INSTRUCTIONS FOR USE

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

The HemiCAP GRS glenoid resurfacing component is intended to interface and articulate with the humeral component when both articular surfaces of the joint are affected.

Materials:
Humeral Component: Cobalt-Chromium Alloy (Co-Cr-Mo) Surface Coating: Titanium (CP Ti)
Taper Post: Titanium Alloy (Ti-6Al-4V)
Glenoid Component: Ultra High Molecular Weight Polyethylene
(UHMWPE)

Indications for Use:

For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implant intended to be used with bone cement.

Patient selection factors to be considered include:
1. Need to obtain pain relief and improve function.
2. Patient age as a potential for early-age-revision of total joint arthroplasty.
3. Patient overall well-being, including ability and willingness to follow instructions and comply with activity restrictions.

Contraindications

Absolute contraindications include:
1. Defects that are not localized.
2. Defects that are located on joint surfaces that are discontinuous.
3. Inflammatory degenerative joint disease, rheumatoid arthritis, infection, sepsis, and osteomyelitis.
4. Patients that have a known sensitivity to Cobalt-Chrome alloys or UHMWPE polymers typically used in prosthetic devices.
5. Significant bone loss or erosion of the anterior, posterior, or vault of the glenoid that would compromise implant fixation.

Relative contraindications include:
1. Uncooperative patient or patient incapable of following preoperative and postoperative instructions.
2. Metabolic disorders which may impair the formation or healing of bone.
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.

Warnings
Improper selection, placement, positioning, alignment, and fixation of the implant components may reduce the service life of the pros- thetic components. Inadequate preparation and cleaning of the implant components mating surfaces may result in improper fixa- tion 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 measurement point, ensuring that the selected implant will be flush or slightly recessed with the articular surface.

When 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 at slowest speeds possible 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.

The HemiCAP GRS glenoid resurfacing system has not been evaluated for safety and compatibility in the MR environment. The HemiCAP GRS glenoid resurfacing system has not been tested for heating or migration in the MR environment.

Precautions

HemiCAP® implants are intended to be fitted and installed with the HemiCAP 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.

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.