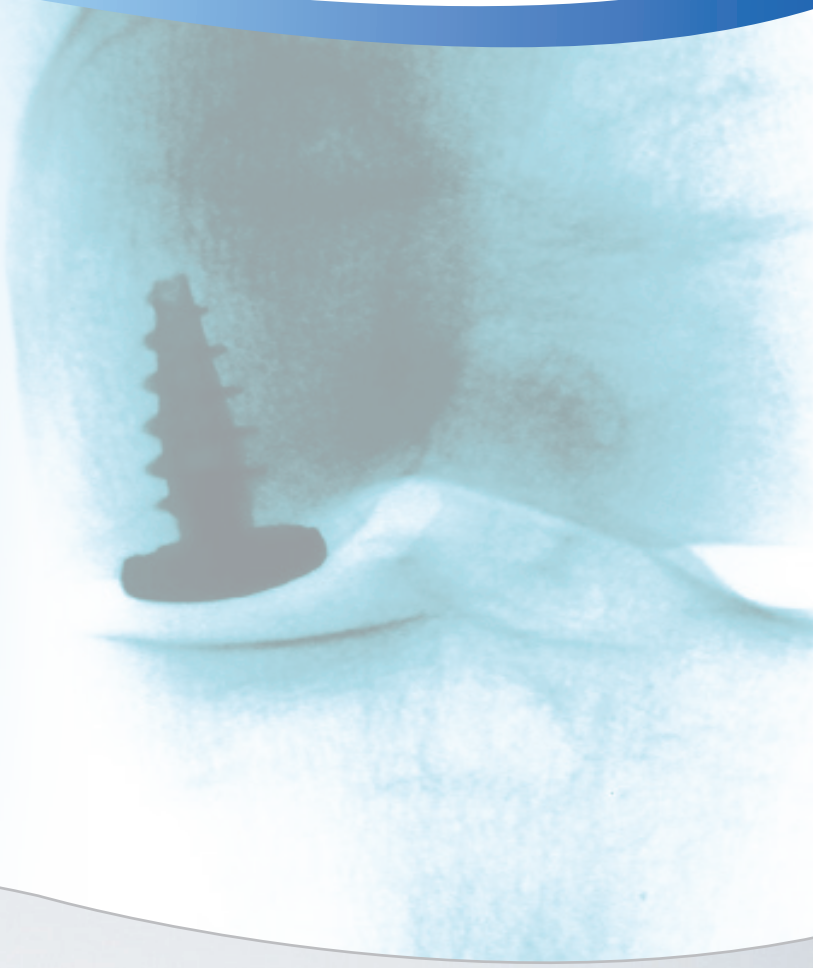
arthrosurface®

Technique Guide

Femoral Condyle Arthroplasty

HemiCAP®



The Arthrosurface® HemiCAP® Knee System restores the unique articular surface geometry of the femoral condyle by using an intraoperative 3 dimensional mapping system and a contoured articular resurfacing implant.

RECREATES
articular surface curvatures

PRESERVES
healthy cartilage & bone

MAINTAINS
joint height & version angle

RESTORES
a new load sharing surface

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.

Materials

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

Indications

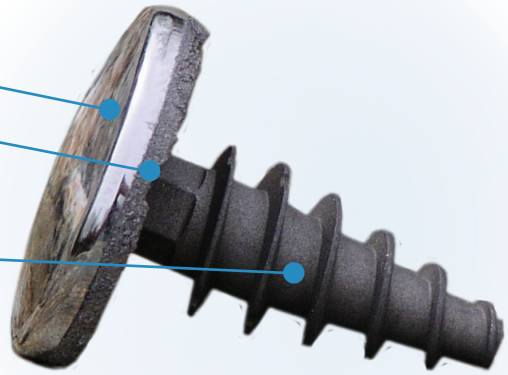
Partial resurfacing of the femoral condylar surface when only one compartment of the knee is affected by large unstable articular defects with significant subchondral bone exposure. Soft tissues and other structures contributing to stability within the joint should be generally intact or reconstructible. The intended use of the device is part of an interim clinical strategy for patients who have not responded to other recognized surgical procedures for the treatment of the defect and who, if left unattended, will likely progress in symptoms and require joint replacement surgery. The device is a single use implant.

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

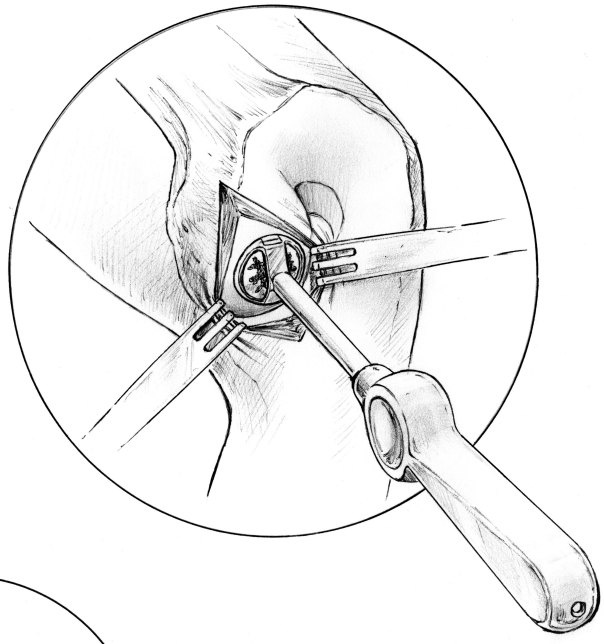
- Cobalt Chrome Component
- Ti Plasma Spray Undercoating
- Morse Taper:
  Interlocks the two components
- Titanium Fixation Component
  (Cannulated, Bead blasted)
- 2 Diameters 20 15
- Over 16 Different Convexities in
  Symmetrical & Asymmetrical Curvatures

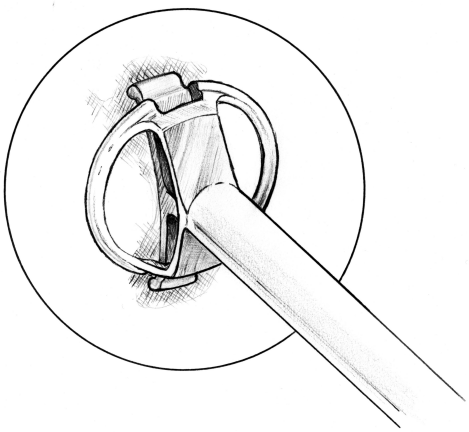


Surgical Technique

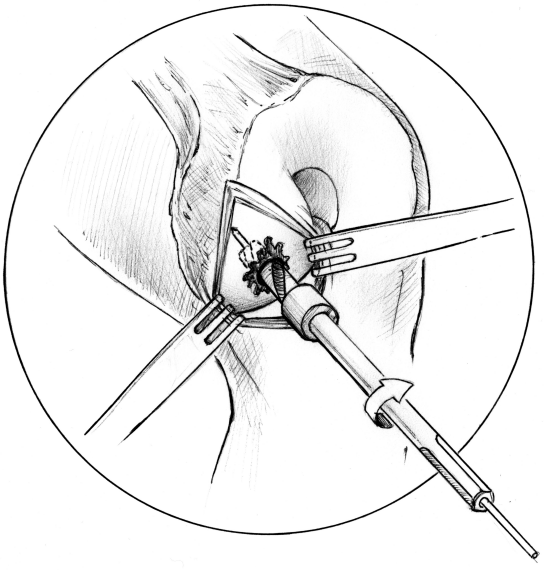
1. Use the **Drill Guide** to locate the axis normal to the articular surface and central to the defect. Choose the correct **Drill Guide** diameter sufficient to circumscribe the defect. Place the **Guide Pin** into a cannulated powered drill and secure at the etch marking on the **Guide Pin**. Advance the **Guide Pin** 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 all 4 points of contact are established on the articular surface. A normal axis and correct **Articular Component** diameter are necessary for proper implant fit).*

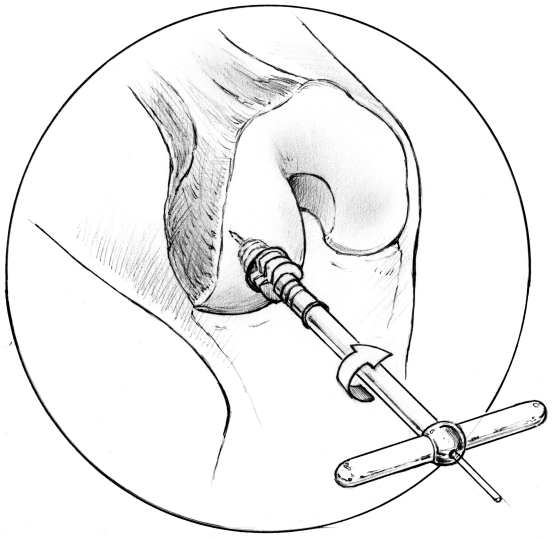




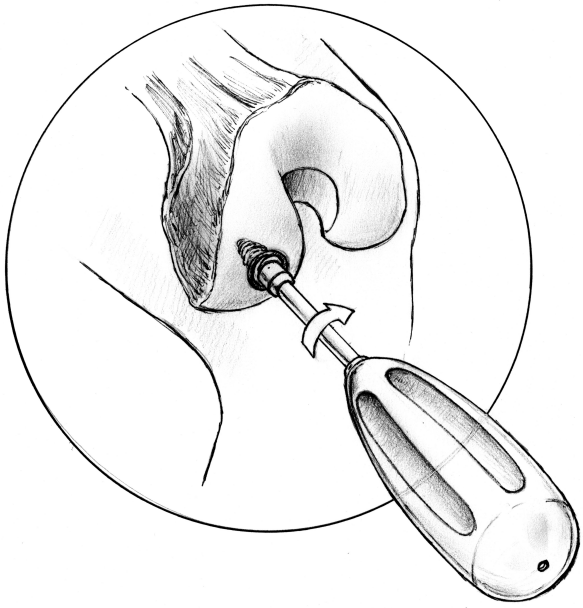
2. Place a cannulated drill over the **Guide Pin** and drive until the proximal shoulder of drill is flush to the articular surface. (Use lavage during drilling to prevent possible tissue damage from heat effects). Should the **Guide Pin** loosen, use the drill to re-center the **Guide Pin** in the pilot hole and advance into the bone.



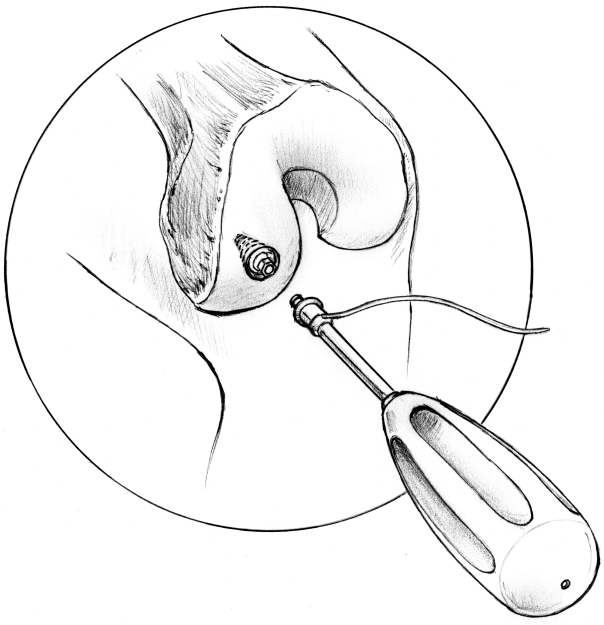
3. Tap the hole to the etched depth mark on the **Tap**.

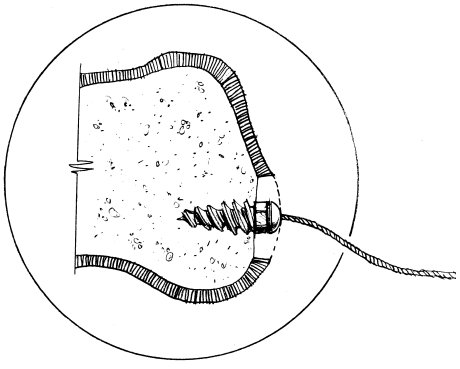


4. Place the **Driver** into the **Fixation Component** and advance the **Fixation Component** until the line on the **Driver** is flush with the contour of the adjacent cartilage surface.

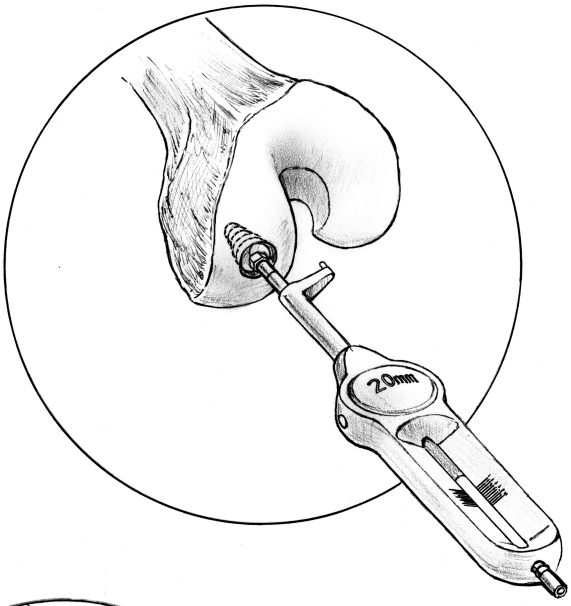


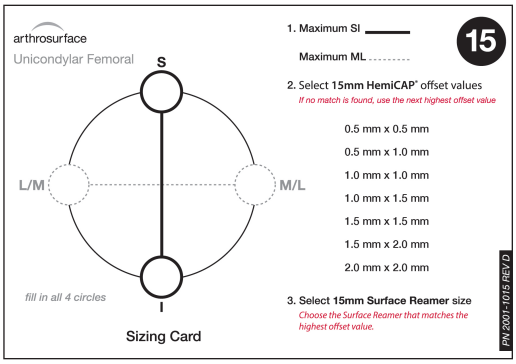
5. Remove the **Guide Pin**. Clean the taper in the **Fixation Component** with the **Taper Cleaner**. Place the **Trial Cap** into the **Fixation Component** to confirm correct depth of the **Fixation Component**. The height of the **Trial Cap** must be flush or slightly below the adjacent articular cartilage surface to avoid the **Articular Component** from being placed too proud. Adjust depth if needed using the **Driver** to rotate the **Fixation Component** (rotate clockwise to advance and counterclockwise to retract). Remove the **Trial Cap**.

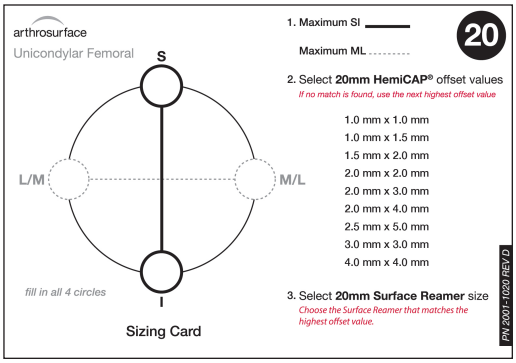


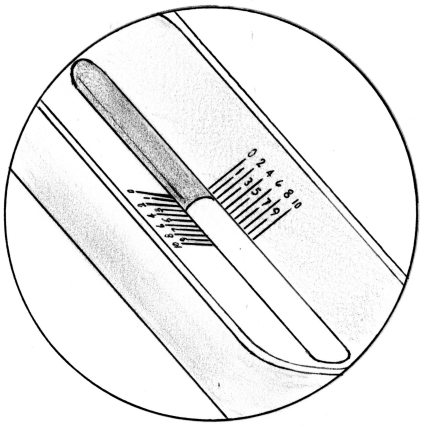


6. Place the **Centering Shaft** into the taper of the **Fixation Component**. Place the **Contact Probe** over the **Centering Shaft** and rotate around the shaft. Read the **Contact Probe** to obtain offsets at four indexing points and mark each of the identified offsets on the appropriate the **Sizing Card**. Select the appropriate **Articular Component** using the **Sizing Card**.

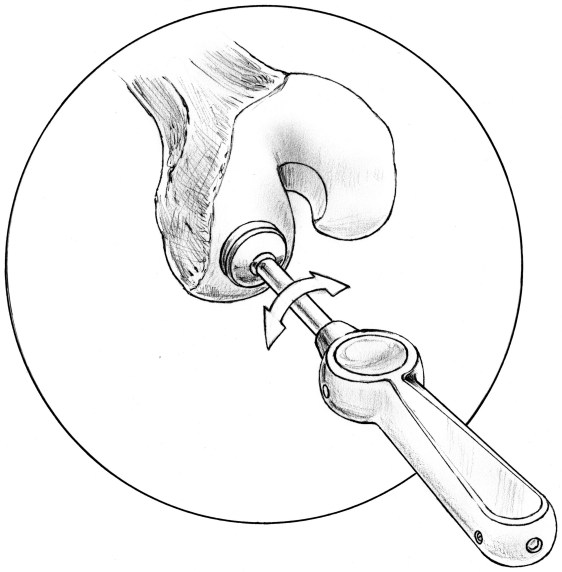




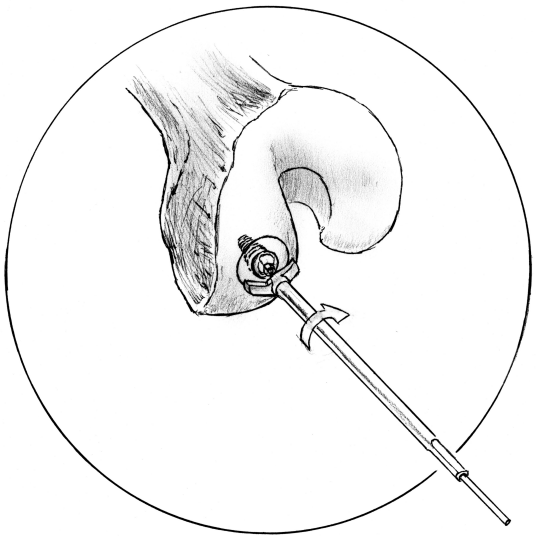




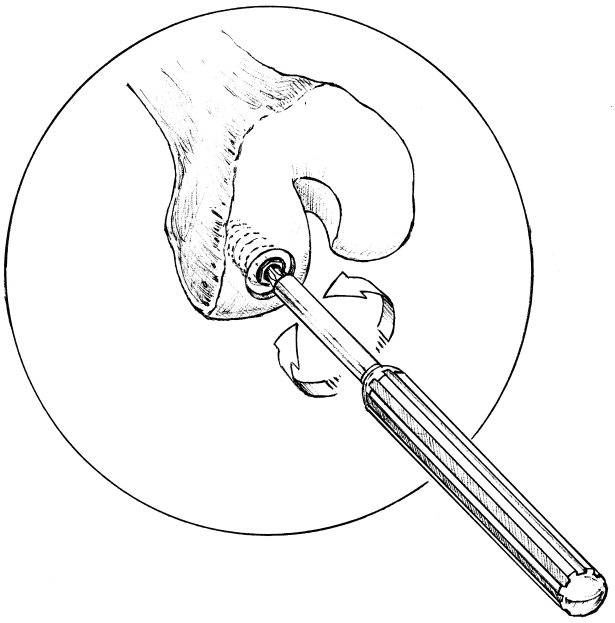
7. Remove the **Centering Shaft** and replace with the **Guide Pin**. Advance the **Circle Cutter** onto the articular cartilage surface by twisting the **Circle Cutter** back and forth avoiding any bending of the **Guide Pin**.



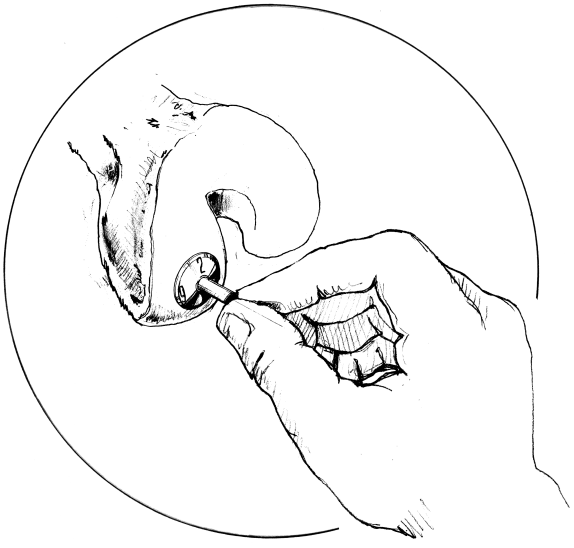
8. Choose the appropriate **Surface Reamer** based on the offsets. Confirm selection by matching the color code on the **Articular Component** package with the colored band on the **Surface Reamer** shaft. Drill the **Surface Reamer** over the **Guide Pin** until it contacts the top surface on the **Fixation Component**. Make sure not to bend the **Guide Pin** during drilling as it may result in **Articular Component** malalignment. Begin the rotation of the **Surface Reamer** prior to contact with bone to prevent chipping of articular rim.



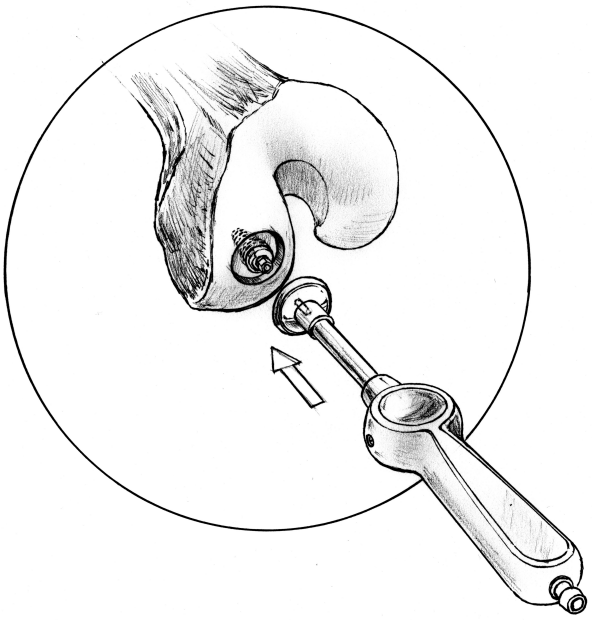
9. Remove the **Guide Pin**. Clean the taper in the **Fixation Component** with the **Taper Cleaner** and remove any debris from the surrounding implant bed.



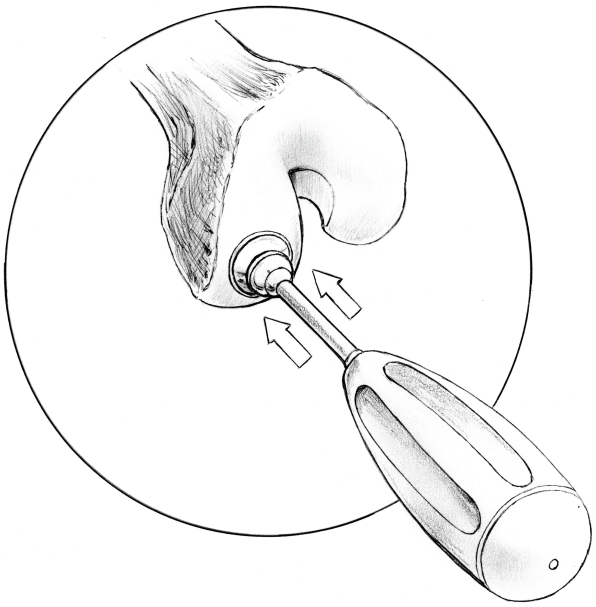
10. Place the **Sizing Trial** into the defect that matches the offset profile of the chosen **Articular Component**. Confirm the fit of the **Sizing Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed. If the **Sizing Trial** is proud at the edge of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



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 the taper of the **Fixation Component**.

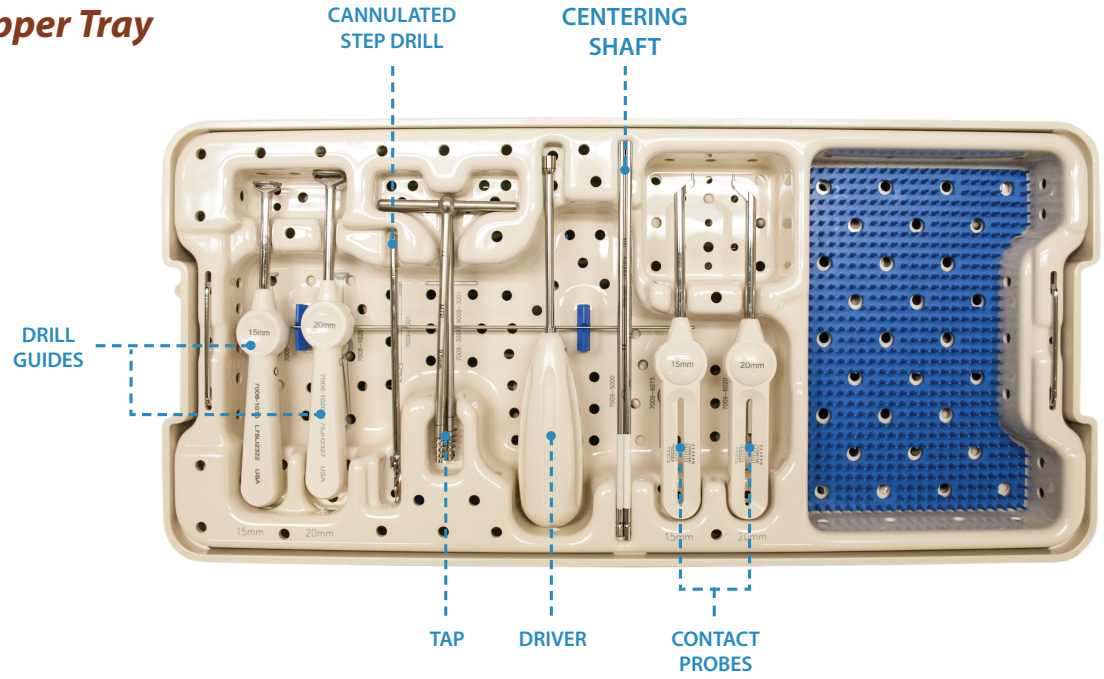


12. Use a slight tap on the **Impactor** to seat the **Articular Component**. Progressively tap the **Impactor** until the **Articular Component** is firmly seated on the bone.

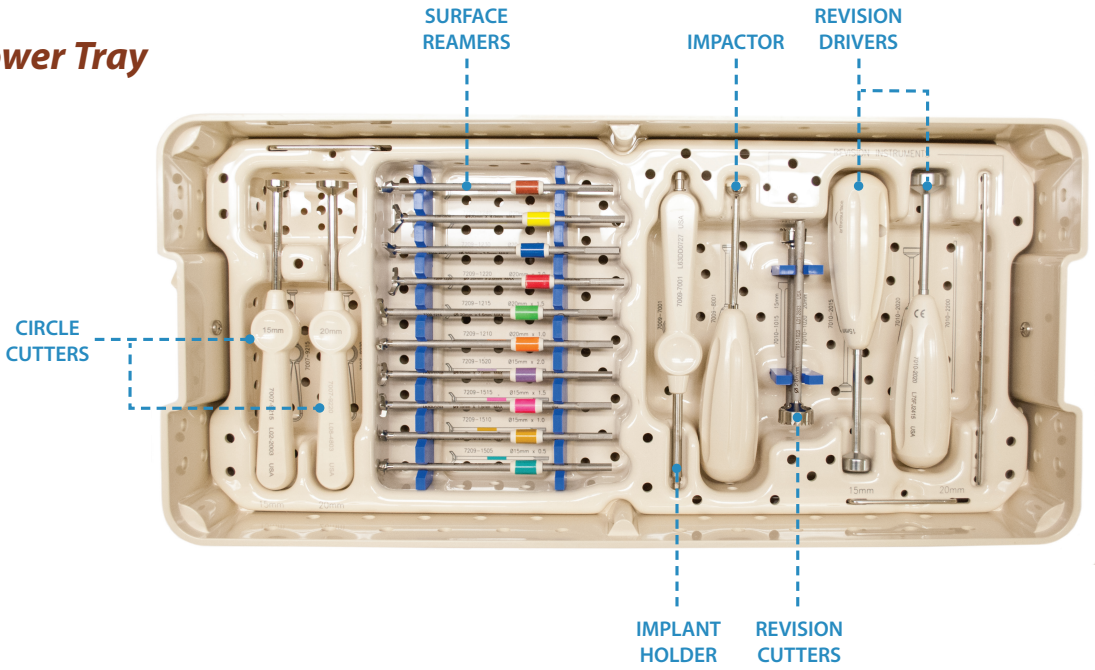


Instrumentation

Upper Tray



Lower Tray



Sizing Trial Caddy

Sizing Cards

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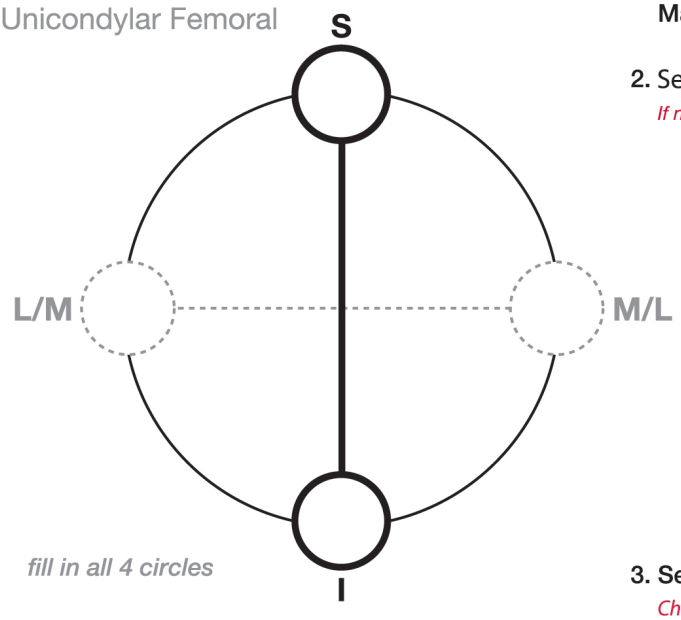
Unicondylar Femoral



fill in all 4 circles

Sizing Card

1. Maximum SI ——— Maximum ML - - - - - - - - -

15

2. Select **15mm HemiCAP®** offset values

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

0.5 mm x 0.5 mm
0.5 mm x 1.0 mm
1.0 mm x 1.0 mm
1.0 mm x 1.5 mm
1.5 mm x 1.5 mm
1.5 mm x 2.0 mm
2.0 mm x 2.0 mm

3. Select **15mm Surface Reamer** size

Choose the Surface Reamer that matches the highest offset value.

PN 2001-1015 REV D

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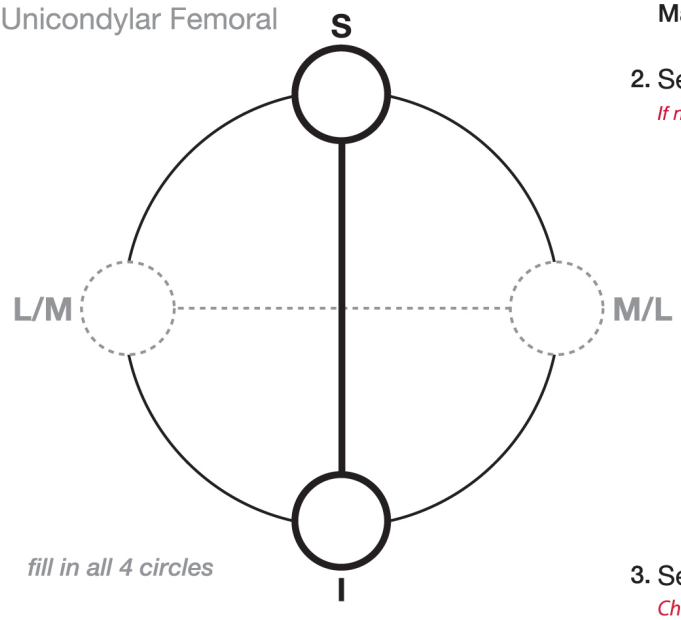
Unicondylar Femoral



fill in all 4 circles

Sizing Card

1. Maximum SI ——— Maximum ML - - - - - - - - -

20

2. Select **20mm HemiCAP®** offset values

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

1.0 mm x 1.0 mm
1.0 mm x 1.5 mm
1.5 mm x 2.0 mm
2.0 mm x 2.0 mm
2.0 mm x 3.0 mm
2.0 mm x 4.0 mm
2.5 mm x 5.0 mm
3.0 mm x 3.0 mm
4.0 mm x 4.0 mm

3. Select **20mm Surface Reamer** size

Choose the Surface Reamer that matches the highest offset value.

PN 2001-1020 REV D

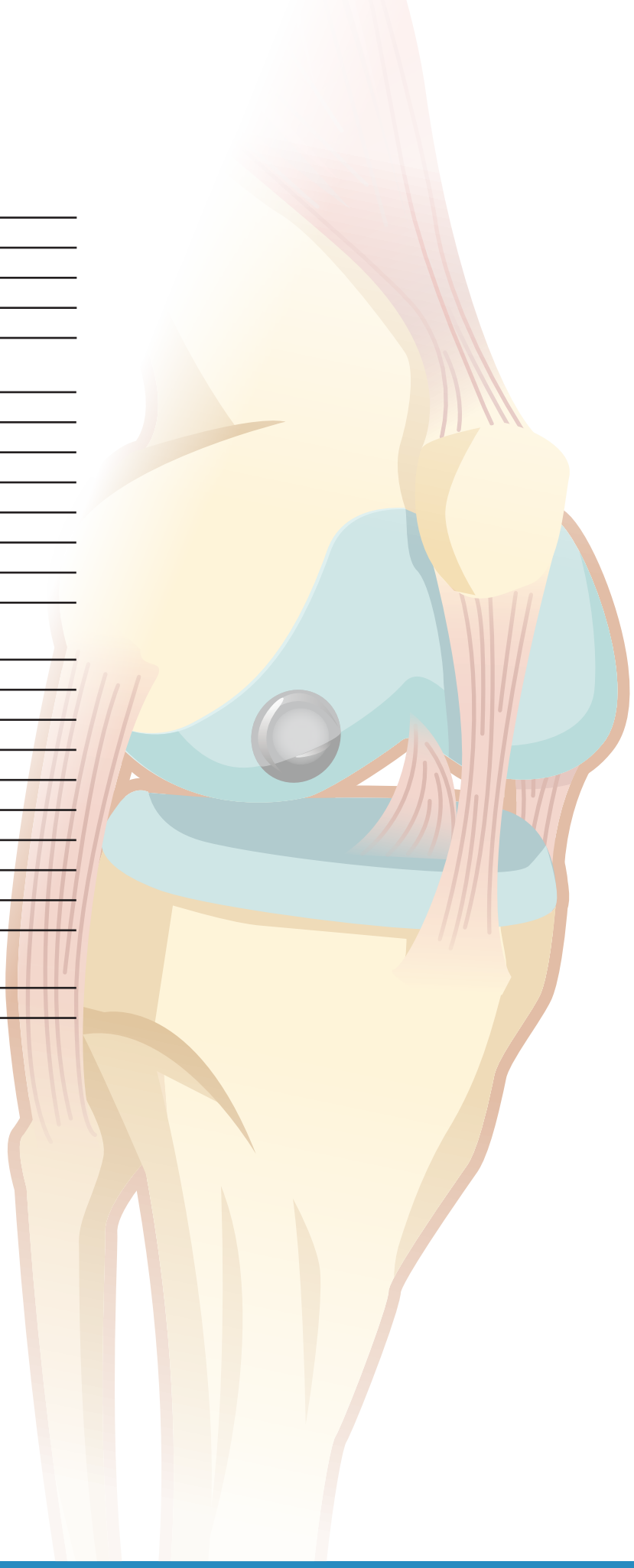
System Catalog

Instrumentation System	
7000-3000	Instrument Kit, Femoral Condyle
6007-1200	2.0mm Guide Pin (each) (sterile)
6007-1205	2.0mm Guide Pins (5 pack) (non-sterile)
7000-0500	Sizing Trials & Case (15mm & 25mm)

Articular Component 15mm	
7152-0505	0.5mm x 0.5mm Offset
7152-0510	0.5mm x 1.0mm Offset
7152-1010	1.0mm x 1.0mm Offset
7152-1015	1.0mm x 1.5mm Offset
7152-1515	1.5mm x 1.5mm Offset
7152-1520	1.5mm x 2.0mm Offset
7152-2020	2.0mm x 2.0mm Offset

Articular Component 20mm	
7202-1010	1.0mm x 1.0mm Offset
7202-1015	1.0mm x 1.5mm Offset
7202-1520	1.5mm x 2.0mm Offset
7202-2020	2.0mm x 2.0mm Offset
7202-2030	2.0mm x 3.0mm Offset
7202-2040	2.0mm x 4.0mm Offset
7202-2550	2.5mm x 5.0mm Offset
7202-3030	3.0mm x 3.0mm Offset
7202-4040	4.0mm x 4.0mm Offset

Taper Post (15mm & 20mm)	
7095-0020	Taper Post, 9.5mm x 20mm



HemiCAP®

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.

HemiCAP®

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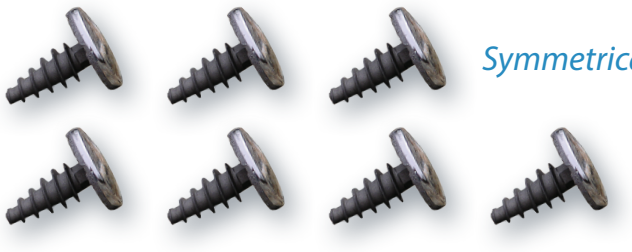

Symmetrical

Asymmetrical

20

Symmetrical

Asymmetrical

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
- Hip

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

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ISO 13485

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