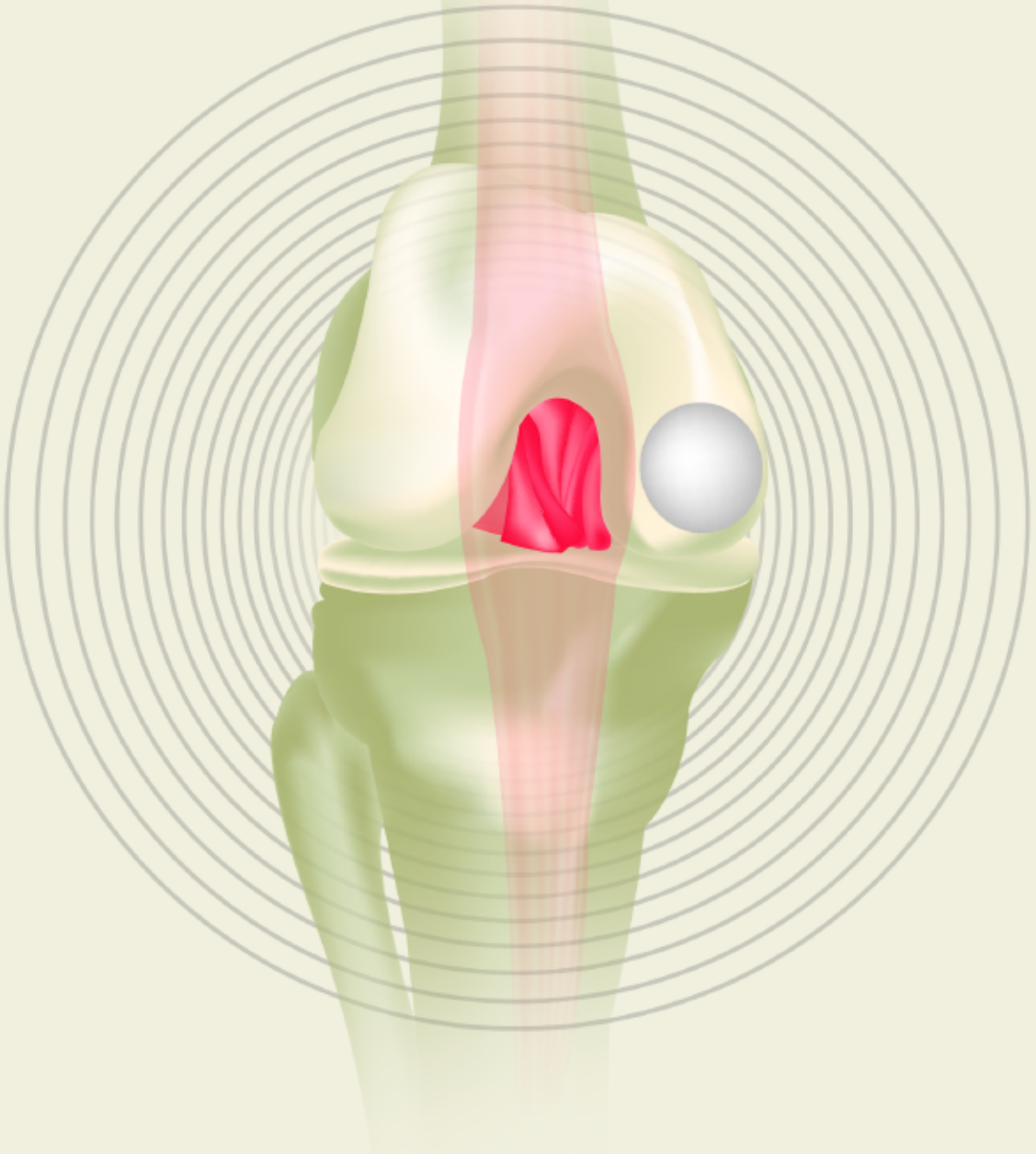
arthrosurface®

Restoring the **Geometry** of *Motion*™

HemiCAP® Anatomic Knee Resurfacing System



The Arthrosurface® HemiCAP® Knee System restores the articular surface geometry of the femoral condyle and preserves functional structures using an innovative 3 dimensional mapping system and a contoured articular resurfacing implant.

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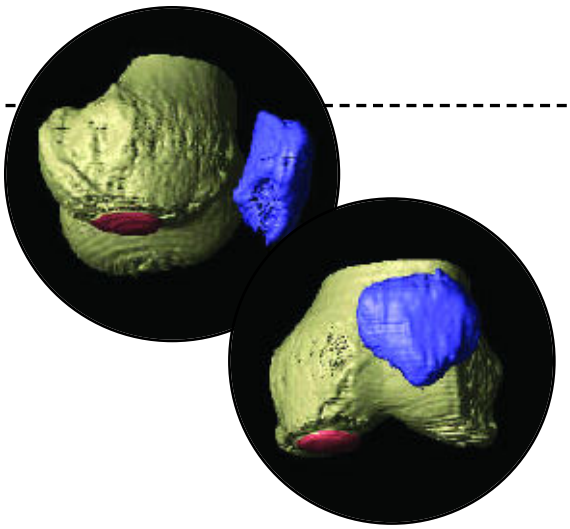
Restoration

The HemiCAP® System is intended for the treatment of large full thickness cartilage lesions of the femoral condyle caused by trauma, localized degenerative joint disease and osteonecrosis.

The instruments precisely align the HemiCAP® implant to the contours of the patient's articular cartilage, thus filling the defect and restoring a smooth and continuous surface.



Standard x-rays do not account for articular cartilage layer

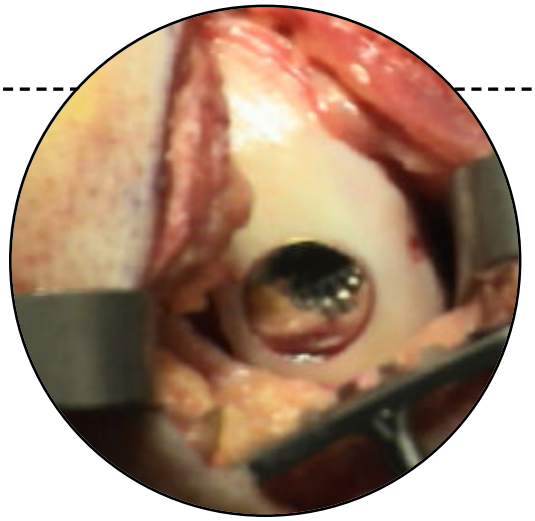
The articular component has a bone contact surface that is coated with Titanium and a polished Cobalt Chrome articular bearing surface. The fixation component is made of Titanium and connects with the articular component via a taper lock. HemiCAP® implants come in a variety of sizes and curvature profiles and are designed for specific surface anatomies.

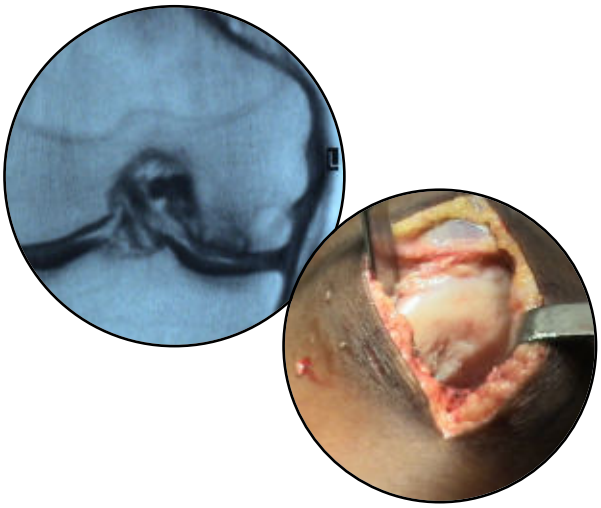
The universal instrumentation is simple and allows for reproducible restoration of a congruent articular surface.

Preservation

The HemiCAP® implant and instruments are designed to remove a minimal amount of bone stock, preserve functional structures and allow for an uncomplicated removal in the event of revision.

The instruments enable the surgeon to precisely map the curves of the articular surface, in real-time, under direct or arthroscopic visualization, with no angle-induced or magnification errors that might exist with MRI or X-ray imaging techniques.



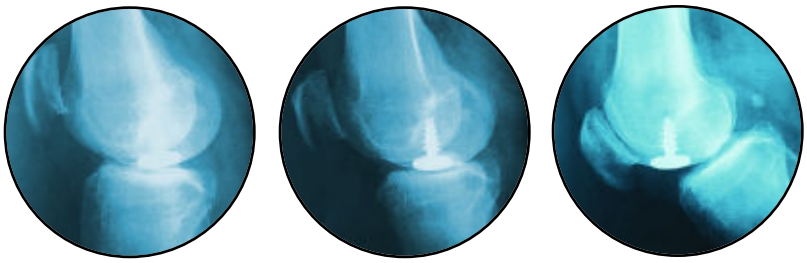


By resurfacing only the damaged cartilage area and restoring a smooth & continuous load-bearing surface, structural effects on the joint are minimized. Soft tissue tension and joint geometry is maintained, thereby reducing the potential for joint wear associated with improper alignment and tissue imbalance.

The HemiCAP® design preserves existing anatomy and minimizes the impact on future surgery.

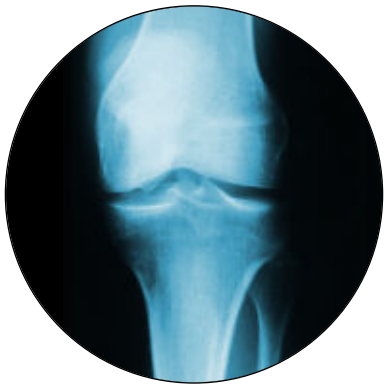
Articulation

The HemiCAP® implants intraoperatively recreate the patients' articular cartilage surface convexities. This unique mapping technology enables the surgeon to place the implant so the implant becomes part of the patient's natural curvatures - both in the medial to lateral aspect as well as the anterior to posterior plane. This patient-matched fit allows for the smooth articulation of the knee throughout the full range of motion.



0 degree *20 degree* *60 degree*

Case Study - OCD Lesion



Preoperative

Preoperative Diagnosis:
Age: 39 years old
Gender: Female
Occupation: Real estate agent
Condition: OCD lesion with large loose body

History:
Past history non-contributory.

Chief Complaint:
Pain, locking and swelling. Patient has trouble walking and going up and down stairs.

Physical Examination:
No tenderness to knee with palpitation. Negative Lachman test. No instability.

Plan:
Left knee, hemi-chondroplasty of the medial femoral condyle with Arthrosurface HemiCAP resurfacing device.

Intraoperative

General anesthesia. Arthroscopic exam of the lateral aspect of medial femoral condyle revealed a Grade IV lesion measuring approximately 15mm in the weight-bearing portion of the condyle. Opposing tibial plateau was normal. All soft tissues were intact and meniscus was normal. Lateral compartment was pristine in regards to articular cartilage and meniscus. The HemiCAP device was implanted to resurface the defect, which left the patient with a smooth, congruent surface completely encompassing the osteochondritic lesion.

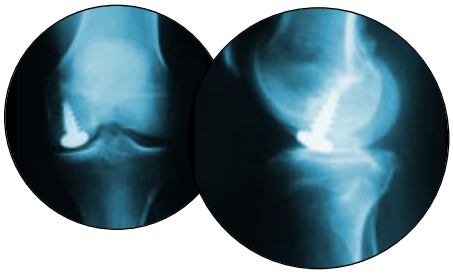
Postoperative

At 3 months postoperative, patient has full range of motion. Normal gait. Level pelvis. Equal leg length. Patient is happy with her results.

Follow-up

At 3 and a half years status post HemiCAP resurfacing procedure, patient has no complaints. Full Extension. Flexion to 125°. No limitations with regard to ADL, work and sports.

WOMAC Scores	Baseline	1 yr. post-op	2 yrs. post-op
Pain (worst score 500)	285	3	13
Joint Stiffness (worst score 200)	91	1	8
Function (worst score 1700)	828	9	19
WOMAC Total	**1203**	**13**	**40**
% Improvement		**99%**	**97%**



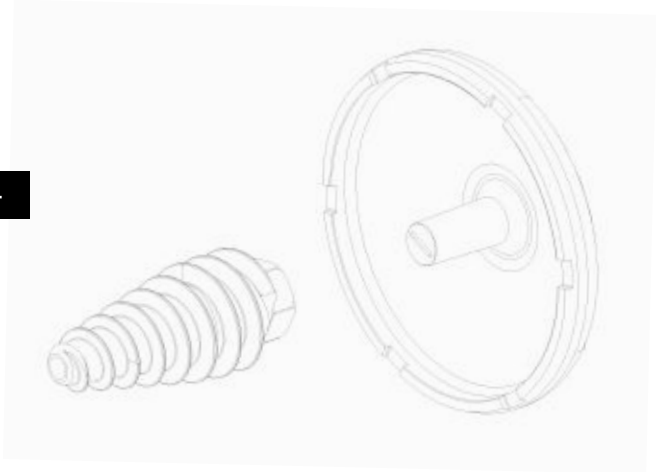
HemiCAP®

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 cancellous fixation 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)
Surface Coating: Titanium (CP Ti)
Fixation Component: Titanium Alloy (Ti-6Al-4V)

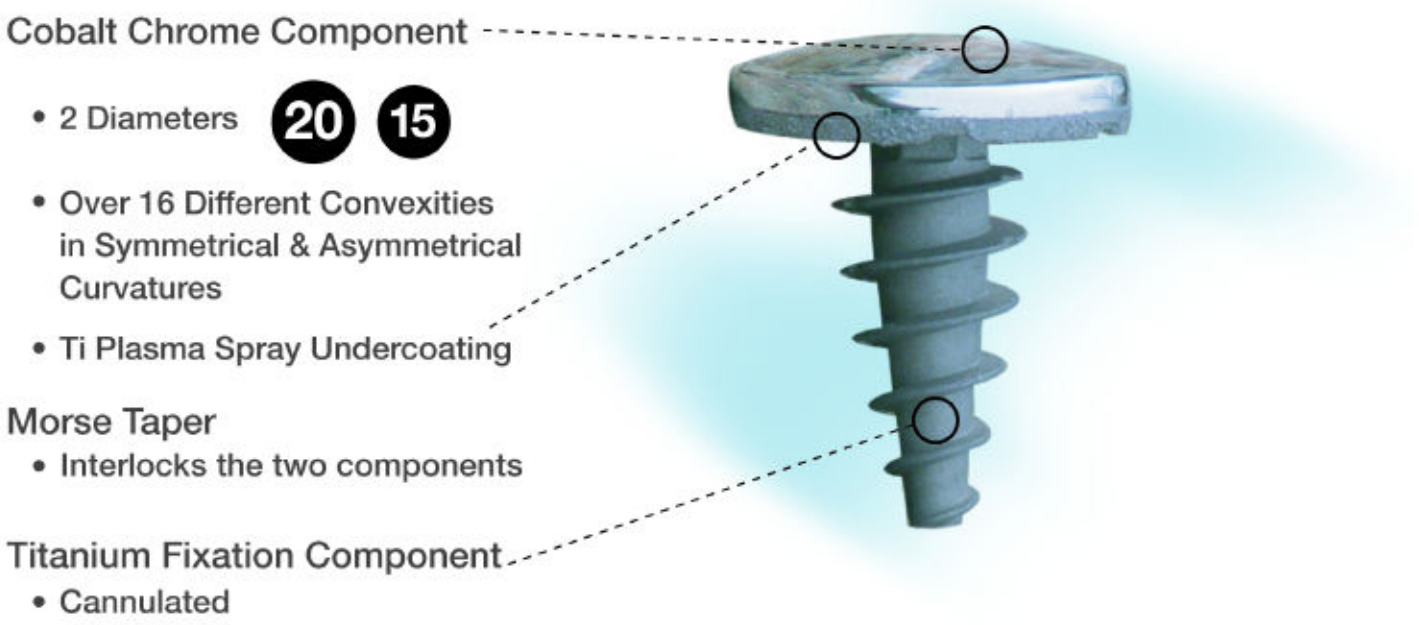


Indications

Partial resurfacing of the femoral condylar surface of the knee 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.

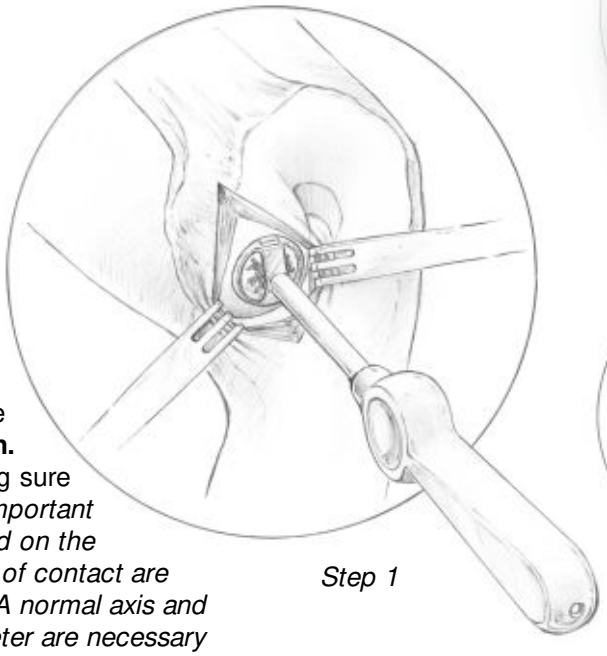
Patient selection factors to be considered include:

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.

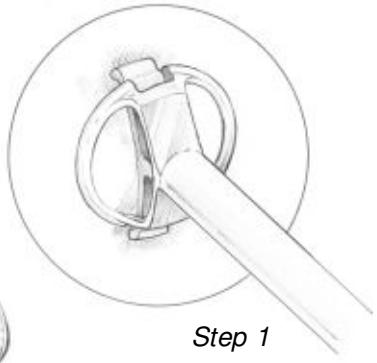


Instructions for Use

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. Place **Guide Pin** into a Cannulated Powered Drill and secure at the etch marking on the **Guide Pin.** Advance **Guide Pin** 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 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).*

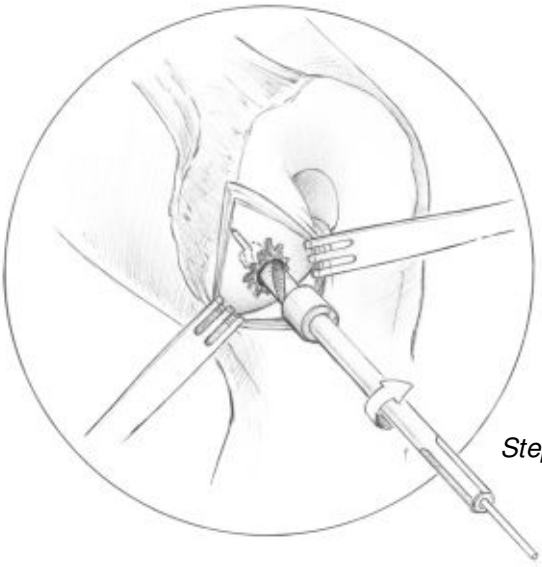


Step 1



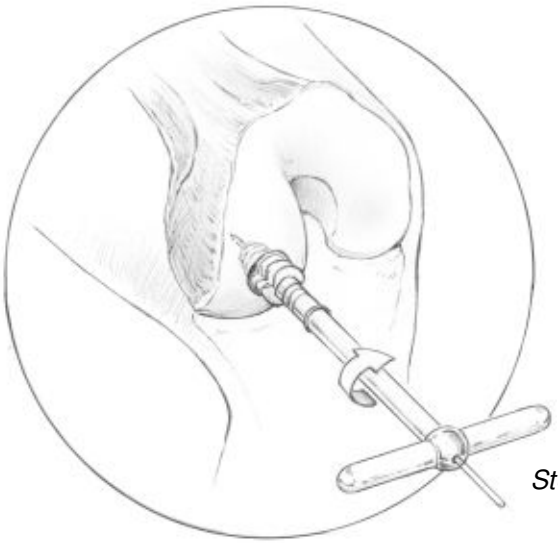
Step 1

2. Place cannulated **Drill** over **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 bone.



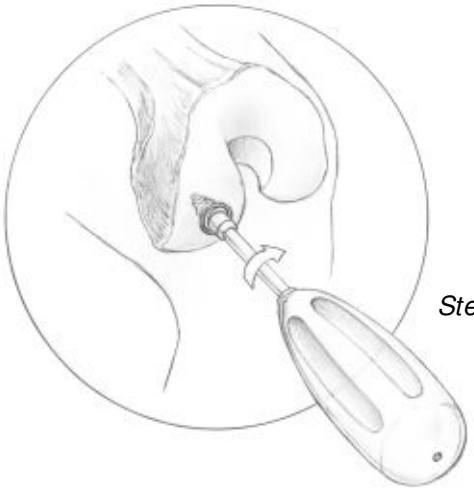
Step 2

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



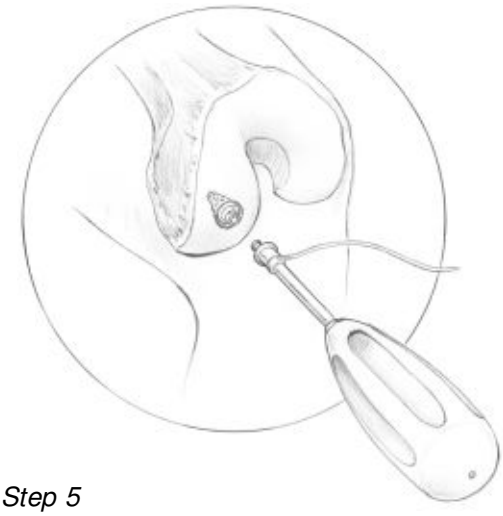
Step 3

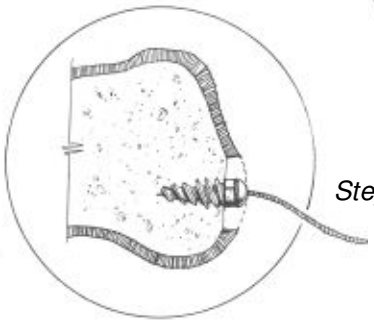
4. Place the **Driver** into the **Fixation Component** and advance **Fixation Component** until the line on the **Driver** is flush with the contour of the adjacent cartilage surface.



Step 4

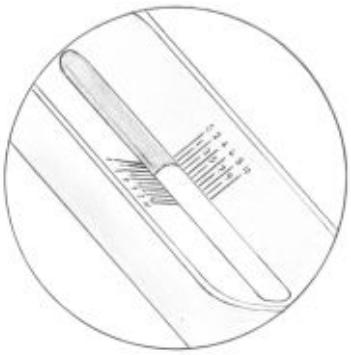
5. Remove **Guide Pin.** Clean taper in **Fixation Component** with **Taper Cleaner.** Place **Trial Cap** into **Fixation Component** to confirm correct depth of **Fixation Component.** The height of the **Trial Cap** must be flush or slightly below the adjacent articular cartilage surface to avoid 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 **Trial Cap.**



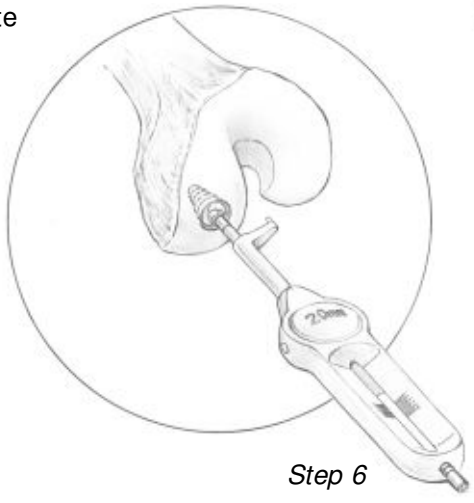


Step 5

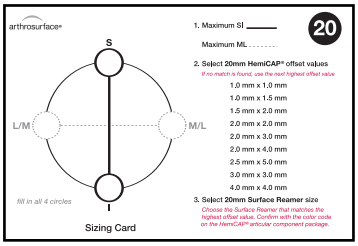
6. Place **Centering Shaft** into taper of **Fixation Component.** Place **Contact Probe** over **Centering Shaft** and rotate around shaft. Read **Contact Probe** to obtain offsets at four indexing points and mark each of the identified offsets on the appropriate Sizing Card. Select appropriate **Articular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



Step 6

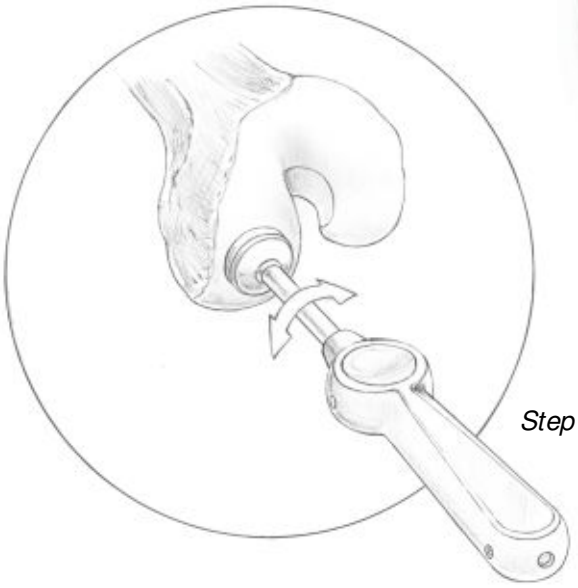


Step 6



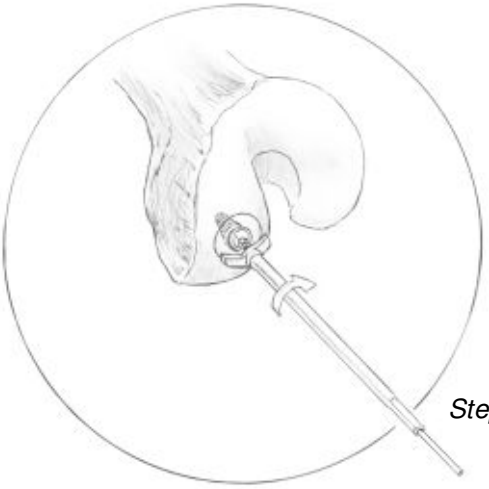
Step 6 Sizing Card

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



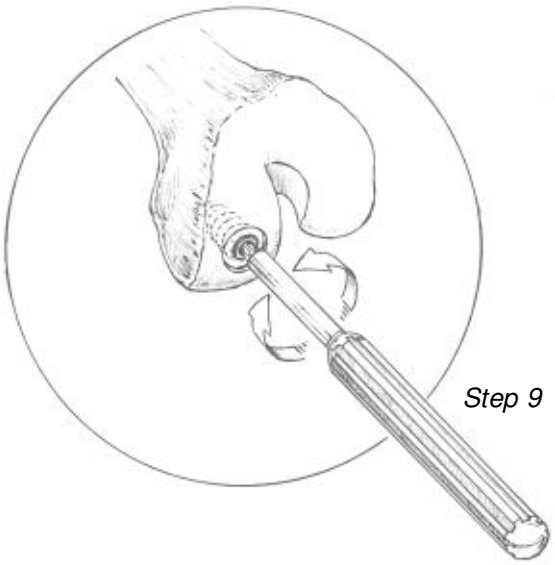
Step 7

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 **Fixation Component .** 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 8

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

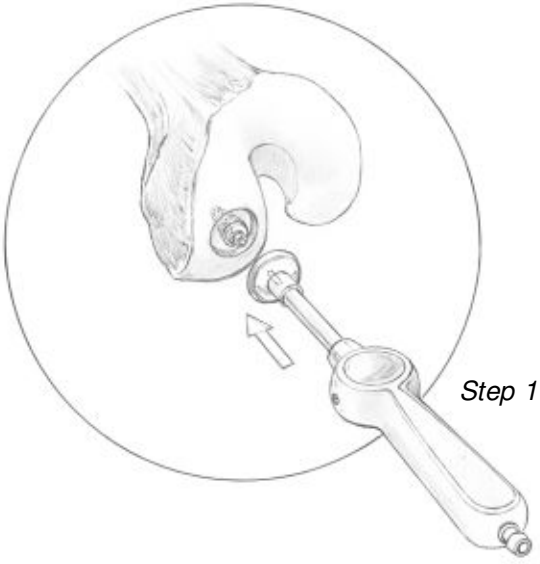


Step 9

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 **Sizing Trial. Sizing Trials** must match the **Surface Reamer's** offset size.

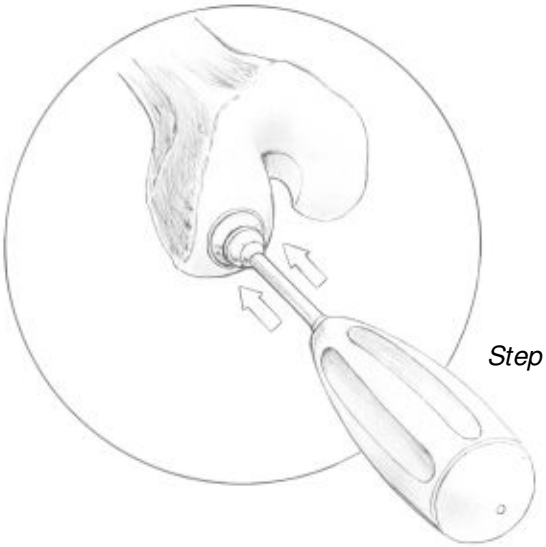
Step 10

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 **Fixation Component .**

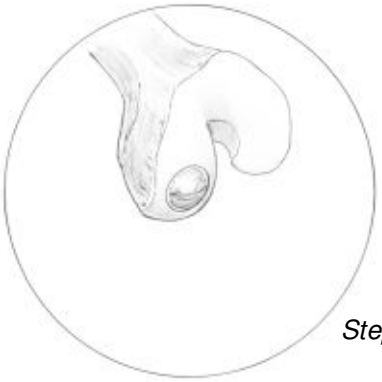


Step 11

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 12



Step 12

Revision Procedure

In the event that the HemiCAP® implant requires removal, please follow these steps.

1. Remove any tissue directly on and up to the outer edge of the HemiCAP® device. Choose the appropriate diameter Revision Cutter and place into a Cannulated Powered Drill. Advance the Revision Cutter *counterclockwise* through the tissue surrounding the outer edge of the device until all the tissue is removed and the full depth of the outer rim of the HemiCAP® device is completely exposed.

2. Place the appropriate diameter Revision Driver over the Articular Component and then impact the Revision Driver until it locks around the edge of the Articular Component. Twist the Revision Driver in a counterclockwise rotation until the implant is removed.

3. If, necessary use an osteotome or rongeur to remove the tissue surrounding the head of the screw until sufficient space is available to insert the Hex Driver. Insert the Driver onto the Fixation Component and then rotate counter clockwise to remove the screw from the bone.

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.

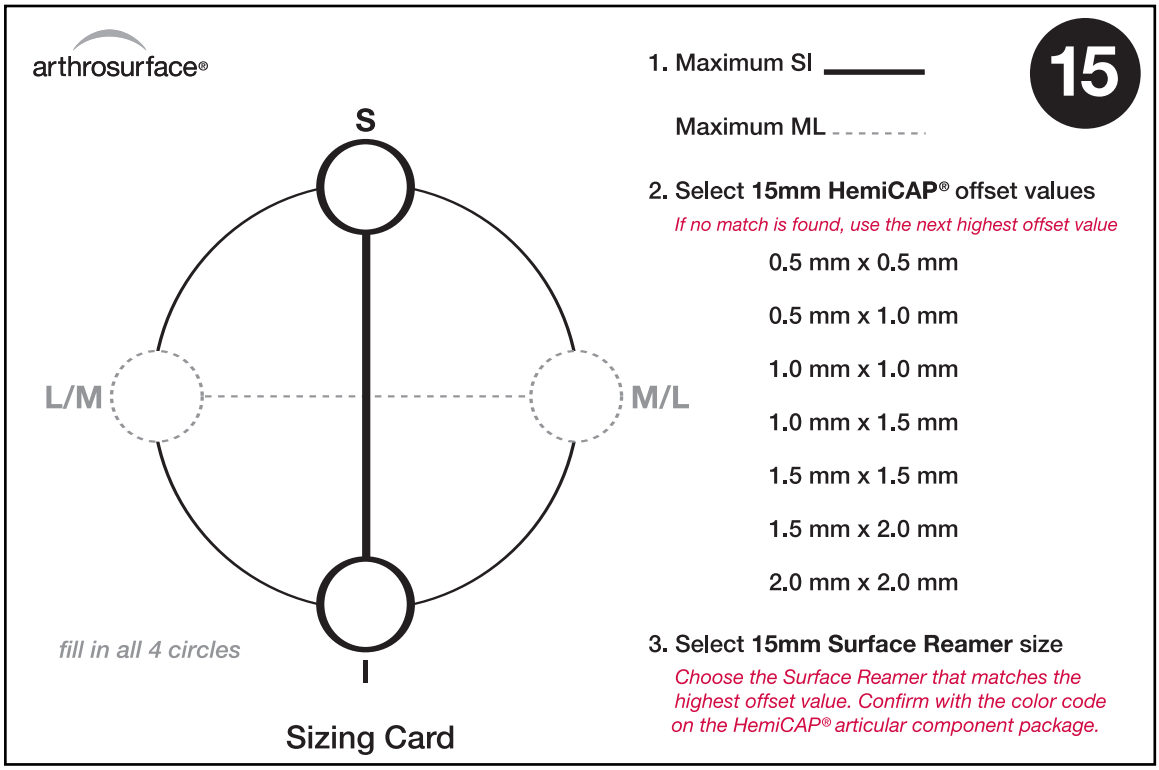
When defining offsets of articular surfaces, care should be taken to ensure that instruments are properly aligned and mated with taper in Fixation Component. Visually confirm distal tip of contact probe is making contact on articular surfaces and free from any soft tissue structures to ensure accuracy. Ensure that the selected implant will be flush or slightly recessed with the articular surface.

When placing implant, carefully trim articular cartilage debris around margin of implant. Remove bone particles and lavage thoroughly. To ensure mechanical interlock of the Fixation Component and implant, carefully clean Fixation Component taper with provided instruments. All drilling or reaming should be done at slowest speeds possible with vigorous lavage to minimize heat effects to adjacent bone and cartilage tissues.

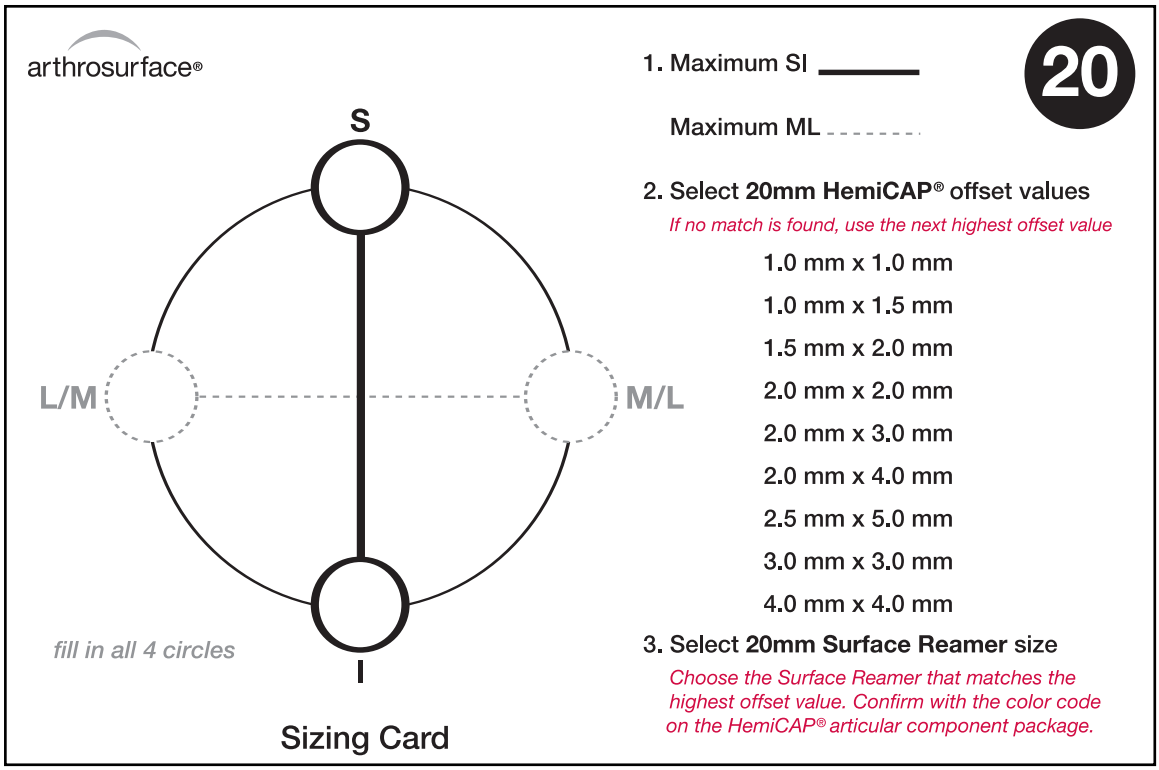
Accepted practices in post operative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to post operative instructions and activity restrictions. Excessive activity, impact, and weight gain have been implicated in the reduction of the benefit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

Precautions

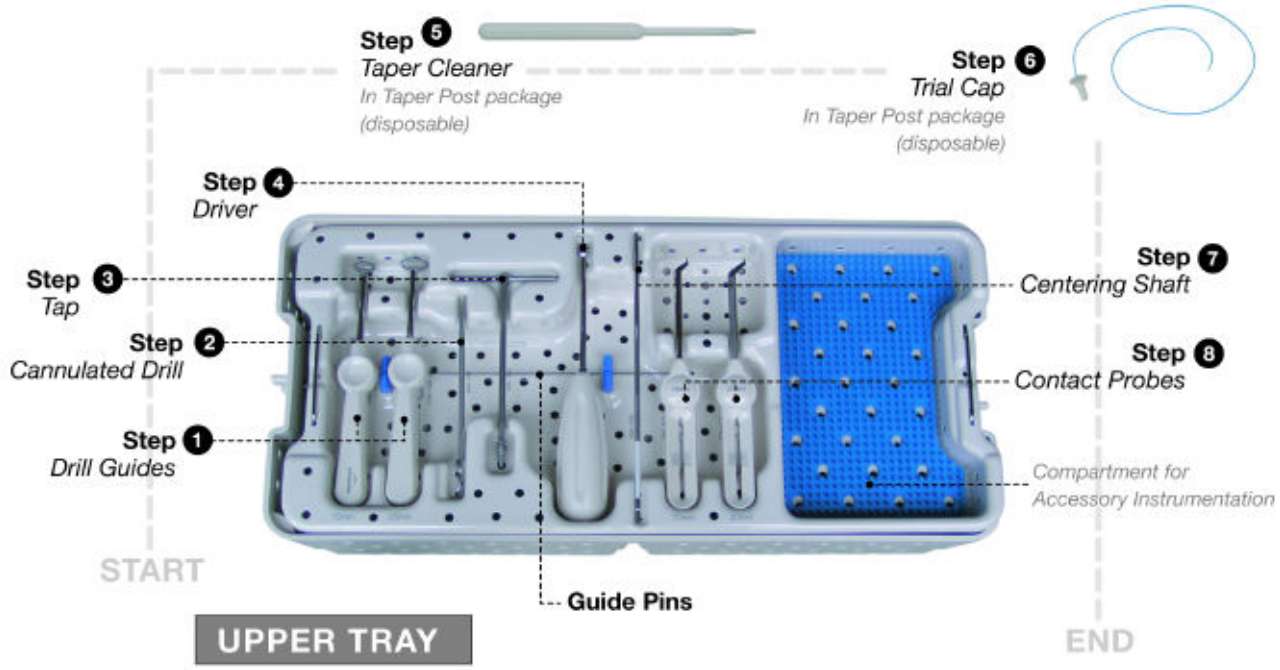
HemiCAP® implants are intended to be fitted and installed with the HemiCAP® instrument set. Use of instruments from other systems may result in improper implant selection, fitting, and placement, which could result in implant failure or poor clinical outcome. The HemiCAP® instrument set should be regularly inspected for any signs of wear or damage. Do not reuse implants.



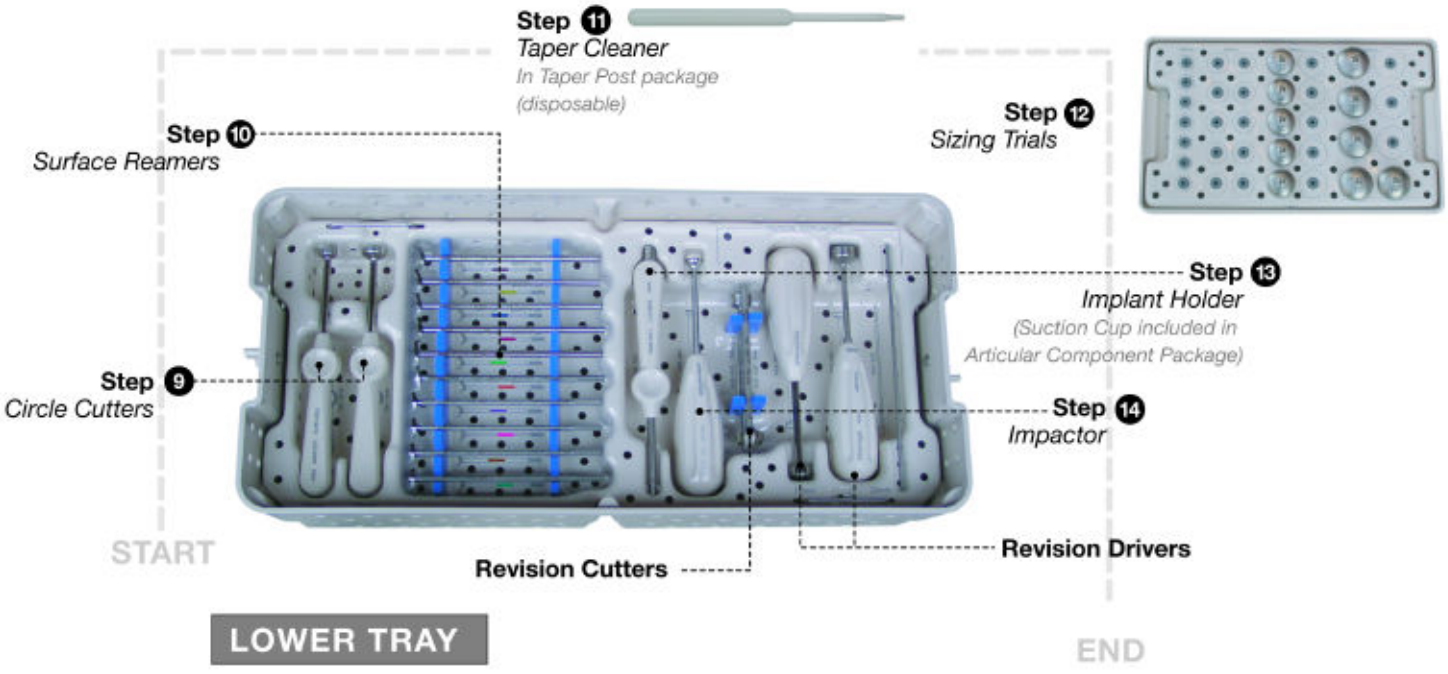
Step 6 Sizing Card 15mm



Step 6 Sizing Card 20mm



UPPER TRAY



LOWER TRAY

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

Knee System # 7000 - 1001

Instrument Kit	7000 - 1520
2.0mm Guide Pin (each) (Sterile)	6007 - 1200
2.0mm Guide Pins (5 pack) (Non sterile)	6007 - 1205
Sizing Trials & Case (15mm & 25mm)	7000 - 0500

Articular Component 15mm

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

Articular Component 20mm

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

Fixation Component 15mm & 20mm

9.5mm x 20mm Fixation Component	7095 - 0020

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Toll Free call +1-866-261-9294

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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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