



The HemiCAP® Shoulder Restoration Systems restore the articular surface geometry of the humeral head and preserve functional structures using an innovative 3 dimensional mapping system and a contoured articular resurfacing implant.

Anterior Deltopectoral Approach

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.



Shouler Hemiarthroplasty



25 mm



30 mm



35 mm



40 mm

KEY FEATURES:

Over 40 anatomically matched implant convexities

AVN, locked dislocators, traumatic lesions, & OA

Clinically proven published peer reviewed data

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 (CPTi)
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 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.

HemiCAP® System Components

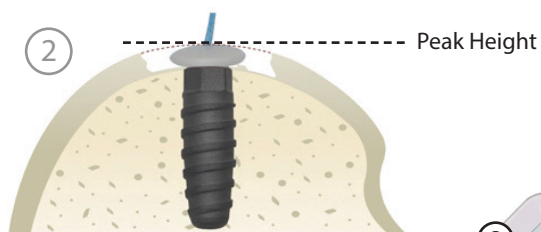
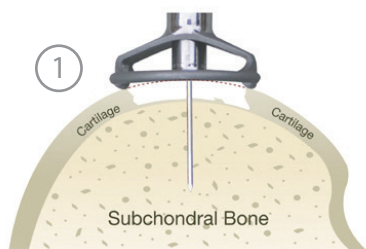
- Cobalt Chrome Component
- Ti Plasma Spray Undercoating
- Morse Taper:
Interlocks the two components
- Titanium Fixation Component
(Cannulated, Bead blasted)
- 5 Diameters **40** **35** **30** **25**
- Over 40 Different Convexities in
Symmetrical and Asymmetrical Curvatures



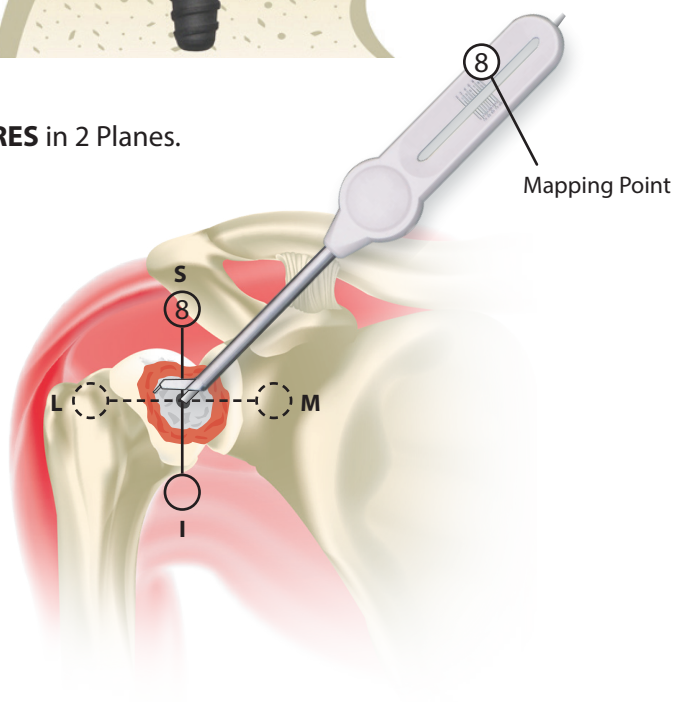
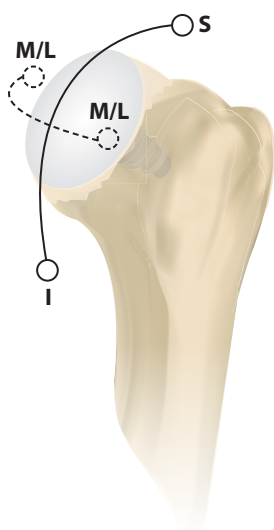
Arthrosurface® 3-Dimensional Mapping

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

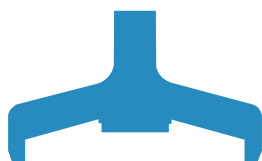
1. The Drill Guide determines the best **DIAMETER** for coverage of defect and establishes perpendicularity.
2. The Trial Cap sets the **PEAK** height of the original joint surface.



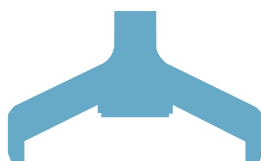
3. The Contact Probe **MAPS** the Surface **CURVATURES** in 2 Planes.



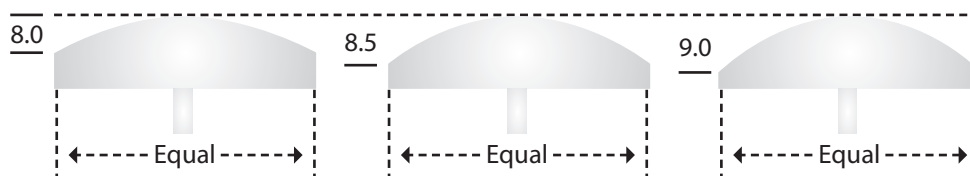
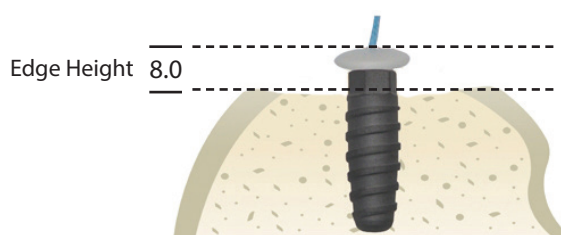
4. The Reamers and Sizing Trials set the **EDGE HEIGHT** to the adjacent articular cartilage.



Flatter
Humeral Head



More Curved
Humeral Head



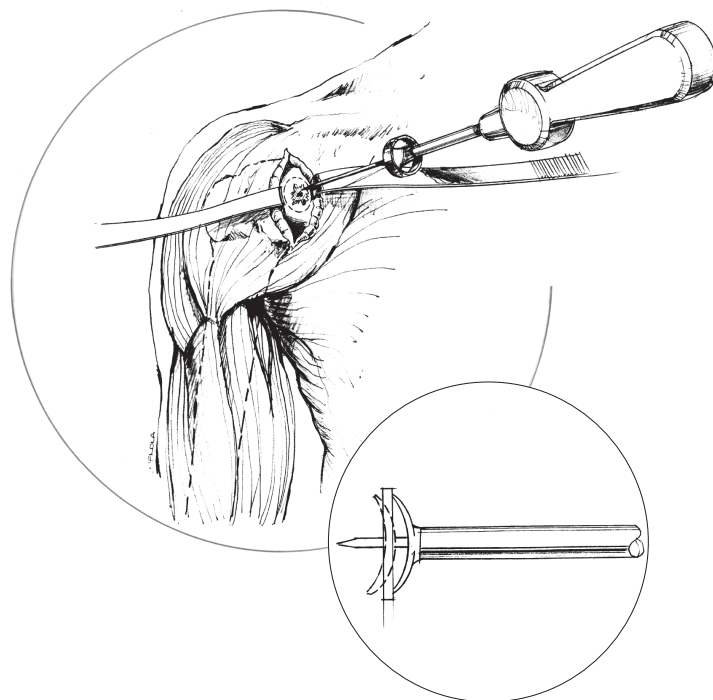
Surgical Technique (Shoulder Hemiarthroplasty)

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.*



Drill Guide



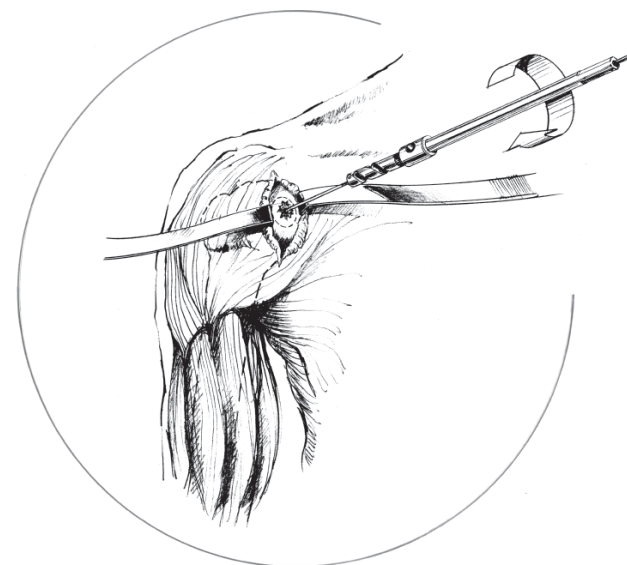
2. Place the **Step Drill** over the **Guide Pin** and drill until the proximal shoulder of the **Step Drill** is flush with the articular surface. Tap the hole to the etched depth mark on the **Tap**.



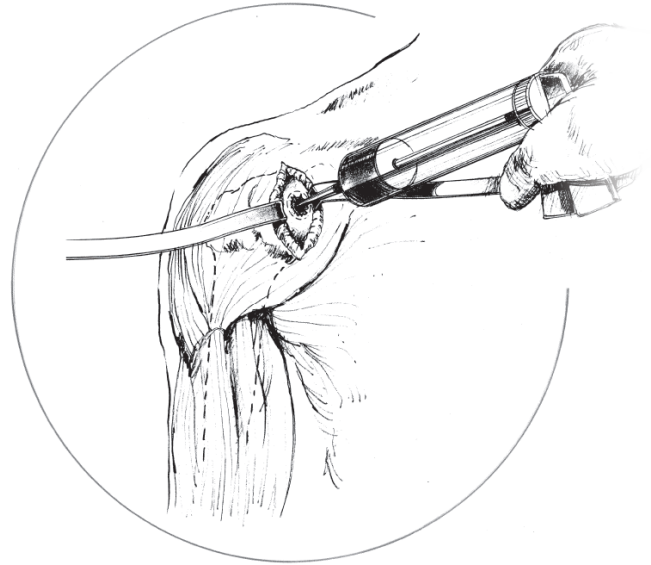
Step Drill



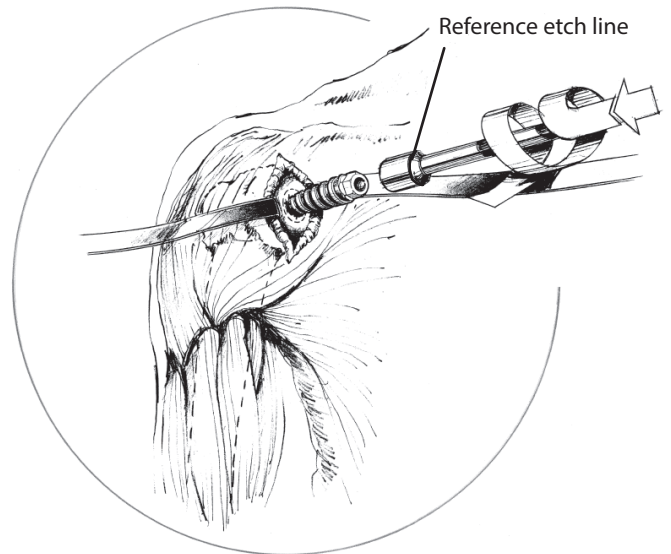
Tap



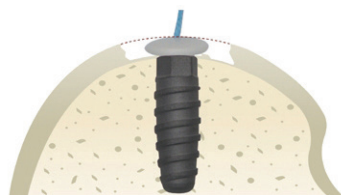
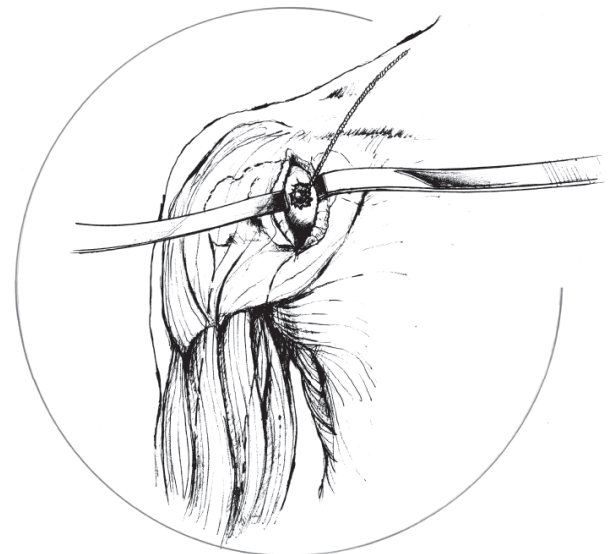
3. Prior to inserting the **Taper Post**, thoroughly cleanse the pilot hole of any debris and inject the cement in a retrograde fashion from the end of the hole upwards.



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 confirm the 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**.

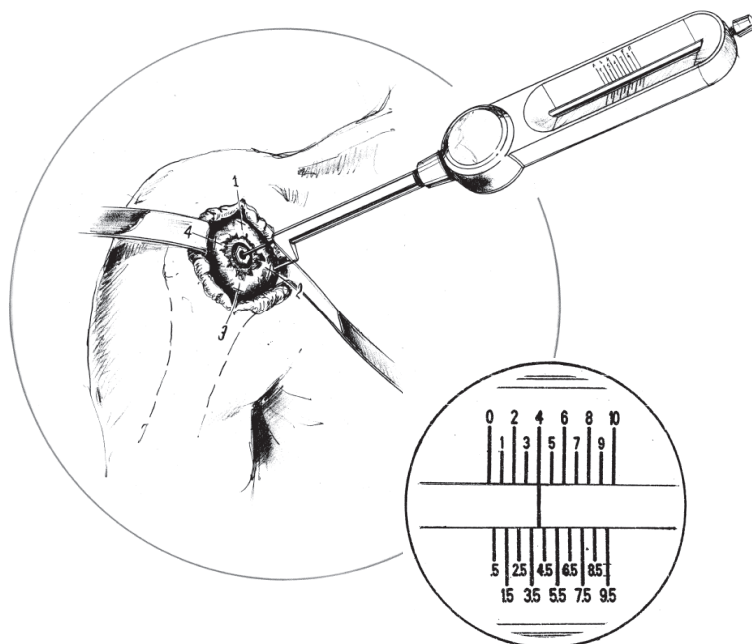


6. Place the **Centering Shaft** into taper of the **Taper Post**. Place the **Contact Probe** over the **Centering Shaft** and rotate around the **Centering Shaft**. Read the **Contact Probe** to obtain offsets at four indexing points (superior/inferior and medial/lateral) and mark each of the identified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

Centering Shaft (colored end up)



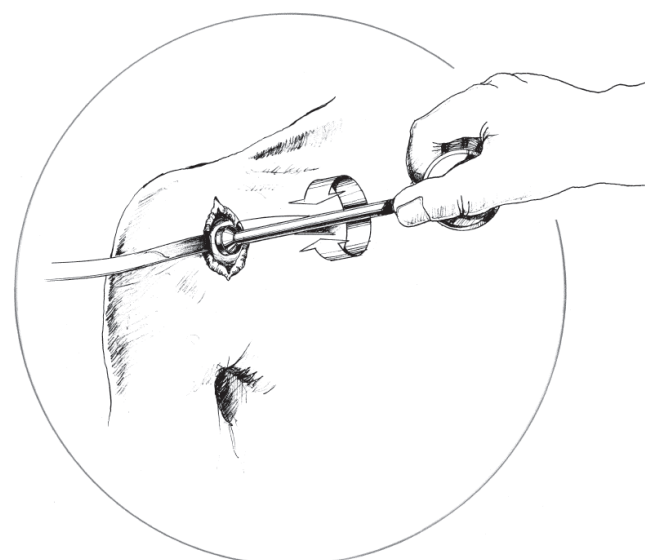
Contact Probe



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 the articular cartilage down to subchondral bone.



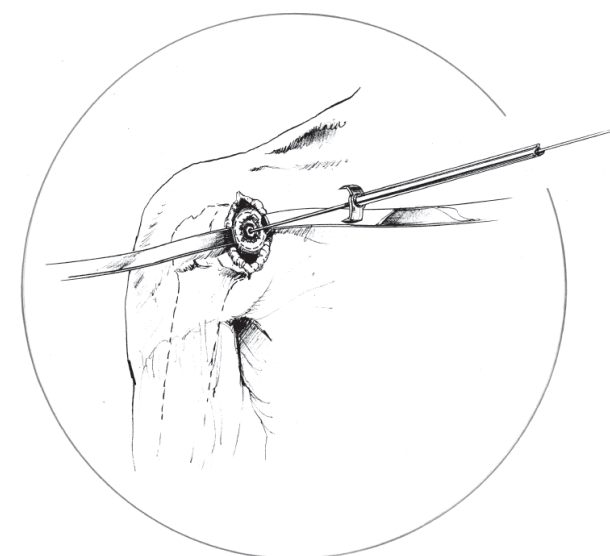
Circle Cutter



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 **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.



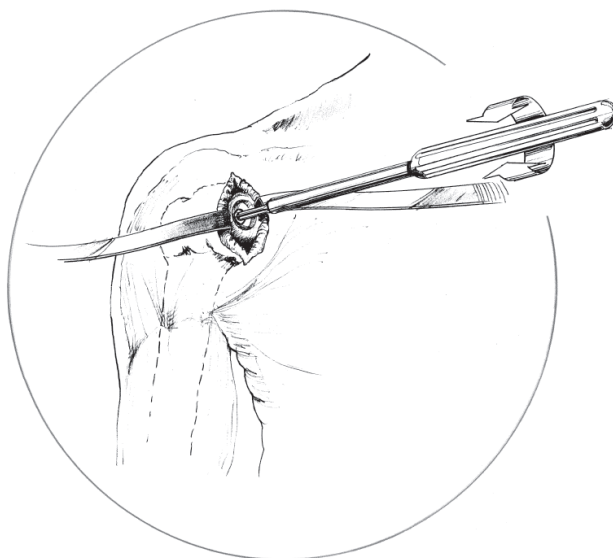
Surface Reamer



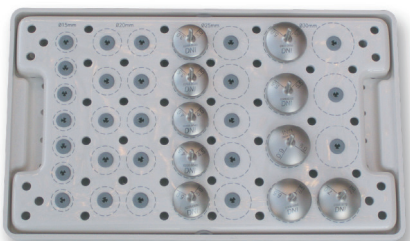
9. Remove the **Guide Pin**. Clean the **Taper Post** with the **Taper Cleaner** and remove any debris from the surrounding implant bed.



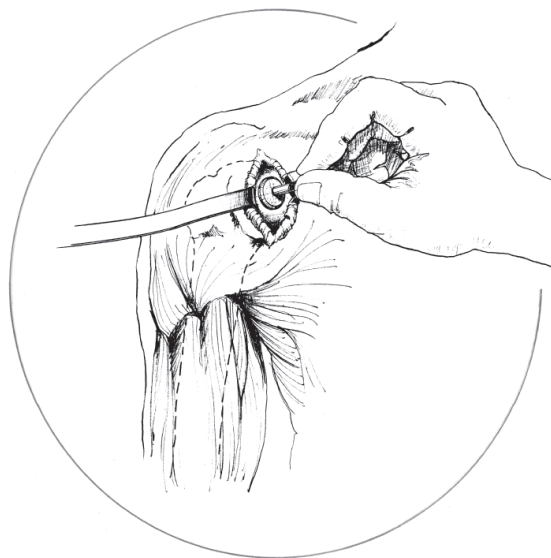
Taper Cleaner



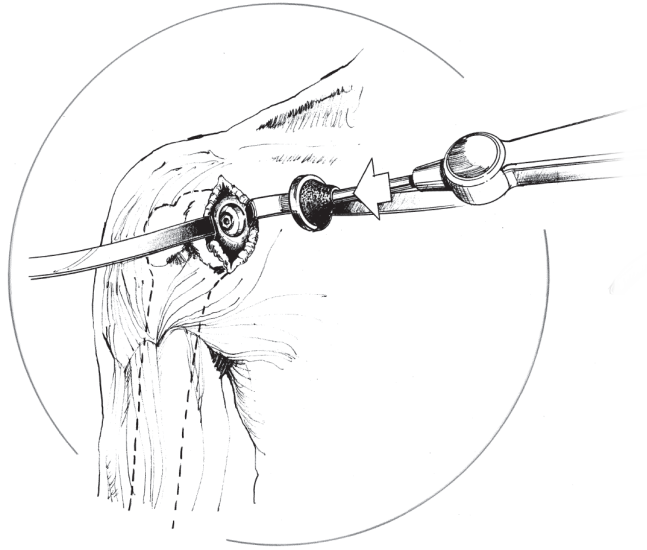
10. Place the **Sizing Trial** into the defect that matches the offset profile of the chosen **HemiCAP® Articular Component**. Confirm the fit of the **Sizing Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed. If the **Sizing Trial** is proud at the edge of the articular cartilage, ream with the next appropriate sized reamer and use the matching **Sizing Trial**. **Sizing Trials** must match **Surface Reamer's** offset size.



Cap Caddy (only for 25/30 mm)

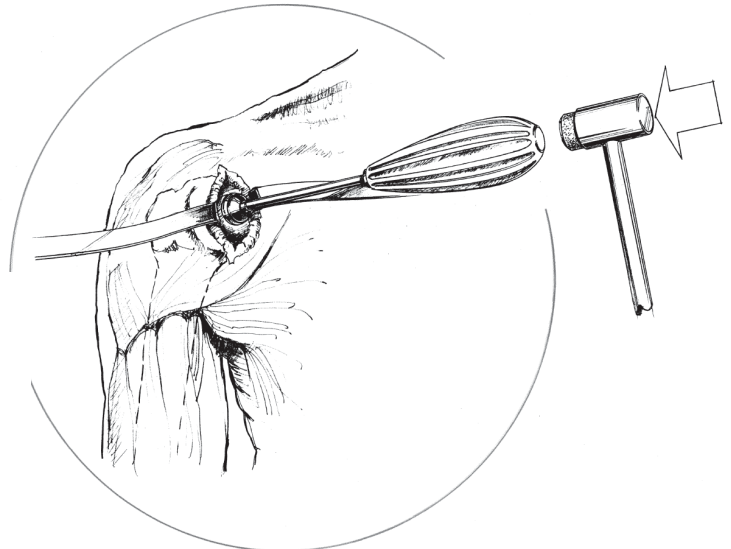


11. Before placing the **Articular Component** on the **Implant Holder**, make sure that sufficient suction is present to hold the device on the distal suction cup. Align the **Articular Component** on the **Implant Holder**. For non-spherical **Articular Components**, orient the etch marks on the back 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 the **Taper Post**.

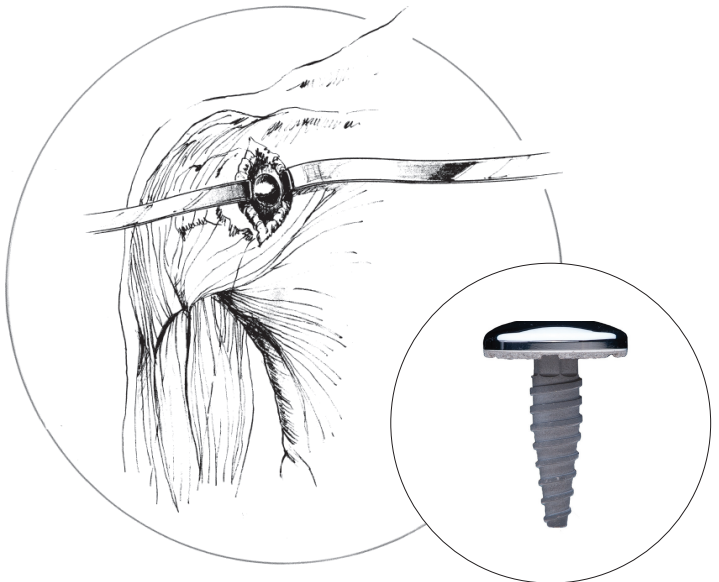


Implant holder

12. 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.



Impactor



Sizing Cards (Shoulder Hemiarthroplasty)

arthrosurface
Humeral Head

Sizing Card

1. Maximum SI _____

Maximum ML _____

40

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.

P/N 3001-1040 Rev A

arthrosurface

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

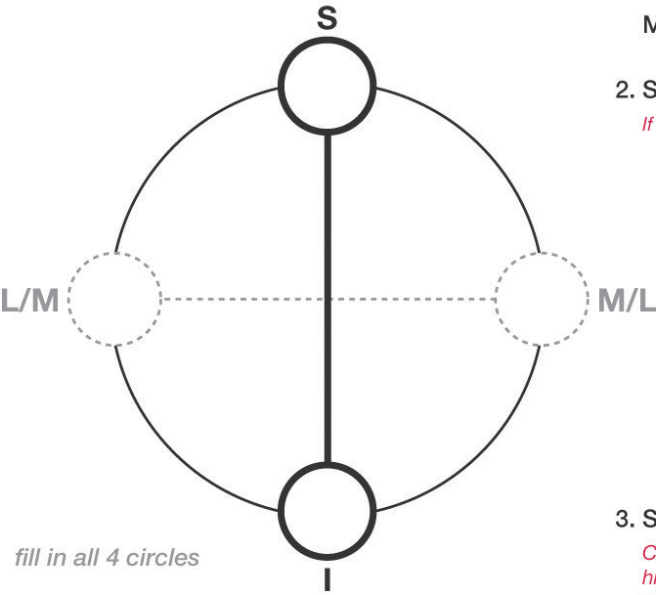
- 6.0 mm x 6.0 mm
- 6.0 mm x 7.0 mm
- 6.5 mm x 6.5 mm
- 7.0 mm x 7.0 mm
- 7.0 mm x 8.0 mm
- 7.5 mm x 7.5 mm
- 8.0 mm x 8.0 mm
- 8.0 mm x 9.0 mm
- 8.5 mm x 8.5 mm
- 9.0 mm x 9.0 mm
- 9.0 mm x 10.0 mm
- 9.5 mm x 9.5 mm

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.

P/N 3001-1035 Rev B

Sizing Cards (Shoulder Hemiarthroplasty)



fill in all 4 circles

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

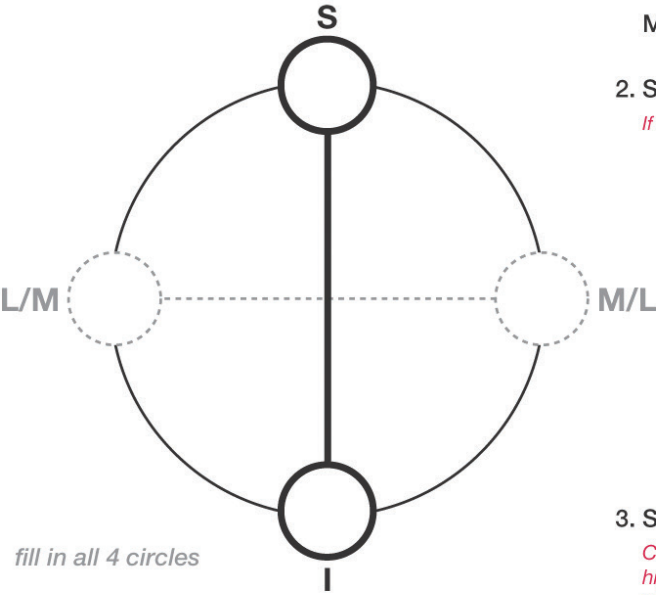
7.0 mm x 7.0 mm

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.

Sizing Card

P/N 1001-1030 Rev D



fill in all 4 circles

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

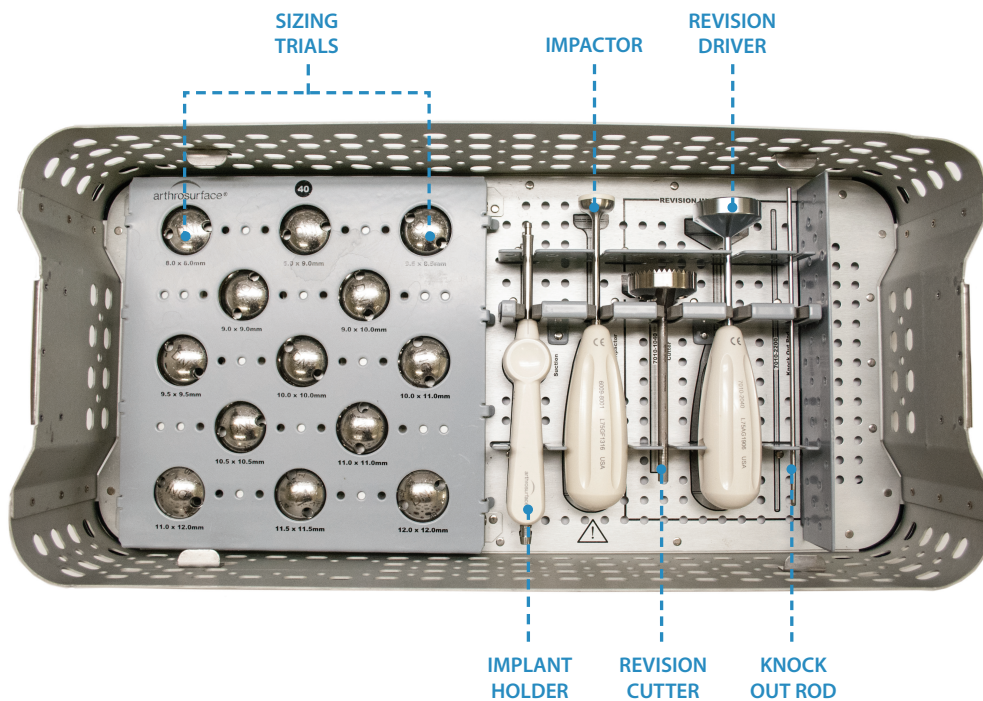
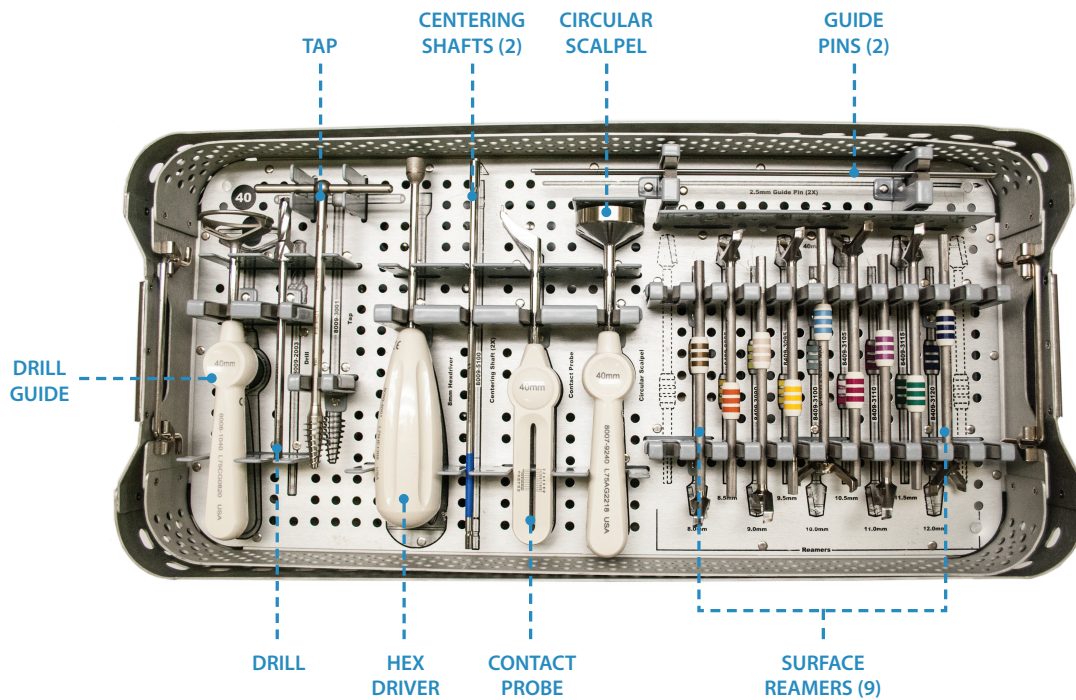
3. Select **25mm Surface Reamer** size

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

Sizing Card

P/N 1001-1025 Rev D

Instrumentation (Shoulder Hemiarthroplasty)



System Catalog (Shoulder Hemiarthroplasty)

Instrumentation System

8000-4000	Instrument Kit, 40mm includes 40mm Sizing Trials
8000-3000	Instrument Kit, 35mm includes 35mm Sizing Trials
6000-3000	Instrument Kit (6000-2530), 25/30mm and 25/30mm Sizing Trials in Cap Caddy (6000-0500)
8007-1200	2.5mm Guide Pin (each) for 35mm & 40mm (sterile)
8007-1205	2.5mm Guide Pin (5 pack) for 35mm & 40mm (non-sterile)
6007-1200	2.0mm Guide Pin (each) for 25mm and 30mm Implants (sterile)
6007-1205	2.0mm Guide Pins (5 pack) for 25mm and 30mm Implants (non-sterile)

Taper Post (Fixation Components)

8135-1875	10mm x 32mm (for 40mm only)
8135-0032	10mm x 31mm (for 35mm only)
6125-0035	9mm x 30mm (for 25mm & 30mm only)

40mm Articular Components

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

35mm Articular Components

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

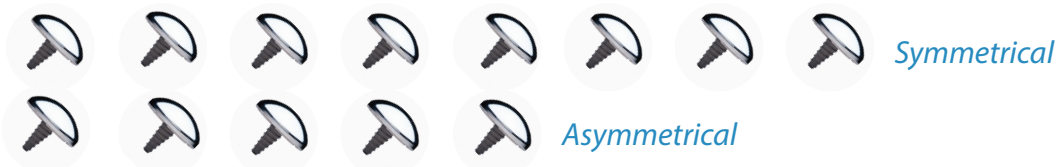
30mm Articular Components

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

25mm Articular Components

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

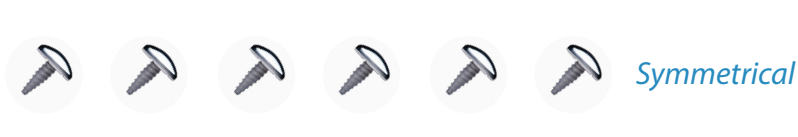
40



35



30



25



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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For more information, visit our website:
www.arthrosurface.com

28 Forge Parkway • Franklin, MA 02038
1 508 520 3003
fax: 1 508 528 3785



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