



Resurfacing Components Patello-Femoral Instructions for Use

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 preoperative 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 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® Wave Patello-Femoral Resurfacing implants are intended to be fitted and installed with the HemiCAP® Wave 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. Reuse of single use devices can increase the risk of patient infection and can compromise service life and other performance attributes of the device.

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.