135-0032	Taper Post, 13.5mm x 32mm (for 35mm only)

Arthrosurface also offers 25mm and 30mm implants for resurfacing smaller lesions in the shoulder.

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*).

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.