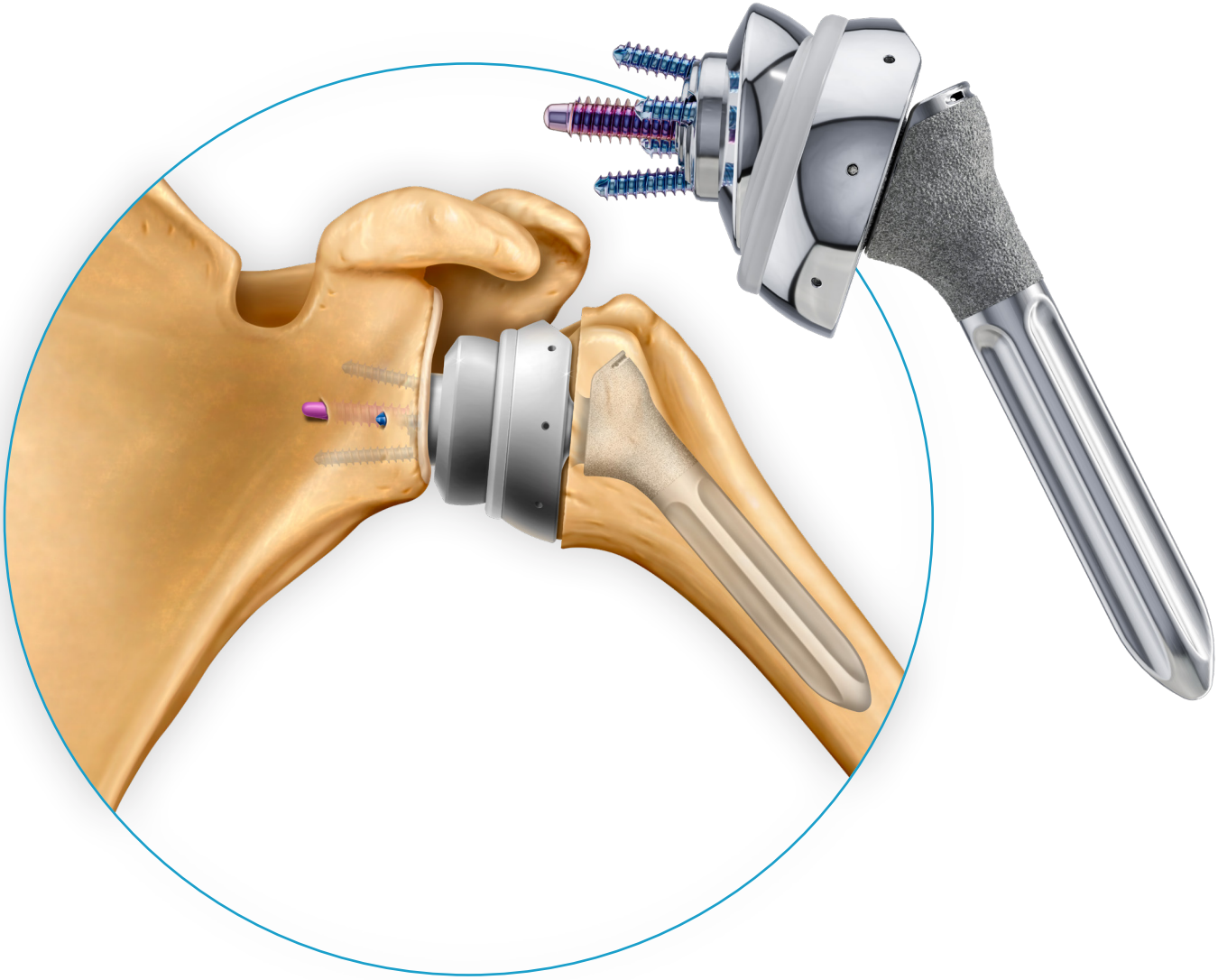
ANIKA

RevoMotion™

Reverse Shoulder Arthroplasty System

Surgical Technique Guide



Anterior Deltopectoral Approach

1. Beachchair position (tilt back to 45 degree angle).
2. Short deltopectoral incision (from coracoid tip to pectoralis major insertion).
3. This incision is utilitarian and can be converted to an extensile approach if necessary.
4. Develop skin flaps over pectoralis and deltoid.
5. Develop deltopectoral interval.
   a. The cephalic vein may go either medially or laterally.
   b. Identify coracoid tip.
   c. Identify pectoralis major insertion.
6. Release subdeltoid and subacromial adhesions. Abducting the shoulder in order to relax the deltoid facilitates this step.
7. Retract the deltoid and pectoralis major muscles. This step is facilitated by the use of a blunt, multi-pronged self-retaining retractor.
8. Identify and develop the lateral border of the conjoined tendon. This step is assisted by flexion of the shoulder, which relaxes the conjoined tendon and facilitates exposure.
9. Remove bursa from atop the subscapularis insertion.
10. Identify the anterior humeral circumflex vessels, which define the inferior aspect of the subscapularis. As needed, a 90 degree pediatric clamp is a useful tool to isolate the vessels. If necessary, a suture can be used to ligate the vessels.
11. Identify and protect axillary nerve. The axillary nerve lies deep to the anterior humeral circumflex vessels and superficial to the subscapularis muscle at the level of the glenoid.
12. Incise the subscapularis. Subscapularis management can be through a peel or osteotomy according to surgeon's preference.
13. Release the rotator interval capsule between the upper border of the subscapularis and the anterior edge of the supraspinatus.

14 Incise the glenohumeral joint capsule along the anatomic neck with electrocautery.

15 Release the glenohumeral capsule from its insertion on the anatomic neck of the humerus anteriorly and inferiorly. External rotation and flexion of the shoulder facilitates capsular release and improves humeral head exposure.

16 Release the capsule completely off the anatomic neck until adequate exposure of the humeral head defect is achieved.

17 Repair subscapularis as indicated.

18 Close utilizing accepted practices.

RevoMotion™ Reverse Shoulder System

The **RevoMotion™ Reverse Shoulder Arthroplasty System** consists of a humeral stem component, a tray component and an adapter that mate together via taper interlock to provide stable 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.

Implant 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.

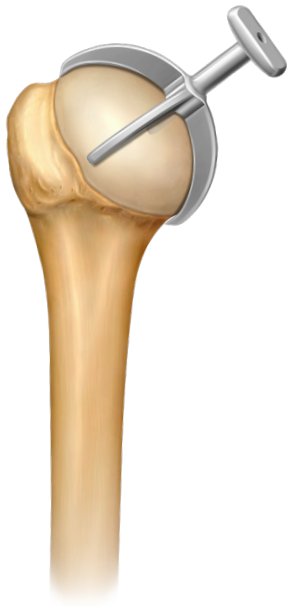
Glenoid Baseplate components are intended for cementless use with the addition of screw fixation. The Humeral Stem components are intended for both cemented and cementless use.

Surgical Technique

RevoMotion Humeral & Glenoid Components

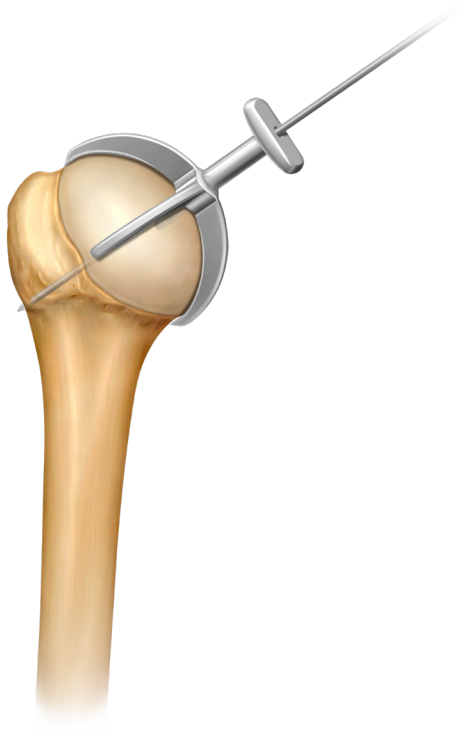
Step 1

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.



Step 2

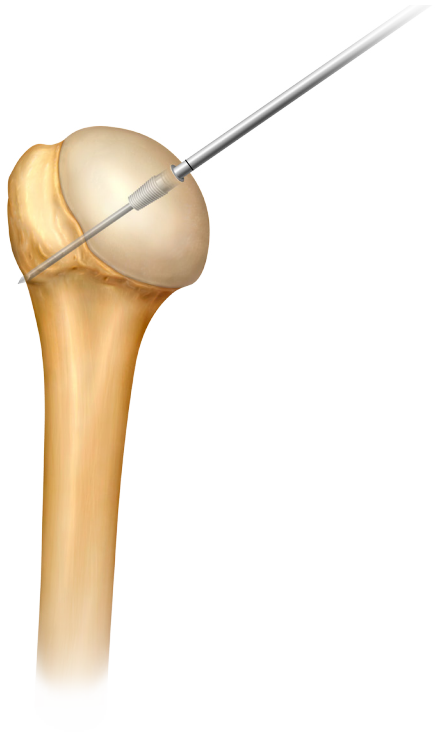
Utilizing the **Drill Guide**, advance the **2.5mm Guide Pin** into the bone using a Cannulated Powered Drill. Advance **Guide Pin** into bone penetrating just through the lateral humeral cortex taking care to avoid the axillary nerve.



Step 3

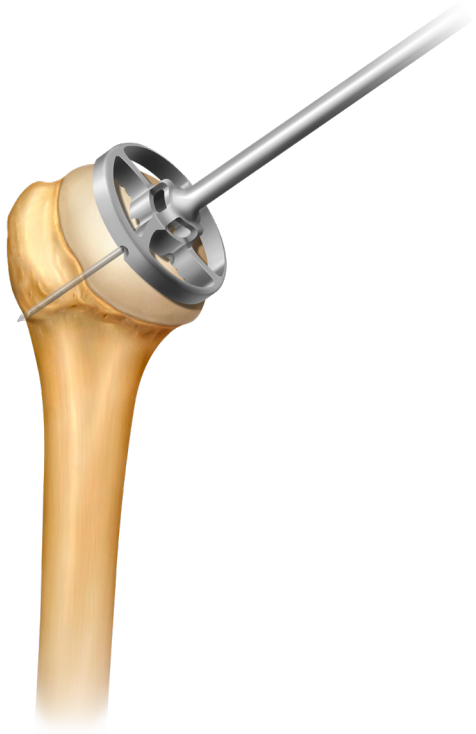
Using a powered drill, advance the **Centering Shaft** over the **Guide Pin** to the laser line.

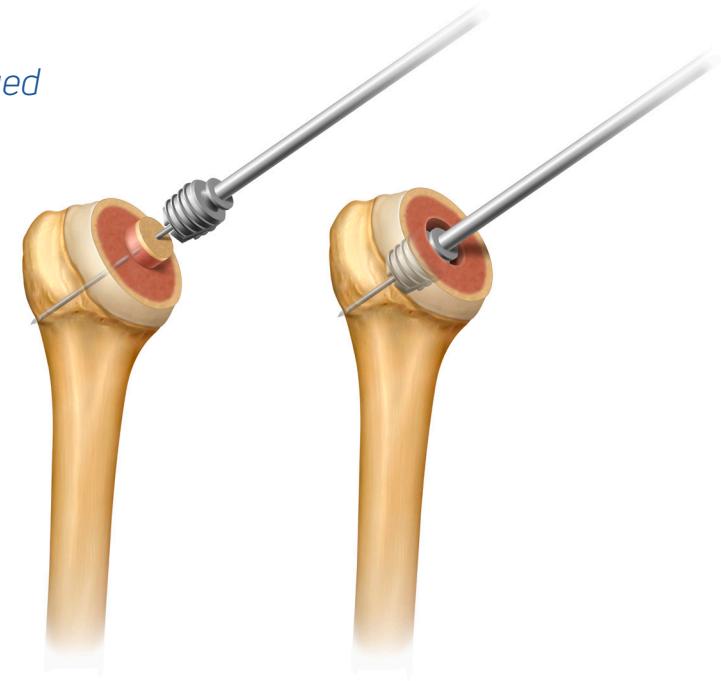
*If there is concern about glenoid exposure, the laser line on the **Centering Shaft** may be sunk further into the humeral head or a thin head cut may be made with an oscillating saw.*



Step 4

Using the **Access Reamer**, advance over the **Centering Shaft** until it reaches the stop on the **Centering Shaft**. Be sure **Reamer** is started before engaging the humeral head.



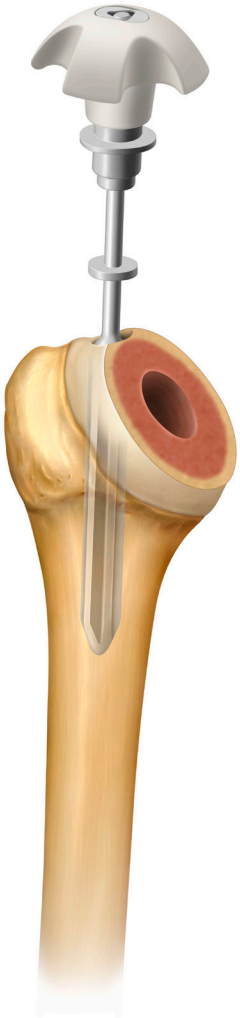


Step 5

Remove the **Centering Shaft**, leaving the **Guide Pin** in place. Advance the **Metaphyseal Broach Cutter** over the **Guide Pin** to the depth of the collar. If desired, the **Preparation Trial** may be used to help maintain alignment. Reverse the **Metaphyseal Broach Cutter** out of the humerus. Remove **2.5mm Guide Pin**.

GLENOID PREPARATION:

After Step 5, you may proceed to the glenoid preparation. Alternatively, for additional glenoid exposure, you may complete Steps 6-10 before performing the glenoid steps.

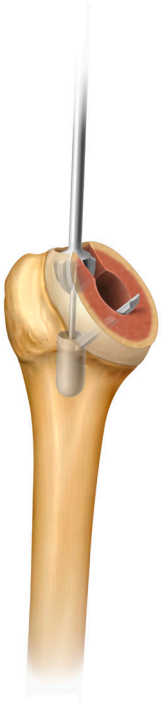


Step 6

Using the **2.5mm Guide Pin**, axially locate and carefully develop access to the humeral canal. Alternatively, a rongeur may be utilized to allow access for the reamer. Manually and progressively ream with the **IM Reamers** mounted in the **IM Reamer Handle**, until friction is felt between reamer and cortical bone. Sizing of the **Stem** should be determined according to the **IM Reamer** which achieves light cortical chatter.

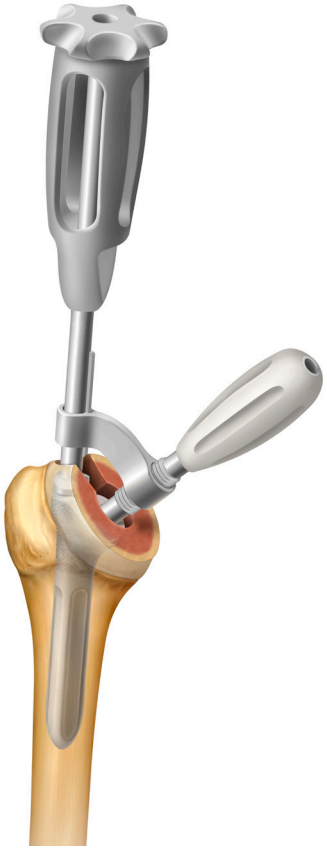
Step 7

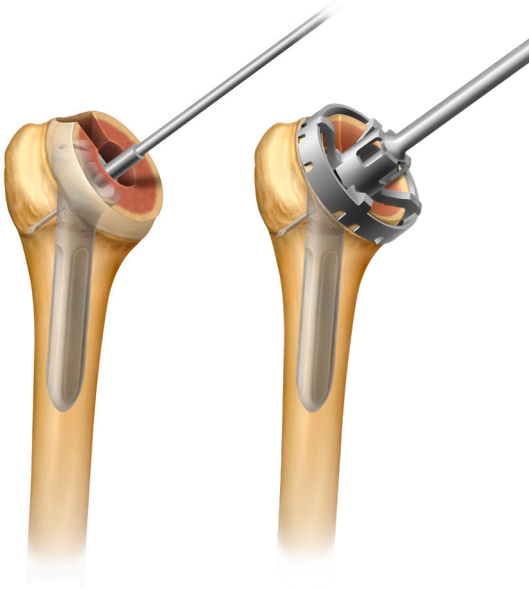
Using the **Canal Sizing Guide**, establish a firm axis for the **Proximal Broach Cutter**. A rongeur may be used to open the proximal humeral bone as needed. Prepare the proximal canal by advancing **Proximal Broach Cutter** over **Canal Sizing Guide** until depth stop is reached.



Step 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. Stem should be seated to a depth where the white bowl of the stem inserter bottoms out on the prepared inferior margin of the humeral bone. Use the **Stem Inserter** to control and prevent rotation of implant as it seats into prepared socket.



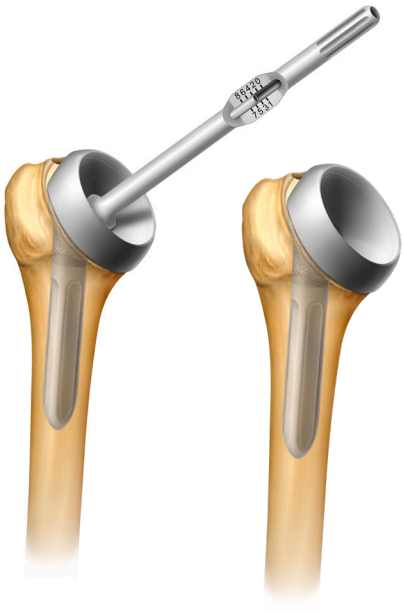


Step 9

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. Under power, advance the **Reverse Calcar Planer** for the definitive **Humeral Tray**. Sizing of the reverse calcar planer should match the A/P dimension of the drill guide utilized in Step 1 (aka the smaller number).

At this point, you're choosing the definitve humeral tray size from the Calcar Planer used.

Sizing of definitive humeral tray correlates to the glenosphere size choices. Please reference chart from Step 19.



Step 10

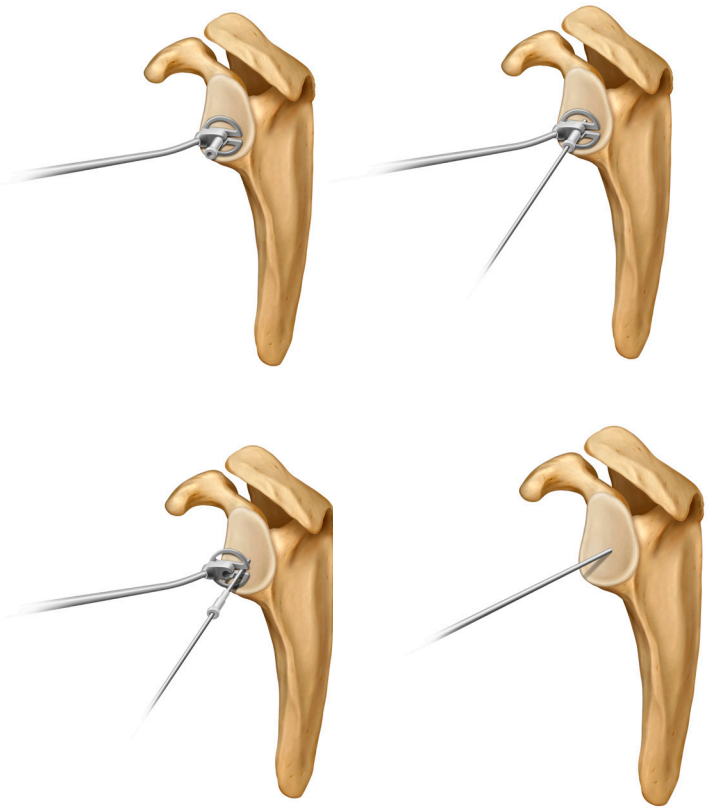
Place the **Tray Trial** and **Adapter Ring Sizing Guide** onto the **Alignment Shaft** to determine **Adapter Ring** size. Remove the **2.5mm Guide Pin**, **Alignment Shaft, Tray Trial** and **Adapter Ring Sizing Guide** and reapply the **Tray Trial** to protect the humeral head during glenoid preparation.

PROCEED TO GLENOID PREPARATION:

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

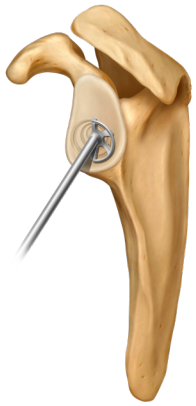
Step 11

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.



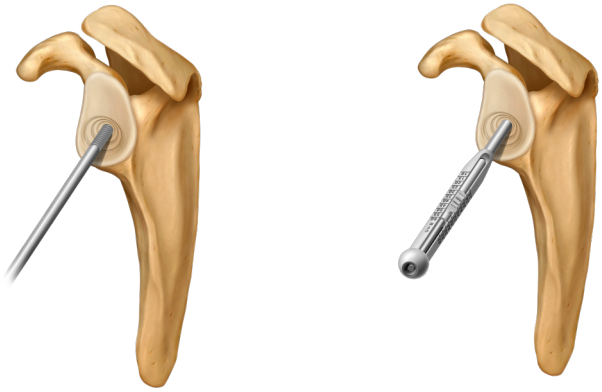
Step 12

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**. Place disposable **Depth Gauge** over **2.5mm Guide Pin** to determine center screw length.



Step 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** and **2.5mm Guide Pin** and use the **Depth Gauge** to confirm **Center Screw** length.



Step 14

Select the appropriate size **Center Screw** and advance it into position using the **3.5mm Hex Driver**. Drive the **Center Screw** only until it has become securely fixed in the bone to facilitate connection of the **Baseplate**.

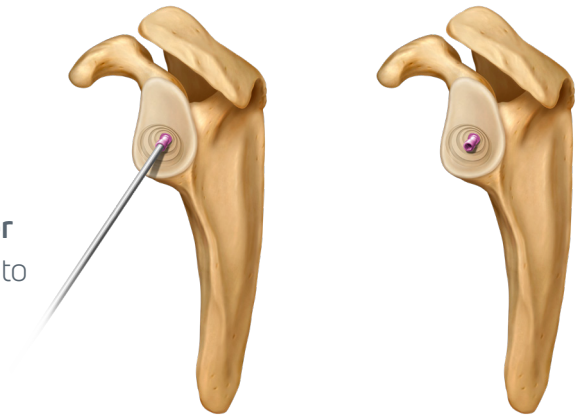
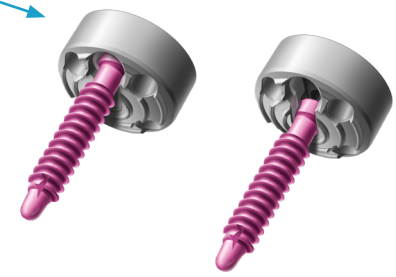
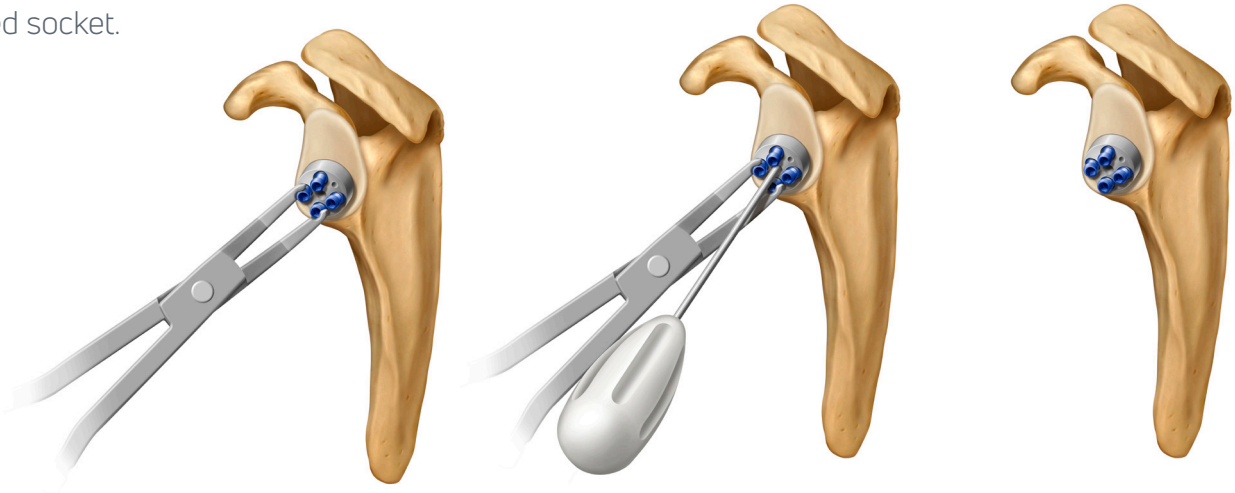


Illustration of **Baseplate** alignment and coupling to **Center Screw**.



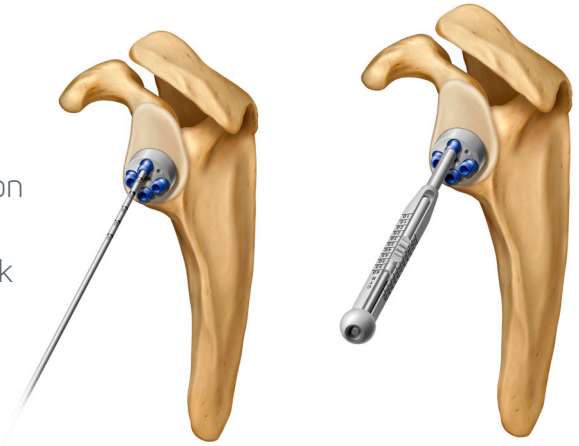
Step 15

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.



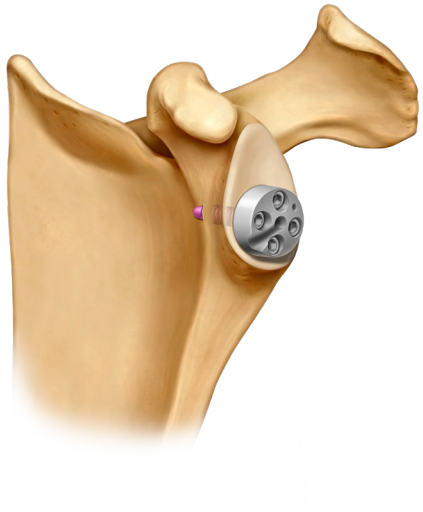
Step 16

Drill pilot holes for **Perimeter Screws** with the **2.8mm Guide Pin** through quick guides. 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 quick guides only after **Depth Gauge** use.



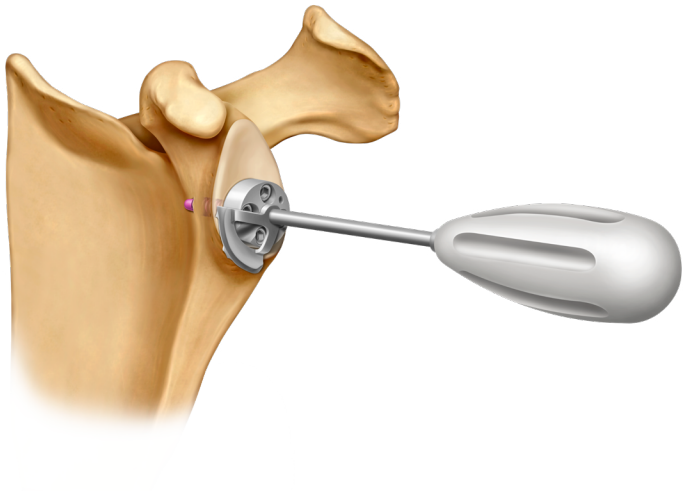
Step 17

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.



Step 18

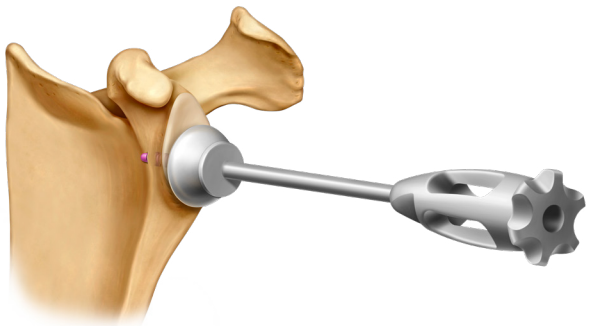
Manually ream around **Baseplate** with **Glenoid Cleanup Reamer** until stop to remove any bone that would interfere with **Glenosphere** insertion.



Step 19

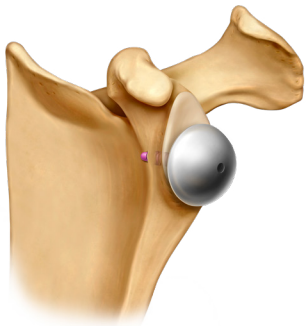
Based on **Humeral Tray** and **Liner** sizing, select the appropriate **Glenosphere** sizing from the table.

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



Step 20

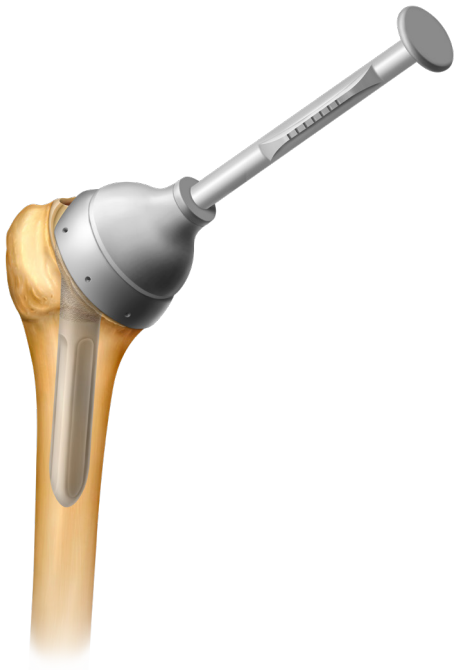
Using **Humeral Tray, Liner,** and **Glenosphere Trials** and **Tray Trial Retainer Pin**, perform functional, range of motion, and stability assessments. Upon completion of satisfactory assessment, use the **Glenosphere Delivery Tool** to locate **Glenosphere** onto **Baseplate**. Impact against **Glenosphere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



COMPLETE HUMERAL SIDE:

Step 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.



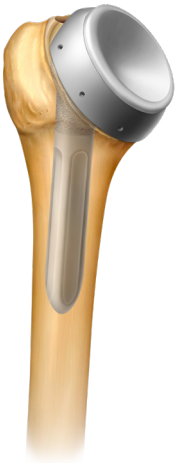
Step 22

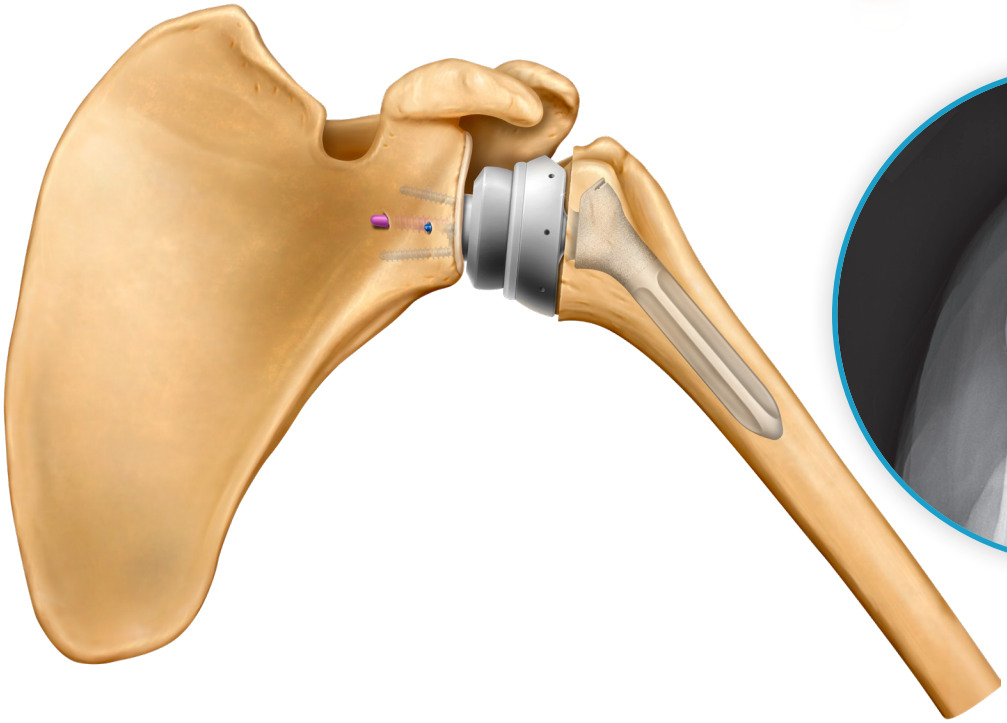
Place selected **Liner** into installed **Humeral Tray**. Position the **Liner Impactor** and use multiple firm mallet strikes to ensure complete engagement.

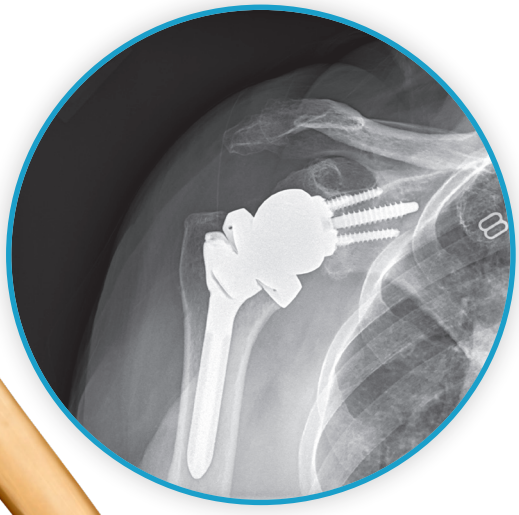
Challenge connection of the humeral tray to the stem to ensure components are firmly connected.

Step 23

Reduce shoulder and perform final functional evaluation. Confirm final implant placement fluoroscopically or radiographically.







REMOVAL INSTRUCTIONS:

Humeral Component Removal

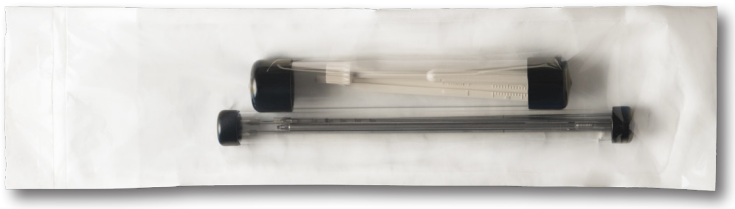
Uncouple the **Articular Components** from the **Stem** at their modular connections by using osteotomes. Once **Stem** is exposed, connect the **Stem Removal Tool** and utilize axial **Slap Hammer Feature** to dislodge **Stem** from humerus.

Glenoid Component Removal

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

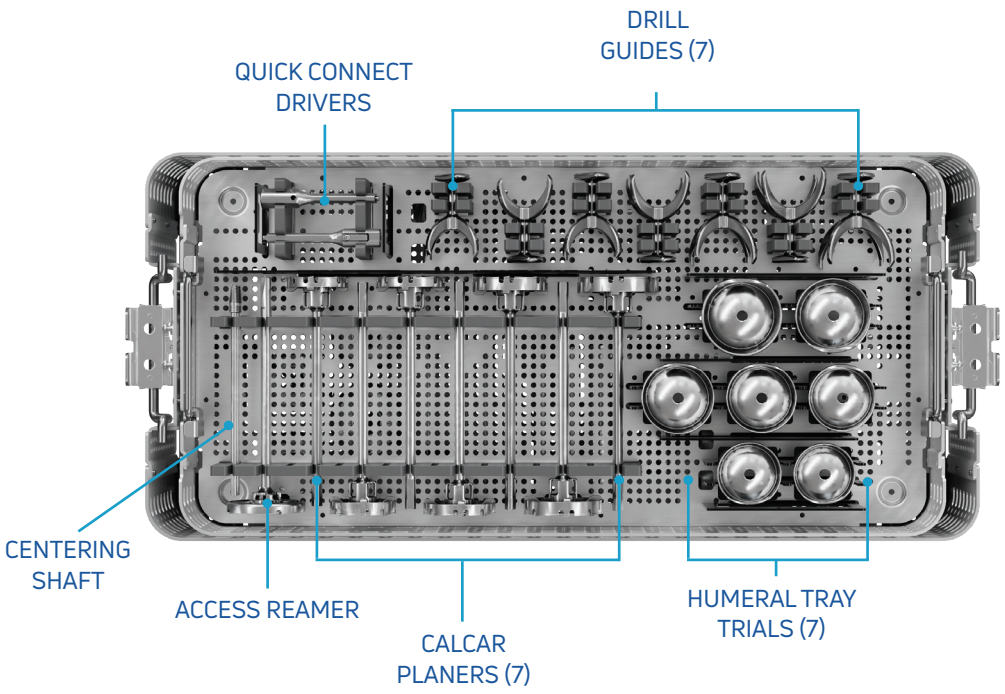
DISPOSABLE INSTRUMENTS:

Reverse Pin Kit

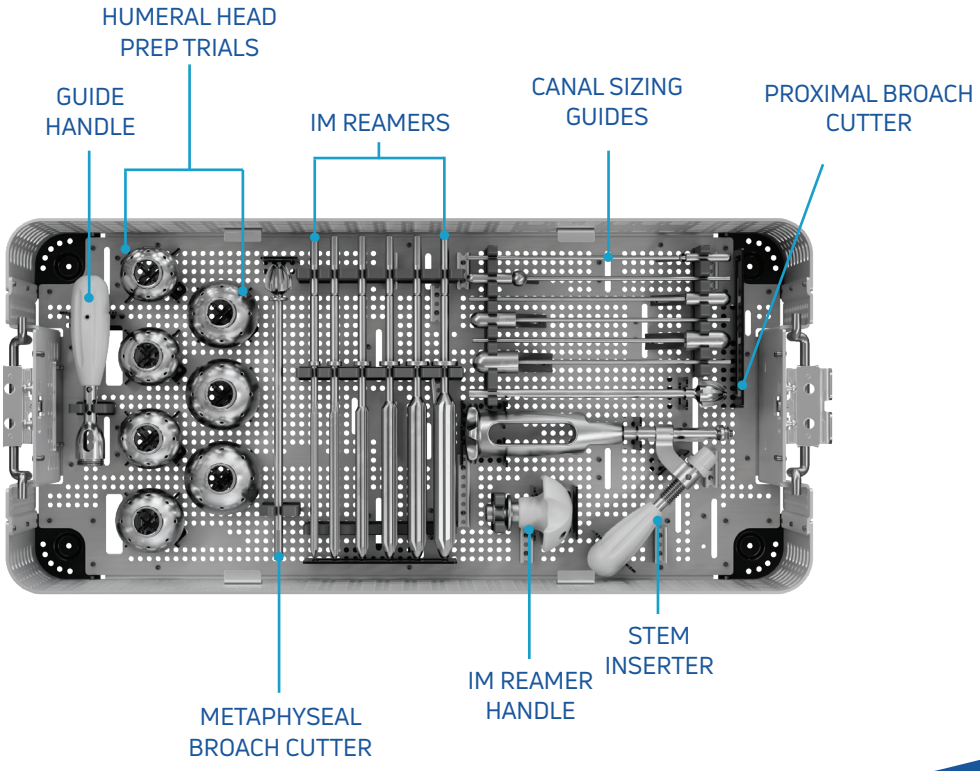


Instrumentation - Tray A

Upper Tray

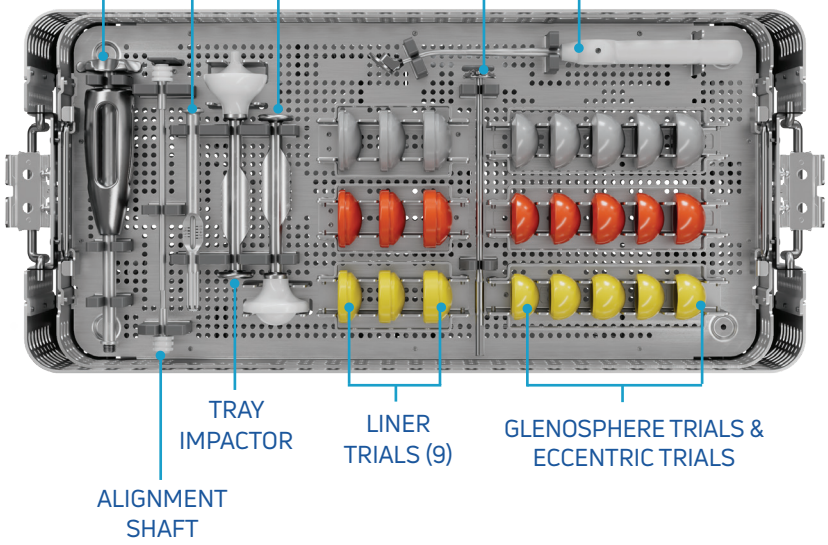


Lower Tray

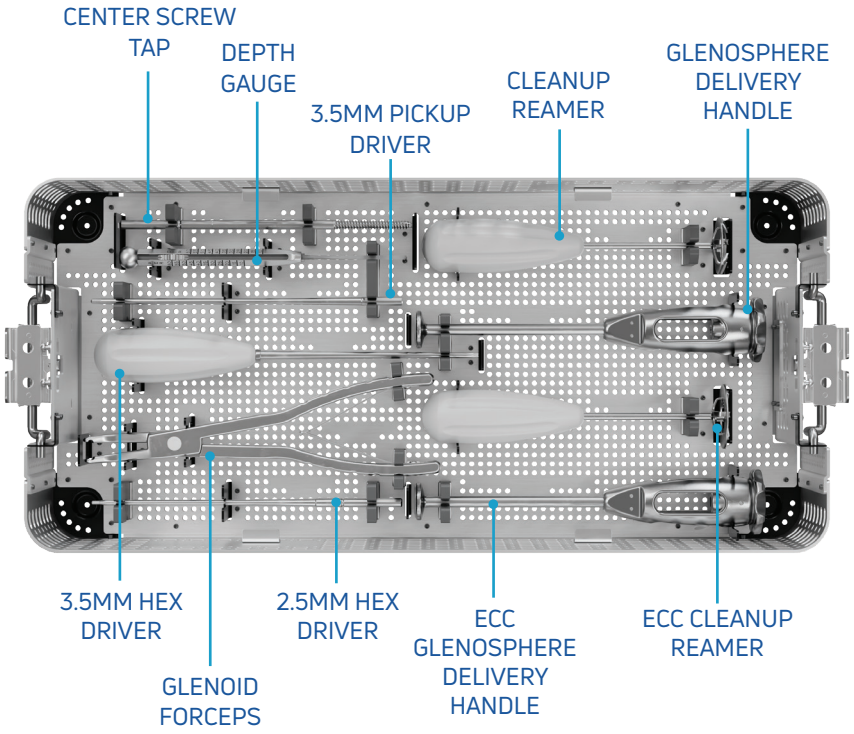


Instrumentation - Tray B

Upper Tray



Lower Tray



System Catalog

Instrument Trays	
8000-540A	Reverse Instrument Set, A
8000-540B	Reverse Instrument Set, B
8RGH-D001	Reverse Pin Kit
Humeral Liners	
8RL0-3200	Humeral Reverse Liner, 32mm, +0 Lateral Offset
8RL2-3220	Humeral Reverse Liner, 32mm, +2 Lateral Offset
8RL4-3240	Humeral Reverse Liner, 32mm, +4 Lateral Offset
8RL0-3600	Humeral Reverse Liner, 36mm, +0 Lateral Offset
8RL2-3620	Humeral Reverse Liner, 36mm, +2 Lateral Offset
8RL4-3640	Humeral Reverse Liner, 36mm, +4 Lateral Offset
8RL0-4000	Humeral Reverse Liner, 40mm, +0 Lateral Offset
8RL2-4020	Humeral Reverse Liner, 40mm, +2 Lateral Offset
8RL4-4040	Humeral Reverse Liner, 40mm, +4 Lateral Offset
Adapter Rings	
8RC1-5000	Adapter Ring, 0
8RC1-5001	Adapter Ring, 1
8RC1-5002	Adapter Ring, 2
8RC1-5003	Adapter Ring, 3
8RC1-5004	Adapter Ring, 4
8RC1-5005	Adapter Ring, 5
8RC1-5006	Adapter Ring, 6
8RC1-5007	Adapter Ring, 7
8RC1-5008	Adapter Ring, 8
Baseplate	
8RB4-2310	Glenoid Baseplate, 23mm

System Catalog

Humeral Stems	
8RM2-0600	Humeral Stem, 6mm x 72mm
8RM2-0800	Humeral Stem, 8mm x 74mm
8RM2-1000	Humeral Stem, 10mm x 77mm
8RM2-1200	Humeral Stem, 12mm x 79mm
8RM2-1400	Humeral Stem, 14mm x 81mm
8RM2-1600	Humeral Stem, 16mm x 84mm
Glenosphere (Concentric)	
8RG0-3200	Glenosphere, 32mm, +0 Lateral Offset
8RG2-3200	Glenosphere, 32mm, +2 Lateral Offset
8RG4-3200	Glenosphere, 32mm, +4 Lateral Offset
8RG0-3600	Glenosphere, 36mm, +0 Lateral Offset
8RG2-3600	Glenosphere, 36mm, +2 Lateral Offset
8RG4-3600	Glenosphere, 36mm, +4 Lateral Offset
8RG0-4000	Glenosphere, 40mm, +0 Lateral Offset
8RG2-4000	Glenosphere, 40mm, +2 Lateral Offset
8RG4-4000	Glenosphere, 40mm, +4 Lateral Offset
Glenosphere (Eccentric)	
8RG0-32EC	Eccentric Glenosphere, 32mm, +0 Lateral Offset
8RG2-32EC	Eccentric Glenosphere, 32mm, +2 Lateral Offset
8RG0-36EC	Eccentric Glenosphere, 36mm, +0 Lateral Offset
8RG2-36EC	Eccentric Glenosphere, 36mm, +2 Lateral Offset
8RG0-40EC	Eccentric Glenosphere, 40mm, +0 Lateral Offset
8RG2-40EC	Eccentric Glenosphere, 40mm, +2 Lateral Offset
Humeral Trays	
8RT0-4642	Humeral Tray, 46mm x 42mm
8RT0-4844	Humeral Tray, 48mm x 44mm
8RT0-5046	Humeral Tray, 50mm x 46mm
8RT0-5248	Humeral Tray, 52mm x 48mm
8RT0-5450	Humeral Tray, 54mm x 50mm
8RT0-5652	Humeral Tray, 56mm x 52mm
8RT0-5854	Humeral Tray, 58mm x 54mm

System Catalog

6.5mm Center Screws	
8RS2-1020	Center Screw, Ø 6.5mm x 20mm
8RS2-1025	Center Screw, Ø 6.5mm x 25mm
8RS2-1030	Center Screw, Ø 6.5mm x 30mm
8RS2-1035	Center Screw, Ø 6.5mm x 35mm
8RS2-1040	Center Screw, Ø 6.5mm x 40mm
8RS2-1045	Center Screw, Ø 6.5mm x 45mm
8.0mm Center Screws	
8RS4-1020	Center Screw, Taper, Ø 8.0mm x 20mm
8RS4-1025	Center Screw, Taper, Ø 8.0mm x 25mm
8RS4-1030	Center Screw, Taper, Ø 8.0mm x 30mm
8RS4-1035	Center Screw, Taper, Ø 8.0mm x 35mm
8RS4-1040	Center Screw, Taper, Ø 8.0mm x 40mm
8RS4-1045	Center Screw, Taper, Ø 8.0mm x 45mm
4.5mm Peripheral Locking Screws	
8RS7-2015	Locking Screw, Ø 4.5mm x 15mm
8RS7-2020	Locking Screw, Ø 4.5mm x 20mm
8RS7-2025	Locking Screw, Ø 4.5mm x 25mm
8RS7-2030	Locking Screw, Ø 4.5mm x 30mm
8RS7-2035	Locking Screw, Ø 4.5mm x 35mm
8RS7-2040	Locking Screw, Ø 4.5mm x 40mm
8RS7-2045	Locking Screw, Ø 4.5mm x 45mm
8RS7-2050	Locking Screw, Ø 4.5mm x 50mm
4.5mm Peripheral Non-Locking Screws	
8RS8-2015	Non-Locking Screw, Ø 4.5mm x 15mm
8RS8-2020	Non-Locking Screw, Ø 4.5mm x 20mm
8RS8-2025	Non-Locking Screw, Ø 4.5mm x 25mm
8RS8-2030	Non-Locking Screw, Ø 4.5mm x 30mm
8RS8-2035	Non-Locking Screw, Ø 4.5mm x 35mm
8RS8-2040	Non-Locking Screw, Ø 4.5mm x 40mm
8RS8-2045	Non-Locking Screw, Ø 4.5mm x 45mm
8RS8-2050	Non-Locking Screw, Ø 4.5mm x 50mm

Safety Information

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 component's 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 should 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.

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

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

- 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.
- Infection or allergic reaction.
- Loosening, migration or loss of fixationof implant.
- Fretting and crevice corrosion can occur at the interface between the implant components.
- Fatigue fracture of the implants as a result of bone resorption around the implant components.
- Wear and damage to the implant articulating surface.
- Wear and damage to the adjacent and opposed articular cartilage surfaces or soft tissue support structures.
- Intraoperative or postoperative bone fracture.
- Postoperative pain or incomplete resolution of preoperative symptoms.
- Periarticular calcification or ossification, with or without impediment of joint mobility.
- Incomplete range of motion due to improper selection or positioning of components.
- Transient nerve palsy.
- Embolism.
- Dislocation of the shoulder prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
- Improper seating of implant component taper connections may result in component disassociation and/or dislocation.

Reference: IFU PN: 3001-2024 REV D

Shoulder Arthroplasty Systems

Shoulder HemiCAP®

37 Different Convexities

OVO® and OVOMotion™ with Inlay Glenoid

This document is intended solely for the use of healthcare professionals. Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions and refer to the package inserts and/or labeling for additional information. Anika does not provide medical advice and recommends that surgeons be trained in the use of the product before using it. Each surgeon should exercise his or her own independent judgment and education in the diagnosis and treatment of each individual patient.

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