OVOMotion™

Shoulder Arthroplasty System
Instructions for Use

Description

The OVOMotion™ Shoulder Arthroplasty System includes:

1) Humeral articular 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;

2) Glenoid resurfacing component intended to articulate with the humeral component when both articular surfaces of the shoulder joint are affected.

The enclosed humeral articular component may be used with an appropriate Arthrosurface glenoid component (sold separately).

Materials

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

Sold Separately
Glenoid Resurfacing Component:
Ultra High Molecular Weight Polyethylene (UHMWPE)

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 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 for hemiarthroplasty or in conjunction with the Arthrosurface glenoid component for total shoulder arthroplasty.

Both humeral and glenoid components of the OVOMotion™ Shoulder Arthroplasty System are intended for cemented use only.

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 located on joint surfaces that are discontinuous.
2) Inflammatory degenerative joint disease, rheumatoid arthritis, infection, sepsis, and osteomyelitis.
3) 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.

OVOMotion™ 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 OVOMotion™ shoulder implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Precautions

OVOMotion™ implants are intended to be fitted and installed with the corresponding 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. Instruments 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

Metallic prosthetic components are sterilized by exposure to gamma radiation.

Glenoid components are sterilized by gas plasma sterilization (sold separately).

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.

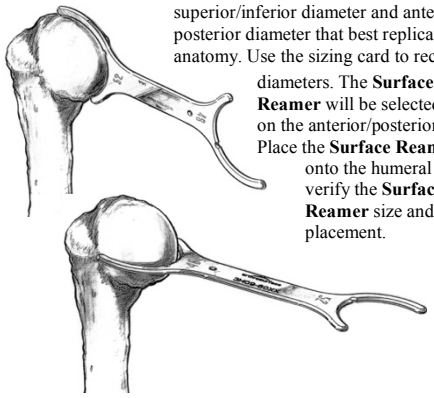
Do not use components if packaging is opened or damaged. Do not use components if beyond expiration date.

Instructions for Use

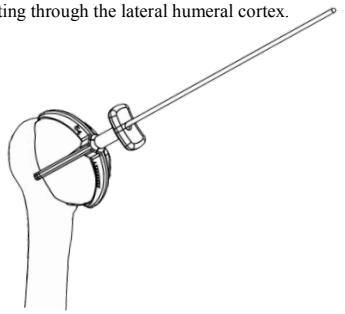
Implantation of the OVOMotion™ Shoulder Arthroplasty System Humeral Component

Implantation of the OVOMotion™ Shoulder Arthroplasty system utilizes instruments from both the OVO™ & OVOMotion™ trays.

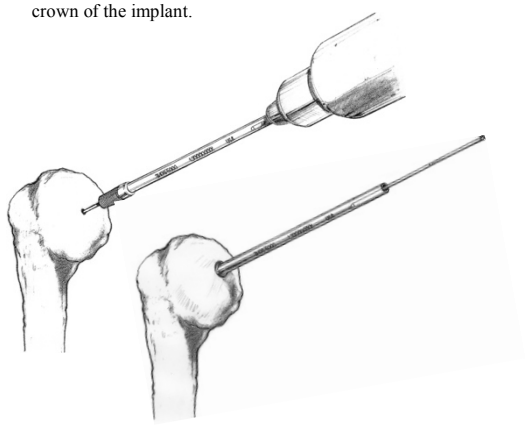
1. Place the appropriate **Mapping Templates** over the articular surface and map the surface in both superior/inferior and anterior/posterior planes. Utilize **Templates** to obtain the superior/inferior diameter and anterior/-posterior diameter that best replicate the anatomy. Use the sizing card to 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.



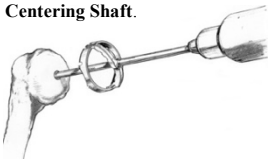
2. Utilizing the **Drill Guide** or the **Surface Reamer** as a guide, advance the 2.5mm **Guide Pin** into the bone using a Cannulated Powered Drill. Advance **Guide Pin** into bone until lateral humeral cortex is reached, with care to avoid penetrating through the lateral humeral cortex.



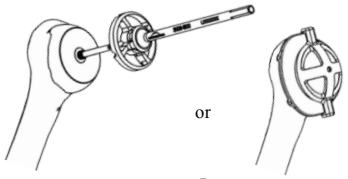
3. Using a powered drill, advance the **Centering Shaft** over the **Guide Pin** until the depth shoulder marking is at the height of the articular surface. The **Centering Shaft** can be placed slightly proud of the surface to compensate for surface flattening of the humeral head. The shoulder of the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



4. a.) Using the **Surface Reamer** that matches the anterior/posterior value, advance **Surface Reamer** over **Centering Shaft** until it reaches the stop on the **Centering Shaft**.

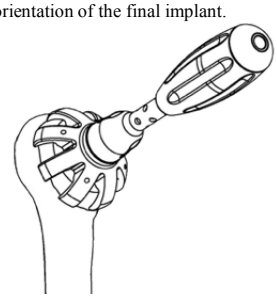


b.) Repeat using the **Access Reamer** or if preferred, utilize the **Sagittal Guide** to locate the sagittal saw cutting plane**.** Be sure all **Reamers** are started before engaging the humeral head.

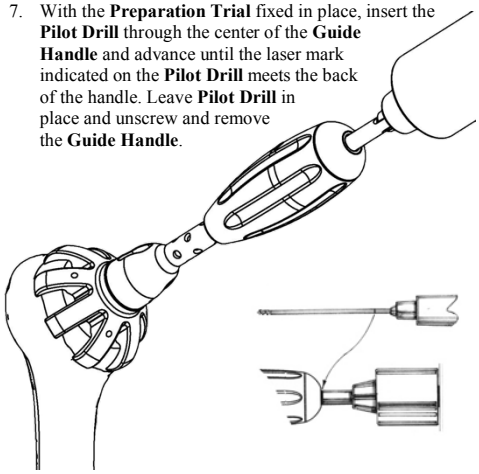


or

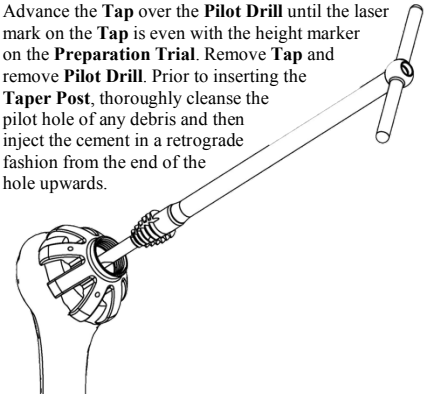
5. If using the Glenoid Resurfacing System, perform glenoid preparation per GRS Technique Guide/IFU prior to proceeding to next step. Refer to GRS Component label to select appropriate glenoid implant for use with the humeral component.
6. Assemble the **Guide Handle** onto the **Preparation Trial** 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.



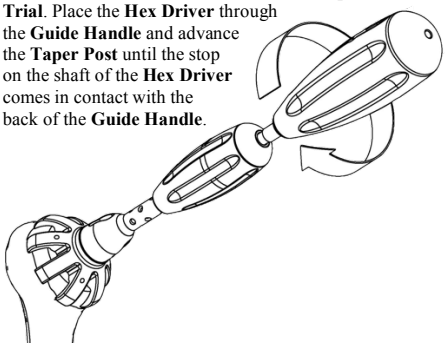
7. With the **Preparation Trial** fixed in place, insert the **Pilot Drill** through the center of the **Guide Handle** and advance until the laser mark indicated on the **Pilot Drill** meets the back of the handle. Leave **Pilot Drill** in place and unscrew and remove the **Guide Handle**.



8. Advance the **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.

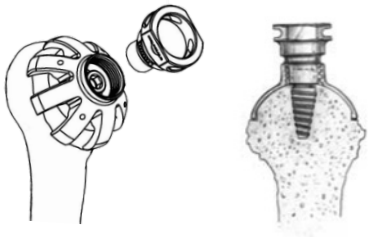


9. Load the **Taper Post** into the distal end of the **Guide Handle** and attach the **Guide Handle** to **Preparation Trial**. Place the **Hex Driver** through the **Guide Handle** and advance the **Taper Post** until the stop on the shaft of the **Hex Driver** comes in contact with the back of the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

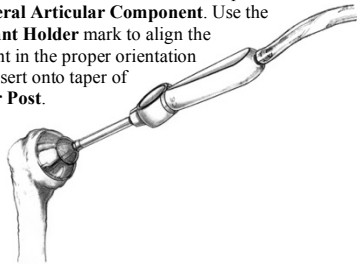


10. Use the **Alignment Gauge** to ensure that the **Taper Post** is seated at the proper depth. The **Alignment Gauge** is inserted into the **Preparation Trial.** The **Gauge** should meet resistance from the **Taper Post** and be flush with the edge of the **Preparation Trial**. If the **Gauge** is 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

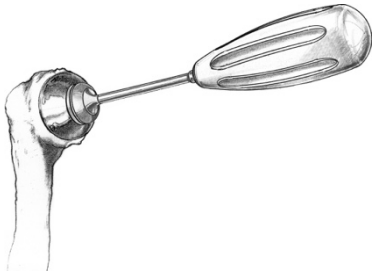
situation, rotate the **Taper Post** counterclockwise and check placement with the **Alignment Gauge**.



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



12. Firmly mallet the **Impactor** until the **Humeral Articular Component** is completely seated onto the **Taper Post**.



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