



Description

The HemiCAP® Contoured Articular Prosthetic incorporates an articular resurfacing component and a cancellous taper post component that mates together via a taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface.

Materials

Articular Resurfacing Component: Cobalt-Chromium-Molybdenum alloy (Co-Cr-Mo)

Surface Coating: Titanium (CP Ti)

Taper Post Component: Titanium Alloy (Ti-6Al-4V)

Indications for Use

Partial resurfacing of the talar dome of the ankle for use in the treatment of patients with localized post-traumatic degenerative disease, necrosis associated with large unstable osteochondral fractures, or osteochondritis dissecans. Soft tissues and other structures contributing to joint stability should be intact or reconstructable. The intended use of the device is part of an interim clinical strategy for patients who have not responded to other treatments and who will likely receive a joint replacement or fusion in the future. The device is a single use implant.

Patient selection factors to be considered include:

1. Patient has localized disease of the ankle and talar dome;
2. Patient's need to obtain pain relief and improve function;
3. Patient's age as relative contraindication to an arthrodesis or joint replacement procedure; and
4. Patient overall well-being, including ability and willingness to follow instructions and comply with activity restrictions.

Contraindications

Absolute contraindications include:

1. Extensive talar necrosis, significant bone demineralization or inadequate bone stock;
2. Inadequate skin, musculotendinous or neurovascular compromise;
3. Inflammatory or rheumatoid arthritis, infection, sepsis, and osteomyelitis; and
4. Patients that have a known sensitivity to Cobalt-Chrome and Titanium alloys typically used in prosthetic devices.

Relative contraindications include:

1. Uncooperative patient or patient incapable of following pre-operative and post-operative instructions;
2. Osteoporosis;
3. Metabolic disorders which may impair the formation or healing of bone;
4. Infections at remote sites which may spread to the implant site;
5. Rapid joint destruction or bone resection visible on roentgenogram;
6. Loss of lateral ligaments, chronic instability or deficient soft tissues and other support structures;
7. Vascular or muscular insufficiency;
8. Diffuse tibiotalar degeneration; and
9. Severe malalignment of the ankle.

Pre-operative Considerations and Assessments

1. Extent of the lesion and radiographic alignment;
2. Neurovascular status and soft tissue coverage;
3. Location of the lesion to be resurfaced and approach that will be required for exposure.

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 mapping 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 mapping points, ensuring that the selected implant will be flush or slightly

recessed just below the articular surface at margins of implant. Prior to placing implant, carefully trim articular cartilage debris around margin of implant. 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

The HemiCAP® Contoured Articular Prosthetic Talar Dome implant is intended to be fitted and installed with the HemiCAP® Contoured Articular Prosthetic Talar Dome 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 instrument set should be regularly inspected for any signs of wear or damage. Do not reuse implants. 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.