arthrosurface®

Reverse Shoulder Arthroplasty
Components

Description

The RevoMotion Reverse Total Shoulder Arthroplasty System consists of a humeral stem component, a tray component and an adapter that mate together via taper interlock to provide stable and immobile fixation of the implants. An UHMWPE Liner attaches to the tray component via a snap-fit connection and articulates against a mating Glenosphere component. A Baseplate component is utilized with a center screw component, and perimeter bone screws to provide stable and immobile fixation of the implants to the glenoid surface and a glenosphere component that mates to the baseplate component via taper interlock.

Materials

Humeral Components:

Stem:
- Titanium Alloy (Ti-6Al-4V)
- Surface Coating: Titanium (CP Ti)

Tray:
- Cobalt-Chromium Alloy (Co-Cr-Mo)
- Surface Coating: Titanium (CP Ti)

Adapter:
- Cobalt-Chromium Alloy (Co-Cr-Mo)

Liner:
- Ultra-High-Molecular Weight Polyethylene (UHMWPE)

Glenoid Components:

Baseplate:
- Titanium Alloy (Ti-6Al-4V)
- Surface Coating: Titanium (CP Ti)

Center Screw:
- Titanium Alloy (Ti-6Al-4V)

Perimeter Screws:
- Titanium Alloy (Ti-6Al-4V)

Glenosphere:
- Cobalt-Chromium Alloy (Co-Cr-Mo)

Indications

The RevoMotion Reverse Shoulder Arthroplasty System is intended for primary total shoulder replacement in a reverse shoulder configuration. The

device is indicated for a patient with painful, disabling joint disease of the shoulder resulting from degenerative arthritis or rheumatoid arthritis. The patient's joint must have gross rotator cuff deficiency, a functional deltoid muscle and be anatomically and structurally suited to receive the selected implants.

Glenoid Baseplate components are intended for cementless use with the addition of screw fixation. The Humeral Stem components are intended for both cemented and cementless use.

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.
4. Failure of previous conservative treatment options in correcting deformity and achieving pain relief.

Contraindications

Absolute contraindications include:

1. Defects that are located on joint surfaces that are discontinuous.
2. Inflammatory degenerative joint disease, 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.

MRI Safety Information

This Reverse Total Shoulder Arthroplasty System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Reverse Total Shoulder Arthroplasty System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Precautions

These implants are intended to be fitted and installed with the associated instruments. 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.

Surgeon or Physician should discuss general risks and potential complications associated with this and any surgical procedure with the patient prior to patient consent.

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.

13. Embolism.
14. Dislocation of the shoulder prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
15. Improper seating of implant component taper connections may result in component disassociation and/or dislocation.

Sterility
Implants and single-use disposable instruments are provided STERILE. Metallic implant components are sterilized by exposure to gamma irradiation. Non-metallic implant components are sterilized by gas plasma sterilization (sold separately). The single-use disposable instruments are sterilized by exposure to gamma irradiation. Do not resterilize. Do not use components if packaging is opened or damaged. Do not use components if beyond expiration date. Do not reuse implants or single-use disposable instruments. Reuse of these devices can increase the risk of patient infection and can compromise service life and other performance attributes of the device(s).

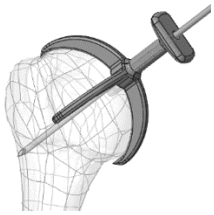
Caution
United States Federal Law restricts this device to sale by or on the order of a physician.

Instructions for Use:
Implantation of the Reverse Total Shoulder Arthroplasty System

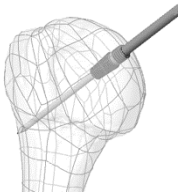
Humeral Components:

1. Place the appropriate **Drill Guide** over the articular surface and map the surface in both superior/inferior and anterior/posterior planes. Utilize the **Drill Guides** to obtain the superior/inferior diameter and anterior/posterior diameter that best represents the existing anatomy.

2. Utilizing the **Drill 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.

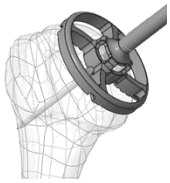


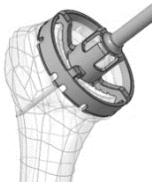
3. Using a powered drill, advance the **Centering Shaft** over the **Guide Pin** until the depth shoulder marking is at the height of the articular surface. The **Centering Shaft** can be placed slightly proud of the surface to compensate for surface flattening of the humeral head. The shoulder of the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



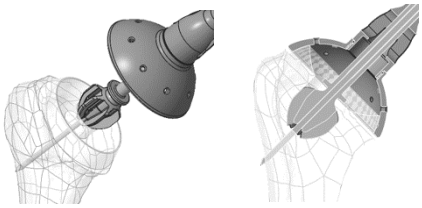
4. a.) Using the **Access Reamer**, advance over the **Centering Shaft** until it reaches the stop on the **Centering Shaft**. Be sure All Reamers are started before engaging the humeral head.

   b.) Under power, advance the **Reverse Calcar Planer** that matches the anterior/posterior value of the previously used **Drill Guide**.

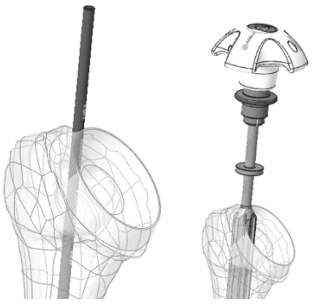




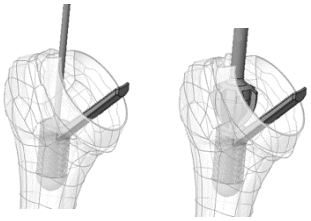
5. Remove the **Centering Shaft**, leaving the **Guide Pin** in place. Using the **Preparation Trial** to maintain alignment, advance the **Metaphyseal Broach Cutter** over the **Guide Pin** until the depth indicator is reached. **Remove 2.5mm Guide Pin.**



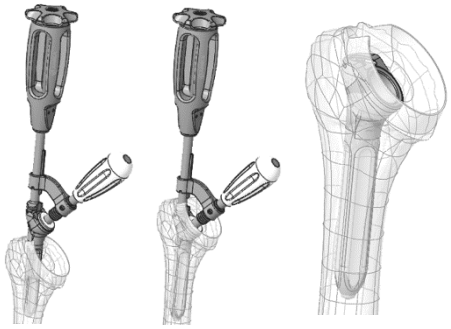
6. Using the **Pilot Drill**, axially locate and carefully develop access to the humeral canal. Manually and progressively ream with the **IM Reamers** mounted in the **IM Reamer Handle**, until friction is felt between reamer and cortical bone. Using the **IM Reamer** with power may increase the likelihood of complication.



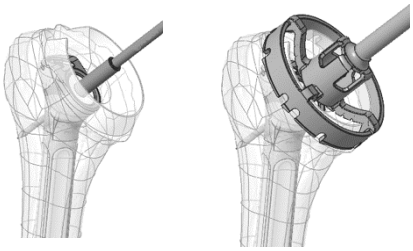
7. Using the **Canal Sizing Guide**, confirm the diameter of the distal canal. Prepare the proximal canal by advancing **Proximal Broach Cutter** over **Canal Sizing Guide** until depth stop is reached.



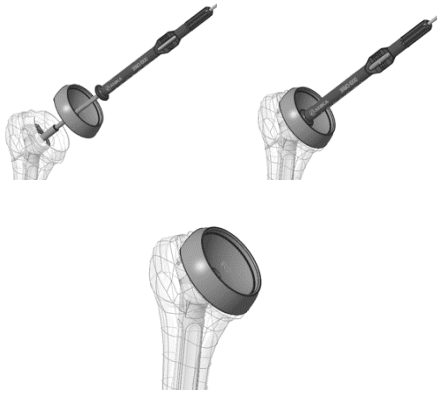
8. Select the appropriate **Stem** and attach it to the **Stem Inserter**. For press-fit applications, the stem size should match the **IM Reamer** size. For cemented applications, the stem size should be 1-2mm smaller than the **IM Reamer** size. Deliver the **Stem** into position using multiple small mallet strikes and avoiding excessive impaction to minimize likelihood of humeral fracture. Use **Stem Inserter** to control and prevent rotation of implant as it seats into prepared socket.



9. Place the **Alignment Shaft** into the **Implanted Stem.** Advance the **2.5mm Guide Pin** through the **Alignment Shaft** and **Stem** into bone until lateral humeral cortex is reached, with care to avoid penetrating through the lateral humeral cortex. Under power, advance the **Reverse Calcar Planer** that was previously used to clean up and align reamed surfaces.



10. Place the **Tray Trial** and **Adapter Ring Sizing Guide** onto the **Alignment Shaft** to determine **Adapter Ring** size**.** Remove the **2.5mm Guide Pin**, **Alignment Shaft**, **Tray Trial** and **Adapter Ring Sizing Guide** and reapply the **Tray Trial** to protect the humeral head during glenoid preparation.

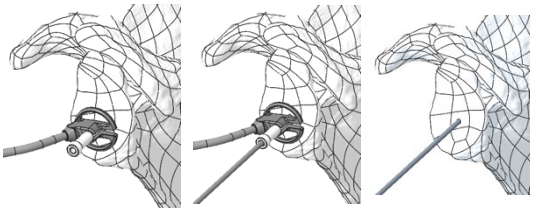


Proceed to glenoid preparation.

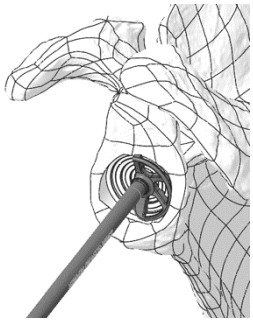
It is recommended that all glenoid components be implanted prior to performing **Humeral Tray** and **Liner** implantation.

Glenoid Components:

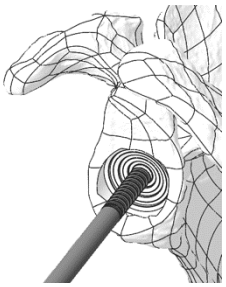
11. Use the **Glenoid Drill Guide** to locate implant position on glenoid surface. Position **Glenoid Drill Guide** central to inferior aspect of glenoid. With **Guide Sleeve** in position in the **Glenoid Drill Guide**, advance **2.5mm Guide Pin** into bone until the anterior medial margin of the scapula is reached. Confirm **2.5mm Guide Pin** placement fluoroscopically. Remove the **Guide Sleeve** and **Glenoid Drill Guide**, leaving the **2.5mm Guide Pin** in place.



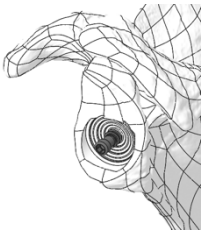
12. Introduce the **Glenoid Reamer** over the **2.5mm Guide Pin** and advance under power until the perimeter ring of the **Glenoid Reamer** is flush or just below the glenoid bone surface. Remove the **Glenoid Reamer**.



13. Introduce the **Center Screw Tap** over the **2.5mm Guide Pin** and advance until the anterior medial margin of the scapula is reached. Confirm **Center Screw Tap** position fluoroscopically. Remove the **Center Screw Tap & 2.5mm Guide Pin** and use the **Depth Gauge** to determine **Center Screw** length.

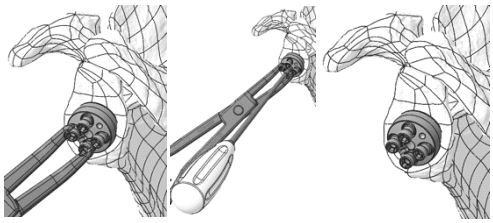


14. Select the appropriate size **Center Screw** and advance it into position using the **Center Screwdriver with Retainer**. Drive the **Center Screw** only until it has become securely fixed in the bone to facilitate connection of the **Baseplate.**

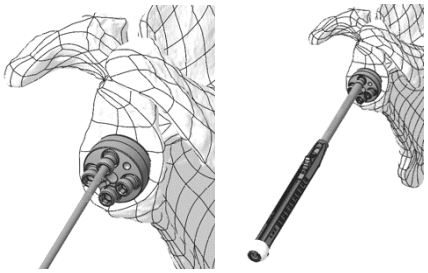


15. Using the **Glenoid Forceps**, deliver the **Baseplate** to reamed glenoid site, align and couple to the **Center Screw**. Orient the **Baseplate** for optimal **Perimeter**

Screw fixation in glenoid. Advance the **Center Screw** using the **3.5mm Hex Driver** until the **Baseplate** is fully seated in prepared glenoid reamed socket.

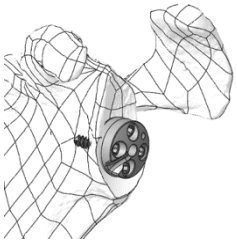


16. Drill pilot holes for **Perimeter Screws** with the **2.8mm Guide Pin** through nubbins. Determine the length of **Perimeter Screws** needed to achieve distal cortical fixation using the laser marked rings on the **2.8mm Guide Pin**. Use the **Depth Gauge** to confirm screw length. Remove nubbins only after **Depth Gauge** use.

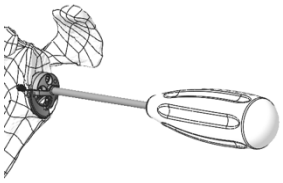


17. Deliver 4 **Perimeter Screws**, **Locking or Non-Locking,** based on surgeon preference, into position to secure the **Baseplate** to the glenoid. The head of the **Perimeter Screw** should be below the level of the surface of the Glenoid Baseplate when it is fully

seated. Confirm **Perimeter Screw** position fluoroscopically.



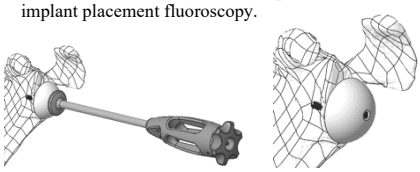
18. Manually ream around **Baseplate** with **Glenoid Cleanup Reamer** until stop to remove any bone that would interfere with **Glenosphere** insertion.



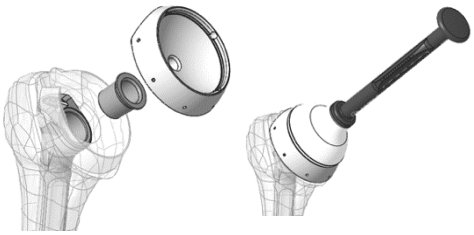
19. Based on **Humeral Tray** and **Liner** sizing, select the appropriate **Glenosphere** sizing from the table below:

Humeral Tray Size	Glenosphere Size
46x42	32mm
48x44	
50x46	36mm
52x48	
54x50	
56x52	40mm
58x54	

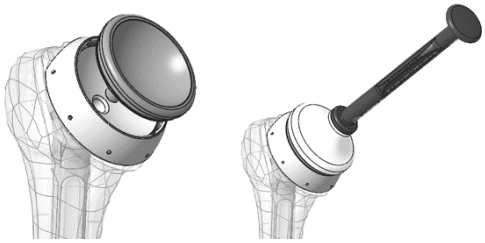
20. Using **Humeral Tray, Liner, and Glenosphere Trials and Tray Trial Retainer Pin**, perform functional, range of motion, and stability assessments. Upon completion of satisfactory assessment, use the **Glenosphere Delivery Tool** to locate **Glenosphere** onto **Baseplate**. Impact against **Glenosphere** Delivery Tool and use multiple firm mallet strikes to engage locking tapers. Confirm implant placement fluoroscopy.



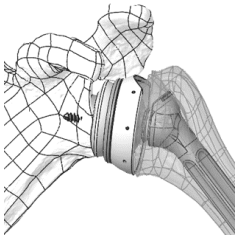
21. Place selected **Adapter Ring** onto the **Humeral Tray**. Align male taper of **Adapter Ring/Humeral Tray** with female taper in **Stem**. Position the **Tray Impactor** and use multiple firm mallet strikes to engage locking tapers. Alternatively, **the Adapter Ring, Humeral Tray, and Liner** may be preassembled prior to delivery into stem.



22. Place selected **Liner** into installed **Humeral Tray**. Position the **Liner Impactor** and use multiple firm mallet strikes to ensure complete engagement.



23. Place selected **Adapter Ring** onto the **Humeral Tray**. Reduce shoulder and perform final functional evaluation. Confirm final implant placement fluoroscopically or radiographically.



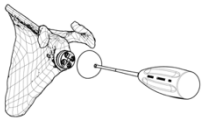
Removal Instructions

Humeral Component Removal:

Uncouple the **Articular Components** from the **Stem** at their modular connections by using osteotomes or sagittal saw. Once **Stem** is exposed, connect the **Stem Removal Tool** and utilize axial **Slap Hammer** Feature to dislodge stem from humerus.

Glenoid Component Removal:

Insert a **2.5mm Hexdriver** into removal port central to **Glenosphere**. Rotate **2.5mm Hexdriver** clockwise to uncouple **Glenosphere** from **Baseplate**. Once **Baseplate** is exposed, the **3.5mm Hexdriver** can be used for screw removal.



	Consult Instructions for Use
	Caution
	Do Not Reuse
	Sterilized using Radiation
	Sterilized using Vaporized Hydrogen Peroxide
	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician
	Do Not Use If Package Is Damaged
	Lot Number
	Expiration Date
	Manufacturer
	Catalogue Number
	Single sterile barrier system with protective packaging inside
	Double sterile barrier system
	Medical Device
	Date of Manufacture

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