Description

The HemiCAP® Contoured Articular Prosthetic 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.

Materials

Articular Resurfacing Component:
Cobalt-Chromium Alloy (Co-Cr-Mo)
Surface Coating: Titanium (CP Ti)
Taper Post: Titanium Alloy (Ti-6Al-4V)

Indications

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 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 typically used in prosthetic devices.

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 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. When placing implant, carefully trim articular cartilage debris or osteophytes 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.

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.

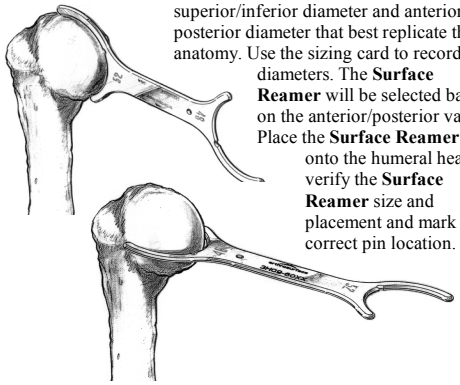
Sterility

Prosthetic components are sterilized by exposure to gamma irradiation. Do not resterilize. Do not use components if packaging is opened or damaged. Reuse of single use devices can increase the risk of patient infection and can compromise service life and other performance attributes of the device. Do not use components if beyond expiration date.

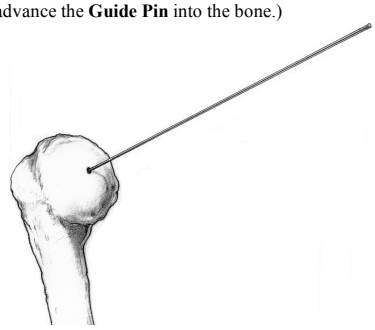
Instructions for Use

Implantation of the HemiCAP® OVO Shoulder Resurfacing Femoral Component

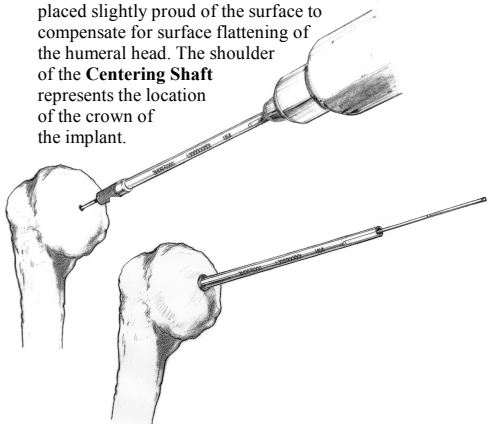
1. Place the appropriate **Mapping Templates** over the articular surface and map the surface in both superior/inferior and anterior/posterior planes. Utilize **Templates** to obtain the superior/inferior diameter and anterior/-posterior diameter that best replicate the anatomy. Use the sizing card to record the diameters. The **Surface Reamer** will be selected based on the anterior/posterior value. Place the **Surface Reamer** onto the humeral head to verify the **Surface Reamer** size and placement and mark correct pin location.



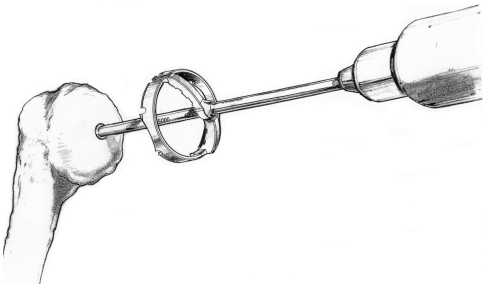
2. Locate the **Reduction Trial** so the **Guide Pin** will pass through the marked central hole. Place the 2.5 mm **Guide Pin** into a Cannulated Powered Drill and secure at the etch marking on the **Guide Pin**. Advance **Guide Pin** into bone with care to avoid penetrating through the lateral humeral cortex. (As an alternative, utilize the **Drill Guide** or **Surface Reamer** as a guide to advance the **Guide Pin** into the bone.)



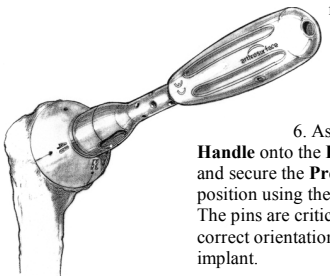
3. Using a powered drill, advance the **Centering Shaft** over the **Guide Pin** until the depth shoulder marking is at the height of the articular surface. The **Centering Shaft** can be placed slightly proud of the surface to compensate for surface flattening of the humeral head. The shoulder of the **Centering Shaft** represents the location of the crown of the implant.



4. Using the **Ovo Reamer** that matches the anterior/posterior value, advance **Ovo Reamer** over **Centering Shaft** until it reaches the stop on the **Centering Shaft**. Repeat using the **Crown Reamer**.If using the **Inlay Glenoid Component**, repeat using the **Crown Reamer**.
Be sure the **Ovo Reamer** is started before engaging the humeral head.

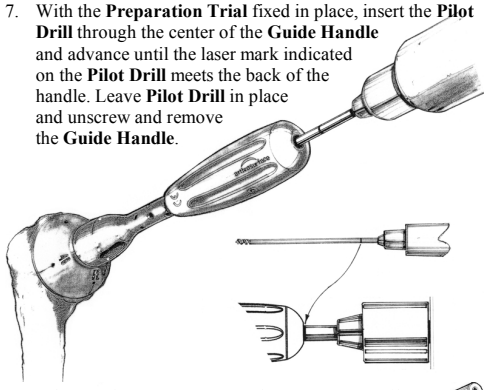


5. Place the appropriate **Reduction Trial** onto the prepared humeral surface and perform a range of motion evaluation.

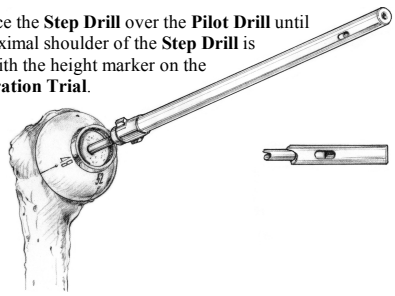


6. Assemble the **Guide Handle** onto the **Preparation Trial** and secure the **Preparation Trial** into position using the **Short Guide Pins**. The pins are critical to maintain the correct orientation of the final implant.

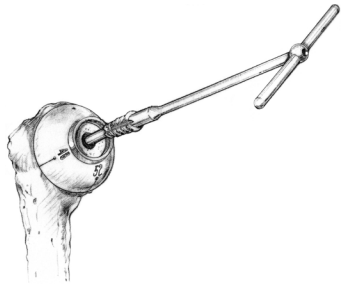
7. With the **Preparation Trial** fixed in place, insert the **Pilot Drill** through the center of the **Guide Handle** and advance until the laser mark indicated on the **Pilot Drill** meets the back of the handle. Leave **Pilot Drill** in place and unscrew and remove the **Guide Handle**.



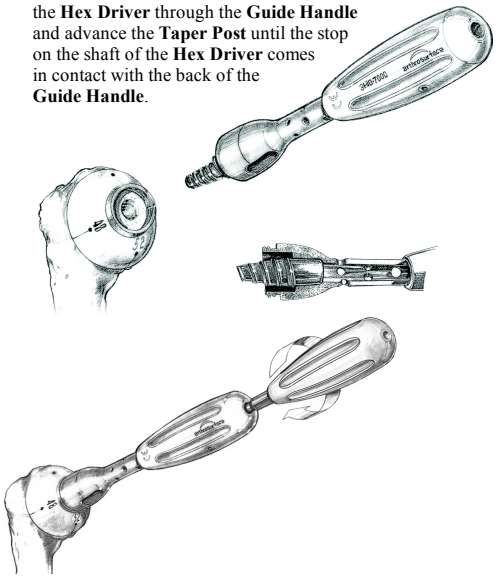
8. Advance the **Step Drill** over the **Pilot Drill** until the proximal shoulder of the **Step Drill** is even with the height marker on the **Preparation Trial**.



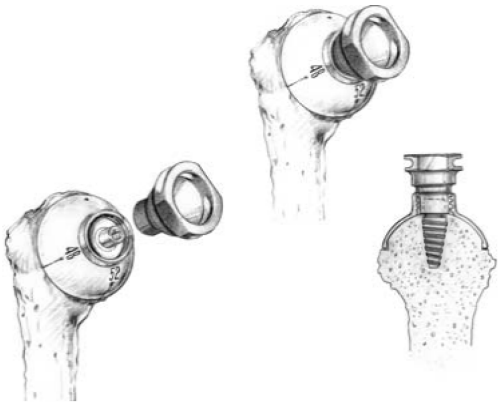
9. Advance the **Tap** over the **Pilot Drill** until the laser mark on the **Tap** is even with the height marker on the **Preparation Trial**. Remove **Tap** and remove **Pilot Drill**. Prior to inserting the **Taper Post**, thoroughly cleanse the pilot hole of any debris and then inject the cement in a retrograde fashion from the end of the hole upwards.



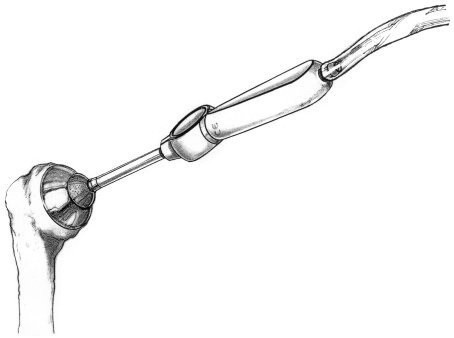
10. Load the **Taper Post** into the distal end of the **Guide Handle** and attach the **Guide Handle** to **Preparation Trial**. Place the **Hex Driver** through the **Guide Handle** and advance the **Taper Post** until the stop on the shaft of the **Hex Driver** comes in contact with the back of the **Guide Handle**.



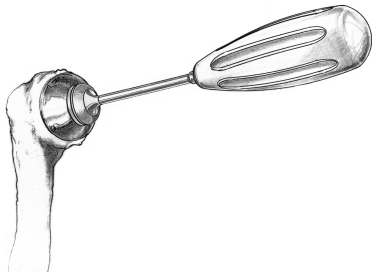
11. Use the **Alignment Gauge** to ensure that the **Taper Post** is seated at the proper depth. The **Alignment Gauge** is inserted into the **Preparation Trial.** The **Gauge** should meet resistance from the **Taper Post** and be flush with the edge of the **Preparation Trial**. If the **Gauge** is sitting proud then leave it in place and use the **Hex Driver** to rotate it until flush with the **Trial**. If the **Alignment Gauge** does not connect with the **Taper Post** then the **Taper Post** has been inserted too far into the bone. To address this situation, rotate the **Taper Post** counterclockwise and check placement with the **Alignment Gauge**.



12. Prior to placing the **Ovo Resurfacing Component** on the **Implant Holder** make sure that sufficient suction is present to hold the device onto the distal suction cup. Align the **Ovo Resurfacing Component** on the **Implant Holder** with the etch mark inline with the superior offset of the **Ovo Resurfacing Component**. Use the **Implant Holder** mark to align the implant in the proper orientation and insert onto taper of **Taper Post**.



13. Firmly mallet the **Impactor** until the **Ovo ResurfacingComponent** is completely seated onto the **Taper Post**.



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Shoulder Instructions for Use