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 Patello-Femoral knee implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Precautions

The Patello-Femoral implants are intended to be fitted and installed with the appropriate Patello-Femoral instrument set(s). 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 Patello-Femoral instrument sets 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

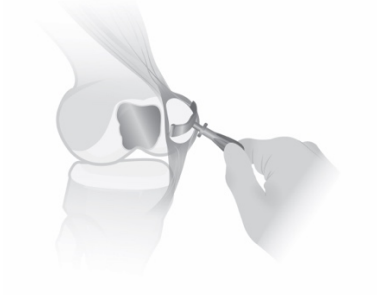
Sterility

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 the device.

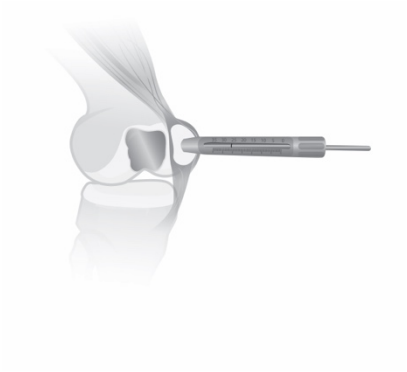
Caution: United States Federal law restricts this device to sale by or on the order of a physician.

Implantation of the Patello-Femoral Wave[Kahuna] Patella Component —

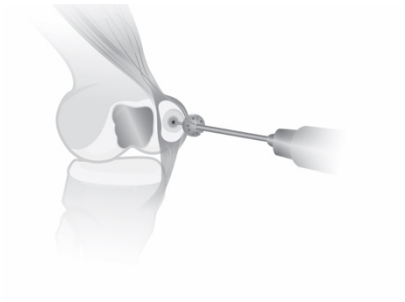
1. With knee in extension, evert the patella and determine the appropriate **Patella Component** diameter by utilizing the **Patella Sizing Trial** to evaluate the most effective coverage. Place the **Patella Pin Guide** onto the patella surface so the medial and lateral feet are in contact with the patella surface and the **Patella Pin Guide** is centered in the M/L and S/I planes. Drill the **Patella Guide Pin** through the patella until it engages the opposite cortex.



2. Leave the **Patella Guide Pin** in place and use the **Patella Depth Gauge** to measure patella thickness. Calculate the target reaming depth based on the **Patella Component** thickness as identified on the **Patella Component** box label.

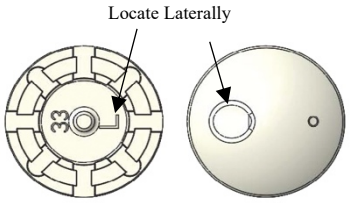


3. Load the **Patella Reamer** into a cannulated powered drill. Using the drill, advance the **Patella Reamer** over the **Patella Guide Pin** until the calculated target reaming depth has been reached. Confirm the reaming depth using the **Patella Depth Gauge**.



4. Load a loop of suture through the corresponding **Patella Sizing Trial** and place into the prepared area. Carefully orient the medial and lateral features of the **Sizing Trial**. The dimple feature on the articular surface of the **Patella Component** is intended to be placed laterally. Confirm the fit of the **Patella Sizing Trial** so that all margins are congruent or recessed to the edge of the surrounding articular surface. Using the **Femoral Reduction Trial**, perform reduction and trial range of motion. Remove or debride any loose tissues if necessary. Remove all osteophytes and confirm PF tracking.

5. Confirm size, open the **Patella Component** and carefully orient medial and lateral features of implant. Apply a sufficient amount of low-viscosity bone cement into the reamed socket of the patella and quickly place the **Patella Component** into position ensuring correct placement of the medial and lateral features of the implant. The dimple feature on the articular surface of the **Patella Component** is intended to be placed laterally.



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

7. Complete implantation of appropriate Left/Right **WaveKahuna™ Femoral Component**.

8. Once implantation of **the WaveKahuna™ Femoral and Patella Components** is complete, ensure no bone cement is left in joint. Remove or debride any loose tissues if necessary. Remove all osteophytes. Close utilizing accepted practices.

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Gas Plasma Hydrogen Peroxide

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PN 2001-2121 REV B

PF Wave™ Wave Kahuna™

Patello-Femoral Wave Arthroplasty Systems
Instructions for Use

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