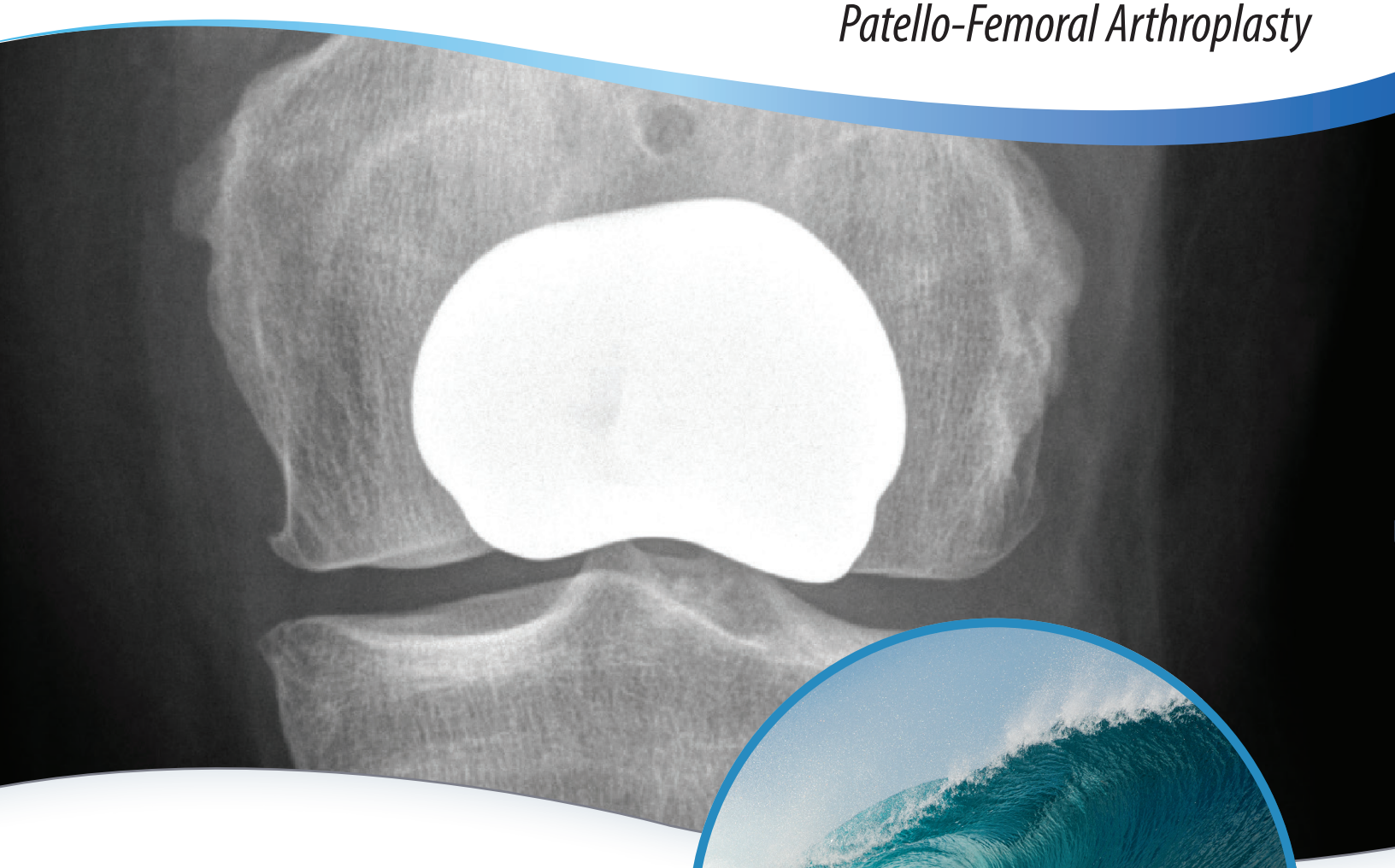
arthrosurface®

Technique Guide

Patello-Femoral Arthroplasty



The HemiCAP® Patello-Femoral Kahuna™ Arthroplasty System restores the unique articular surface geometry of the Patella and the Femoral Trochlear groove.

HemiCAP® Kahuna

The HemiCAP® Patello-Femoral *Kahuna*™ Arthroplasty System

Treatment Considerations for Patello-Femoral Arthroplasty

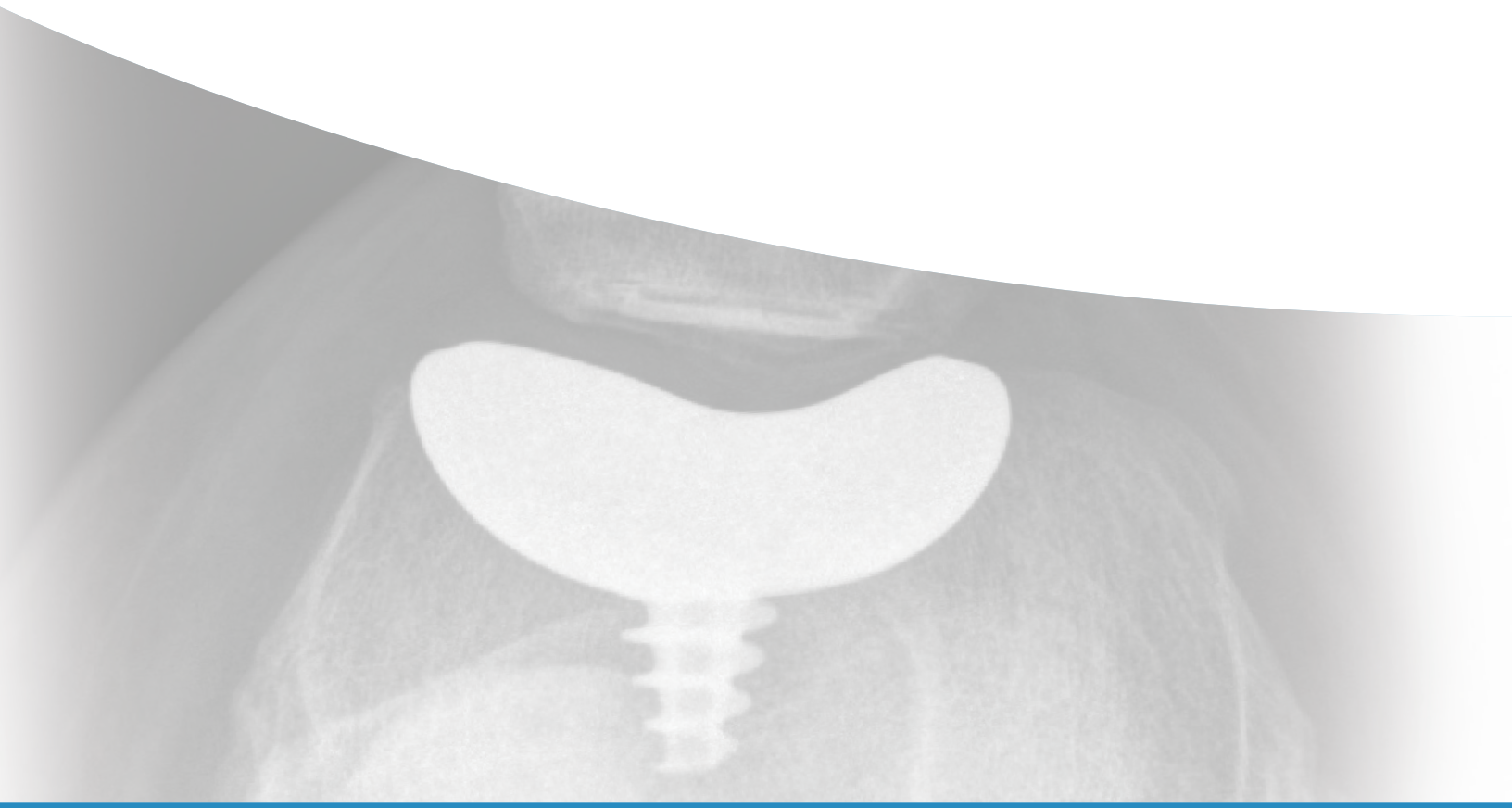
Patients with Patello-Femoral disease can be divided into two groups:

Group A: Patients with normal patello-femoral tracking and no dysplasia.
Group B: Patients with patello-femoral malalignment and / or trochlea dysplasia.

Group A patients can be treated with patello-femoral arthroplasty alone, whereas Group B patients require concominant procedures to optimize tracking and outcomes.

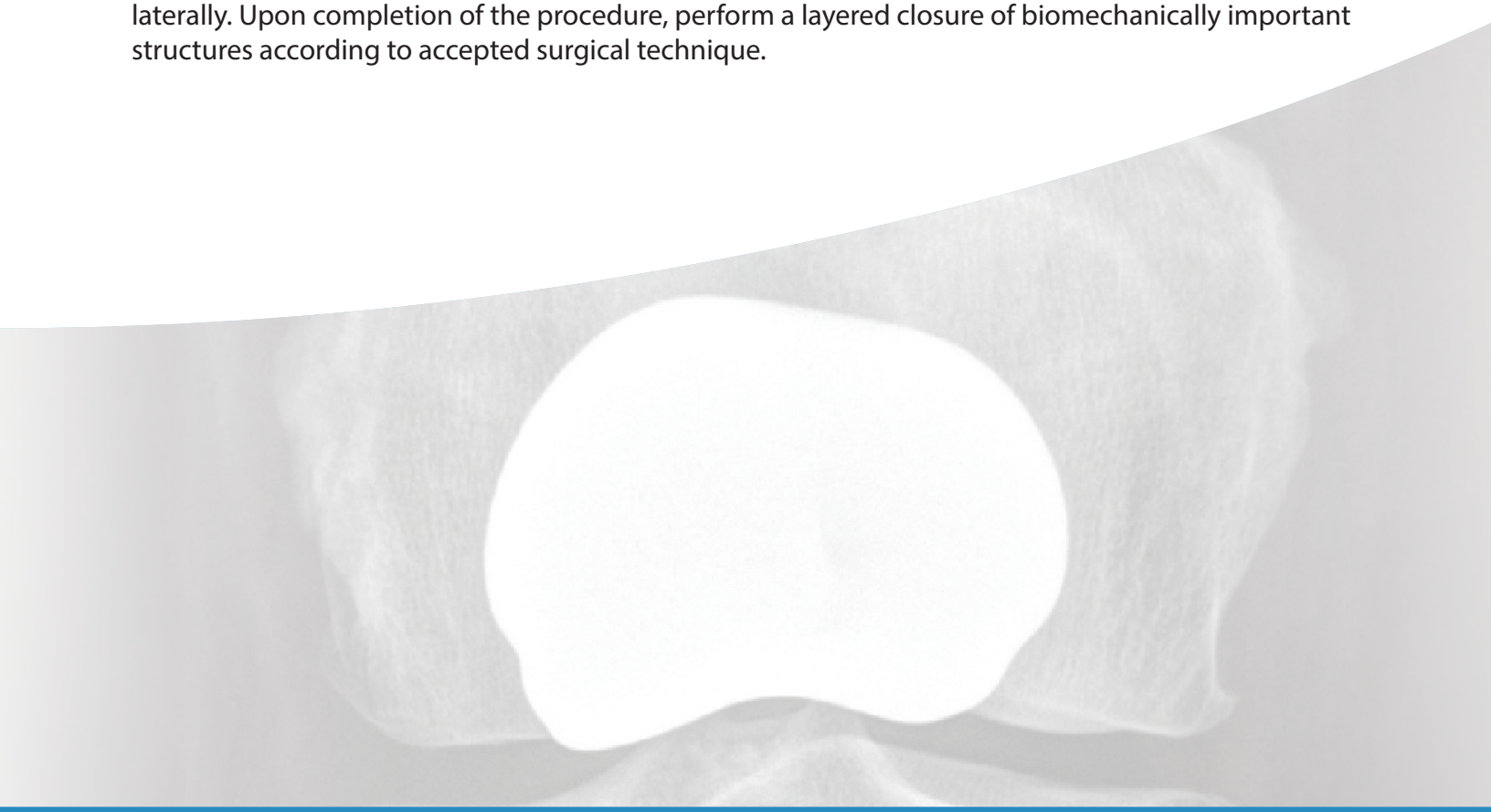
Supplementary Literature:

1. Cotic M, Forkel P, Imhoff AB (2017) [Patellofemoral arthroplasty]. Oper Orthop Traumatol 29:40-50
2. Cotic M, Imhoff AB (2014) [Patellofemoral arthroplasty: indication, technique and results]. Orthopade 43:898-904
3. Imhoff A, Beitzel K, Stamer K, Klein E (2014) Rehabilitation in der orthopädischen Chirurgie: OP-Verfahren im Überblick-Physiotherapie-Sporttherapie. Springer-Verlag
4. Imhoff AB, Feucht MJ, Meidinger G, Schottle PB, Cotic M (2015) Prospective evaluation of anatomic patello-femoral inlay resurfacing: clinical, radiographic, and sports-related results after 24 months. Knee Surg Sports Traumatol Arthrosc 23:1299-1307



Surgical Approaches for HemiCAP® Kahuna™ Arthroplasty

- The surgical approach for patello-femoral arthroplasty is determined by several factors including surgeon preference, the patient's surgical history, and underlying pathology taking blood supply and stabilizing soft tissues into consideration.
- 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 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.



Description

The HemiCAP® Patello-Femoral Kahuna™ Arthroplasty System incorporates a distal femoral trochlear surface articular component that mates to a taper post 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-Chronium Alloy (Co-Cr-Mo)
Surface Coating:	Titanium (CPTi)
Taper Post:	Titanium Alloy (Ti-6Al-4V)
Patella Component:	Ultra-High-Molecular Weight Polyethylene (UHMWPE)

Indications

The HemiCAP® Patello-Femoral Kahuna™ Arthroplasty System 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) Need to obtain pain relief and improve function
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
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

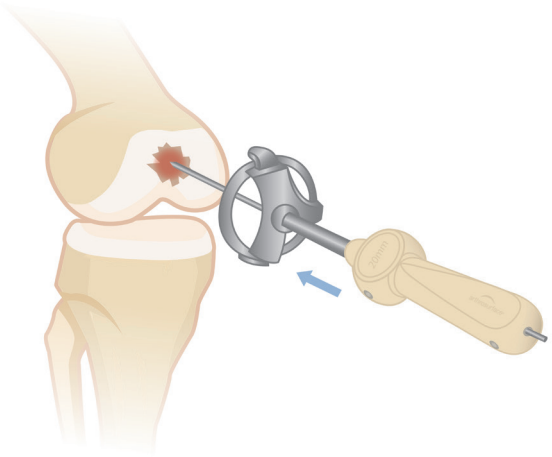
Relative contraindications include:

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

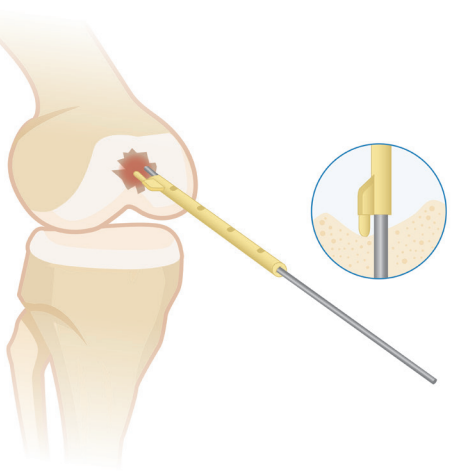
Surgical Technique (Kahuna™ Femoral Component)

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 the "L" laser mark to the lateral aspect of the femur. Place the **2.5mm Guide Pin** into a cannulated powered drill and secure at the etch marking on the **Guide Pin**. Advance the **Guide Pin** into the bone.

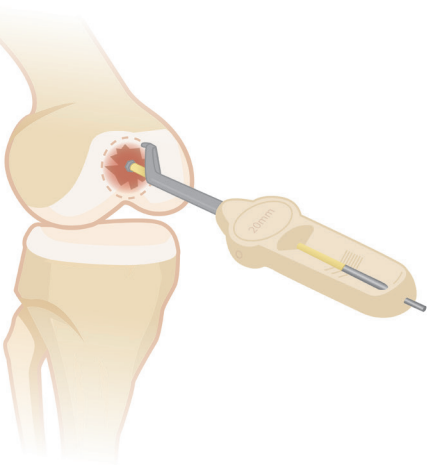
   *Note: It is important to verify that the **Drill Guide** is seated on the curved surface such that all 4 points of contact are established on the articular surface. A normal axis is necessary for proper implant fit.*

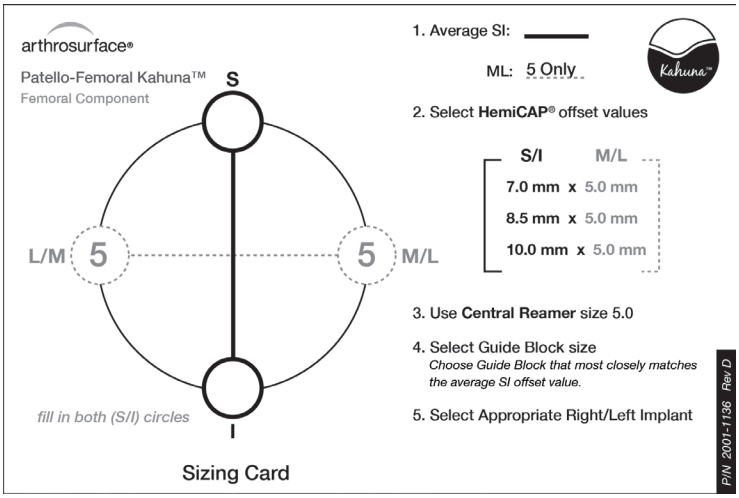


2. Place the yellow **Offset Sleeve** over the **Guide Pin** so the foot of the **Offset Sleeve** is touching the deepest (medial) portion at the center of the trochlea. Place the **Contact Probe** over the **Offset Sleeve** and use light pressure on the **Contact Probe** to ensure proper contact with the articular surface.



3. Read the **Contact Probe** to obtain positive (+) superior/inferior offsets and negative (-) medial/lateral offsets. Alternatively, the **Sizing Templates** can be utilized. Mark each of the identified offsets on the appropriate **Sizing Card**. Use the **Sizing Card** to record the average superior/inferior offset.

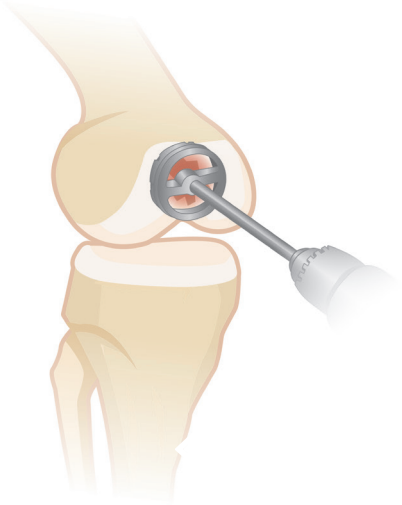




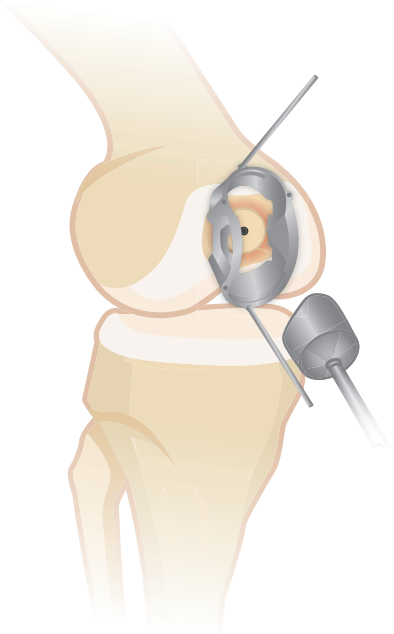
Sizing Card

S/I Template

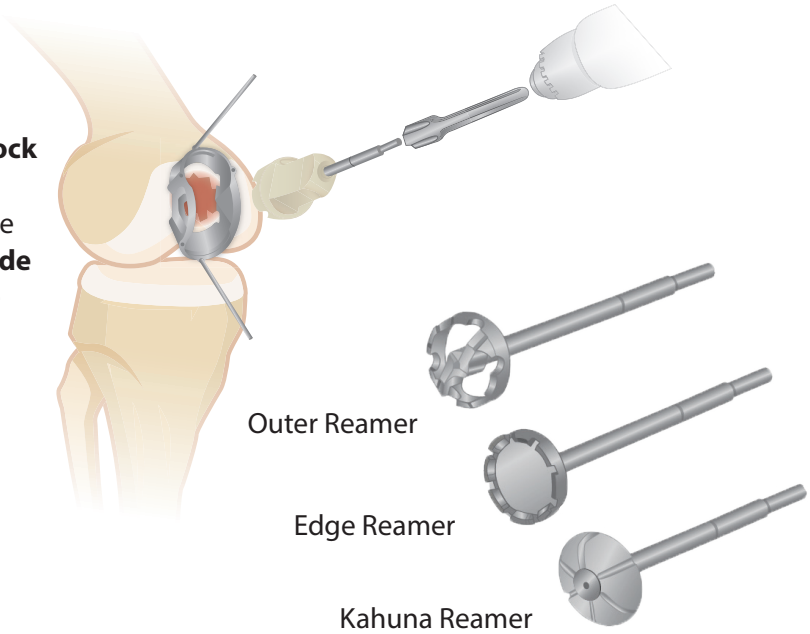
4. Select the **35mm Central Reamer** (5mm) and advance it over the **Guide Pin** until the etched mark on the side of the **Central Reamer** is flush with the medial/lateral facets.



5. Select the **Guide Block** that corresponds with the offset from the superior/inferior mapping point and place onto the trochlear groove (7.0mm, 8.5mm or 10.0mm). Align the **Guide Block** per medial and lateral indicator laser marks. Secure the **Guide Block** onto the femur using **Guide Pins**. In knees with a dysplastic or flattened trochlea, the **Guide Block** may not sit flush to the reamed area. Use an osteotome to create slots in the bone to accept the proximal and distal feet of the **Guide Block**. Creating these slots will allow the **Guide Block** to sit flush to the reamed area. 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.

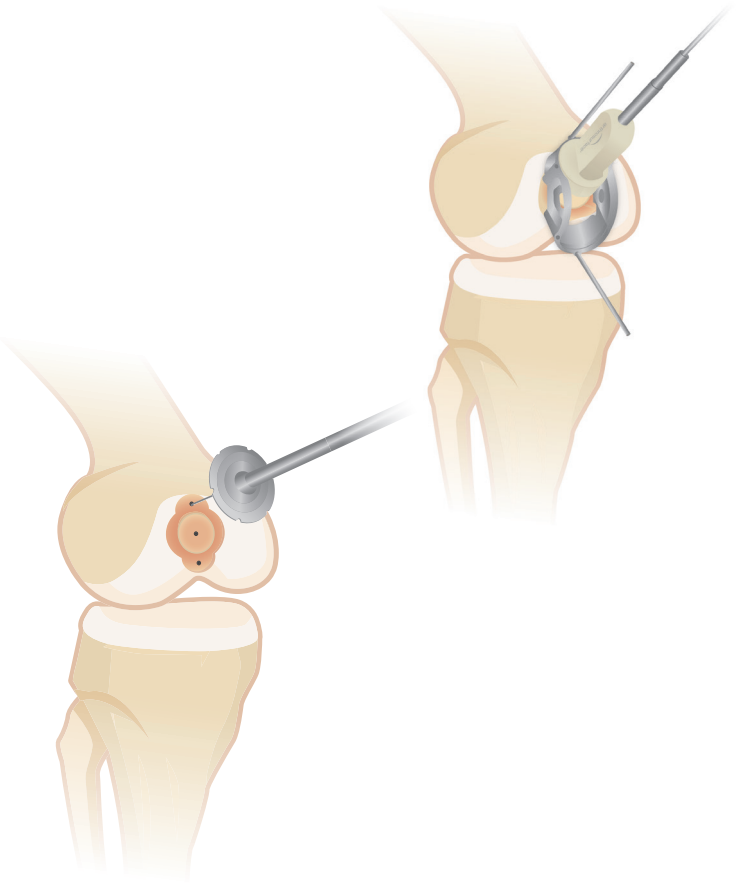


6. Assemble the **Outer Reamer** into the **Guide Bushing**. Secure the **Guide Bushing** into the superior **Guide Block** bore. Advance the **Outer Reamer** into the bone until the depth mark on the reamer shaft is reached. Remove assembly and repeat reaming through the inferior **Guide Block** bore. It is critical to keep the **Guide Block** stable during reaming. Repeat for the **Edge Reamer**.

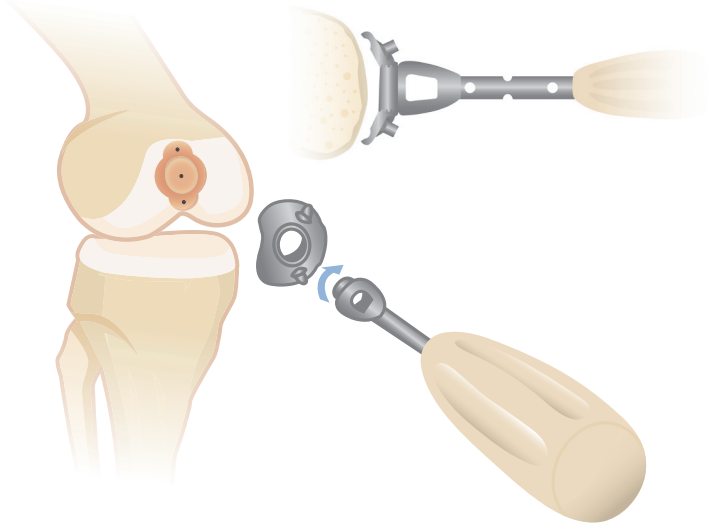


6.1 Using **Outer Reamer** in **Guide Bushing** place **Guide Pin** into Superior Position.

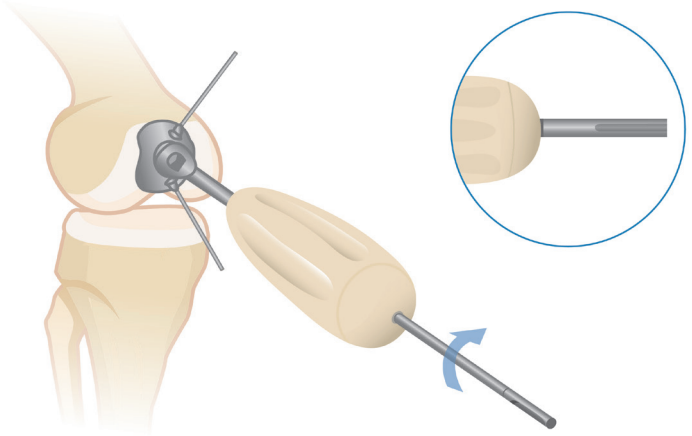
6.2 Remove **Guide Block**. Ream over **Guide Pin** with **Kahuna Reamer** until reamer bottoms out on the central part of the previously reamed surface.



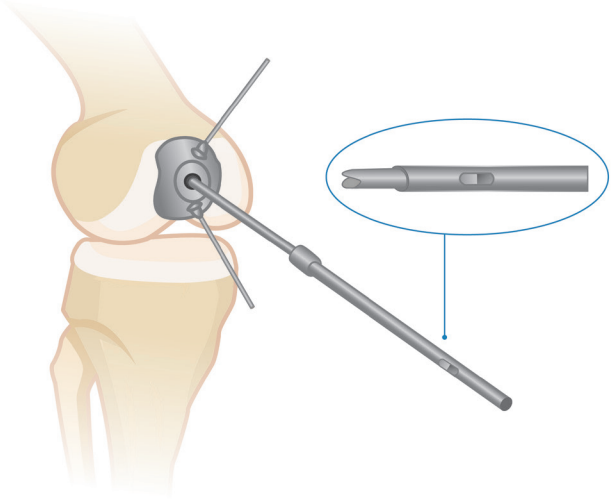
7. Assemble the **Trial Handle** onto the **Sizing Trial** and place the **Sizing Trial** into the prepared site that matches the offset profile from the **Sizing Card**. Confirm the fit of the **Sizing Trial** so that all margins are congruent or recessed to the edge of the surrounding articular surface.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



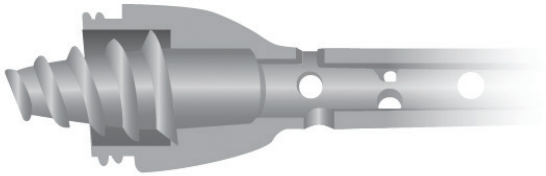
8. Fix the **Sizing Trial** in place and insert the **Pilot Drill** through the center of the **Guide Handle** and advance to the laser mark indicated on the **Pilot Drill**. Leave the **Pilot Drill** in place and remove the **Trial Handle** from the **Sizing Trial**.

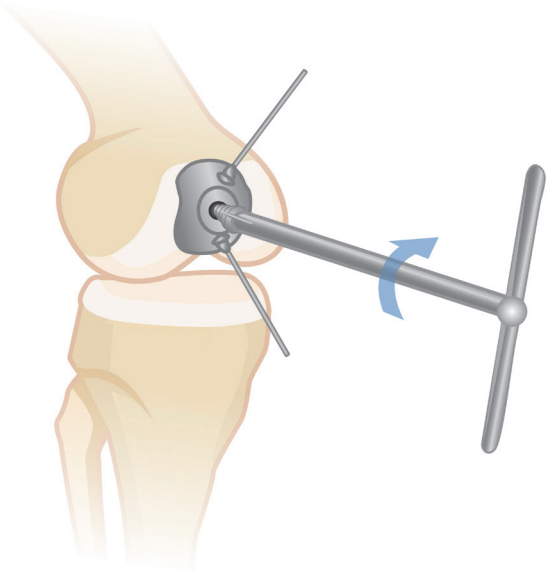


9. Advance the **Step Drill** over the **Pilot Drill** until it bottoms out on the back of the **Pilot Drill**. Remove the **Step Drill**.

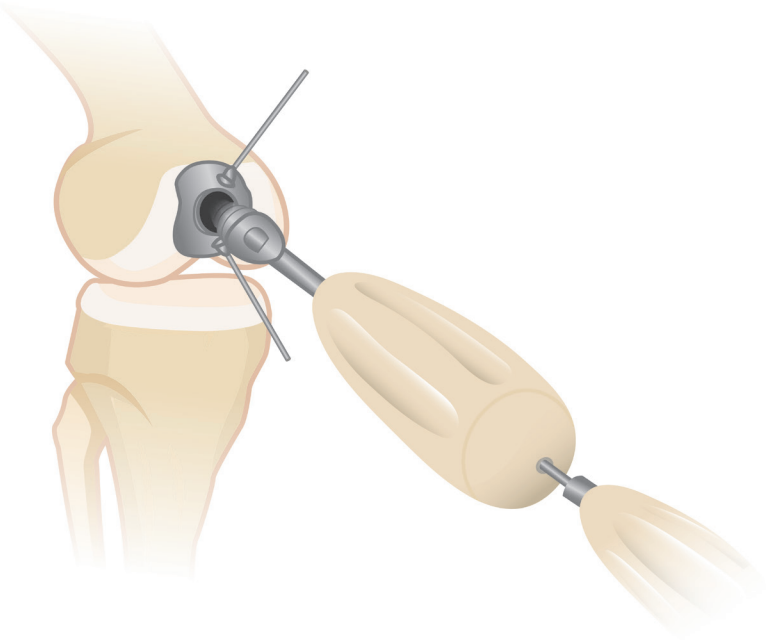


10. Advance the **Tap** over the **Pilot Drill** so the end stops when the **Pilot Drill** is flush to the back of the cannulation in the **Tap**. Remove the **Tap** and **Pilot Drill**.

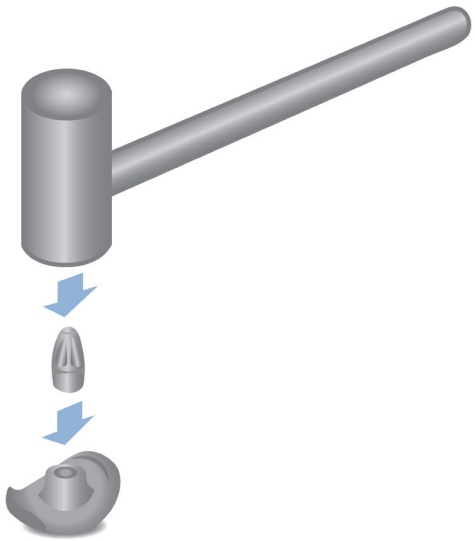




11. Apply a small amount of low-viscosity bone cement into the **Taper Post** tunnel. Place the **Taper Post** into the morse taper of the **Trial Handle** and attach to the **Sizing Trial**. Place the **Hex Driver** through the **Trial Handle** and advance the **Taper Post** until the stop on the shaft of the **Hex Driver** comes in contact with the back of the **Trial Handle**. Place the **Depth Gauge** into the **Sizing Trial** to ensure that the **Taper Post** is at proper depth to engage the **Kahuna™ Femoral Component**.

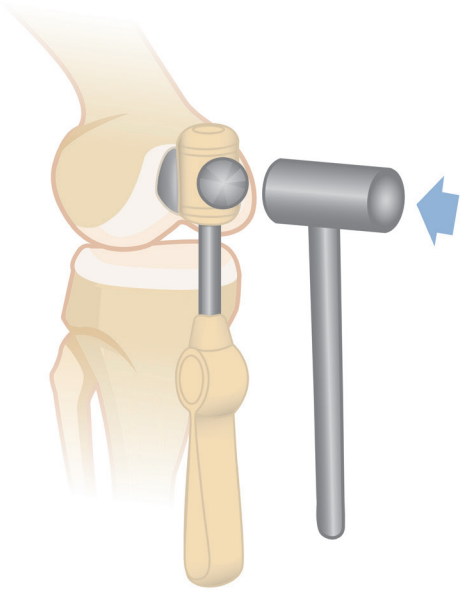


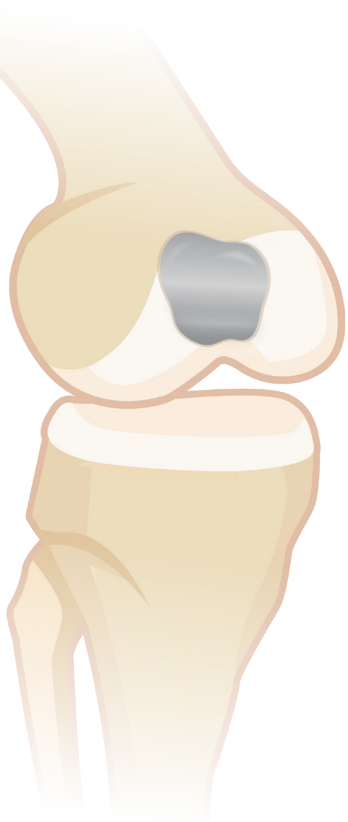
12. An alternative approach to fixation is to pre-assemble the **Threadless Stud** to the **Kahuna™ Femoral Component**. Be sure to protect the articular face of the **Kahuna™ Femoral Component** by using slight impaction with the mallet to seat the morse taper of the **Threadless Stud** onto the **Kahuna™ Femoral Component**.



NOTE: Prepare and implant the **Patella Component** (p. 26) prior to the final placement of the **Kahuna™ Femoral Component**.

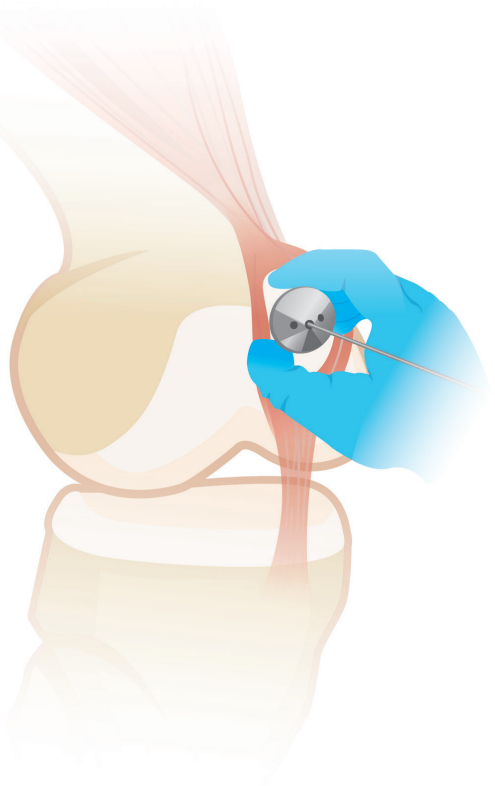
13. Prior to placing the **Kahuna™ Femoral Component** on the **Implant Holder**, make sure that sufficient suction is present to hold the device on the distal suction cup. Align the **Kahuna™ Femoral Component** on the **Implant Holder** with the medial etch mark facing the medial aspect of the knee and lateral mark facing the lateral plane. Insert into the taper of the **Taper Post**. Firmly mallet the **Impactor** until the **Kahuna™ Femoral Component** is completely seated.





Surgical Technique (HemiCAP® Patella Component)

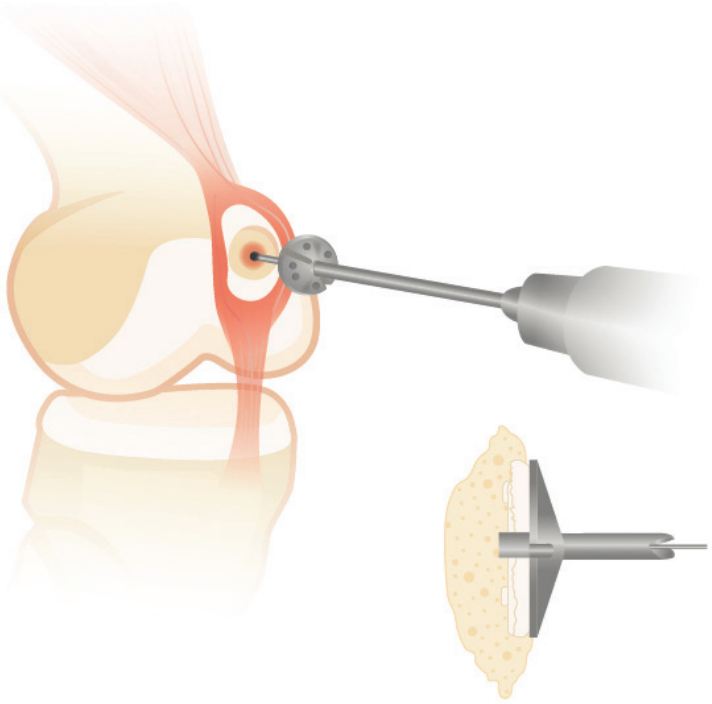
1. With knee in extension, evert the patella and determine the **Patella Component** with the proper diameter by selecting the **Patella Reamer** or **Trial** that provides the most effective coverage.



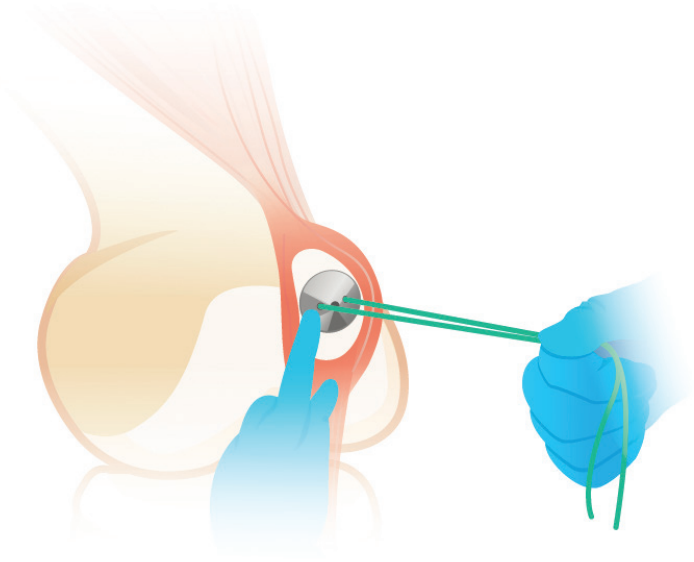
2. Load the **2.5mm Guide Pin** into a Jacobs chuck and cannulated powered drill. Insert the **2.5mm Guide Pin** through the appropriate **Patella Trial** and locate the **Patella Trial** in an anterior position to develop a working axis normal to the patella surface. The **Patella Trial** acts as a guide for placing the **Guide Pin** appropriately. (Alternatively the **Patella Reamer** can be used to locate the **Guide Pin**.)

3. Holding the cannulated powered drill and **Patella Trial** perpendicular to the patella, drill the **Guide Pin** through the **Patella Trial** until it engages the opposite cortex of the patella. Leave the **Guide Pin** in place and remove the cannulated powered drill from the **Guide Pin**.

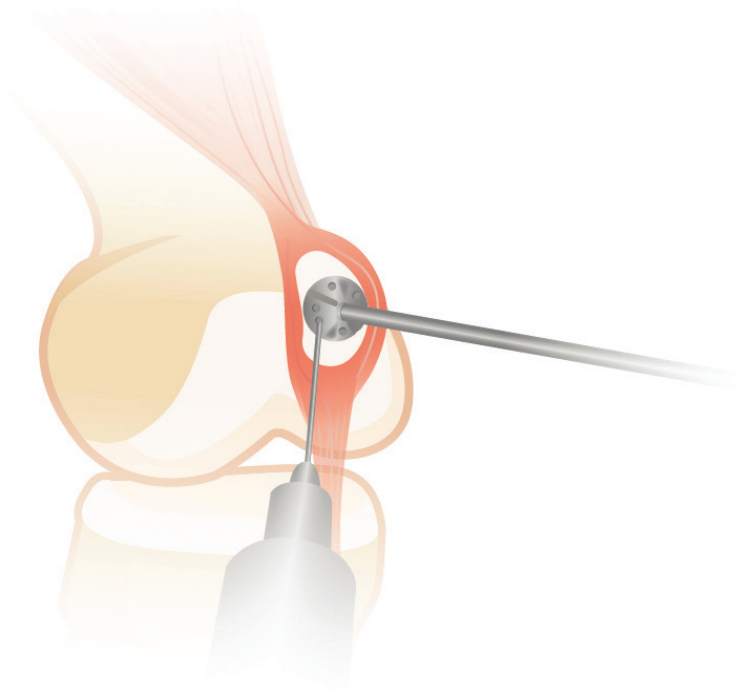
4. Load the **Patella Reamer** into the Jacobs chuck of the cannulated powered drill. Using the drill, advance the **Patella Reamer** over the **Guide Pin** until it reaches the depth indicator markings. The depth markings are located on the side of the **Patella Reamer** just superior to the cutting flutes.



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



6. Reinsert the **Patella Reamer** and insert the **Guide Pin** into the cement channel holes in the patella bone. This will create a series of offset channels for cement fixation. Remove the **Guide Pin**.

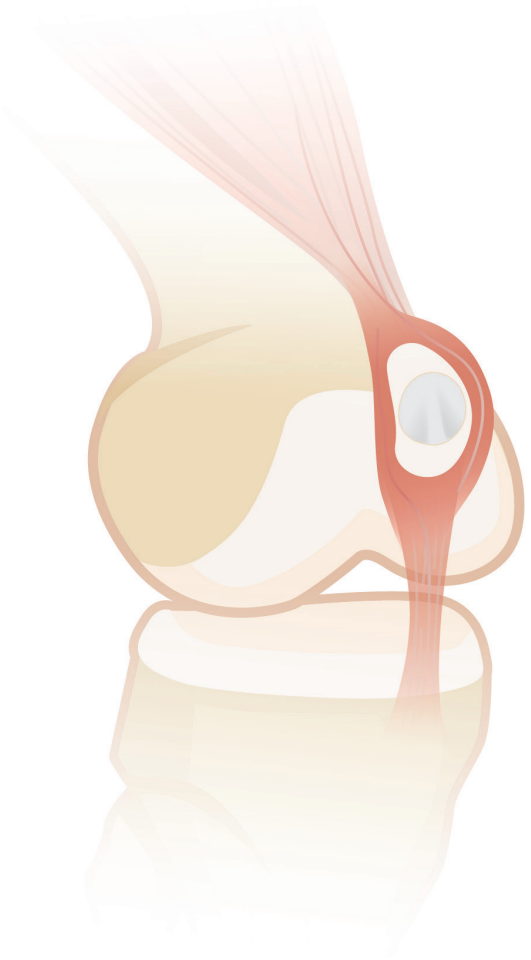


7. Confirm size and open the **Patella Component**.

   *Note: When using the **Anatomic Patella Component**, make sure to align the superior and inferior orientation of the component with the superior and inferior poles of the patella.*

Button Anatomic Dome

8. Apply a sufficient amount of low-viscosity bone cement into the reamed socket of the patella and quickly place the **Patella Component** into position.

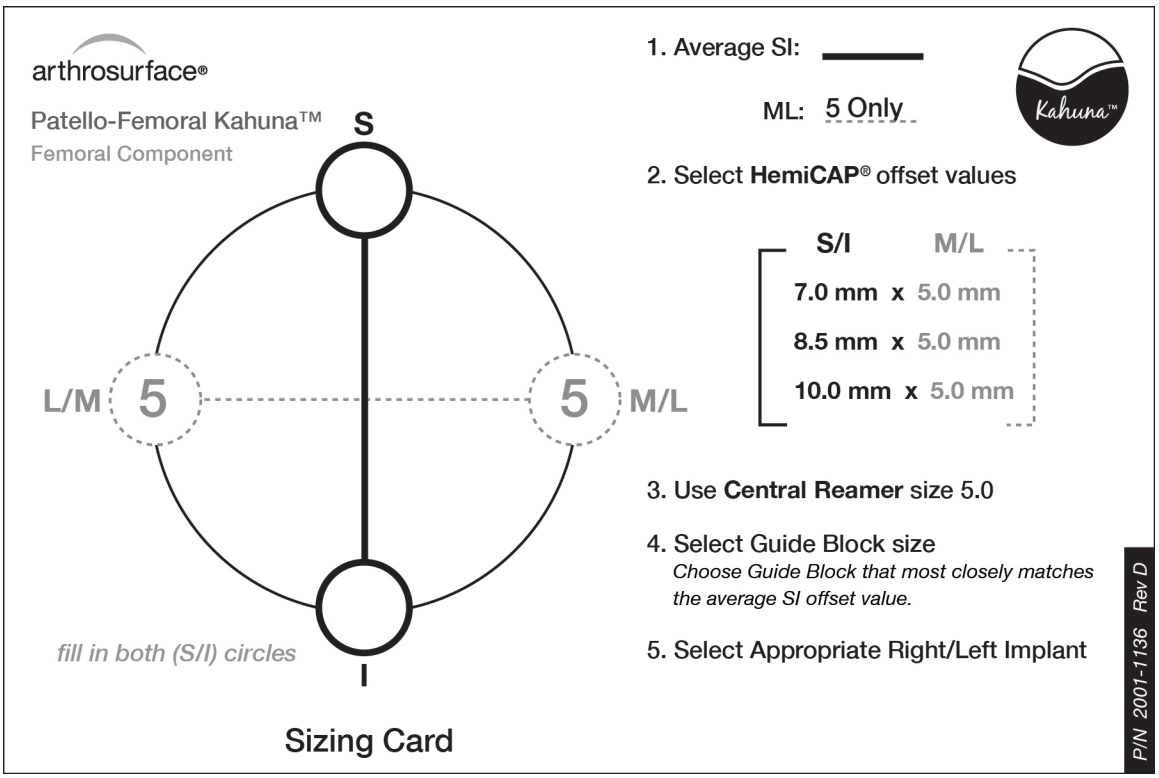


9. Using the **Patella Clamp**, firmly press the **Patella Component** into the patella until the bone cement has sufficiently cured for proper fixation. Clean out any remaining exposed cement and debris.

NOTE: Complete implantation of appropriate Left/Right **Kahuna™ Femoral Component** (p. 9)

10. Once implantation of the **Kahuna™ 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.

Sizing Card (HemiCAP® Kahuna)



System Catalog

Instrumentation System	
7000-2300	Instrument Kit, Patello-Femoral Wave
PW09-1500	Reamer Kit, Kahuna, CE
7000-2302	Instrument Kit, 25/30mm Patella
PX07-1205	2.5mm Guide Pin, Wave (5 Pk) (non-sterile)
PX00-0200	2.5mm Guide Pin Kit, Wave (sterile)

Articular Component, Patella	
P255-1050	25mm Anatomic, 7.0mm thick
P306-0070	30mm Button, 7.0mm thick
P306-0090	30mm Dome, 9.0mm thick

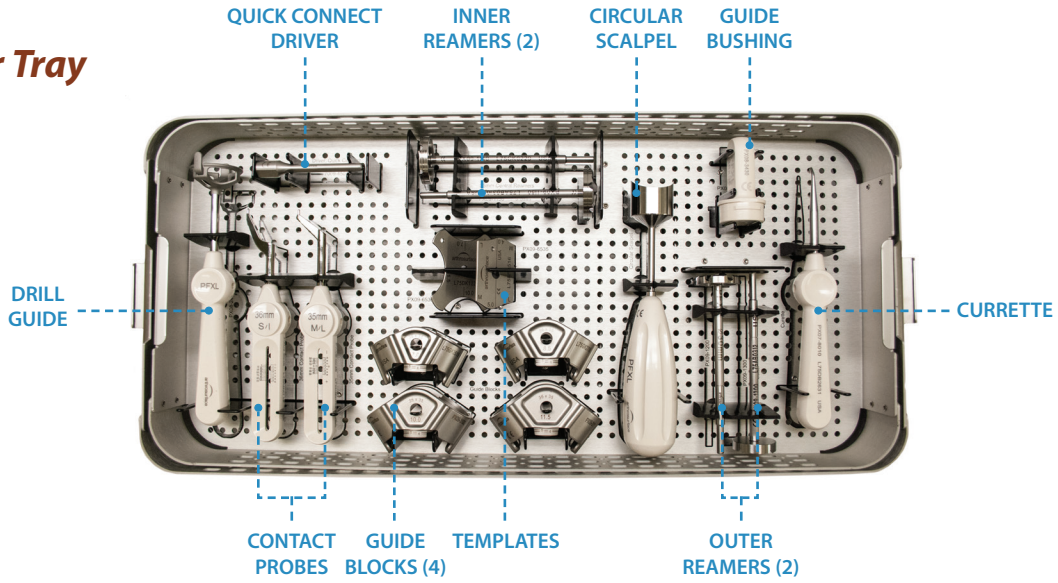
Taper Post	
PX11-0218	Taper Post, 11mm x 21.5mm

Fixation Stud	
PX75-0173	Fixation Stud, 7.5mm x 18.5mm

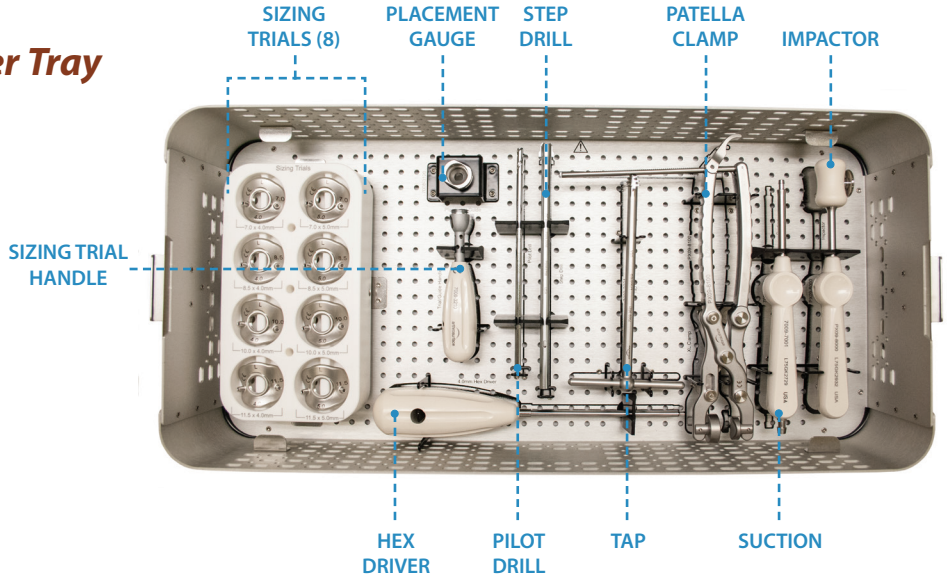
Articular Component, Femoral	
	S/I
Left	
PWL2-0705	7.0mm Offset, Left
PWL2-0855	8.5mm Offset, Left
PWL2-1005	10.0mm Offset, Left
Right	
PWR2-0705	7.0mm Offset, Right
PWR2-0855	8.5mm Offset, Right
PWR2-1005	10.0mm Offset, Right

Instrumentation

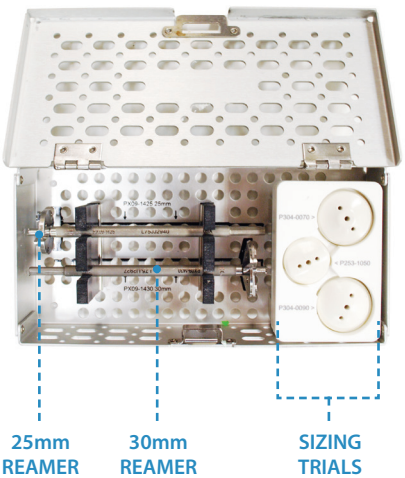
Upper Tray



Lower Tray



Patella Tray



Kahuna Reamer

(Disposable)

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

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.

Patello-Femoral Inlay Arthroplasty Systems

HemiCAP® PF Classic


13 Different Sizes & Convexities

Anatomic

Button

HemiCAP Wave®


8 Different Sizes & Convexities

Dome

Button

Anatomic

HemiCAP Kahuna™


6 Different Sizes & Convexities
(3 Left & 3 Right)

Dome

Button

Anatomic

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