Description

The Patello-Femoral Wave Arthroplasty Systems incorporate 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 Component:
Cobalt-Chromium Alloy (Co-Cr-Mo)
Undersurface Coating: Titanium (CP Ti)
Taper Post: Titanium Alloy (Ti-6Al-4V)
Patella Component:
Ultra-High-Molecular Weight Polyethylene (UHMWPE)

Indications

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.
6) Failure of previous conservative treatment options in correcting deformity and achieving pain relief.

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, musculotendinous or neurovascular system status.

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 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 Taper Post and Femoral Component, 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.

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.

The Patello-Femoral implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of The Patello-Femoral knee implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Precautions

Patello-Femoral implants are intended to be fitted and installed with the appropriate Patello-Femoral instrument sets. 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. The operating surgeon or physician should discuss general risks and potential complications associated with this and any surgical procedure with the patient prior to patient consent.

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.
13. Embolism.

Sterility

The implant components and single use disposable instruments are provided sterile. 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 as indicated on package label. Reuse of single use devices can increase the risk of patient infection and can compromise service life and other performance attributes of these devices.

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

Instructions for Use —

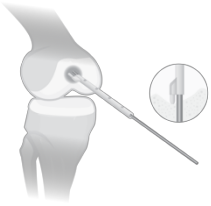
Implantation of the Patello-Femoral Femoral Component —

1. With knee in extension, use the **Mapping Template** to identify the S/I curvature of the trochlear groove.

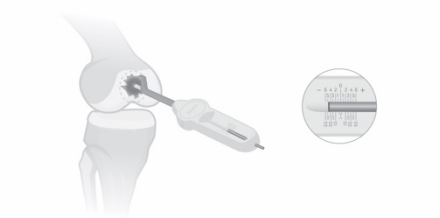
2a. Select corresponding S/I curvature **Sizing Trial** and attach the **Femoral Pin Guide**. Place the **2.5mm Femoral Guide Pin** into a cannulated powered drill and advance **2.5mm Femoral Guide Pin** until secure in the bone (approximately 10mm deep).

2b. Alternatively, the Offset Drill Guide **may be used to place the** 2.5mm Femoral Guide Pin**. Align the "L" laser mark to the lateral aspect of the femur.**

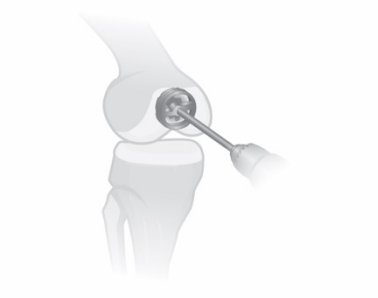
I. Place the yellow **Offset Sleeve** over the **2.5mm Femoral Guide Pin** so the foot of the **Offset Sleeve** is touching the deepest (medial) portion at the center of the trochlea. Place the **Contact Probe** over the **Offset Sleeve** and use light pressure on the **Contact Probe** to ensure proper contact with the articular surface.



II. Read the **Contact Probe** to confirm superior/inferior offsets. Use the **Sizing Card** to record the average superior/inferior offset.

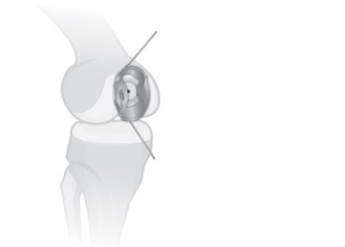


3. Select the **35mm Central Reamer (5mm)** and advance it over the **2.5mm Femoral Guide Pin** until the etched mark on the side of the **Central Reamer** is flush with the medial/lateral facets.

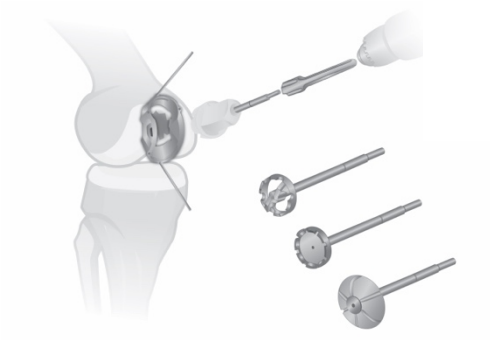


4. Select the **Guide Block** that corresponds with the S/I curvature value and place onto the trochlear groove. Insert the central portion of the **Guide Block** into the reamed area and secure the **Guide Block** onto the femur using the **2.0mm Guide Pins**.

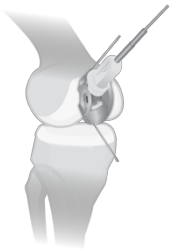
In knees with a dysplastic or flattened trochlea, the **Guide Block** may not sit flush to the reamed area. Use an osteotome or burr to create slots in the bone to accept the proximal and distal feet of the **Guide Block**. Creating these slots will allow the **Guide Block** to sit flush to the reamed area.



5. Assemble the **Outer Reamer** into the **Guide Bushing**. Secure the **Guide Bushi**ng into the inferior **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 superior **Guide Block** bore. It is critical to keep the **Guide Block** stable during reaming. Repeat the same sequence for the cannulated **Kahuna Tooth Cutter**.



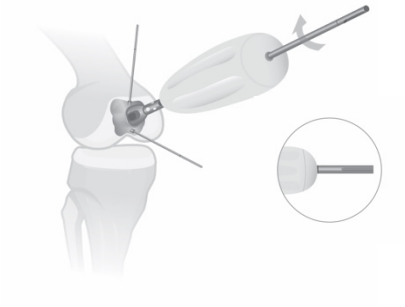
6. With the Kahuna Tooth Cutter in the **Guide Bushing** at the superior **Guide Block** bore position, drive the **2.5mm Femoral Guide Pin** into bone to create a stable working axis for the **Kahuna Reamer** (approximately 10mm deep).



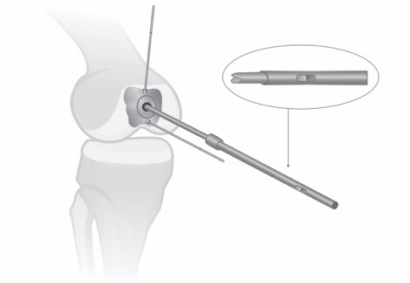
7. Remove the **Guide Block**. Ream over the **2.5mm Femoral Guide Pin** with the **Kahuna Reamer** until reamer bottoms out on the central part of the previously reamed surface.

8. Assemble the **Trial Handle** onto the **Sizing Trial** that corresponds with the S/I curvature value. Place the **Sizing Trial** into the prepared site. 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 the reamed surfaces to ensure the **Sizing Trial** is fully seated. Fix the **Sizing Trial** in place using the **2.0mm Guide Pins**.

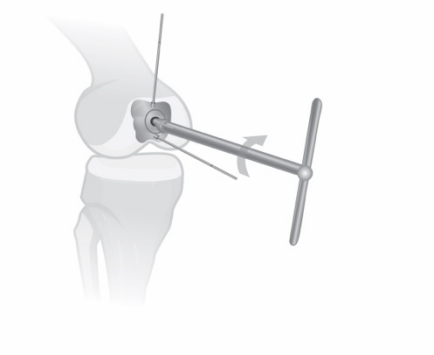
9. Insert the **Pilot Drill** through the center of the **Trial Handle** and advance to the laser mark indicated on the **Pilot Drill**. Leave the **Pilot Drill** in place and remove the **Trial Handle** from the **Sizing Trial**.



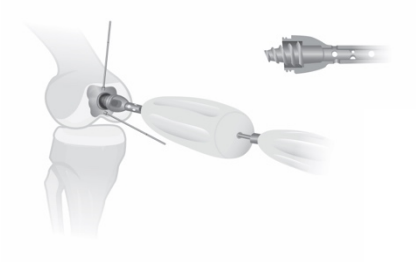
10. Advance the **Step Drill** over the **Pilot Drill** until it bottoms out on the back of the **Pilot Drill**. Remove the **Step Drill**.



11. 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**.



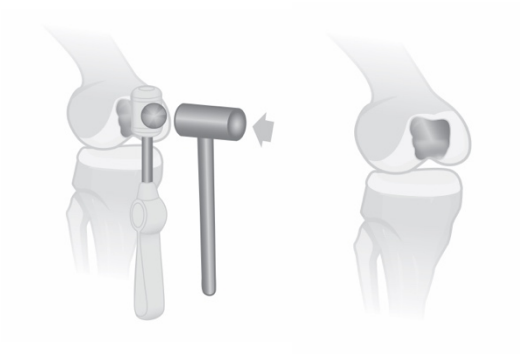
12. Apply a small amount of low-viscosity bone cement into the **Taper Post** bone tunnel. Place the **Taper Post** into the morse taper of the **Trial Handle** and attach to the **Sizing Trial**. Place the **Hex Driver** through the **Trial Handle** and advance the **Taper Post** until the stop on the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



13. An alternative approach to fixation is to pre-assemble the **Threadless Stud** to the **WaveKahuna™ 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 the **Patella Component** implant site prior to the final placement of the **WaveKahuna™ Femoral Component**.

14. Prior to placing the **WaveKahuna™ Femoral Component** on the **Implant Holder**, make sure that sufficient suction is present to hold the device on the distal suction cup. Align the **WaveKahuna™ Femoral Component** on the **Implant Holder**. Insert into the taper of the **Taper Post**. Firmly mallet the **Impactor** until the **WaveKahuna™ Femoral Component** is completely seated.



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Patello-Femoral Wave Arthroplasty Systems
Instructions for Use

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