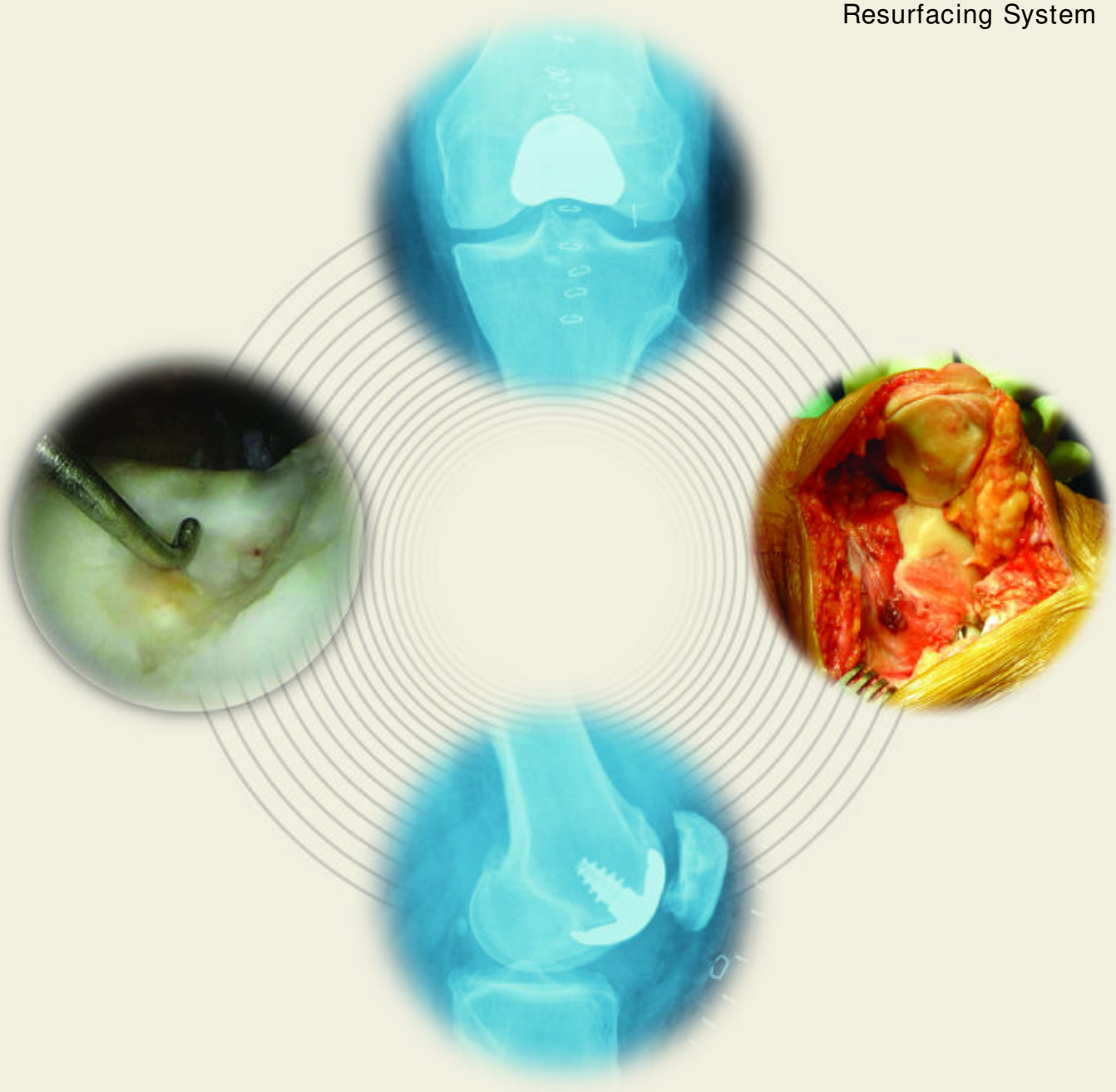
arthrosurface®

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

HemiCAP™ Wave

Patello - Femoral
Resurfacing System



The Arthrosurface® HemiCAP® WAVE Patello-Femoral System restores the unique articular surface geometry of the Patella and the Femoral Trochlear groove; creating a congruent pathway by using an intraoperative 3 dimensional mapping system and contoured articular resurfacing implants.

Description

The HemiCAP^{Wave} Patello-Femoral Resurfacing Prosthesis incorporates a distal femoral trochlear surface articular component that mates to a fixation stud via a taper interlock, and an all-polyethylene patella component. The prosthesis is intended to be used in cemented arthroplasty.

Materials:
Femoral Resurfacing Component: Cobalt-Chromium Alloy (Co-Cr-Mo)
Undersurface Coating: Titanium (CP Ti)
Fixation Stud: Titanium Alloy (Ti-6Al-4V)
Patella Component: Ultra-High-Molecular Weight Polyethylene (UHMWPE)

Indications

The HemiCAP^{Wave} Patello-Femoral Resurfacing Prosthesis is intended to be used in cemented arthroplasty in patients with osteoarthritis limited to the distal patello-femoral joint, patients with a history of patellar dislocation or patellar fracture, and those patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release, etc.) where pain, deformity or dysfunction persists.

Patient selection factors to be considered include:

1. Patient's need to obtain pain relief and improve function is significant;
2. Patient's tibio-femoral joint is substantially normal;
3. Patient exhibits no significant mechanical axis deformity;
4. Patient's menisci and cruciates are intact with good joint stability, and good range of motion; and
5. Patient's overall well-being is good, including the ability and willingness to follow instructions and comply with activity restrictions.

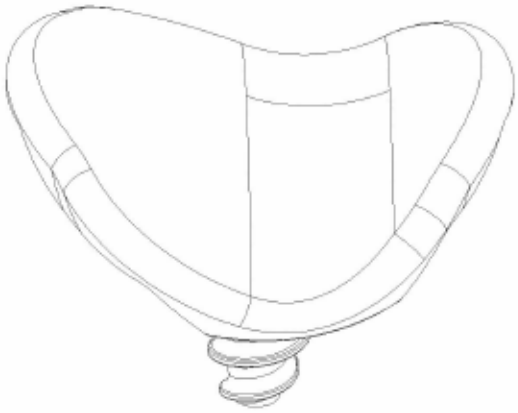
Contraindications

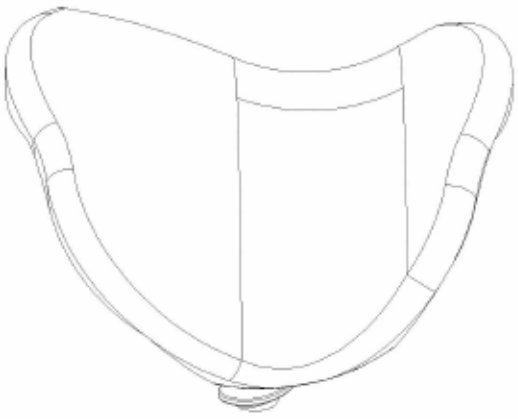
Absolute contraindications include:

1. Defects that are not localized.
2. Inflammatory degenerative joint disease, rheumatoid arthritis, infection, sepsis, or osteomyelitis.
3. Patients that have a known sensitivity to materials typically used in orthopedic prosthetic devices or bone cements.

Relative contraindications include:

1. Uncooperative patient or patient incapable of following pre-operative and post-operative instructions.
2. Metabolic disorders, which may impair the formation or healing of bone; osteoporosis.
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.
7. Inadequate skin, musculotendinus or neurovascular system status





Etiology and Surgical Management of Patello-Femoral Arthritis

As described by Philip Schlotte, M.D., Associate Professor Department of Orthopaedic Sports Medicine Hospital Rechts der Isar University of Munich Germany and Andreas Imhoff, M.D., Professor of Orthopaedic Surgery and Traumatology, Director Department of Orthopaedic Sports Medicine, Hospital Rechts der Isar, University of Munich, Germany.

Patello-femoral degeneration is a complex entity which requires careful examination and surgical planning in order to treat the underlying cause and associated degeneration. Depending on the etiology, concomitant procedures will be an important component for a successful outcome with the HemiCAP^{Wave} Patello-Femoral Resurfacing system. Patient management is guided by two main diagnostic groups:

Group A: P-F arthritis due to direct compression trauma, traumatic dislocation, OCD, high BMI and overuse. Depending on defect size, resurfacing with the 20mm focal P-F HemiCAP® or the larger HemiCAP^{Wave} component can restore an anatomic inlay surface.

Group B: Complex etiology with P-F arthritis due to malalignment (valgus, rotational deformities), trochlear morphology (dysplasia), ligamentous instability, and patella mal-positioning. HemiCAP^{Wave} Patello-Femoral Resurfacing should be augmented by concomitant procedures to address the underlying pathology.

The HemiCAP^{Wave} Patello-Femoral System supports both simple and complex P-F surface reconstructions with its array of congruent articular inlay components for both the trochea and patella.

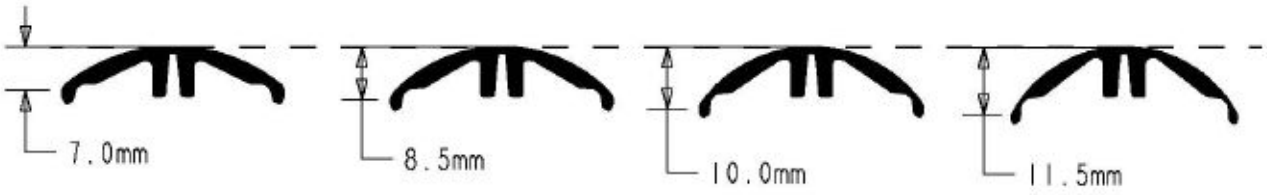
Surgical Approaches for Arthrosurface® HemiCAP^{WAVE} Arthroplasty

As described by Anthony A. Schepsis, M.D., Professor of Orthopedic Surgery, Director of Sports Medicine, Boston University Medical Center

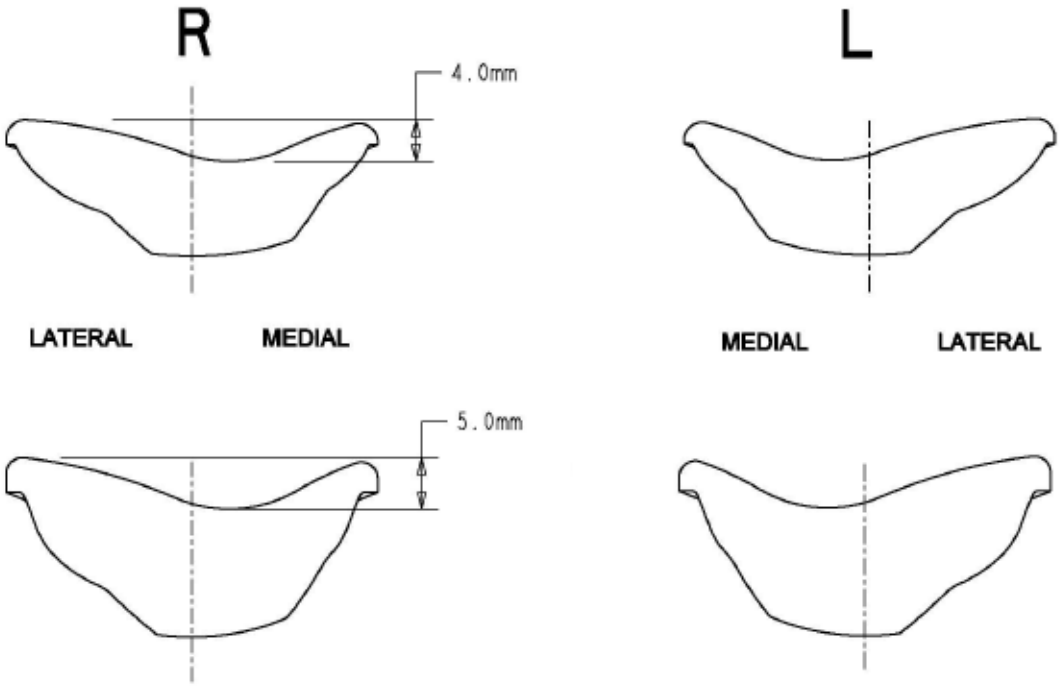
The patient is positioned in the supine position, with a tourniquet on the proximal thigh. The tourniquet is inflated and a longitudinal incision centered over the patella is made, extending from the quadriceps tendon down to just medial of the tubercle. The subcutaneous tissue and superficial fascia are reflected over the patella medially by a blunt, sharp dissection. The fascia is divided and retracted, making sure to leave a cuff of tissue on the medial border of the patella for re-suture or advancement. The dissection is deep in between the vastus medialis muscle and the medial border of the quadriceps tendon and the capsule subsequently incised along the medial border of the patella and patellar tendon. As an alternative, a subvastus approach can be utilized. This approach preserves the vascularity of the patella as well as the quadriceps tendon and the VMO attachment. The same straight longitudinal incision is made, at which point the superficial fascia is incised slightly medial to the patella and bluntly dissected off of the vastus medialis muscle fascia, down to the muscle insertion. The inferior edge of the vastus medialis is identified and bluntly dissected off of the periosteum and intramuscular septum for a distance of 8-10 centimeters proximal to the adductor tubercle. The tendinous insertion of the muscle on the medial patellar retinaculum is identified and the vastus medialis muscle is lifted anteriorly. An L-shaped arthrotomy, beginning medially through the vastus insertion on the medial patellar retinaculum, is performed, carrying it along the medial edge of the patella, at which time the patella can be everted laterally. Upon completion of the procedure, perform a layered closure of biomechanically important structures according to accepted surgical technique.

HemiCAP™ Wave

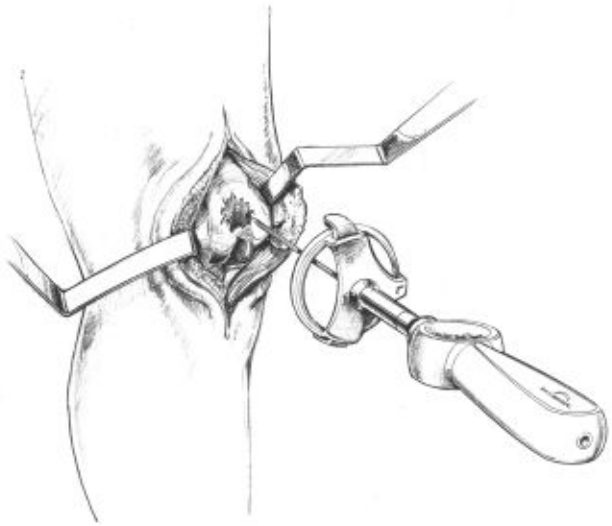
Arthrosurface® brings its intraoperative mapping technology to solve the challenges of anatomic arthroplasty of the patello-femoral joint



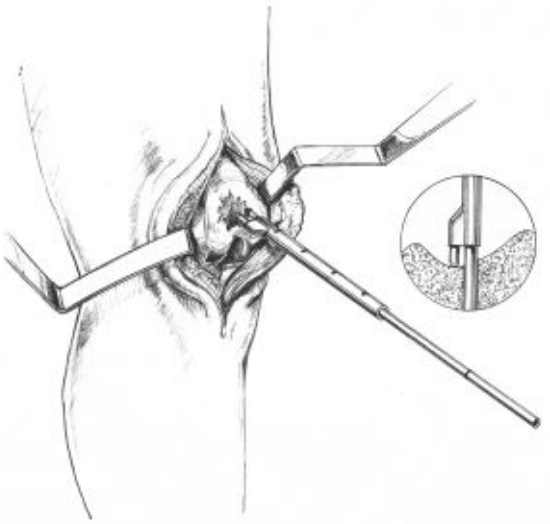
- Inlay resurfacing does not alter joint biomechanics
- Trochlear implant design avoids notch impingement and superior “catching” during flexion
- Multiple convexities assure anatomic fit

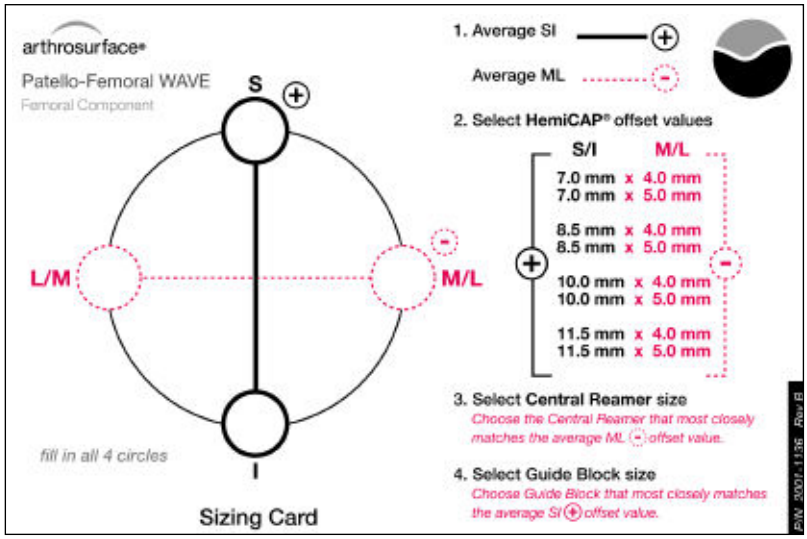


1. With knee in extension, locate the **Offset Drill Guide** in an anterior position to develop a working axis normal to the central trochlear articular surface. Align "L" laser mark to the lateral aspect of femur. Place the 2.5mm **Guide Pin** into a Cannulated Powered Drill and secure at the etch marking on the **Guide Pin**. Advance **Guide Pin** into bone. *(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 is necessary for proper implant fit).*



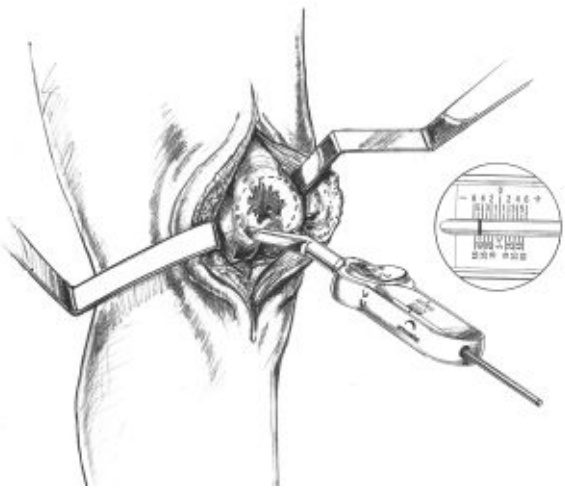
2. Place the yellow **Offset Sleeve** over the **Guide Pin** so that the **Offset Sleeve** foot is touching the deepest *(medial)* portion at the center of the trochlea.



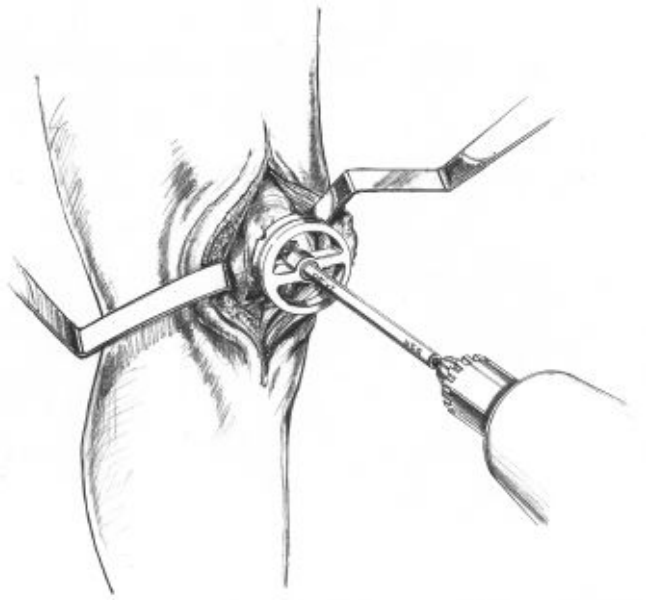


3. Read **Contact Probe** to obtain positive (+) superior and inferior offsets and negative (-) medial and lateral offsets.

   Mark each of the identified offsets on the appropriate sizing card. Use the sizing card to record the ***average*** *superior/inferior* offset and the ***average*** *medial/lateral* offset.

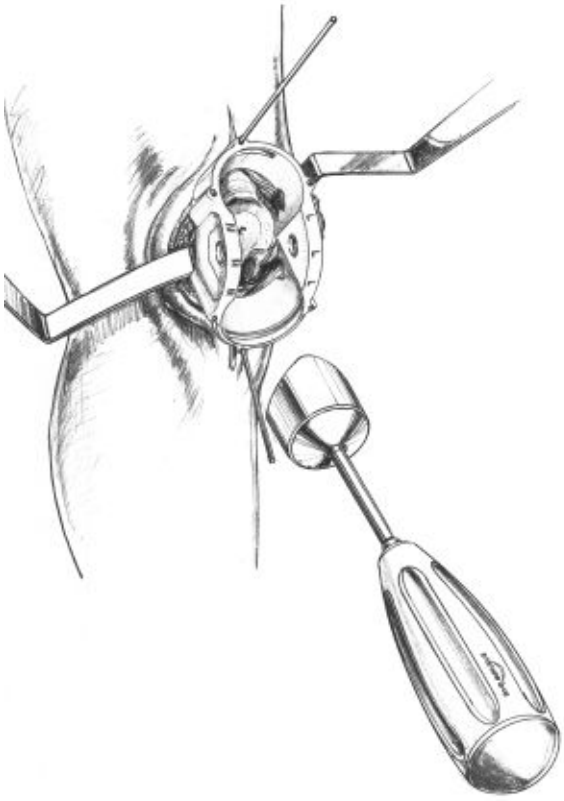


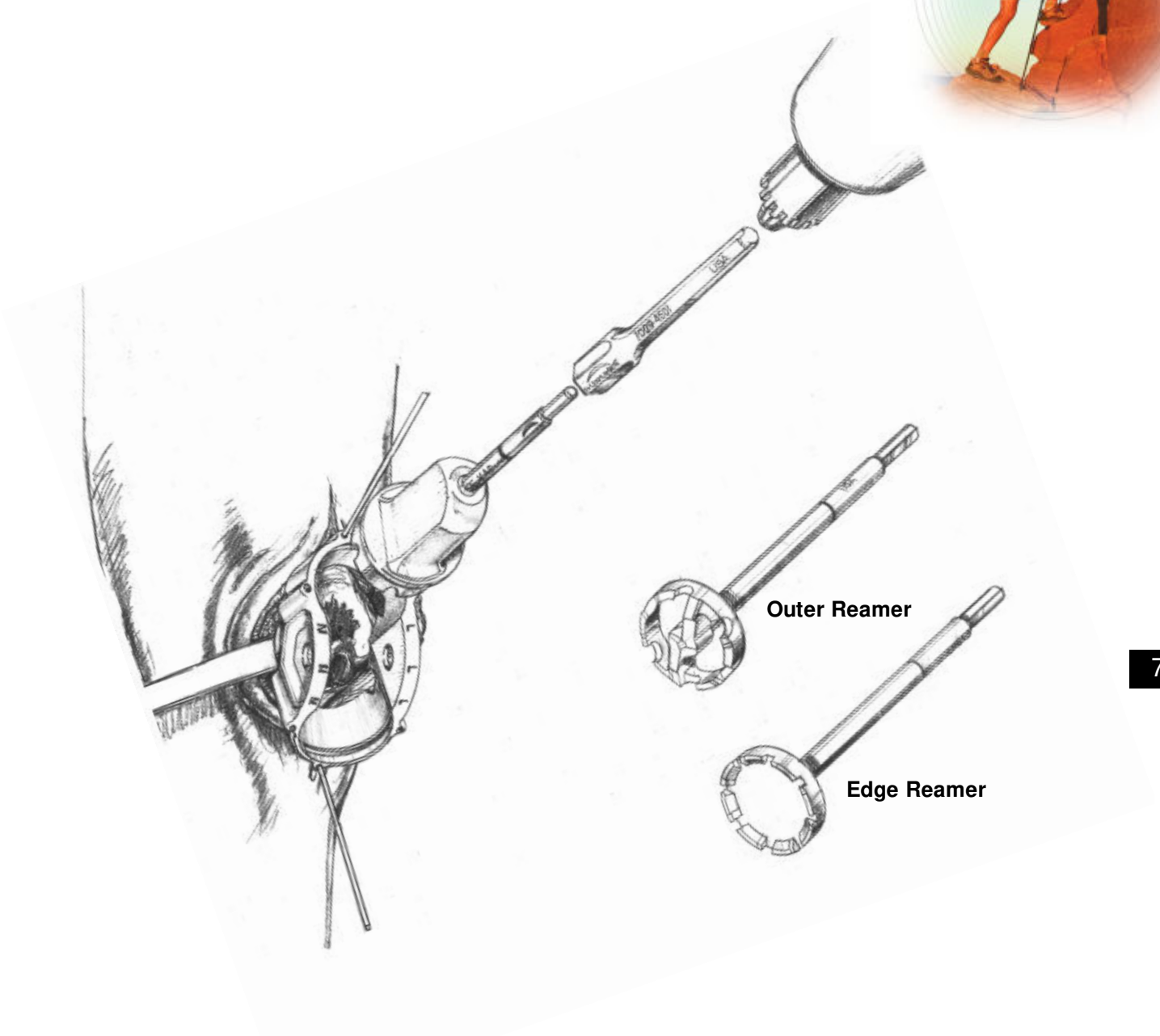
4. Select the **35mm Central Reamer** based on the medial/lateral offset (either 4 or 5mm) and advance it over the **Guide Pin** until the etched mark on the side of the **Central Reamer** is flush with the medial and lateral facets.



5. Select the **Guide Block** that corresponds with the offset from the superior/inferior mapping point and place onto the trochlear groove. Align the **Guide Block** per medial and lateral indicator laser marks. Secure the **Guide Block** onto the femur using **Guide Pins**.

   Advance the **Circular Scalpel** into the superior/inferior bores of the **Guide Block** and onto the articular surface using a twisting motion to create a cut through the articular surface.



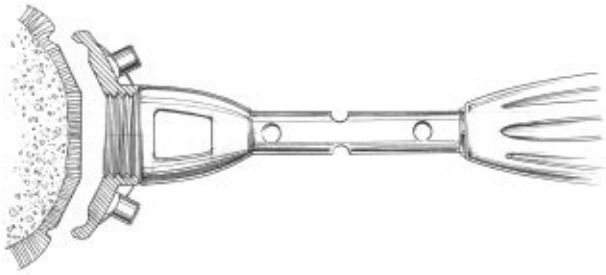


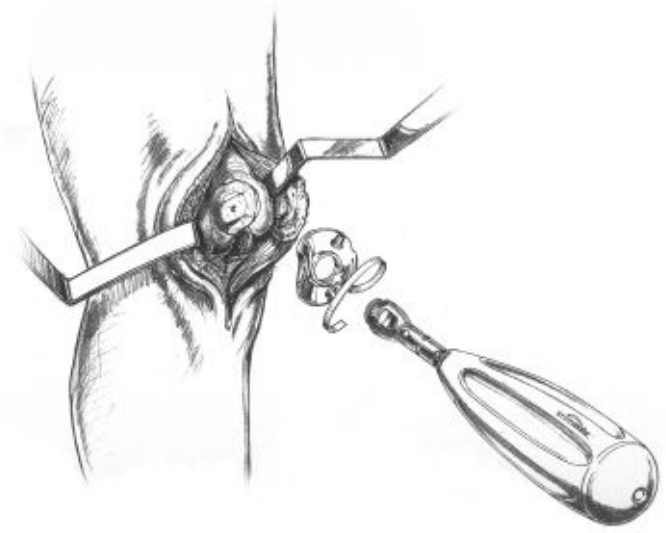
6. Assemble the **Outer Reamer** into the **Guide Bushing**.

   Secure **Guide Bushing** into the superior **Guide Block** bore.

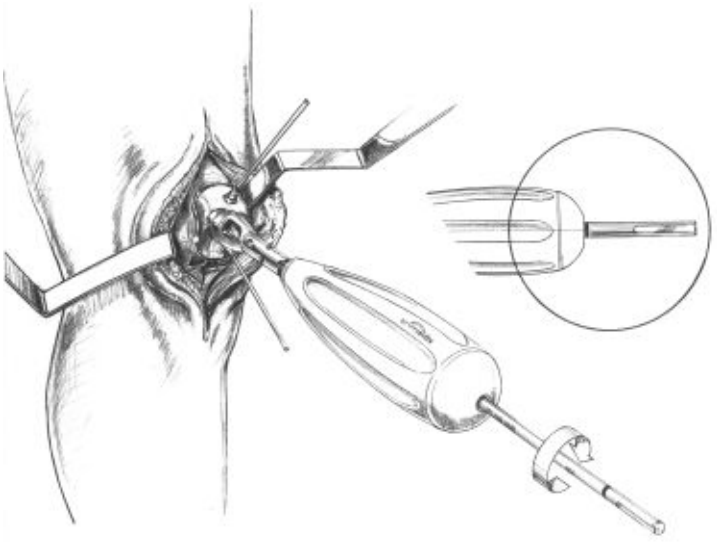
   Advance **Outer Reamer** into bone until depth mark on the reamer shaft is reached. Remove assembly and repeat reaming through the inferior **Guide Block** bore. (It is critical to keep the **Guide Block** stable during reaming.)

   Repeat for the **Edge Reamer**.



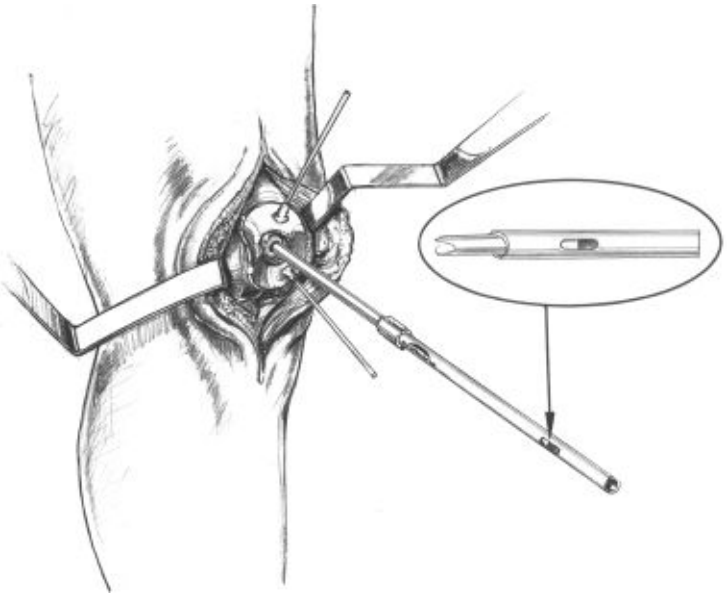


7. Assemble the **Trial Handle** onto the **Sizing Trial** and place the **Sizing Trial** into the prepared site that matches the offset profile from the **Sizing Card**. Confirm the fit of the **Sizing Trial** so that all margins are congruent or recessed to the edge of the surrounding articular surface. Trim the transition areas between reamed surfaces to ensure the **Sizing Trial** is fully seated.



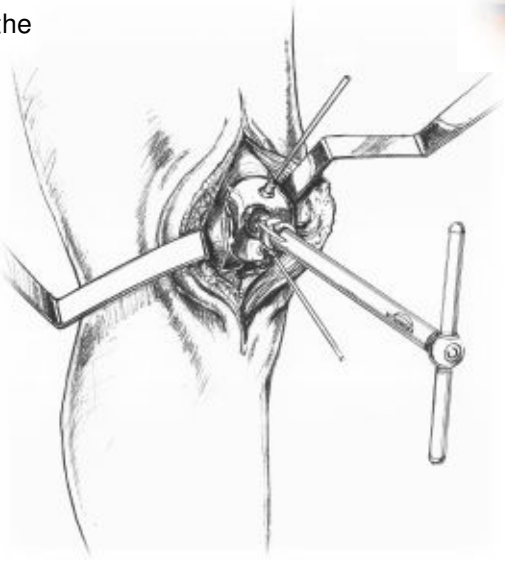
8. Fix the **Sizing Trial** in place and insert the **Pilot Drill** through the center of the **Guide Handle** and advance to the laser mark indicated on the **Pilot Drill**.

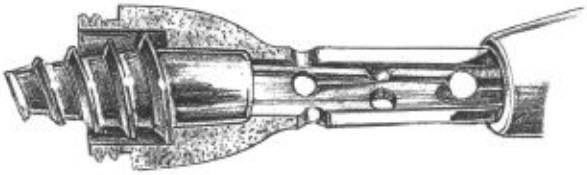
   Leave in place and remove the **Trial Handle** from **Sizing Trial**.

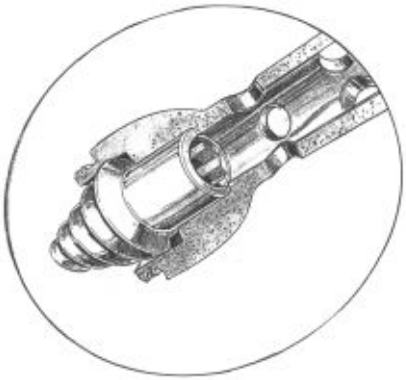


9. Advance the **Step Drill** over the **Pilot Drill** until it bottoms out on the back of the **Pilot Drill**. Remove **Step Drill**.

10. Advance the **Tap** over the **Pilot Drill** so that the end stops when the **Pilot Drill** is flush to the back of the cannulation in the **Tap**. Remove **Tap** and remove **Pilot Dril**l.

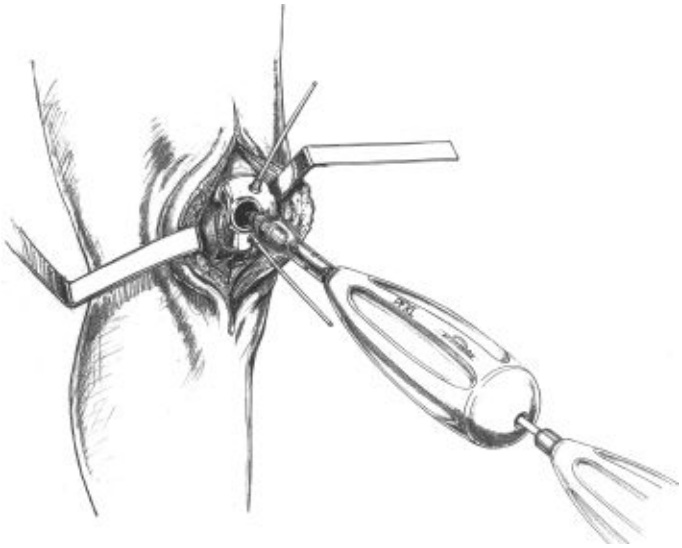


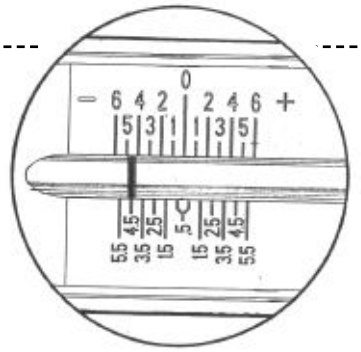




Zoom views of Post in Handle

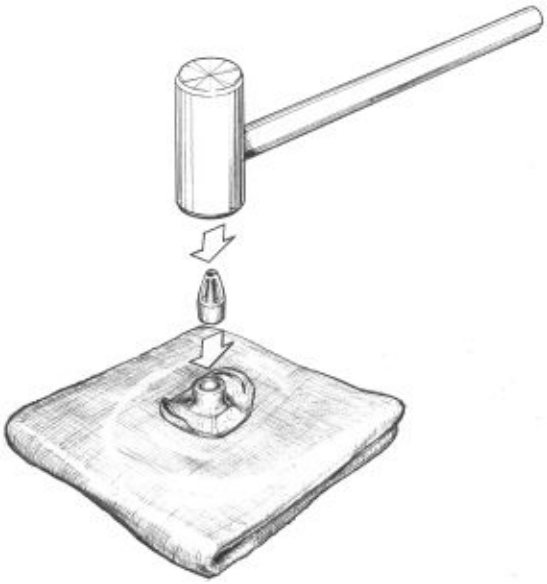
11. Place the **Taper Post** inside the morse taper inside the **Trial Handle** and attach to the **Sizing Trial**. Place the **Hex Driver** through the **Trial Handle** and advance the **Taper Post** until the stop on the shaft of the **Hex Driver** comes in contact with the back of the **Trial Handle**. Place **Depth Gauge** into **Sizing Trail** to ensure **Taper Post** is at proper depth to engage **Femoral Component.**





12. Alternative fixation is to pre-assemble the **Threadless Stud** to the **Femoral Resurfacing Component**.

    Be sure to protect the articular face of the **Femoral Resurfacing Component**, use slight impaction with the mallet to seat the morse taper of the **Threadless Stud** onto the **Femoral Resurfacing Component**.



NOTE:
Prepare and implant the **Patella Component**

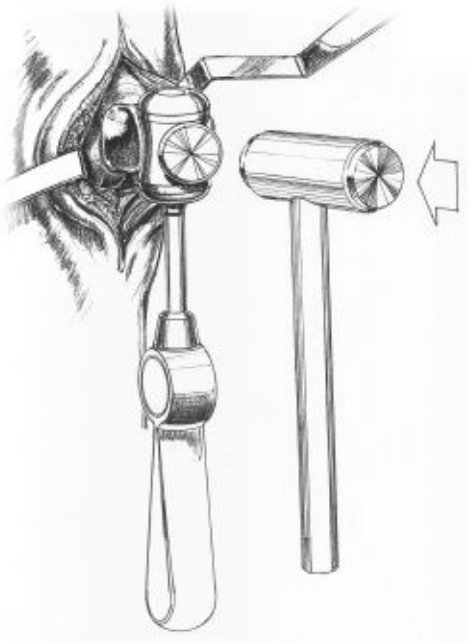
PRIOR TO

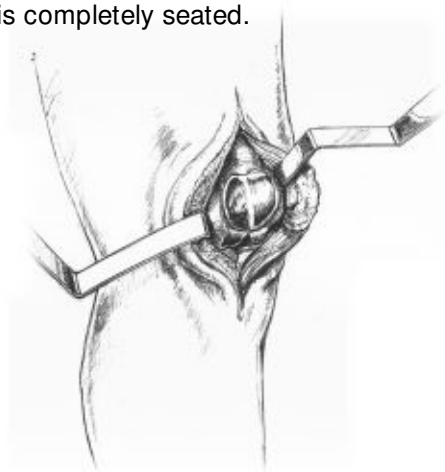
final placement of the **Femoral Trochlear Component**

13. Prior to placing the **Femoral Resurfacing Component** on the **Implant Holde**r make sure that sufficient suction is present to hold the device on the distal suction cup.

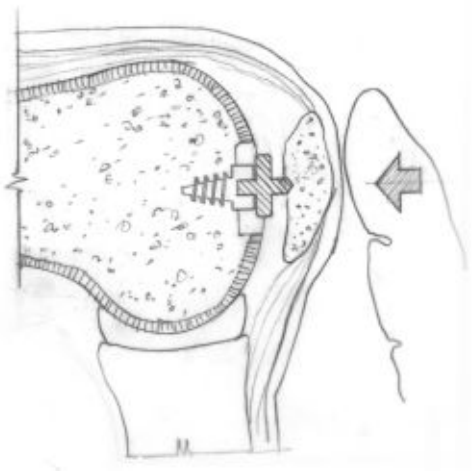
    Align the **Femoral Resurfacing Component** on the **Implant Holder** with the medial etch mark facing the medial aspect of the knee and lateral mark facing the lateral plane. Apply a small amount of bone cement to the backside of the **Femoral Resurfacing Component.** Insert into taper of **Taper Post**.

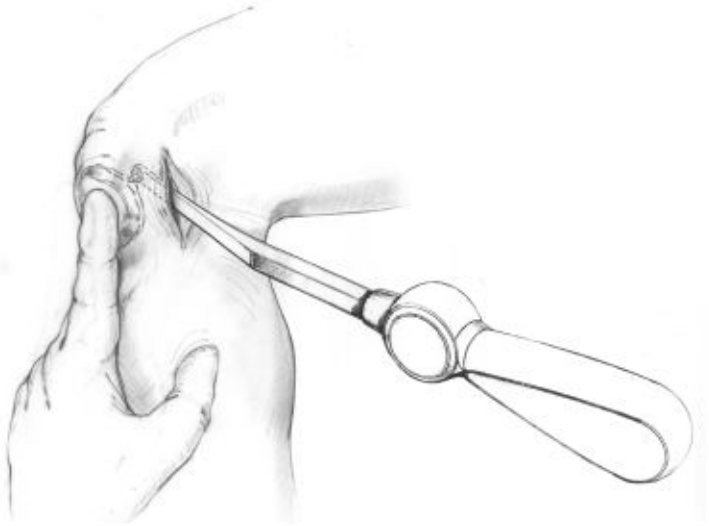
    Firmly mallet the **Impactor** until the **Femoral Resurfacing Component** is completely seated.



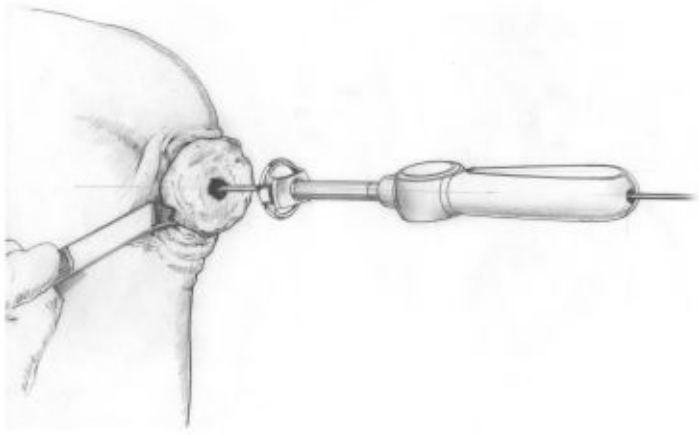


1. Confirm that the patella's anterior to posterior thickness will accept the **Patella Component**; typically a 6.5mm reaming depth. With knee in extension, locate the **Alignment Guide** so that the pin fits into the **Fixation Stud.** While observing range of motion, identify target placement of the **Patella Component** using the pointer on the **Alignment Guide** to transfer the **Fixation Stud's** central axis. (Typically 20 to 30 degrees of flexion). Use slight pressure against the patella so that the pointer on the **Alignment Guide** creates an indentation on the patella surface.

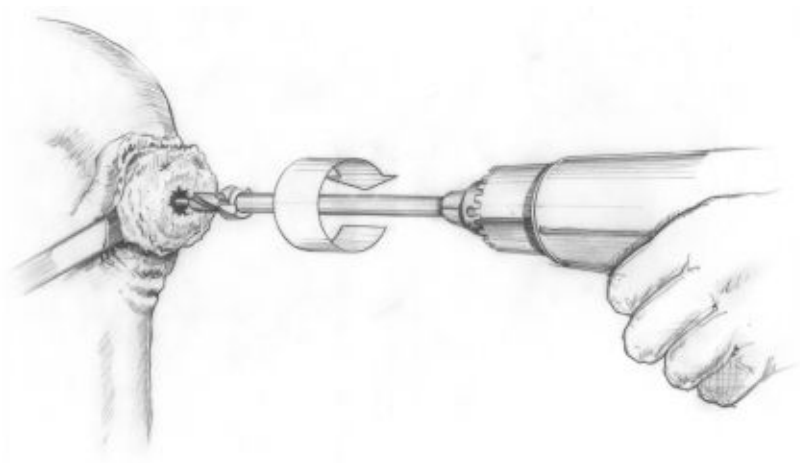




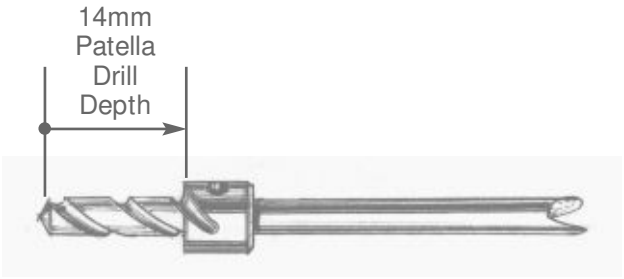
2. Place the **Drill Guide** so that its central axis passes through the **Alignment Guide** indentation created on the patella surface. Drill the **Guide Pin** through until it engages the opposite cortex of the patella. *(It is important to verify that the **Drill Guide** is seated on the curved surface such that all 4 points of contact are established on the articular surface. Feet on the **Drill Guide** will typically orient medial and lateral. A normal axis is necessary for proper implant fit).*



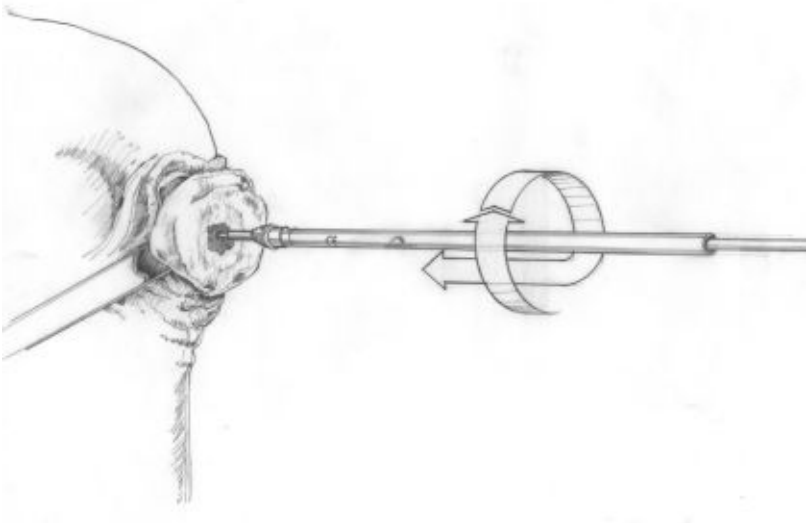
3. Remove the **Drill Guide.** Advance **Circular Scalpel** onto the articular surface to create a cut through the articular surface.

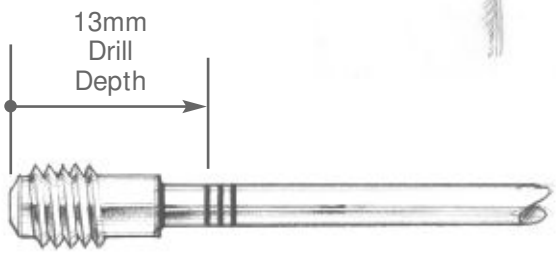


4. Place the cannulated **Drill** over **Guide Pin.** Verify that the **Drill** is not bending the **Guide Pin** and advance until the distal shoulder of **Drill** is flush to the articular surface. Should the guide pin loosen, use the **Drill** to re-center the **Guide Pin** in the pilot hole and advance into bone.

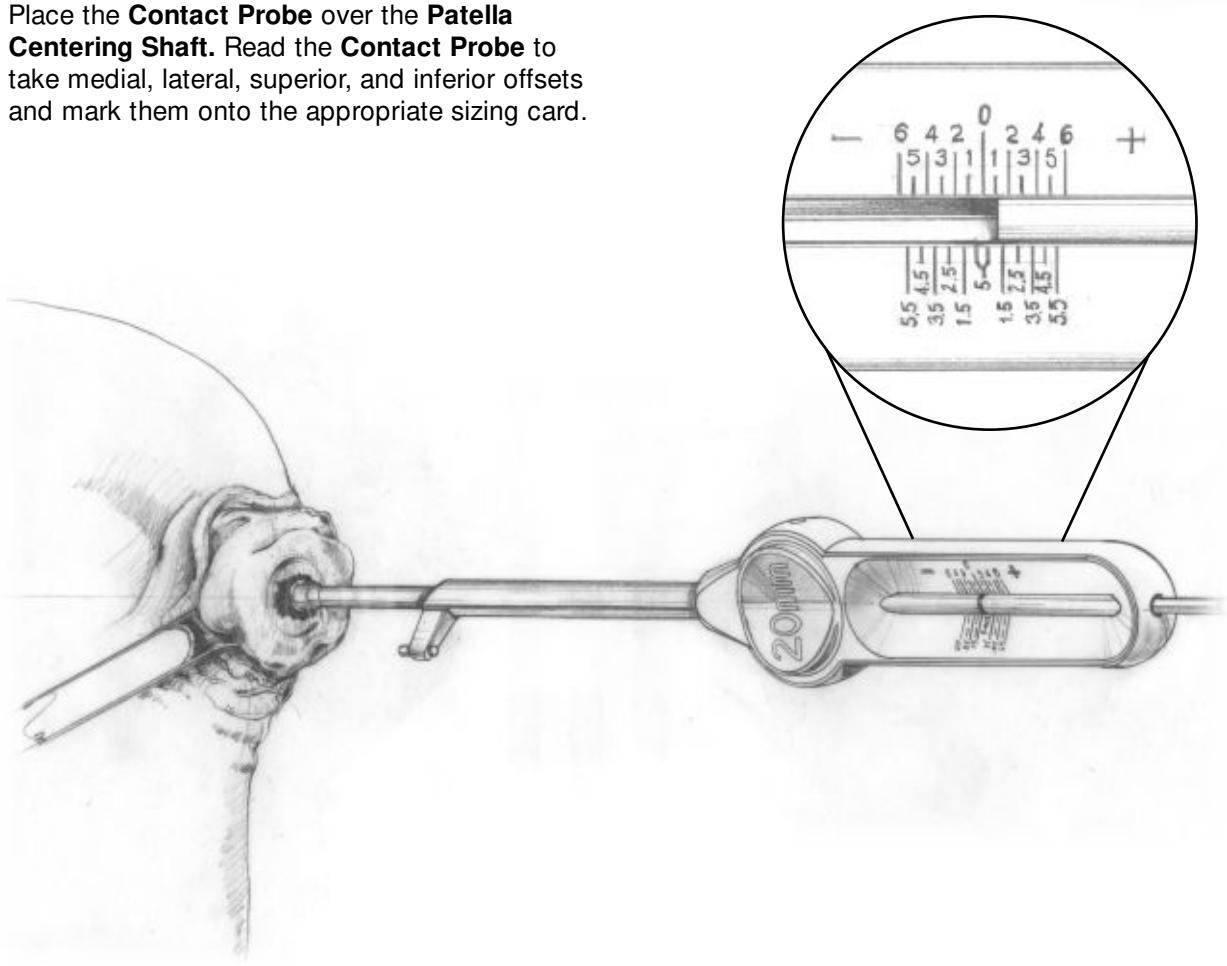


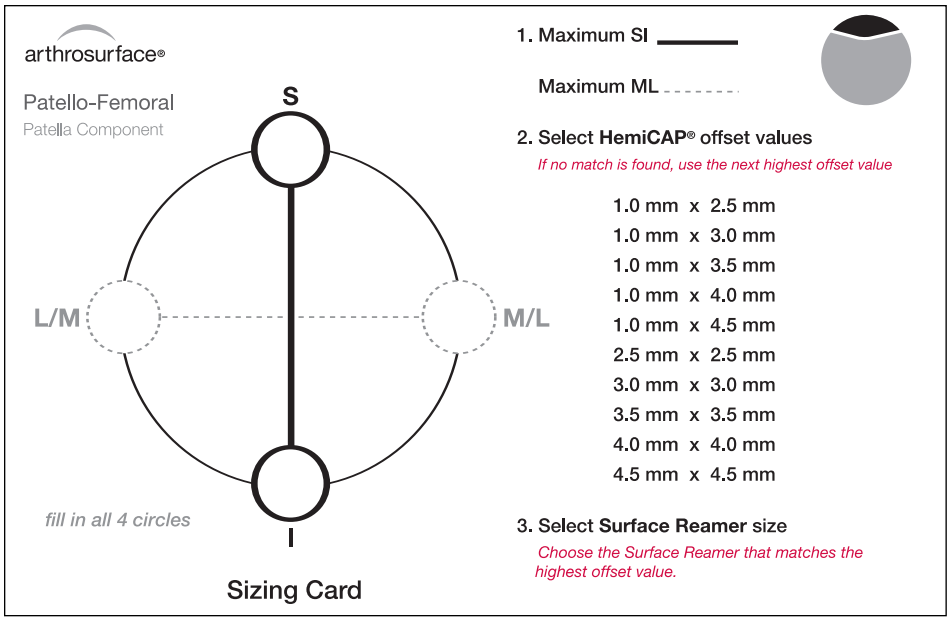
5. Using a powered drill, advance the **Patella Centering Shaft** over the **Guide Pin** until it reaches the distal laser marked depth marking.



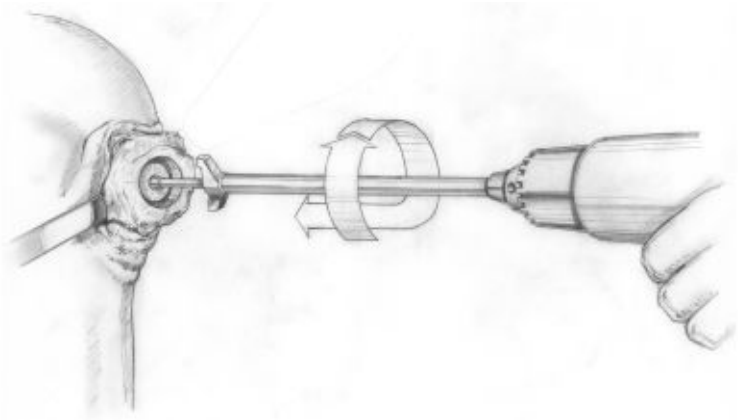


6. Place the **Contact Probe** over the **Patella Centering Shaft.** Read the **Contact Probe** to take medial, lateral, superior, and inferior offsets and mark them onto the appropriate sizing card.

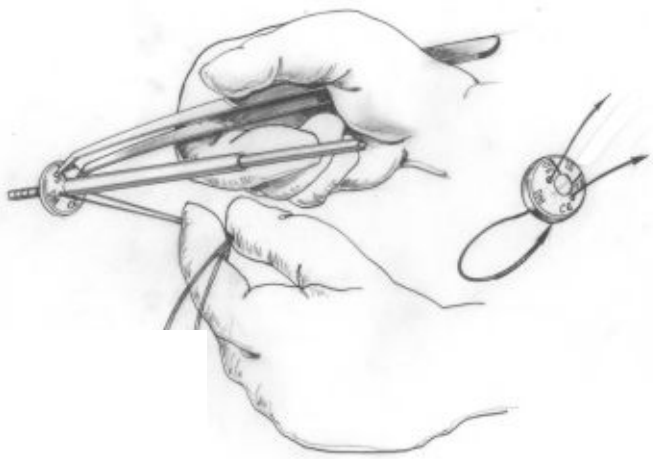


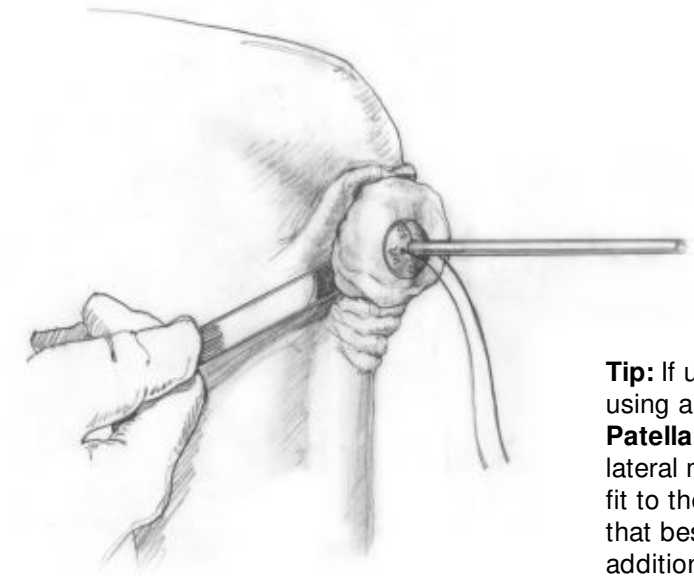


7. Select the 2.5mm **Patella Reamer**. Advance **Patella Reamer** over the **Patella Centering Shaft** until it contacts the blade stop. *(Use lavage during drilling to prevent possible tissue damage from heat effects).*



8. Load a loop of #2 suture through the appropriately sized **Patella Sizing Trial** and place into the prepared area. Confirm the fit of the **Patella Sizing Trial** so that all margins are congruent or slightly recessed to the edge of the surrounding articular surface.



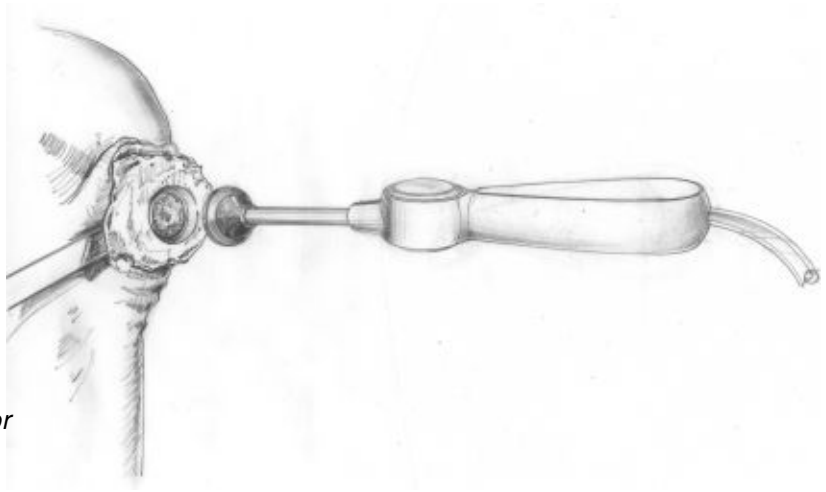


Tip: If using an **Anatomic Patella Component:** After using a 2.5mm **Patellar Reamer,** place a 1.0 x 2.5 **Patella Sizing Trial** and confirm fit of medial and lateral margins. Once M/L margins are a congruent fit to the medial/lateral cartilage, select the trial that best fits the superior/inferior margins without additional reaming.

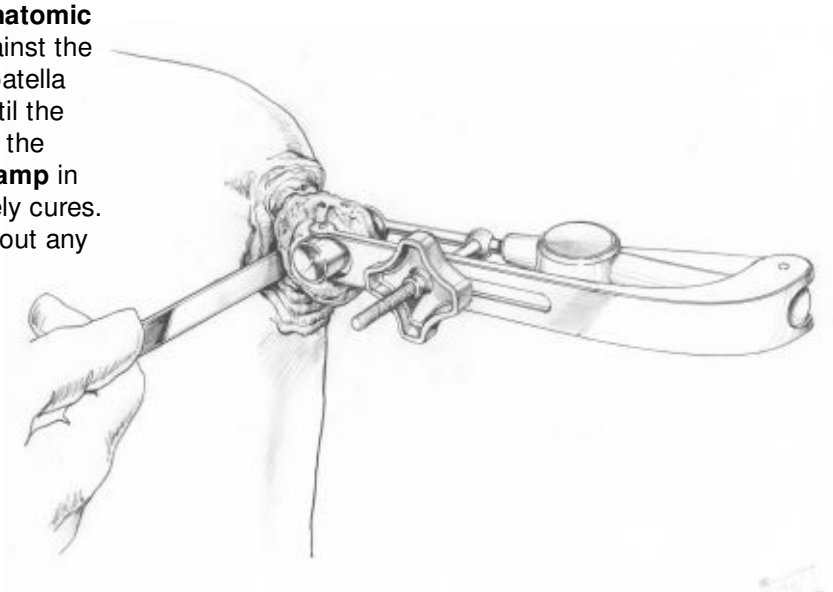
If proud at the M/L margin, drill with the next sized **Patella Reamer** and repeat trialing to fit.

9. Apply a small amount of low-viscosity bone cement onto the underside of the **Patella Component** and quickly place into position.

10. Prior to placing the **Patella Component** on the **Implant Holder** make sure that sufficient suction is present to hold the device on the distal suction cup. Align the **Patella Component** on the **Implant Holder.** *(When using the **Anatomic Patella Component** make sure to align the superior and inferior orientation divots with the superior and inferior poles of the patella).*



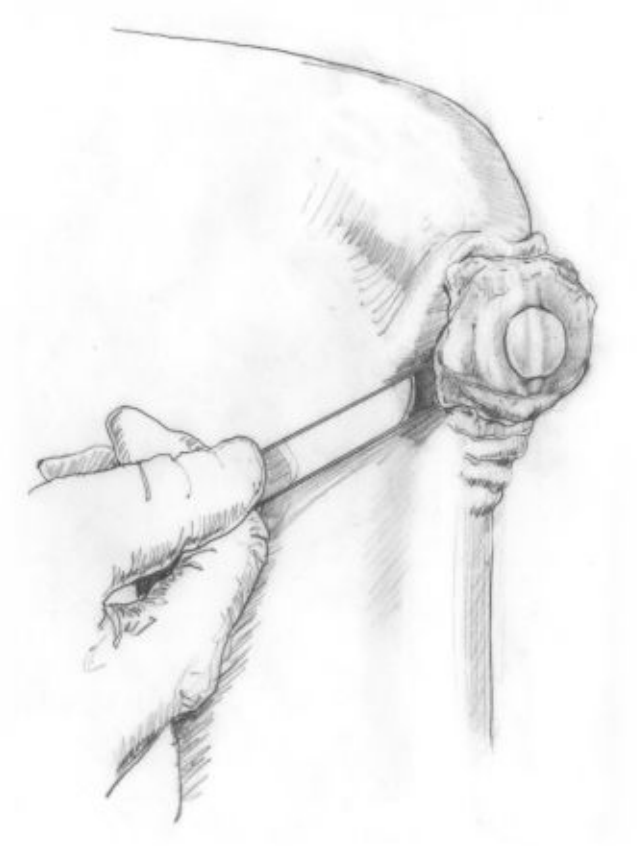
11. Using the **Patella Clamp,** place the **Anatomic *OR* Button Contoured Swivel Pin** against the **Patella Component** and the anterior patella surface. Tighten the **Patella Clamp** until the **Patella Component** is firmly seated in the prepared socket. Leave the **Patella Clamp** in place while the bone cement adequately cures. Remove the **Patella Clamp** and clean out any remaining exposed cement.



12. Implantation of the **Patella Component** is complete.

NOTE:
Complete implantation of **Femoral Trochlear Component.** Refer to page 10.

13. Once implantation of the **Femoral** and **Patella Components** is complete, perform a trial range of motion. Remove or debride any loose tissues if necessary. Remove all osteophytes. Close utilizing accepted practices.



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 Stud. 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 mapping 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 Fixation Stud and Femoral Resurfacing Component, carefully clean Fixation Stud taper with provided instruments. All drilling or reaming should be done with vigorous lavage to minimize heat effects to adjacent bone and cartilage tissues.

Ensure that care is taken to obtain complete and uniform bone cement coverage at implant site. Unsupported components or unevenly supported components may result in implant failure.

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® Patello-Femoral Resurfacing implants are intended to be fitted and installed with the HemiCAP® Patello-Femoral Resurfacing 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.

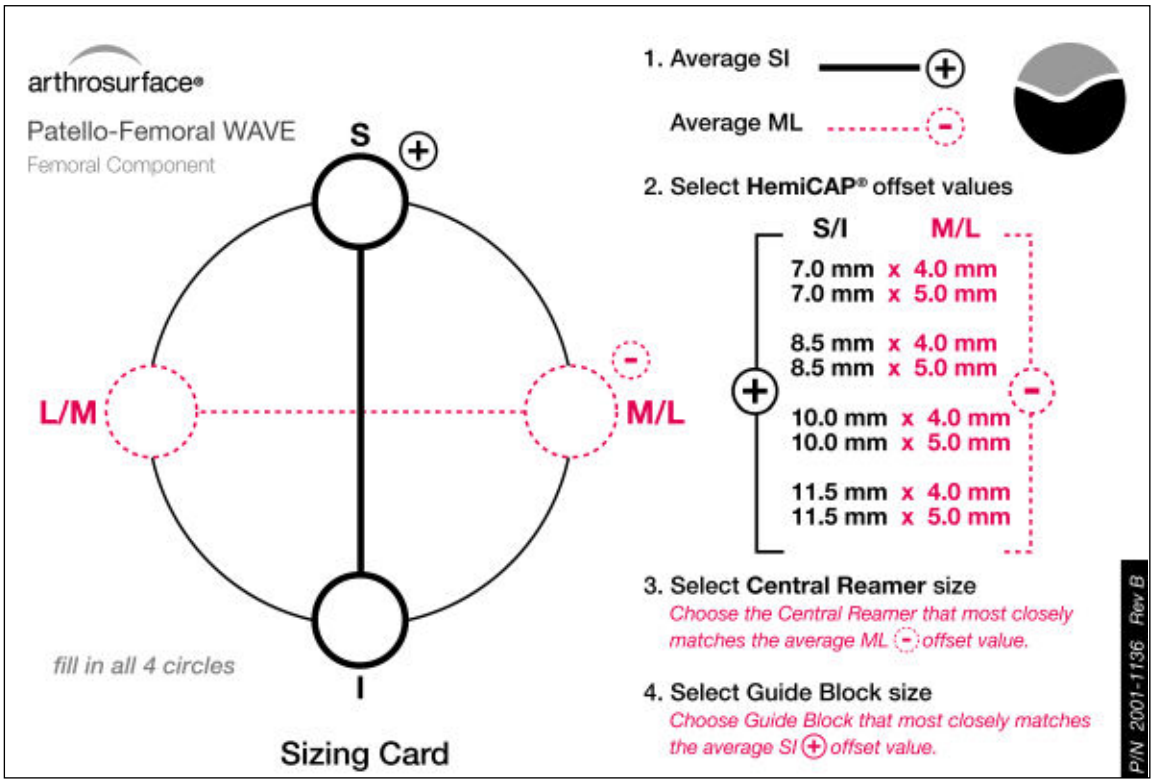
Possible Adverse Effects

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.
9. Postoperative pain or incomplete resolution of preoperative symptoms.
10. Periarticular calcification or ossification, with or without impediment of joint mobility.
11. Incomplete range of motion due to improper selection or positioning of components.
12. Transient nerve palsy.

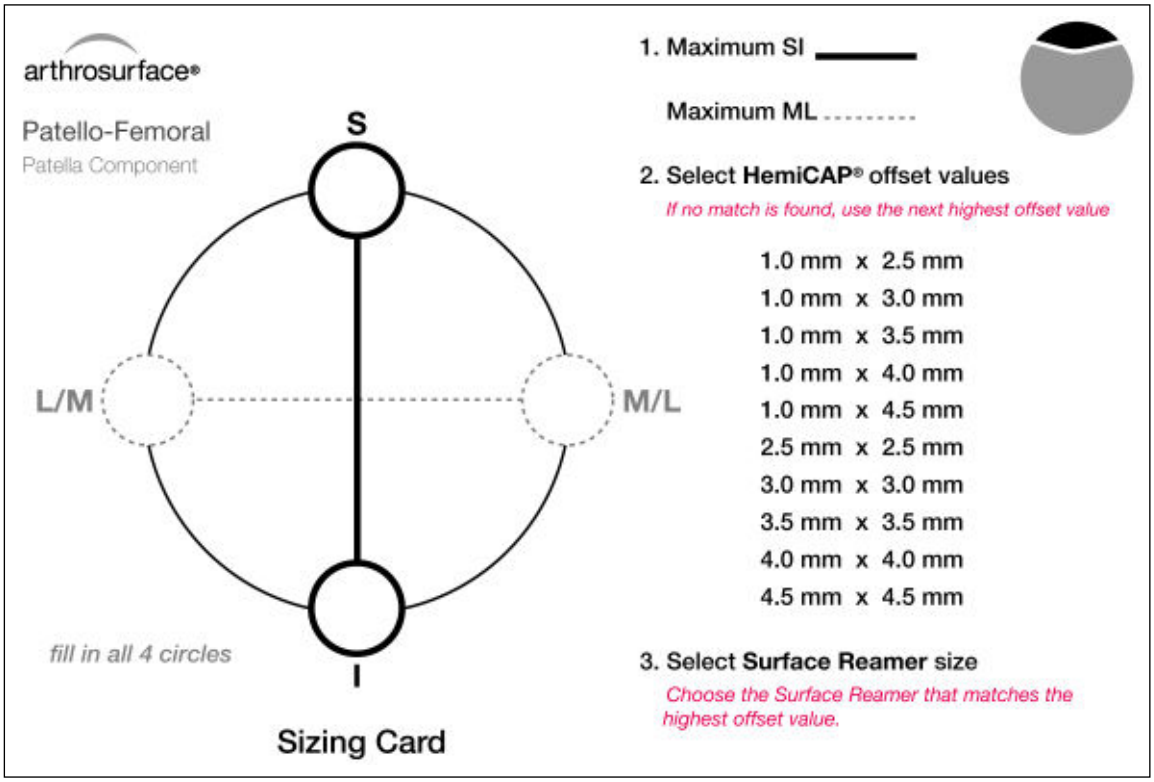
Sterility

Metallic prosthetic components are sterilized by exposure to gamma irradiation. Non-metallic prosthetic components are sterilized by gas plasma sterilization. Do not resterilize any components. Do not use components if packaging is opened or damaged. Do not use components if beyond expiration date.

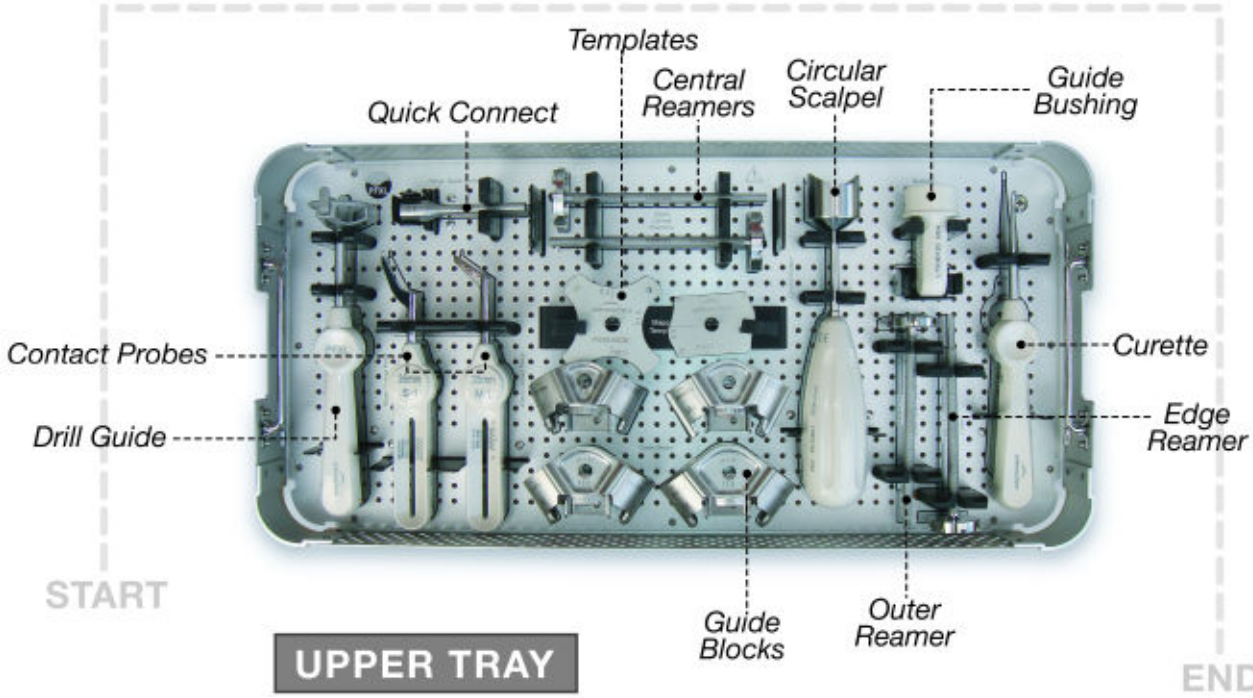
Caution: United States Federal law restricts this device to sale by or on the order of a physician.



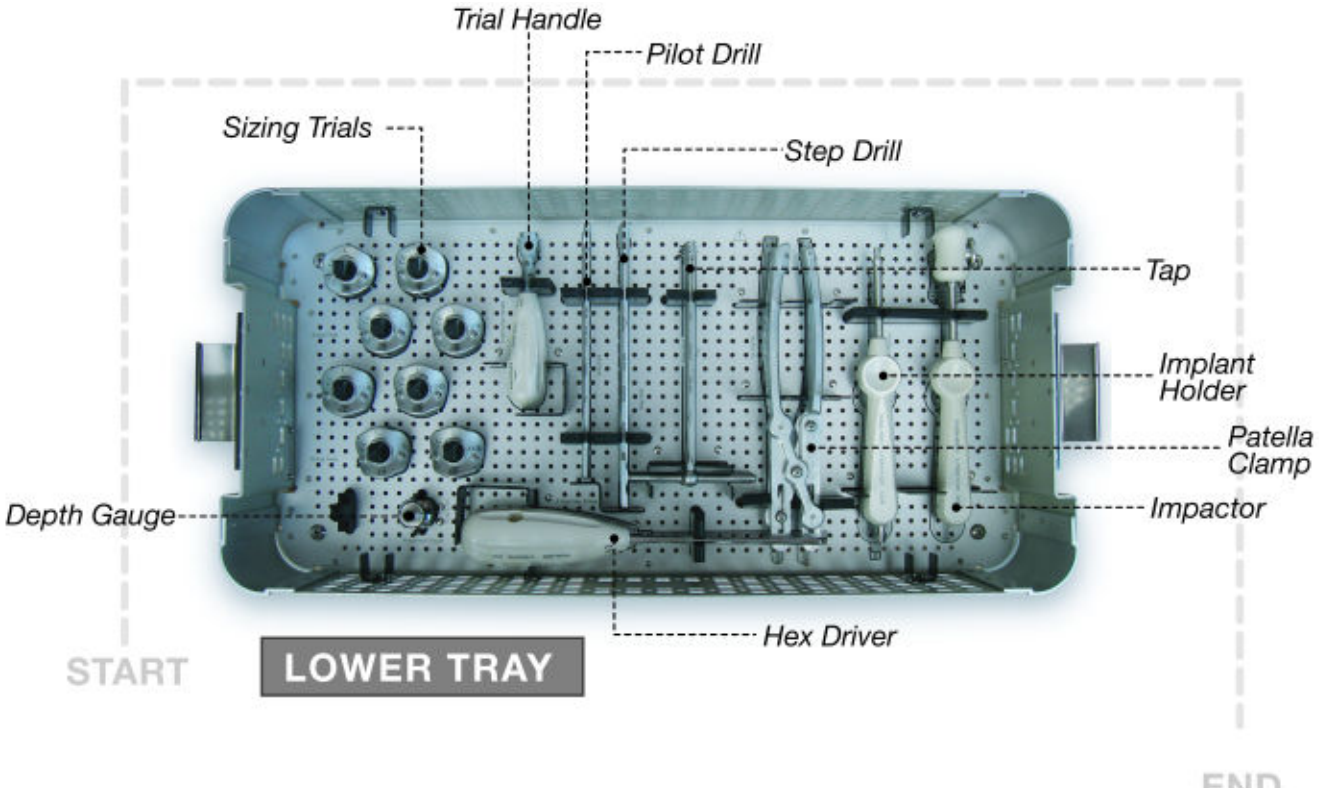
Sizing Card - Femoral Trochlear Component



Sizing Card - Patella Component



UPPER TRAY



LOWER TRAY

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

Catalog Number	Description
7000-2300	Instrument Kit, Patello-Femoral WAVE
PX07-1205	2.5 mm Guide Pin, WAVE (5 Pk) (non-sterile)
PX00-0200	2.5 mm Guide Pin Kit, WAVE (sterile)

Articular Component, Trochlear

⊕ S/I ⊖ M/L

PX02-0704	7.0 mm x 4.0 mm Offset
PX02-0705	7.0 mm x 5.0 mm Offset
PX02-0854	8.5 mm x 4.0 mm Offset
PX02-0855	8.5 mm x 5.0 mm Offset
PX02-1004	10.0 mm x 4.0 mm Offset
PX02-1005	10.0 mm x 5.0 mm Offset
PX02-1154	11.5 mm x 4.0 mm Offset
PX02-1155	11.5 mm x 5.0 mm Offset

Articular Component, Patella

P205-1025	1.0 mm x 2.5 mm Offset	**Anatomic**
P205-1030	1.0 mm x 3.0 mm Offset	
P205-1035	1.0 mm x 3.5 mm Offset	
P205-1040	1.0 mm x 4.0 mm Offset	
P205-1045	1.0 mm x 4.5 mm Offset	
P206-0025	2.5 mm x 2.5 mm Offset	**Button**
P206-0030	3.0 mm x 3.0 mm Offset	
P206-0035	3.5 mm x 3.5 mm Offset	
P206-0040	4.0 mm x 4.0 mm Offset	
P206-0045	4.5 mm x 4.5 mm Offset	

Taper Post

PX11-0218	Taper Post, 11 mm x 21.5 mm

Fixation Stud

PX75-0173	Fixation Stud, 7.5 mm x 18.5 mm

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

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