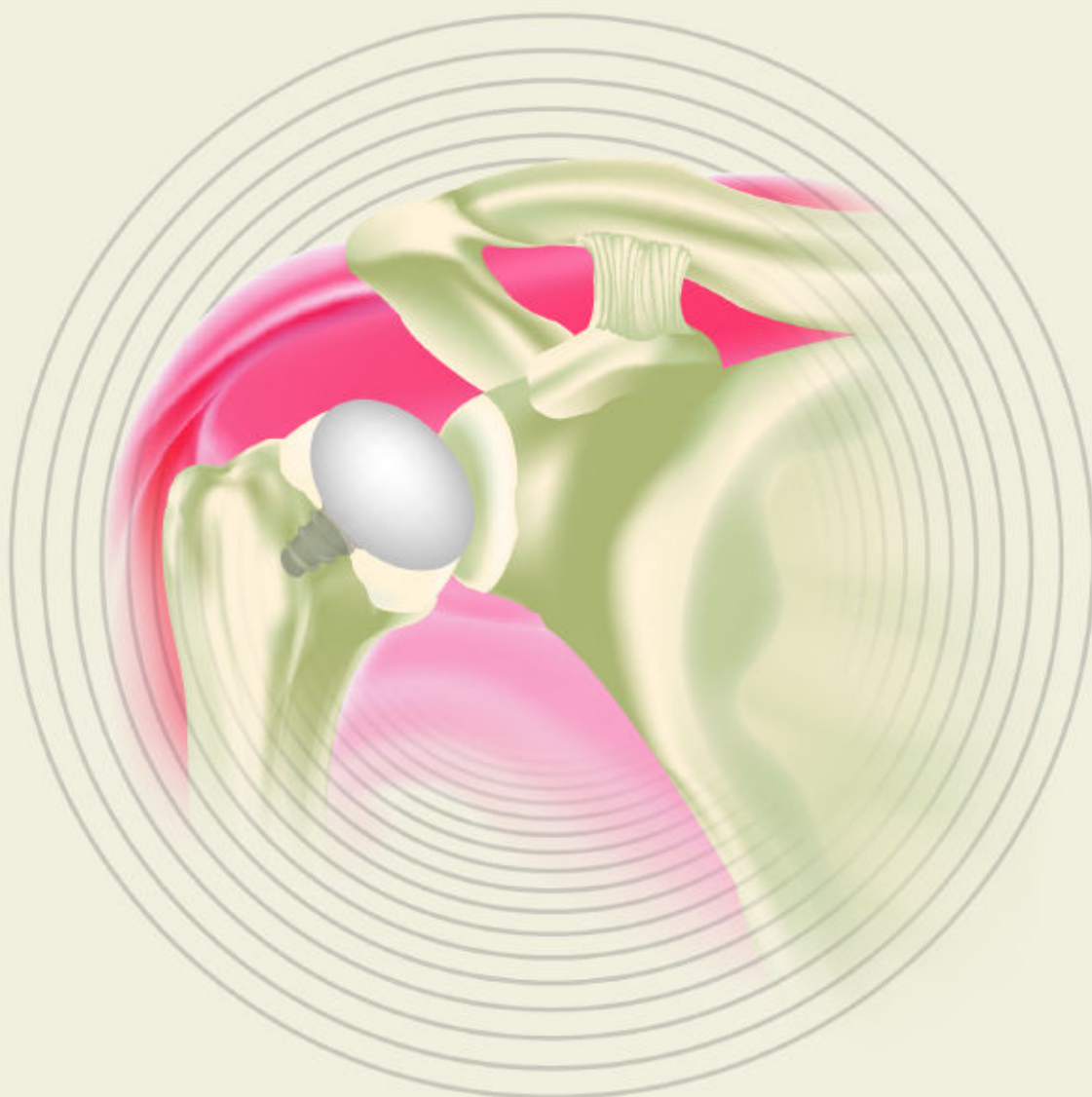
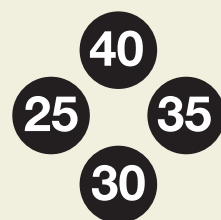




Anatomic Shoulder
Resurfacing System



The Arthrosurface® HemiCAP® Shoulder 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.

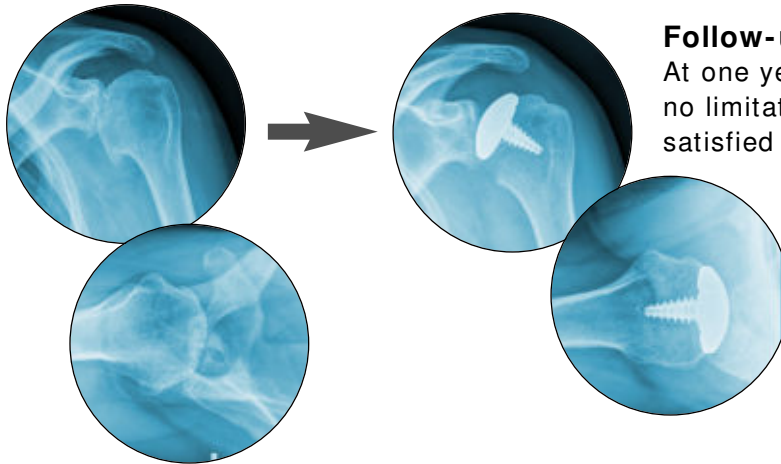


Case Studies

Hemiarthroplasty

Patient:

47 y/o Male with
Osteoarthritis



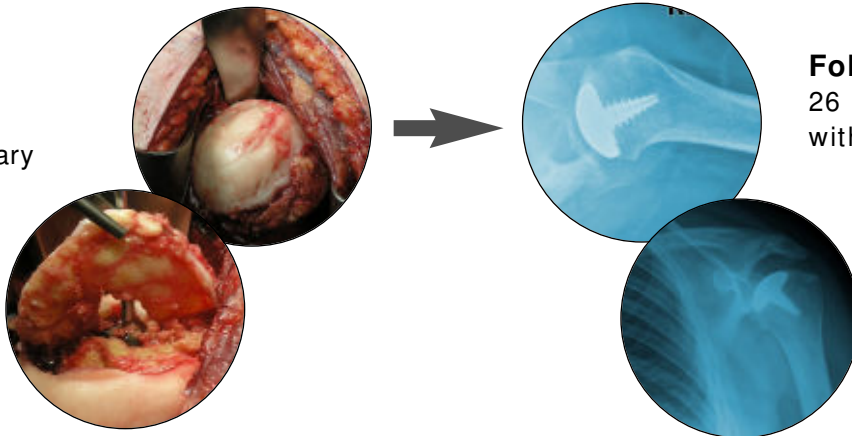
Follow-up:

At one year, patient has
no limitations and very
satisfied with outcome

Osteonecrosis/AVN

Patient:

36 y/o Male with
Neurosarcoidosis
with AVN secondary
to steroid use



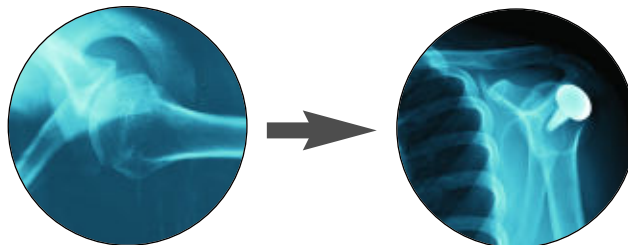
Follow-up:

26 months Pain free
with full range of motion

Focal & Traumatic Lesions

Patient:

36 y/o Male waiter
with Focal Traumatic
Osteochondral Defect



Follow-up:

3 1/2 years
Pain free with
full active ROM
and normal
strength

Patient:

35 y/o Male
auto mechanic
with a Traumatic
Lesion



Follow-up:

4 years returned to full
strength and off disability



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 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:

Articular Resurfacing Component:

Cobalt-Chromium Alloy (Co-Cr-Mo)

Undersurface Coating: Titanium (CP Ti)

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

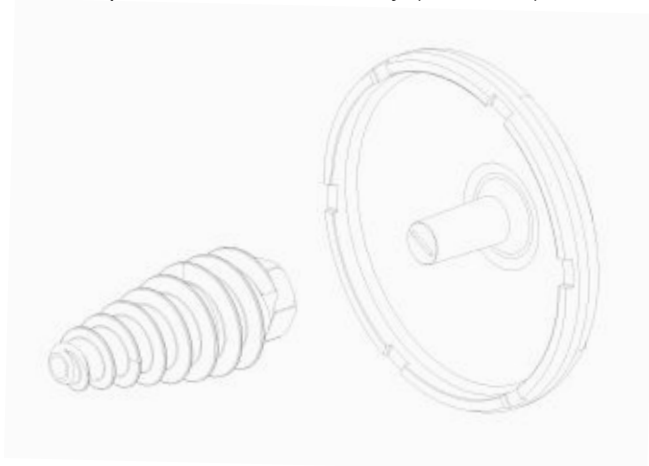
Indications

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.



Cobalt Chrome Component

- 4 Diameters

40 35 30 25

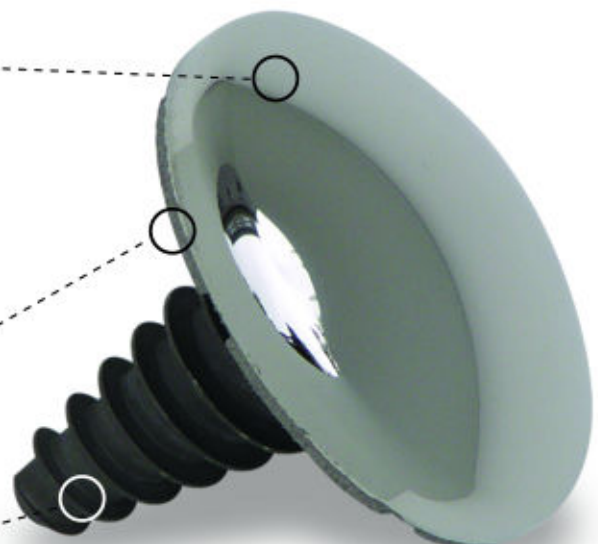
- Over 35 Different Convexities in Symmetrical & Asymmetrical Curvatures
- Ti Plasma Spray Undercoating

Morse Taper

- Interlocks the two components

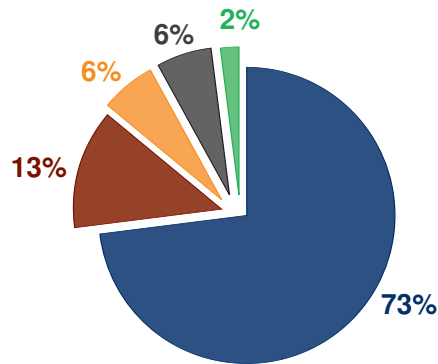
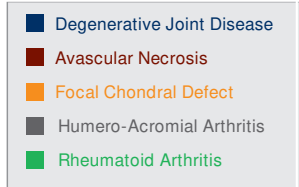
Titanium Fixation Component

- Cannulated



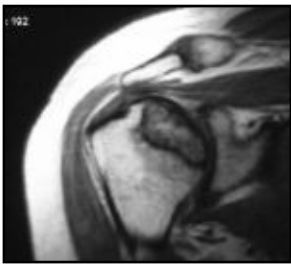
Hemiarthroplasty

Patient Profile



Hemiarthroplasty is the largest treated patient population using the HemiCAP® system. With the introduction of the larger sized implants, a surgeon can remove the osteophytes, match the humeral anatomy and recreate a new surface with ease. The instruments and implants allow for real-time anatomic reconstruction by using the patient's remaining landmarks to restore a new humeral surface and avoid overstuffing the joint.

Osteonecrosis/AVN



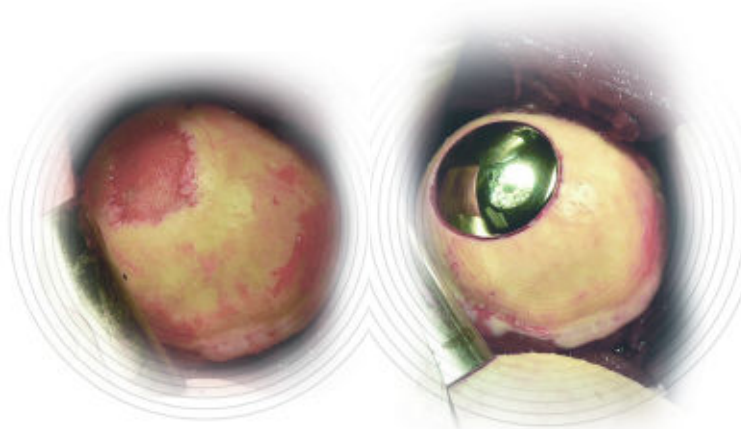
Preoperative coronal MRI demonstrating zone of AVN demarcation



Postoperative AP x-ray

AVN is typically a young person's disease with the mean age being 36 yrs old. Treatment options have been limited and because most impart non-native geometry to the joint, future glenoid wear has been a significant concern. The HemiCAP® implant system removes the necrotic bone while leaving normal cartilage and bone intact. The drilling and tapping creates a "decompressing effect", the taper post provides strong and stable fixation and the anatomic HemiCAP® implant provides a new load sharing surface that virtually eliminates any stress shielding to the underlying bone.

Focal & Traumatic Defects



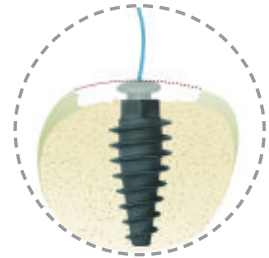
Focal or localized defects may not be appropriately treated using a stemmed or full hemi replacement and conservative treatment results are usually inconsistent or short lived. Overtightening may accelerate joint degeneration and create more significant clinical issues in the future. Using the smaller sized HemiCAP® implants surgeons can "cap" the defect and protect the adjacent healthy cartilage, while preventing the defect from further deterioration and possibly causing damage to the glenoid. This concept is similar to a dentist filling a cavity thereby avoiding tooth loss, soft tissue decay and the associated pain.

Arthrosurface® 3-Dimensional Mapping

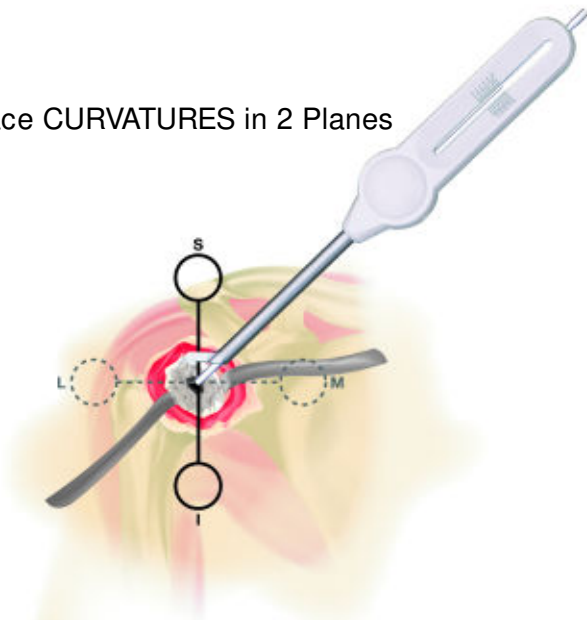


1. The Drill Guide determines the best DIAMETER for coverage of defect and establishes perpendicularity.

2. The Trial Cap sets the PEAK height of the original joint surface



3. The Contact Probe MAPS the Surface CURVATURES in 2 Planes



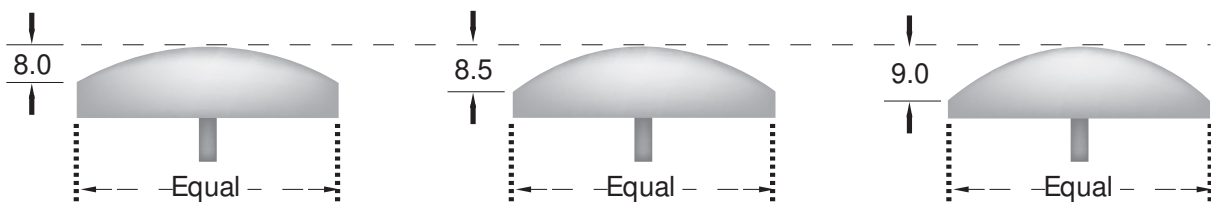
The Reamers and Sizing Trials set the EDGE HEIGHT to the adjacent articular cartilage.



Flatter Humeral Head



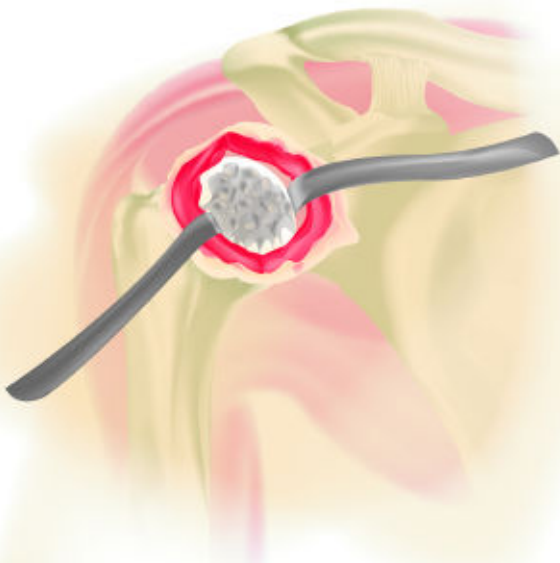
More Curved Humeral Head



This technique allows the surgeon to interoperatively place an implant with precision in terms of diameter, peak height and recreation of the natural S/I and M/L curvatures.

Anterior Deltopectoral Approach

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



6

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.

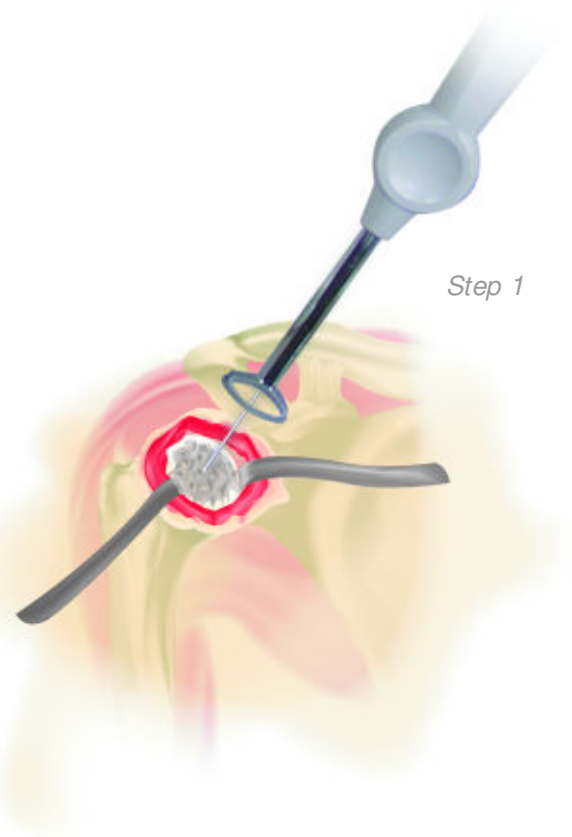


- a. Patients with anterior-inferior instability may be candidates for capsular shift and/or Bankart repair. In such cases, begin the subscapularis incision inferiorly and proceed superiorly in order to best differentiate the tendon from the underlying capsule.
 - b. Alternatively, the subscapularis 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.

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.)*

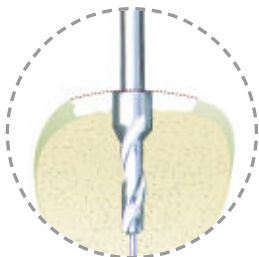
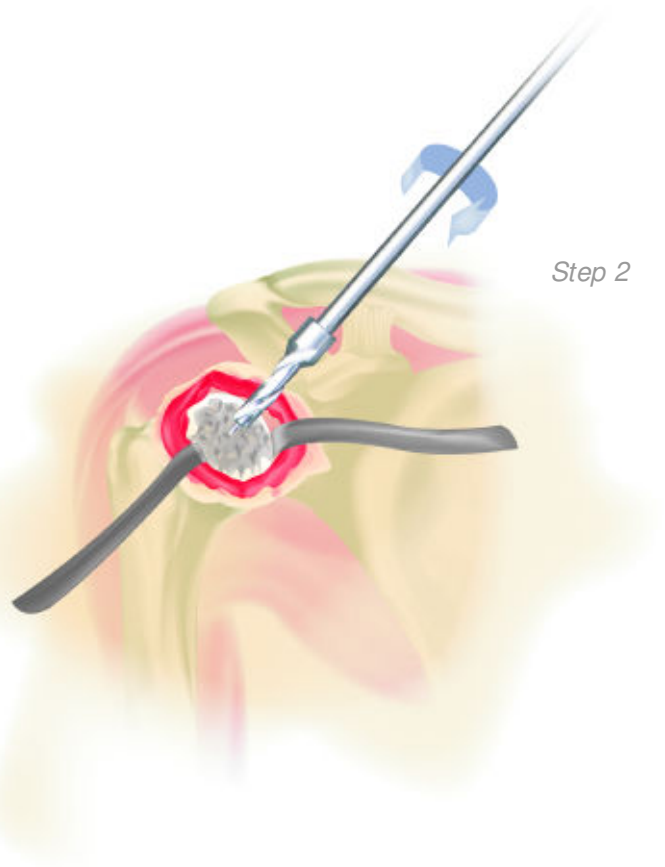
Step 1



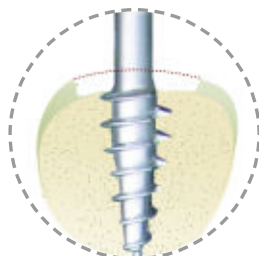
Step 1a

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 2

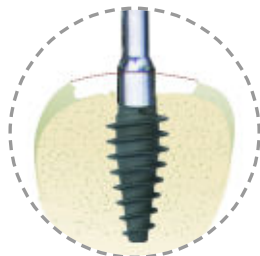


Step 2a: Drill to proximal shoulder of drill.

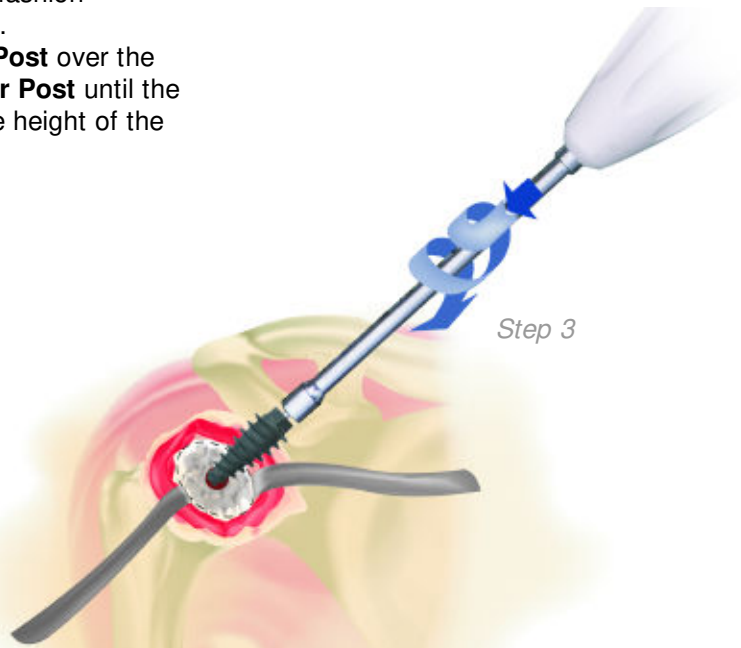


Step 2b: Tap laser mark to the height of original articular cartilage level.

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. 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.

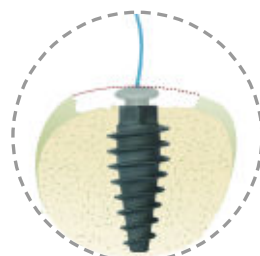


Step 3a

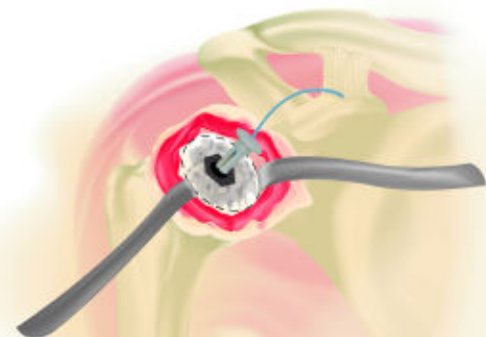


Step 3

4. 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**.

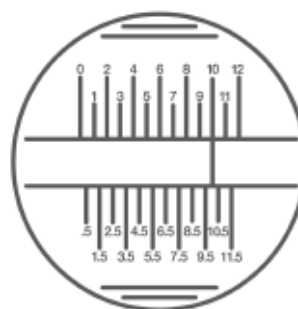


Step 4a

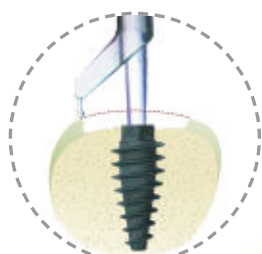


Step 4

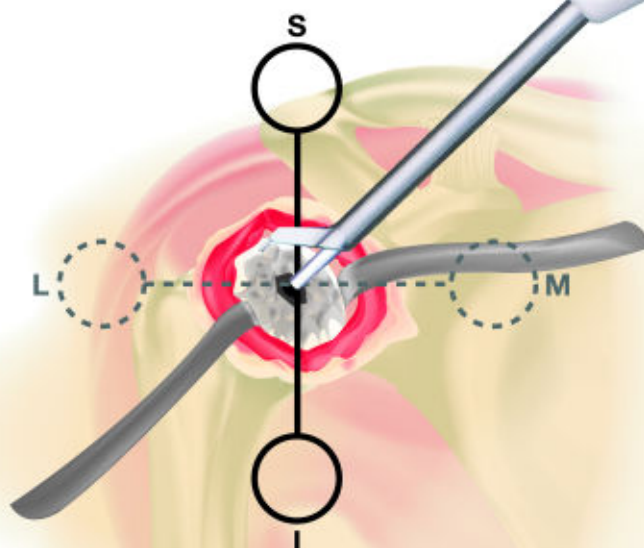
5. Place **Centering Shaft** into taper of **Taper Post**. Place **Contact Probe** over **Centering Shaft** and rotate around **Centering Shaft**. Read **Contact Probe** to obtain offsets at four indexing points (*superior/inferior and medial/lateral*) and mark each of the identified offsets on the appropriate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



Step 5a



Step 5b



Step 5

10

1. Maximum SI **10**

Maximum ML **11**

2. Select 40mm HemiCAP® offset values

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

- 8.0 mm x 8.0 mm
- 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
- 10.0 mm x 10.0 mm
- 10.0 mm x 11.0 mm
- 10.5 mm x 10.5 mm
- 11.0 mm x 11.0 mm
- 11.0 mm x 12.0 mm
- 11.5 mm x 11.5 mm
- 12.0 mm x 12.0 mm

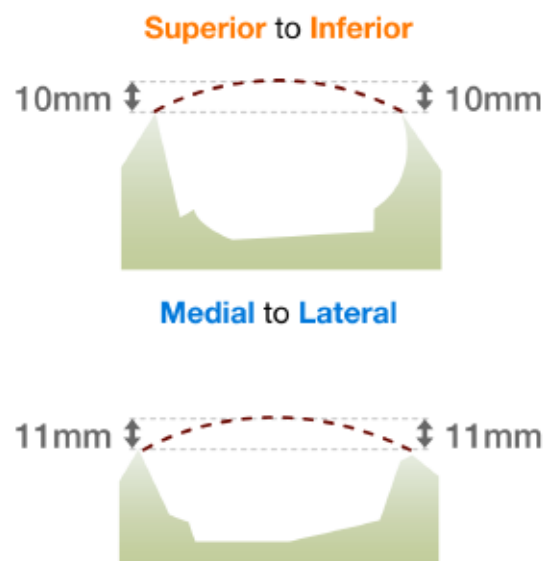
3. Select 40mm Surface Reamer size

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

fill in all 4 circles

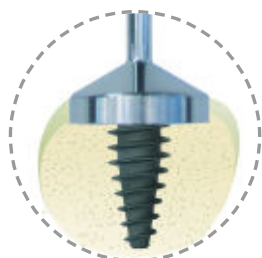
Sizing Card

Step 5c Sizing Card

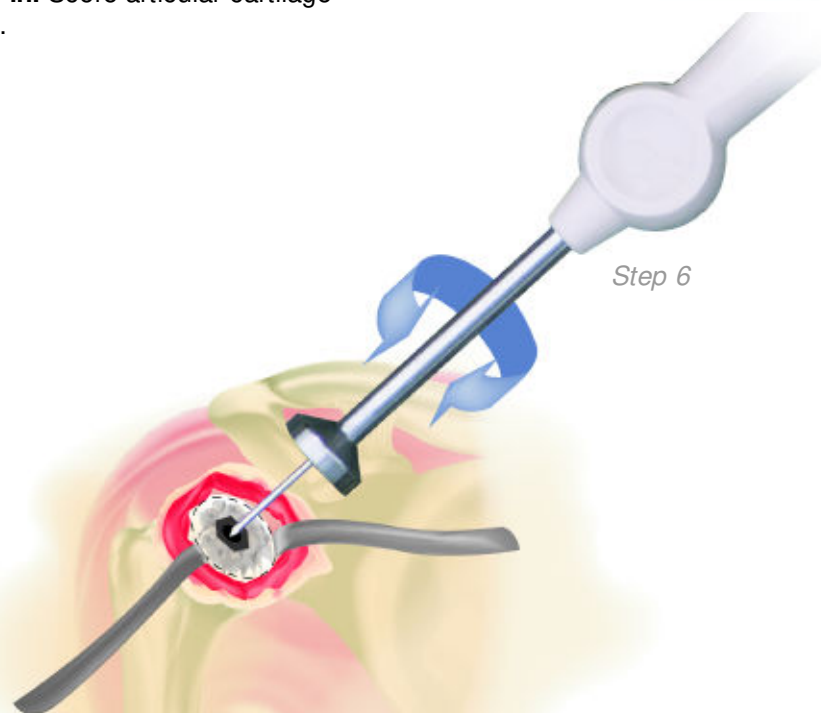


Step 5d

6. 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 6a

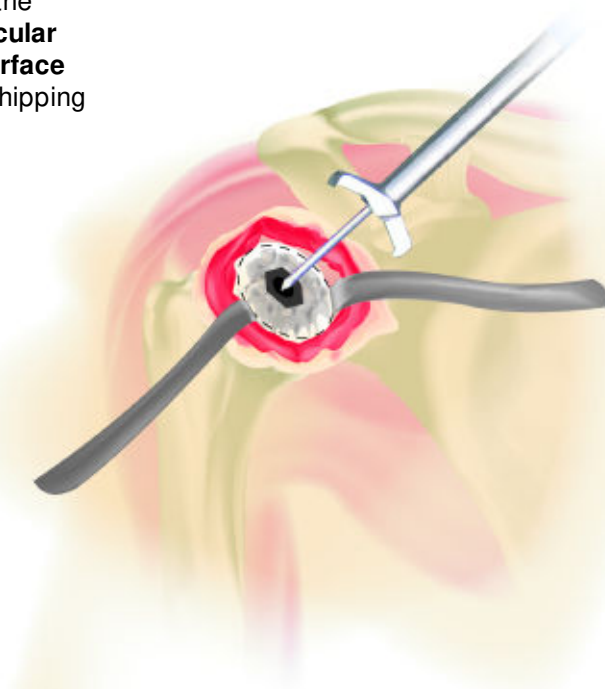


Step 6

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. 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.

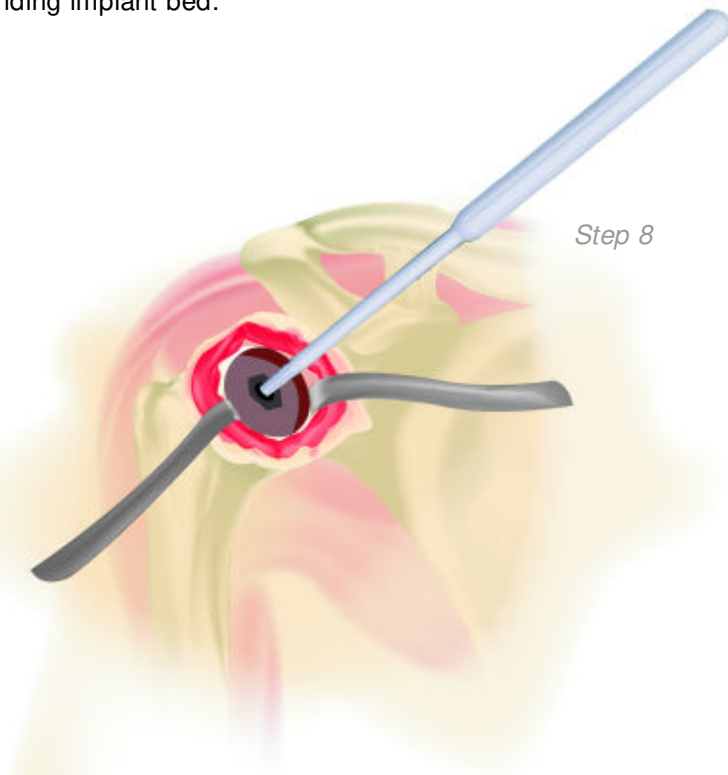


Step 7a

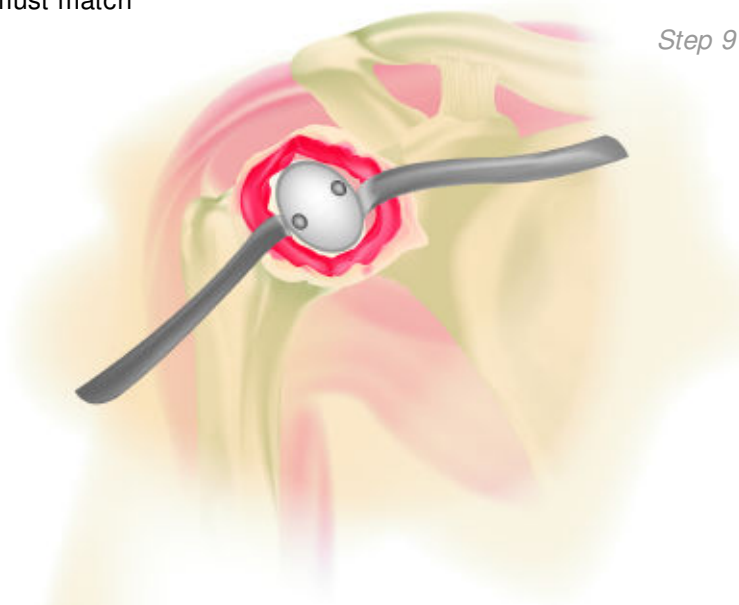


Step 7

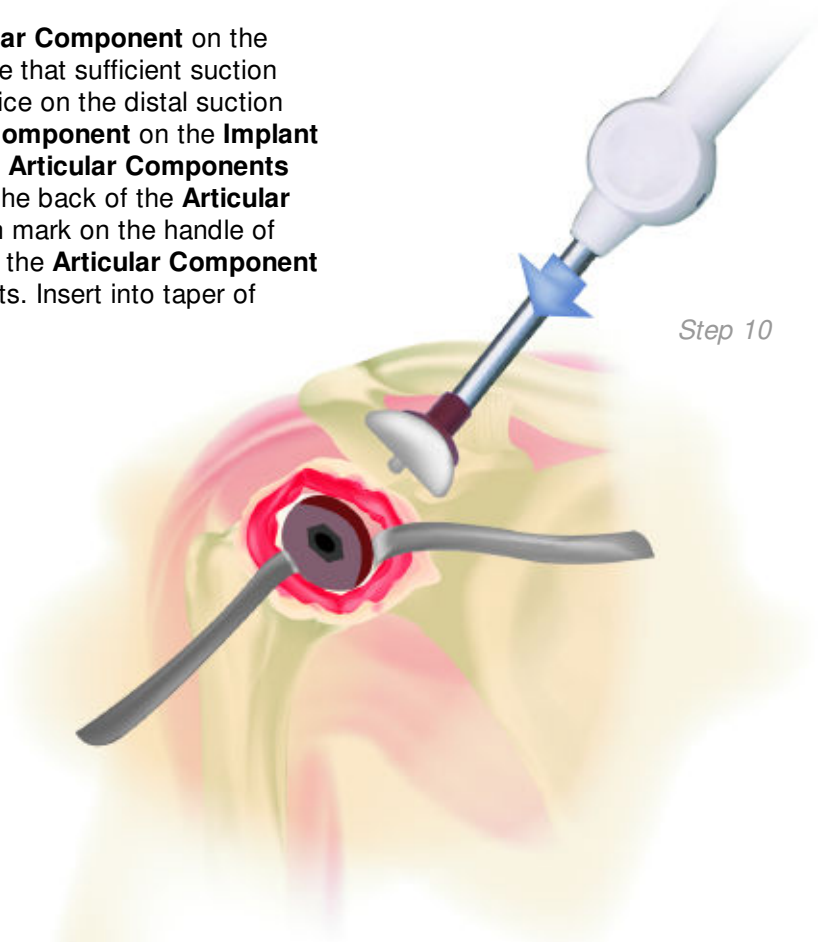
8. Remove **Guide Pin**. Clean taper in **Taper Post** with **Taper Cleaner** and remove any debris from the surrounding implant bed.



9. 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.



10. 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**.

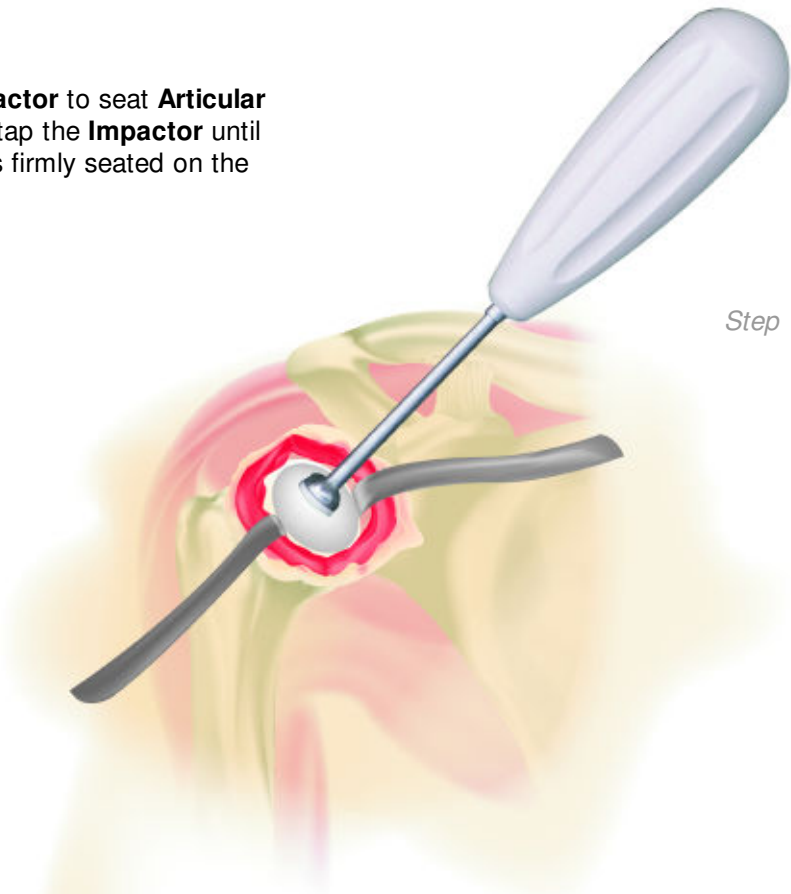


Step 10

11. 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 11a



Step 11

HemiCAP® Shoulder Sizing Cards

arthrosurface®
Humeral Head

S
I
L/M M/L

fill in all 4 circles

Sizing Card

1. Maximum SI _____

Maximum ML _____

2. Select 40mm HemiCAP® offset values

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

- 8.0 mm x 8.0 mm
- 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
- 10.0 mm x 10.0 mm
- 10.0 mm x 11.0 mm
- 10.5 mm x 10.5 mm
- 11.0 mm x 11.0 mm
- 11.0 mm x 12.0 mm
- 11.5 mm x 11.5 mm
- 12.0 mm x 12.0 mm

3. Select 40mm Surface Reamer size

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

40

arthrosurface®
Humeral Head

S
I
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

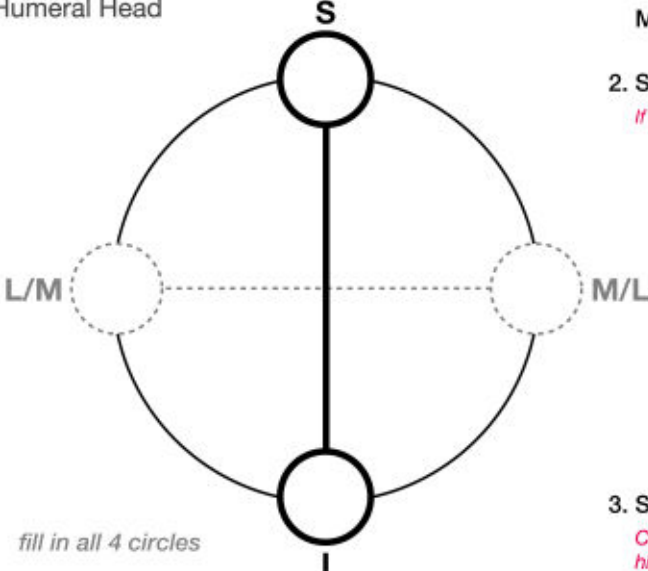
- 6.0 mm x 6.0 mm
- 6.0 mm x 7.0 mm
- 6.5 mm x 6.5 mm
- 7.0 mm x 7.0 mm
- 7.0 mm x 8.0 mm
- 7.5 mm x 7.5 mm
- 8.0 mm x 8.0 mm
- 8.0 mm x 9.0 mm
- 8.5 mm x 8.5 mm
- 9.0 mm x 9.0 mm
- 9.0 mm x 10.0 mm
- 9.5 mm x 9.5 mm

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

arthrosurface®
Humeral Head



Sizing Card

30

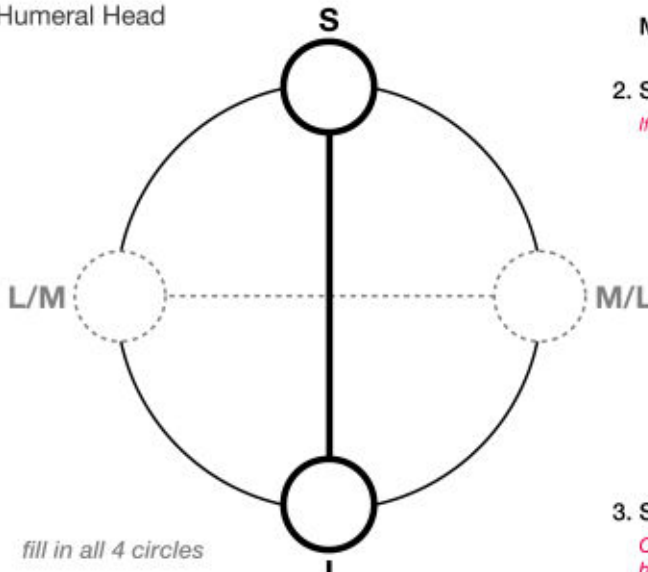
1. Maximum SI _____
Maximum ML _____

2. Select 30mm HemiCAP® offset values
If no match is found, use the next highest offset value

- 4.5 mm x 4.5 mm
- 5.0 mm x 5.0 mm
- 5.5 mm x 5.5 mm
- 6.0 mm x 6.0 mm
- 6.5 mm x 6.5 mm
- 7.0 mm x 7.0 mm

3. Select 30mm Surface Reamer size
Choose the Surface Reamer that matches the highest offset value. Confirm with the color code on the HemiCAP® articular component package.

arthrosurface®
Humeral Head



Sizing Card

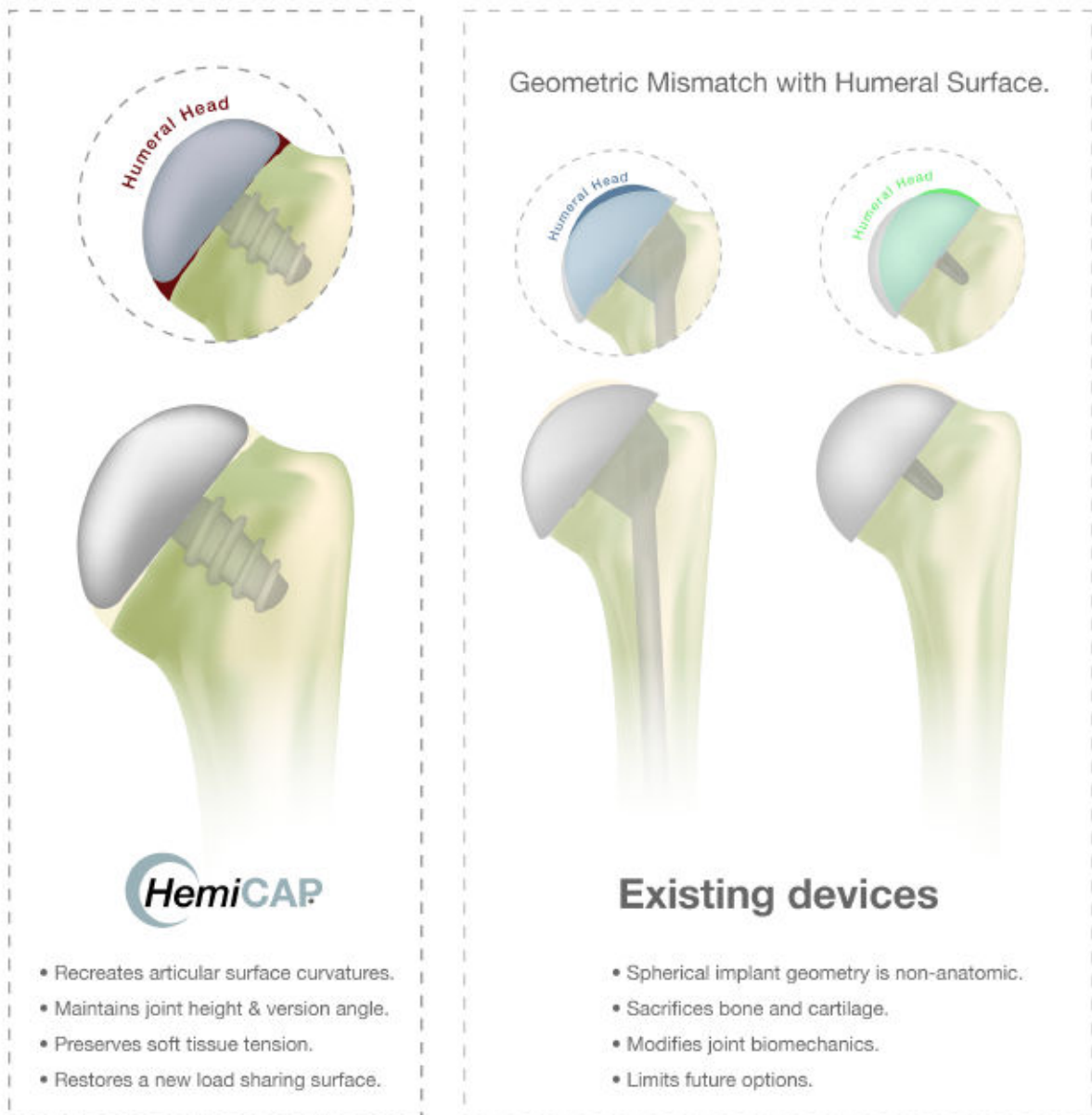
25

1. Maximum SI _____
Maximum ML _____

2. Select 25mm HemiCAP® offset values
If no match is found, use the next highest offset value

- 2.5 mm x 2.5 mm
- 3.0 mm x 3.0 mm
- 3.5 mm x 3.5 mm
- 4.0 mm x 4.0 mm
- 4.5 mm x 4.5 mm
- 5.0 mm x 5.0 mm

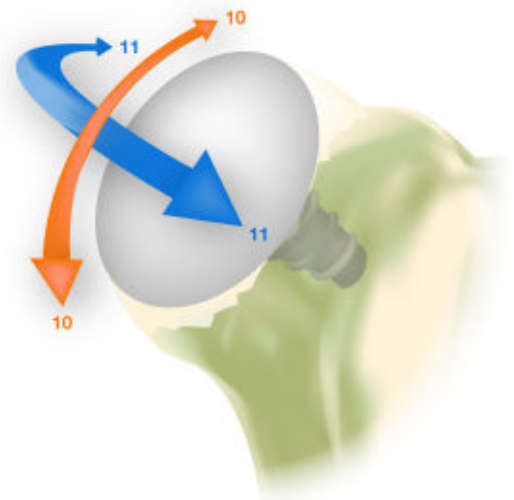
3. Select 25mm Surface Reamer size
Choose the Surface Reamer that matches the highest offset value. Confirm with the color code on the HemiCAP® articular component package.



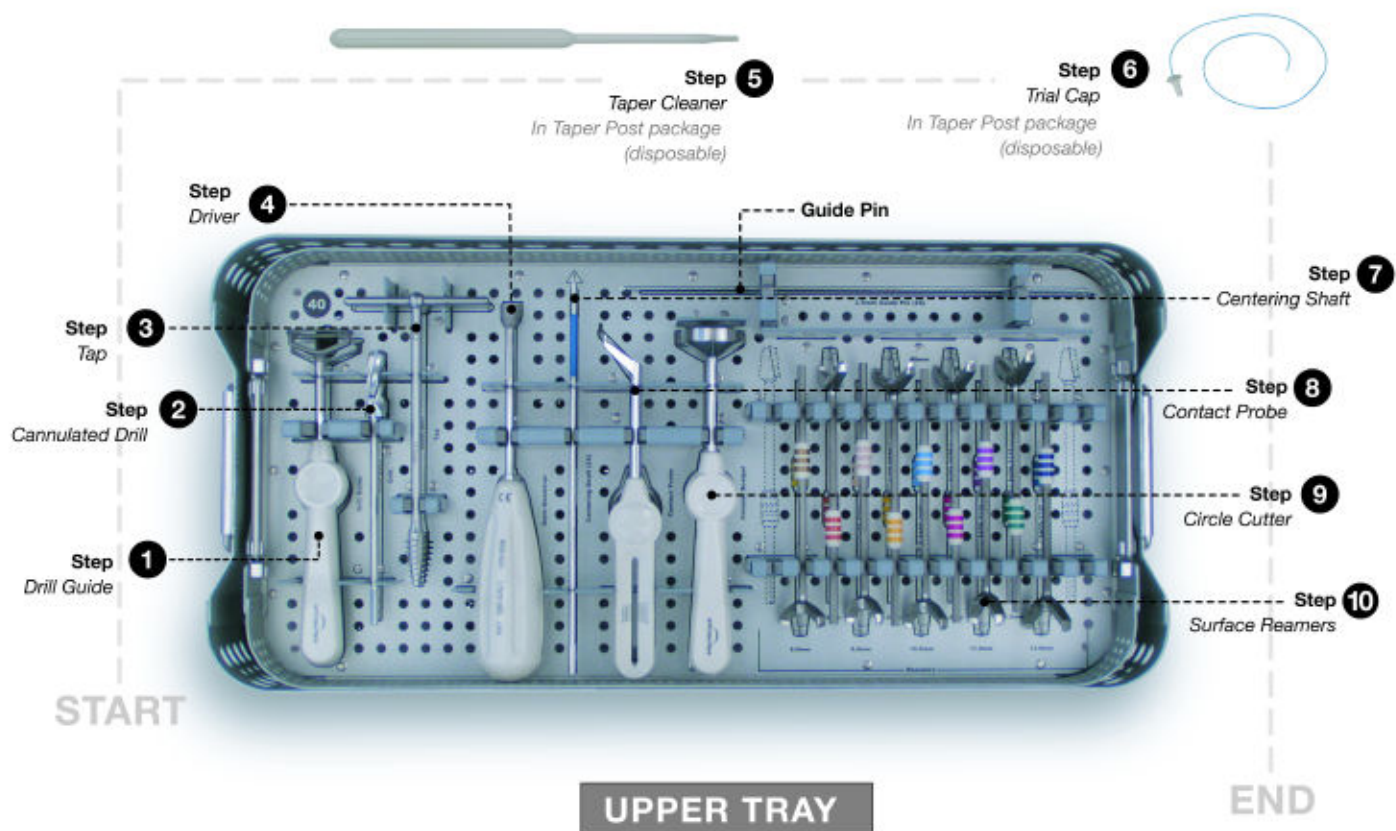
The spherical geometry and instrumentation of existing hemiarthroplasty devices limit the surgeons' ability to recreate the patient's original articular surface geometry and joint biomechanics. The HemiCAP® system allows the surgeon to map the patient's articular surface intraoperatively and restore 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."

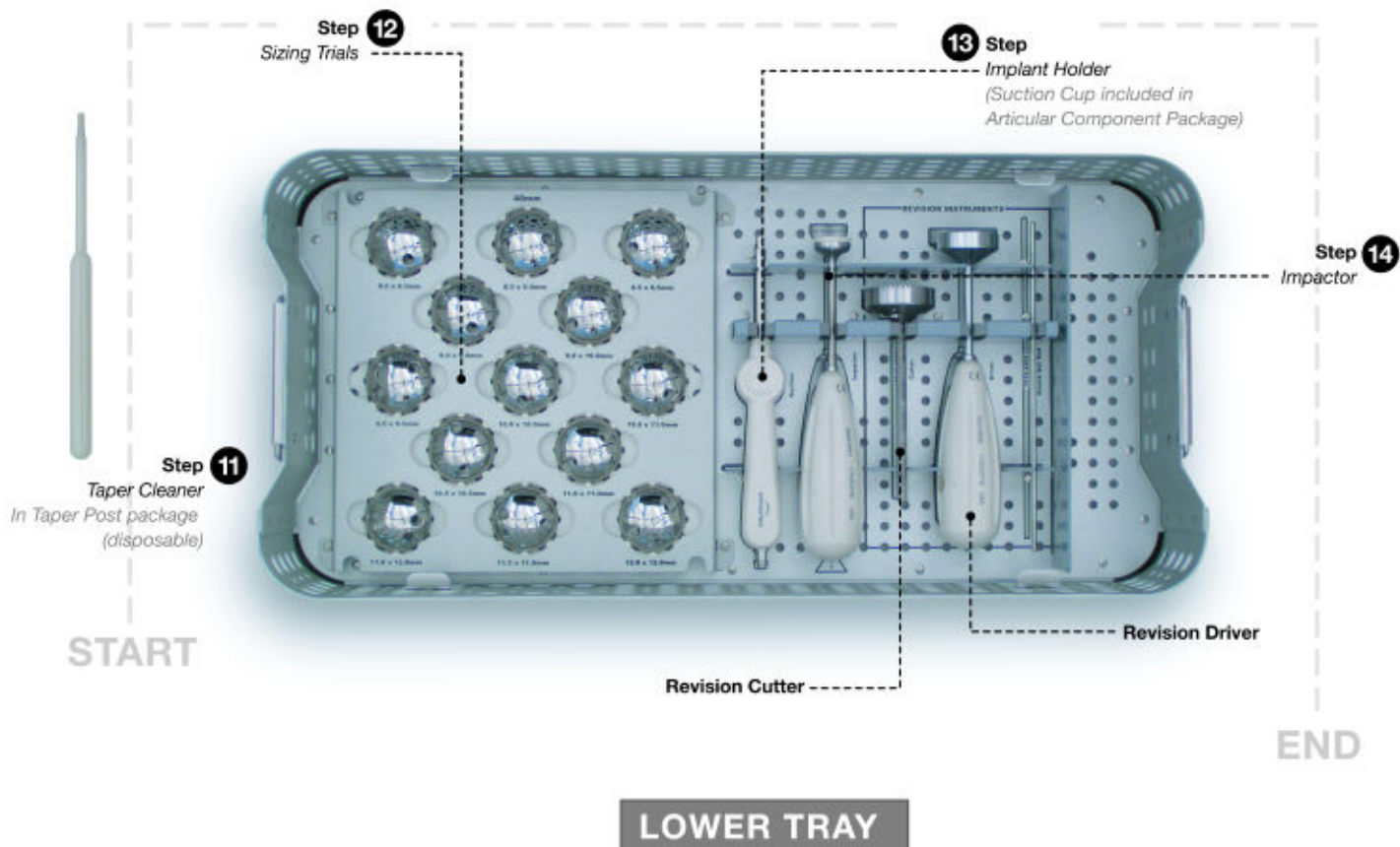
– Anthony Miniaci, M.D., FRCSC, Cleveland Clinic, OH



HemiCAP® Shoulder Instrumentation



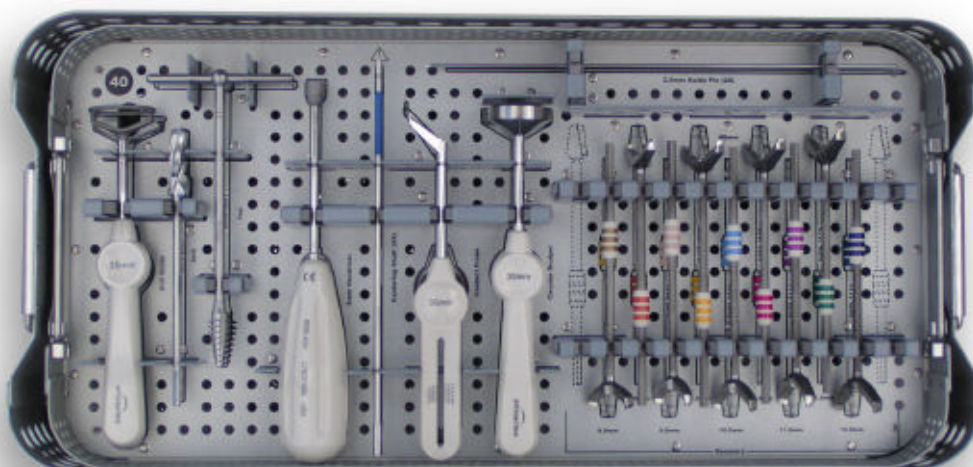
17



Instrumentation System

8000 - 4000
8000 - 3000
6000 - 3000
8007 - 1200
8007 - 1205
6007 - 1200
6007 - 1205

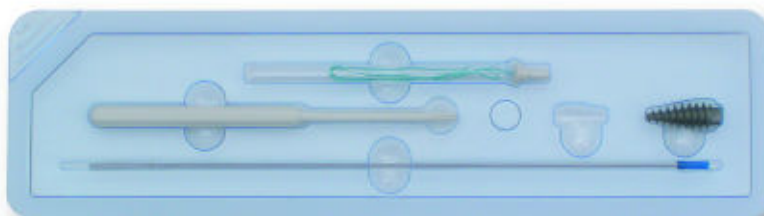
Instrument Kit, 40mm includes 40mm Sizing Trials
Instrument Kit, 35mm includes 35mm Sizing Trials
Instrument Kit, 25/30mm includes 25/30mm Sizing Trials
2.5mm Guide Pin (each) for 35mm and 40mm Implants (sterile)
2.5mm Guide Pin (5 pk) for 35mm and 40mm Implants (non-sterile)
2.0mm Guide Pin (each) for 25mm and 30mm Implants (sterile)
2.0 mm Guide Pins (5 pk) for 25mm and 30mm Implants (non-sterile)



Taper Post (Fixation Components)

8135 - 1875
8135 - 0032
6125 - 0035
6105 - 0028

13.7mm x 31mm (for 40mm only)
13.5mm x 32mm (for 35mm only)
12.5mm x 32mm (for 25mm & 30mm only)
10.5mm x 28mm (for 25mm & 30mm only)





40

Articular Components 40mm

8402 - 8080	8.0 x 8.0mm Offset
8402 - 8090	8.0 x 9.0mm Offset
8402 - 8585	8.5 x 8.5mm Offset
8402 - 9090	9.0 x 9.0mm Offset
8402 - 9010	9.0 x 10.0mm Offset
8402 - 9595	9.5 x 9.5mm Offset
8402 - 1010	10.0 x 10.0mm Offset
8402 - 1011	10.0 x 11.0mm Offset
8402 - 0505	10.5 x 10.5mm Offset
8402 - 1111	11.0 x 11.0mm Offset
8402 - 1112	11.0 x 12.0mm Offset
8402 - 1515	11.5 x 11.5mm Offset
8402 - 1212	12.0 x 12.0mm Offset

35

Articular Components 35mm

8352 - 6060	6.0mm x 6.0mm Offset
8352 - 6070	6.0mm x 7.0mm Offset
8352 - 6565	6.5mm x 6.5mm Offset
8352 - 7070	7.0mm x 7.0mm Offset
8352 - 7080	7.0mm x 8.0mm Offset
8352 - 7575	7.5mm x 7.5mm Offset
8352 - 8080	8.0mm x 8.0mm Offset
8352 - 8090	8.0mm x 9.0mm Offset
8352 - 8585	8.5mm x 8.5mm Offset
8352 - 9090	9.0mm x 9.0mm Offset
8352 - 9010	9.0mm x 10.0mm Offset
8352 - 9595	9.5mm x 9.5mm Offset

30

Articular Components 30mm

8302 - 0045	4.5mm x 4.5mm Offset
8302 - 0050	5.0mm x 5.0mm Offset
8302 - 0055	5.5mm x 5.5mm Offset
8302 - 0060	6.0mm x 6.0mm Offset
8302 - 0065	6.5mm x 6.5mm Offset
8302 - 0070	7.0mm x 7.0mm Offset

25

Articular Components 25mm

8252 - 0025	2.5mm x 2.5mm Offset
8252 - 0030	3.0mm x 3.0mm Offset
8252 - 0035	3.5mm x 3.5mm Offset
8252 - 0040	4.0mm x 4.0mm Offset
8252 - 0045	4.5mm x 4.5mm Offset
8252 - 0050	5.0mm x 5.0mm Offset

Manufactured by:

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



40



Symmetrical

Asymmetrical

35



Symmetrical

Asymmetrical

30



Symmetrical

25



Symmetrical

Arthrosurface's HemiCAP® resurfacing system is also available for the following joints:

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- Hip
- MTP
- Femoral Condyle *(Available in most International markets via CE mark and as part of a IDE study in the US).*

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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.
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