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Introduction
The Titan™ Reverse Shoulder System was developed in conjunction with Phillip Duke, MB.BS, FRACS, FA(ORTH)A; William Geissler, MD; Sanford Kunkel, MD; Matthew Ramsey, MD; Mark Ross, MB.BS.FRACS, FA(ORTH)A; Jean-Marc Glasson, MD; and Reza Omid, MD.

Indications
The Titan™ Reverse Shoulder System is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previous failed joint replacement with a grossly deficient rotator cuff joint. The patient’s joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device. The Titan™ Reverse Shoulder System is indicated for primary, fractures - including proximal humeral, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. The glenoid base plate is intended for cementless application with the addition of screws for fixation. The humeral stem is indicated for cemented or uncemented use and the humeral body component is intended for cementless use.

Contraindications
The following conditions are contraindications for reverse total shoulder arthroplasty:

- Patients without a functional deltoid muscle.
- Active local or systemic infection.
- Inadequate bone stock in the glenoid fossa for supporting the components.
- Poor bone quality, such as osteoporosis, where there could be considerable migration of the prosthesis and/or a chance of fracture of the humerus or glenoid.
- Pregnancy.
- Muscular, neurologic, or vascular deficiencies that compromise the affected extremity.
- Known metal allergies.

Warnings
The following conditions tend to adversely affect shoulder replacement implants;

- Excessive patient weight.
- High levels of patient activity.
- Likelihood of falls.
- Poor bone stock.
- Metabolic disorders.
- Disabilities of other joints.

Precautions
- Do not reuse this device. Reuse of this product may result in infection or other systemic complication that may affect the patient’s overall health. Additionally, the reuse of this product could adversely affect the function of the device. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage that could result in implant fracture and/or particulate and should be discarded.
- The Titan Reverse Shoulder 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 Titan Reverse Shoulder System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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Humeral Liners
Standard and Retentive Polyethylene Humeral Liners options in four thicknesses designed to optimize soft tissue tensioning.
- Standard: +0mm, +3mm, +6mm, +9mm
- Retentive: +0mm, +3mm, +6mm, +9mm

Humeral Stems
- Humeral Stems made from Titanium for press fit applications
  - 11 sizes (6-16mm) 1mm increments
- Humeral Stems made from Cobalt Chrome for cemented applications
  - 5 sizes (6-14mm) 2mm increments

Glenosphere
- 38mm diameter Glenospheres made of Cobalt Chrome
- 4 Glenosphere options designed to allow for soft tissue tensioning, improve stability, increase range of motion and minimize scapular notching
  - Concentric Glenosphere, 2mm & 5mm Lateralized
  - 4mm Eccentric Glenosphere, 2mm & 5mm Lateralized

Instrumentation
- 3 systems in one
  - Total Shoulder Arthroplasty
  - Hemiarthroplasty for Proximal Humeral Fracture
  - Reverse Total Shoulder Arthroplasty
- All with one set of instruments (4 trays)
Reverse Shoulder System-S Glenoid Instruments (Top Tray)

1. RSS Drill Depth Gauge-S
2. Glenosphere Removal Handle-S
3. Glenosphere Impactor
4. Glenosphere Inserter
5. Glenosphere Eccentric Trials-S
6. Glenosphere Concentric Trials-S
7. Peripheral Reamers-S
8. Glenoid Baseplate Impactor-S
9. Anti-Rotation Baseplate Peg
10. Baseplate Boss Drills
12. Double Drill Guide-S
13. Slotted T-15 Star Driver for Screw Locking Cap
14. TX-15 Star Driver for 4.5mm Screws
15. 2.5 Drill for 4.5mm Screws
16. Baseplate Central Drill-S
17. Cannulated Drills for 13mm Central Peg
18. Glenoid Wire Guides

Reverse Shoulder System-S Humeral Instruments (Bottom Tray)

1. Head cutting template, 142°
2. RSS Stem Depth Stops
3. IM Head Cutting Guide, 142°
4. RSS Reamer Guide Bodies
5. Definitive Stem RSS Reamer Guide Bodies
6. Reamer Guide Body Inserter/Extractor
7. Inserter/Extractor Knobs
8. Humeral Reamer
9. Reverse Humeral Body Inserter/Extractor
10. Humeral Body Trials
11. Definitive Stem Humeral Body Trials
12. Standard Poly Trial Liners
13. Retentive Poly Trial Liners
14. Humeral Liner Impactor
15. RSS Stem Impaction Stand
Surgical Technique

As the manufacturer of this device, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Caution: Federal law restricts this device to sale by or on the order of a physician or practitioner.

Step 1 • Preoperative Templating & Patient Positioning

Preoperative evaluation of the humerus using the Reverse Shoulder System X-ray Templates helps determine the size of the prosthesis and level of the humeral head resection. The goal is to remove the humeral head at the neck shaft inclination angle of 142°, and humeral version indicated by the patient’s natural version.

Reverse total shoulder arthroplasty can be performed using general anesthesia, regional anesthesia (i.e., interscalene block), or a combination. Place the patient in beach chair position. This position would have the patient supine with the hips flexed approximately 30°, knees bent approximately 30° and back elevated approximately 30°. Specialized headrests, such as the MAYFIELD® Cranial Stabilization Devices or the McConnell, arm mounts or operating tables with breakaway side panels can facilitate further access to the top and back of shoulder.

Step 2 • Exposure

A deltopectoral approach is used to provide exposure to the anterior aspect of the glenohumeral joint, the upper humeral shaft and the humeral head. The initial incision line runs from the mid-clavicle, over the top of the coracoid and extends in a straight line down the anterior aspect of the arm. It should follow the path of the cephalic vein along the interval between the deltoid and the pectoralis major. The length of the initial incision along this line can vary, depending on the exposure needed to provide adequate access and visualization of the joint, and is determined by patient body habitus.

Once the initial incision is made, expose, incise and release the fascia. Locate the cephalic vein at the deltopectoral interval. Separate the deltoid and pectoralis major muscles so that the deltoid muscle is completely free from its origin to its insertion, especially along its deep surface. Abduct and externally rotate the arm. Gently retract the cephalic vein medially or laterally along with the deltoid and pectoralis muscle.

Incise the clavipectoral fascia lateral to the conjoined tendon. If needed, release the upper 25% of the pectoralis major tendon from its insertion on the humerus, using an electrocautery cutting blade. Place a Hohmann retractor over the top of the humeral head, pulling the upper part of the deltoid posteriorly. Introduce self-retaining Weitlander and Kobel retractors underneath the conjoined tendon and underneath the middle deltoid.

Release the biceps tendon from the bicipital groove and along the rotator interval down to its glenoid attachment. Resect the long head of the biceps at the origin of the superior glenoid. Open the rotator interval along the line of the biceps to define the superior margin of the subscapularis. Isolate, clamp and ligate or coagulate the anterior humeral circumflex vessels lying across the anterior/inferior third of the subscapularis tendon. It is important to be aware of the musculocutaneous nerve, which penetrates the coracobrachialis muscle 1-2” distally from the coracoid. The nerve may not be palpable within the surgical field, but remember its proximity to the conjoined tendon. Digitally locate the axillary nerve. This is especially important as it will protect the axillary nerve, define and expose the inferior capsule.
Step 3 • Subscapularis Tendon Management

Lesser Tuberosity Osteotomy

1. Locate the insertion of the subscapularis tendon onto the lesser tuberosity. Place the saw blade or osteotome just lateral to the subscapularis insertion point and resect approximately 4-5mm of the lesser tuberosity.

Subscapularis Tenotomy

2. Alternatively, the tendon can be removed from its insertion with sharp dissection about 1cm medial to the lesser tuberosity. This will allow for tendon to tendon reattachment of the subscapularis.

Step 4 • Capsule Release & Humeral Head Dislocation

Using blunt dissection, separate the capsule from the subscapularis, inferiorly and medially. Release the rest of the anterior capsule from the subscapularis to the glenoid rim. Release the coracohumeral ligament from the base of the coracoid. Place traction sutures in the subscapularis tendon to control and mobilize it from the anterior glenoid neck. The subscapularis traction sutures will be utilized as a “shoe horn” to control the humeral head dislocation and relocation.

The ‘subscapularis tendon-capsule complex’ is dissected and elevated as one unit from the humerus at the medial aspect of the bicipital groove. If this complex is contracted, a superior 180° release of the subscapularis must be performed to mobilize the tendon to gain eventual external rotation.

Further humeral neck joint capsule release may be performed medially, anteriorly or inferiorly as needed. The posterior capsule is maintained to facilitate centralization and prevent posterior subluxation. Take care to protect the axillary nerve as it passes inferior to the subscapularis and capsule. The location of the axillary nerve should be kept in mind at all times during capsular release.

Note:
If the capsule is tented over large inferior osteophytes, it may be safer to remove the osteophytes with an osteotome, moving away from the articular surface in an inferior direction.

Once the osteophyte has been separated from the bone, it may be peeled off the capsule, and the capsular release can then be completed adjacent to the capsular attachment to the humerus. This decreases the risk of inadvertently damaging the axillary nerve when attempting to mobilize the capsule out from beneath large inferior osteophytes.
Place a large Darrach retractor underneath the upper part of the humeral head and dislocate the humerus. Put a medium size retractor on the inferior part of the humeral head and continue to bring the arm into full external rotation. The entire humeral head should now be in vision, with all capsular tissues removed from around the neck to provide excellent exposure.

Release of the anterior, inferior and posterior gleno-humeral ligaments is vital to properly and concentrically centralize the humeral head as noted above. At this point, the humeral head should freely rotate into maximum external rotation, slight abduction and significant extension allowing the head to dislocate anteriorly for preparation of the humeral head.

Proper anterior and inferior capsular releases are needed for ease of dislocation and proper humeral head preparation as well as re-establishing concentricity of the gleno-humeral joint. Releasing the inferior capsule off the humerus past 6 o’clock position is essential in gaining exposure. Bone preparation is initiated by debridement of sufficient amount of anterior inferior osteophytes to properly identify the anatomic neck.

Step 5 • Humeral Head Preparation and Resection

Assess the humeral head and remove any unwanted osteophytes to return the proximal humerus to near native anatomy.

Note:
An optional Monoblock Sounder is offered which can replace the Stem Trial / Stem Handle construct. The Monoblock Sounder offers the same functionality as the Stem Trial / Stem Handle construct. The Monoblock Sounder or Stem Trial / Stem Handle construct are used in Step 5 and Step 6 to prepare the humerus.

Freehand Head Resection Technique

Place the 142° Head Cutting Template along the anterior aspect of the arm parallel to the shaft of the humerus and mark the angle at which the humeral head will be resected with an oscillating power saw or mallet and large osteotome. There are two proximal holes on the Head Cutting Template for 3.2 mm Fixation Pin placement, if preferred. 0, 10, 20 and 30 degree threaded version holes for the Template Handle are also available to assess retroversion.

The saw or osteotome should enter the anterior surface of the humerus above the anatomic neck and exit 2-3 mm proximal to the posterior cuff attachment. Once complete, the resection will remove less humeral head than the primary total shoulder resection of 135°.

Head Resection with an Intramedullary Cutting Guide

Attach the T-Handle to the Starter Awl and create a pilot hole at the top of the humerus, in line with the long axis of the humerus just lateral to the articular surface of the head of the humerus and medial to the attachment of the rotator cuff.

Note:
This surgical step should not be performed with power reamers or drills.
Leave the Starter Awl in place and clamp the IM Head Cutting Guide, 142° around the awl shank by tightening knob 1. The Version Rod is then passed through the holes in the resection guide and is rotated into the desired retroversion. The holes denote 20°, 30°, and 40° of retroversion, in reference to the forearm axis. A zero degree version hole is provided on the IM Head Cutting Guide, 142°. If more or less retroversion is required, use the orientation holes on the resection guide collar and rotate the forearm to desired angle accordingly.

Slide the Reverse IM Head Cutting Guide, 142° against the humerus and tighten knob 2. Adjust the resection level by sliding the IM Head Cutting Guide, 142° up or down and tightening knob 3.

The Head Cutting Depth Gauge can be used to assess the cutting plane. Before the oscillating saw blade (33 x 0.8 mm) is placed along the flat surface of the IM Head Cutting Guide, 142°, drill two 3.2 mm Fixation Pins through the Reverse IM Cut Block and into the underlying bone which will stabilize the guide. Remove the Head Resection Guide-Starter Awl assembly by loosening knob 3 on the IM Head Cutting Guide, 142° and removing the Starter Awl out of the humerus. Use an oscillating saw through the capture to remove the humeral head. If additional head resection is needed, lower the blade to the next slot. This will remove 3 mm of additional bone. After removing the humeral head, extract the Fixation Pins using the Pin Puller.

Note: For larger canals, it may be preferable to start impacting up, using the Stem Trials (or the Monoblock Sounders), until a solid fit is achieved in the canal. The IM Cutting Guide, 142° can then be attached to the Stem Trial Handle (or the Monoblock Sounder handle) in the same manner as described in Step 5 (Fig. 5-3, 5-4A and 5-4B).

Step 6 • Humeral Canal Preparation

This system is a bone-preserving shoulder system. It utilizes a bone impaction technique vs. the traditional reaming systems. Bone impaction is achieved by using the stem trials and trial bodies to impact the cancellous bone in the humerus. This creates a secure envelope for the final implant.

Note:
Humeral canal preparation can be completed using either of the two methods identified below:
A. Humeral Stem Trial and Stem Trial Handle
B. Monoblock Sounder

A. Humeral Stem Trial and Stem Trial Handle
With the RSS Stem Depth Stop slid over the Stem Trial Handle, attach the Stem Trial Handle to the 6 mm Humeral Stem Trial. Place the tip of the stem trial at the most superior point on the resected humerus just behind the long head of the bicipital groove, so that it is aligned with and ready to pass directly down the intramedullary canal. Using the Stem Trial, create a pilot hole and then sequentially trial/impact the medullary canal in line with its long axis. If the 142 Head Cutting Template was used the Starter Awl can be used to create the pilot hole. Continue sequential trialing/impacting, following the path created through the intramedullary canal, increasing the Stem Trial diameter in 1 mm increments until a solid fit is achieved in the humerus.

B. Monoblock Sounder
Place the tip of the Monoblock Sounder at the most superior point on the resected humerus just behind the long head of the biceps groove, so that it is aligned with and ready to pass directly down the intramedullary canal. Using the Monoblock Sounder, create a pilot hole and then sequentially trial/impact the medullary canal in line with its long axis. If extramedullary cutting guide was used the Starter Awl can be used to create the pilot hole. Continue sequential trialing/impacting, following the path created through the intramedullary canal, increasing the Monoblock Sounder diameter in 1mm increments until a solid fit is achieved in the humerus.

Note:
The Monoblock Sounders have diagonal laser markings which correspond to the depth required for the Small, Standard, and Large Proximal Bodies.
A. Humeral Stem Trial and Stem Trial Handle
Note the horizontal laser lines and hole on the Stem Trial Handle. These correspond to the depth required for the Small, Standard, and Large Reverse Bodies. If using a Small body height, impact until the top of the sliding Depth Stop lines up with the most inferior laser etched horizontal line on the Stem Trial Handle. The Large body height will correspond with the most superior laser etched horizontal line on the Stem Trial Handle. It is recommended to size to the small body initially, thus allowing for additional up-sizing possibilities should additional soft tissue tensioning be needed.

B. Monoblock Sounder
The laser etchings on the Monoblock Sounder correspond to the body height: LRG, STD, and SML (Fig 6-2b). Impact the Monoblock Sounder until the appropriate laser etching is parallel with the osteotomy. It is recommended to size to the small body initially, thus allowing for additional up-sizing possibilities should additional soft tissue tensioning be needed.

Long Stem Option
The surgical technique for implanting a Titan Long Stem differs slightly from the standard length stems.

Attach the T-Handle to the Starter Awl and create a 6mm pilot hole within the humerus. Continue progressively reaming using cylindrical reamers of increasing diameter to 8, 10, or 12mm in either the 125mm or 165mm stem length options. The canal is reamed until cortical chatter is present and inserted to the depth of the laser mark associated with the desired height of humeral body. It is important to prepare the medullary canal over its total length. The final reamer used will correlate to the proper trial stem selected. The reamer, trial, and implant are line to line; minimizing cement to the stem flutes and within the surrounding trabecular bone. If a greater cement mantle is desired, choose an implant smaller than the reamer and trial stem used for preparation.

Step 7 • Proximal Humerus Preparation

Load the Humeral Reamer on the appropriate power tool.
Power reaming should be carried out carefully and always starting the Humeral Reamer while not in contact with bone. The T-Handle may be utilized with the Humeral Reamer if a manual reaming technique is preferred. Place the Humeral Reamer over the Humeral Reamer Guide Body and ream the proximal humerus until the Humeral Reamer is in contact with the stop point of the Humeral Reamer Guide Body.

Step 8 • Reverse Body/Stem Trial Insertion

With the selected Stem Trial from Step 6, attach it to the corresponding height of Body Trial. Attach the Reverse Body/Stem Trial construct to the Humeral Body Inserter/Extractor by tightening the Humeral Reamer Guide Body Inserter/Extractor Knob until the Reverse Body/Stem Trial is secure.

Using the Slotted Mallet, carefully drive the Reverse Body/Stem Trial into the humerus, keeping in line with the long axis. Using the Version Rod on the Humeral Body Inserter/Extractor, impact the stem in the correct retroversion, which corresponds to the version set during the humeral head osteotomy. Seat the Reverse Body/Stem Trial until flush with the osteotomy/reamed metaphyseal area. Remove the Humeral Body Inserter/Extractor.

Glenoid Preparation

Place a standard Fukuda Retractor or Toothed Glenoid Retractor posterior to the glenoid, resting on the osteotomy and Body Trial, and a Bankart retractor anterior to the shoulder. Position the humerus to allow for the best access to the glenoid. Remove any remnants of soft tissue, such as the biceps tendon and the superior and posterior labrum, to ensure the entire glenoid is visualized.

Glenosphere Options

- Concentric Glenosphere, 2mm Lateralized
- Concentric Glenosphere, 5mm Lateralized
- Eccentric Glenosphere, 2mm Lateralized
- Eccentric Glenosphere, 5mm Lateralized

Guide Pin Placement

When exposure is deemed adequate, choose either the Glenoid Wire Guide or the Glenoid Wire Guide (Concentric or Eccentric) With Lip to determine proper 2.0mm x 150mm Guide Pin positioning.
Placement of the Glenoid Wire Guide should take into consideration the 5mm eccentric Glenosphere as well as the inherent 18° inferior screw trajectory built into the baseplate design. There is an additional 21° of total convergence/divergence allowable with each superior and inferior screw. These design features should be considered to allow for a more centrally placed baseplate.

Note: The Glenoid Wire Guide without the lip references the inferior edge of the Baseplate.

Note: The Glenoid Wire Guide (Concentric or Eccentric) With Lip both reference the inferior rim of the Glenosphere.

Placing the guide too low and diverging the inferior screw could allow for inadequate inferior screw fixation.

The Glenoid Wire Guide chosen should allow for the post of the Baseplate to be positioned for adequate fixation of peripheral Baseplate screws. Positioning should also allow for enough Glenosphere overhang the inferior glenoid rim to minimize or eliminate contact between the humeral Poly Liner and the lateral scapula border during glenohumeral adduction.

Drive the Guide Pin through the Glenoid Wire Guide until adequate purchase is achieved into the glenoid. If increased retroversion is noted on preoperative imaging studies, then orient the Glenoid Wire Guide to correct this retroversion by placing the Glenoid Wire Guide in a plane that is anteverted from the native glenoid plane prior to Guide Pin insertion.

Place the Black Cannulated Center Starter Drill onto the Straight Drill Shaft and drill over the Guide Pin until drill stop reaches the glenoid.
Attach the Extra Small Glenoid Reamer to the Straight Drill Shaft and ream accordingly until proper concavity has been achieved and cartilage has been removed. The spherical radius of the Reamer matches the backside of the Baseplate and sufficient reaming will allow the Baseplate to fully seat in the glenoid. It is important to remember that over-reaming will both decrease the surface area of the glenoid face and reduce the depth of the glenoid vault. Excessive glenoid reaming should be avoided.

With the Guide Pin still in place, connect the Center Drill to the power source and drill over the Guide Pin until full contact between the drill and bone is obtained. Remove the Center Drill and the Guide Pin.

Center the Baseplate Boss Drill Guide over the glenoid with the post within the center hole. Orient the Boss Drill Guide so the superior screw hole is positioned to allow the superior screw to be directed toward the base of the coracoid process which should also allow trajectory of the inferior screw toward the scapular neck. Using the Baseplate Boss Drill, drill the inferior hole until the Baseplate Boss Drill is in full contact with the Baseplate Boss Drill Guide. After removing the drill, a RSS Anti-Rotation Baseplate Peg should be placed through the Baseplate Boss Drill Guide in the inferiorly drilled hole to maintain baseplate orientation. The superior hole may now be drilled. Remove the Drill, RSS Anti-Rotation Baseplate Peg, and Baseplate Boss Drill Guide. Using a rongeur, remove the bone remaining between the superior and inferior holes and the central screw hole to create space for the baseplate to seat.

**Step 10 • Baseplate Insertion**

With the internal rod of the Glenoid Baseplate Impactor unscrewed, place the Baseplate on the Glenoid Baseplate Impactor taking care to orient the Baseplate so the antirotation tabs are seated within the anterior/posterior screw holes of the Baseplate. With the Baseplate sitting flush against the Glenoid Baseplate Impactor, fully tighten the internal rod of the Glenoid Baseplate Impactor to secure the Baseplate.

The laser lines on the Baseplate Impactor align with the superior and inferior screw holes and should be referenced to help orient the Baseplate into desired position on the glenoid. Use the Slotted Mallet to impact the Baseplate Impactor until the backside of the Baseplate is fully seated on the glenoid. Unscrew the top of the Baseplate Impactor to back out the internal rod and remove the Baseplate Impactor.
Screw Placement

10-3 Place the central side of the Double Drill Guide within the center post hole of the Baseplate. Using the 2.5mm Drill Bit on power, drill and push until the anterior cortex of the scapula has been perforated.

10-4 The length of the screw is indicated on the drill bit by laser markings. The RSS Depth Gauge can also be used to assess optimal screw length.

Select the appropriate length screw and insert into the Baseplate center hole with the Ratcheting Screwdriver Handle and the TX-15 Star Driver for 4.5mm screws, advancing the screw just before it is fully seated.

Note:
The screws should not be tightened using a power driver.

10-5 The peripheral side of the Double Drill Guide is placed in the inferior peripheral screw hole of the Baseplate and angled inferiorly targeting the pillar of the scapula. The system is designed to allow screws to lock +/- 10.5 degrees; further angulation may prevent the locking caps from seating. Use the 2.5mm Drill Bit on power and drill trans-cortically. The length of the screw is indicated on the drill bit by laser markings. The RSS Depth Gauge can also be used to assess optimal screw length directly through the Baseplate. The appropriate 4.5mm Screw is introduced into the inferior hole and fully tightened using the TX-15 Star Driver and Ratcheting Screw Driver Handle.

10-6 The superior, anterior, and posterior screw holes are filled in a similar manner taking care to drill and place screws in the optimal bone stock and obtaining trans-cortical purchase when possible. In the event of poor screw fixation, the orientation of the drill guide should be reoriented and the hole drilled again into sufficient bone stock. The anterior and posterior screws will not sit as flush in the baseplate as the superior and inferior screws.

Once peripheral screws have been placed, retighten the central screw as additional compression may have occurred during peripheral screw placement.
Locking Screw Caps

Secure the superior and inferior screws by placing Locking Caps over the previously placed screws. The Torque Limiter, Ratcheting Screwdriver Handle and Slotted T-15 Star Driver for Screw Locking Caps are used to thread and tighten the Locking Caps directly over the superior and inferior screw heads.

Tighten the Locking Caps until they are fully seated within the Baseplate securing the 4.5mm screws in place. The Torque Limiter will click when the Cap is fully seated.

Note: The torque limiter is designed to tighten the Locking Caps to 2 Nm. The Locking Caps should not be tightened using a power driver.

Step 11 • Humeral and Glenoid Component Trialing

Varying Glenosphere Trial options are available for determining optimal Glenosphere offset and positioning through a series of trial reductions.

The Glenosphere Trials have a snap feature when fully seated in the Baseplate to assess bone and soft tissue clearance, as well as provide stability during trial reduction.

Use the associated Peripheral Reamer - Concentric or Eccentric - to manually clear any remaining bone around the periphery of the Baseplate.

Failure to perform this step can prevent the Glenosphere from seating.

Glenosphere trialing should begin with the Concentric 2mm Glenosphere Trial and progress to the more lateraled and eccentric options if additional soft tissue tensioning and/or inferior orientation on the glenoid be necessary.

The Standard Poly Trial Liner, +0 is attached to the RSS Humeral Body Trial. A trial reduction is performed and stability of the implant assessed. The shoulder should be placed through a range of motion to assess the stability of the construct and that the components do not impinge on bony structures. If tension is inadequate, additional thickness options are available, up to 9mm. If additional stability is required, Retentive Poly Liner options are available in the same thickness as the Standard Poly Liners. Additional trial reductions should be performed to confirm adequate stability if the trial components are changed.

Varying Glenosphere Trial options are available for determining optimal Glenosphere offset and positioning through a series of trial reductions.

The Glenosphere Trials have a snap feature when fully seated in the Baseplate to assess bone and soft tissue clearance, as well as provide stability during trial reduction.

Note: When possible the Reverse-Humeral Body should be positioned within the metaphyseal bone to maximize implant construct support.
Glenosphere Placement

11-5

Thread the Glenosphere Inserter into the Glenosphere and place the Glenosphere into the Morse taper of the Baseplate by lightly tapping the top of the Glenosphere Inserter with a mallet. Unthread the Glenosphere Inserter to remove from the Glenosphere.

11-6

Use the Glenosphere Impactor and Slotted Mallet to impact the Glenosphere on-axis onto the Baseplate with three to four controlled firm strikes.

To confirm taper engagement:
1. Fully thread the Glenosphere Inserter into Glenosphere
2. Pull axially
3. Twist the T-Handle of the Glenosphere Inserter clockwise

If the Glenosphere separates from the Baseplate, check for soft tissue impingement or screw head prominence. Repeat 11-4 – 11-6 to reinsert the Glenosphere.

11-4

After selection of the appropriate Glenosphere utilizing the Glenosphere Trials, clear any soft tissue around the circumference of the Baseplate using the Concentric or Eccentric Peripheral Reamer and ensure that the Baseplate surface, including the Morse taper, is clean and dry.

Note:
Peripheral Reaming and cleaning the Morse Taper are critical to promote Glenosphere engagement. Ensure that both the male and female components of the taper are dry before engaging the taper.

Step 12 • Humeral Implant Assembly

12-1

The Reverse Humeral Body Inserter/Extractor is attached to the Reverse Body Trial and the humeral stem trial construct. Using the Slotted Mallet, remove the humeral trial construct. Select the Reverse Body and Humeral Stem that corresponds to the final trials used during humeral preparation. Seat and secure the Reverse Body implant onto the RSS Stem Impaction Stand. Place the Humeral Stem implant into the Reverse Body with finger pressure. Place the Stem Impactor over the tip of the humeral stem and engage the tapers with a few mallet strikes.

Step 13 • Stem/Body Implantation

13-1

Insert the assembled Body/Stem implant into the prepared humerus using the Reverse Humeral Body Inserter/Extractor. Use the Version Rod on the Reverse Humeral Body Inserter/Extractor to set the stem in the desired version which should match the version set at the time of the humeral osteotomy and trialing. Slowly impact the implant and stop once the stem is firmly seated and the Reverse Body is flush with the level of the humeral osteotomy. Remove the Reverse Humeral Body Inserter/Extractor.

Note:
Following the definitive stem/body insertion and prior to definitive poly liner insertion, a secondary poly liner trial reduction may be performed to reaffirm proper soft tissue tensioning for stability.

13-2

Remove the Reverse Humeral Body Screw from its packaging and insert into the in-situ Reverse Body with the Driver Handle, Body Screw Torque Limiter, and 1/8 Hex Driver. Tighten the screw until the torque limiter clicks.

Note:
The torque limiter is designed to tighten the screw to 2 Nm. This surgical step should not be performed using a powered driver.
Humeral Poly Liner Insertion

Place the definitive Standard or Retentive Poly Liner in the implanted Reverse Body taking care to orient the pilot tip on the underside of the Poly Liner with the inferior/medial hole in the Reverse Body (13-3b). Using the Liner Impactor and light taps with the Slotted Mallet, fully seat the Poly Liner making sure to maintain a 90 degree angle to the osteotomy. There may be up to a 1mm gap circumferentially between the Poly Liner and the lip of the Reverse body.

Reduce the joint and perform a final assessment of joint stability and range of motion.

Step 14 • Wound Closure

Once final implant is in place, the subscapularis tendon repair can be completed with the sutures placed prior to implant seating. Tenodese the biceps tendon to the humeral shaft prior to wound closure.

Thoroughly irrigate the wound with antibiotic solution. If a regional anesthetic is not used then infiltrate the soft tissue with a local anesthetic that will last 6-8 hours. A wound drainage system is recommended to prevent formations of postoperative hematoma. The wound may be closed according to surgeon preference. Careful attention to wound closure will result in a cosmetically acceptable incision. After the dressing and shoulder immobilizer are in place, the use of a cold wrap is recommended. This pre-frozen wrap can be placed on the shoulder in the operating room and replaced with another unit every three hours. The combination of regional anesthetic or local anesthetic and the immediate cooling seems to decrease the amount of postoperative pain.

Step 15 • Fracture Procedures

Tuberosity Reconstruction

Prior to sizing and trialing the humeral components, sutures are placed in the appropriate rotator cuff tendons for use in the anatomic reconstruction of the tuberosities. Pass two horizontal sutures through the infraspinatus tendon and two horizontal sutures through the teres minor tendon just medial to their insertion on the greater tuberosity from outside to inside. These four sutures will be passed around the inferior neck of the final implant to secure the fracture.

The Reverse Body/Stem Trial should be positioned at the correct height to preserve the anatomic reconstruction of the tuberosities. If the Reverse Body Trial is too short, the prosthesis will not allow space for the anatomic reconstruction of the tuberosities. If this happens remove the Standard Reverse Body Trial and replace it with the Large Reverse Body Trial. This will increase the overall prosthesis height and allow for consolidation of the tuberosities. If the overall prosthesis is too proud with the Standard Reverse Body Trial, replace it with the Small Reverse Body Trial. If more height is desired after increasing to a Large Reverse Body Trial, increasing stem diameter will result in a higher seated prosthesis.

A slight overlap of the tuberosities on the prosthesis is desirable. Reduce the tuberosities to ensure they will fit around the prosthesis and can be attached to one another. A towel clip or reduction forceps can be utilized to hold the tuberosities around the prosthesis. Check soft tissue tensioning by performing a gentle range of motion test.

After completing the range of motion test, remove the Reverse Body/Stem Trial. Drill two suture holes, one on each side of the bicipital groove, into the humeral shaft to assist in repair of the tuberosities. Place two heavy, non-absorbable sutures through the drill holes before proceeding with prosthesis implantation.

Once the assembled Body/Stem implant is placed to the correct height, pass the four sutures previously placed in the rotator cuff around the inferior neck of the prosthesis posterior to anterior.

Select one superior and one inferior suture and tie off their corresponding tails creating a cerclage to reduce the greater tuberosity to the prosthesis. The two remaining sutures (inferior and superior) are pushed through the subscapularis tendon from inside to outside and then tied off to their corresponding tails creating a cerclage to reduce the lesser tuberosity.

The diaphyseal placed sutures are used to reduce the tuberosities in the vertical plane. Pass one suture through the subscapularis and supraspinatus tendons and tie off to its corresponding tail. The other suture is passed through the infraspinatus and supraspinatus and tied off to its corresponding tail.
Step 16 • Revision Procedures

Removing Reverse Components

Prior to performing a revision case, verify the post diameter of the baseplate used. This technique and associated instrumentation is only valid for GBP-0961-094-S (RSS GLENOID BASEPLATE-S). If a different baseplate was used, please reference the Titan™ Reverse Shoulder System Surgical Technique (LC-04-0960-0047) for the appropriate technique and instrumentation.

To remove the in situ Glenosphere, the Glenosphere Removal Handle is fully threaded into the in situ Glenosphere to release the taper lock of the Glenosphere from the Baseplate. If a central screw is in the Baseplate, the tip of the Glenosphere Removal Handle will push the two components apart with advancement. If no central screw is in the Baseplate use the slotted mallet on the Glenosphere Removal Handle to disengage the Glenosphere from the Baseplate with gentle strikes.

Note:
The Glenosphere Removal Handle will not work to remove the Glenosphere from the Baseplate without use of the slotted mallet, if the central screw was not previously placed in the Baseplate.

The Humeral Poly Liner is removed using an osteotome. The 1/8 Hex Driver is used to remove the body screw. The Body Separator is threaded into the Reverse Body and threaded until the Reverse Body is disengaged from the in-situ stem. The Humeral Body Inserter/Extractor may be attached to the Reverse Body to help remove the Reverse Body from the proximal humerus.

Converting Anatomic Shoulder to Reverse Shoulder

Removal of the humeral head and/or proximal humeral body during revision surgery can be achieved without disturbing a well-fixed distal stem.

Removing the Humeral Head
The Humeral Head can be removed using the Humeral Head Extractor. Place the two prongs of the extractor between the humeral head and the osteotomy surface so that the prongs will advance in each side of the linking component. Lift the head off the proximal humeral body taper by impacting the end of the extractor with the slotted mallet.

Removing the Proximal Humeral Body
The Humeral Body can be removed using the Body Separator and the final Implant Inserter/Extractor. Disengage the Humeral Body Screw and remove using the 1/8 Hex Driver. Unthread the inner rod from the Implant Inserter/Extractor and replace with the Body Separator. Place the Inserter/Extractor over the taper, and thread the Body Separator into the Humeral Body until resistance is felt. Grip the Inserter/Extractor firmly to control rotation of implant and continue to tighten the Body Separator to disengage the morse taper between the Humeral Body and Distal Stem. Remove the Humeral Body, which will be threaded onto the Body Separator.

Removing the Stem
The stem is designed to remain in the humeral canal. After the Humeral Body has been removed and it is determined that the stem should be removed also, the Titan Modular Shoulder system Long Stem tray or the Titan Modular Shoulder System Monoblock Sounder tray include a Slap Hammer and Stem Adaptor that can attach to the implanted stem for removal.

The 142° Head Cutting Template is used to determine desired version and removal of superior aspect of the greater tuberosity. This osteotomy will allow for easier alignment of the Humeral Reamer Guide Body and RSS Humeral Body Trials with the in-situ stem.
Postoperative Therapy Protocol

The patient is placed in a comfortable immobilizer with arm at their side and regional block analgesia as preferred. Active pendulum exercises are not encouraged in order to prevent stretch of the anterior repair. However, supine passive range of motion within 24-72 hours of surgery is of the utmost importance. The limits to the extent of passive range of motion performed should not exceed the safe zone of rotation observed at surgery after subscapularis closure.

Supervised physical therapy program is recommended after 24-48 hours. Supervised active assisted and passive range of motion mobilization is suggested for the first 72 hours. Active assisted and passive assistance is recommended for 6 weeks after which terminal stretching and active range of motion is initiated. Home pulley system is initiated at 72 hours.

The sling immobilizer may be abandoned at approximately 6 weeks to protect the subscapularis repair. Most patients are able to perform all their exercises at home in a physician supervised therapy program. Supervision of all post-operative therapy is recommended. Therapy should be individualized and based on the status of the repaired tissues and muscle strength. Most importantly, protection of the subscapularis repair and/or rotator cuff repair will dictate the amount of stretching or resistance as well as the duration of immobilization. Progressive resistance for the rotator cuff including the subscapularis is initiated at 10-12 weeks depending on the quality of rotator cuff tissue and of the repair. Guarded loading of the shoulder should be observed for the first 4-6 months post-operatively. Complete recovery from surgery generally occurs at 9-12 months.

Humeral Preparation for Reverse Body

When converting from an anatomic shoulder to reverse shoulder the specific Reamer Guide Bodies (16-8A) and RSS Humeral Body Trials that are dedicated for use with definitive stems in place must be utilized to protect the in-situ stem taper during humeral preparation. Place the Definitive Stem RSS Reamer Guide Body that correlates to the same height of humeral body that was just explanted. Use X-ray/fluoroscopy to confirm in-situ positioning of the Definitive Stem RSS Reamer Guide Body (16-8B). The reaming of the humerus is performed as per the technique described in the Proximal Humerus Preparation section. The corresponding sized Definitive Stem RSS Body Trial can now be placed in-situ on the well-fixed stem and the remainder of humeral and glenoid preparation resumed as in standard fashion.
Essential Product Information

IMPORTANT: The information presented below is also provided in the product package insert. This information was current at the time of surgical technique printing, but may have been revised after that date.

Device Description

The Titan™ Reverse Shoulder System is a semi-constrained total shoulder construct. The humeral components consist of humeral stems, varying heights of reverse bodies, and humeral poly liners. The Poly Liners are available in varying thicknesses and constraints to achieve stability of the glenohumeral joint. The variable length and proximally-filling shape are designed to accommodate the natural humeral geometry and provide stable fixation as well as proximal bone loading. The glenoid components are composed of a Baseplate secured by 4 peripheral screws, two of which can be locked, as well as a central compression screw. The Baseplate is covered with a Glenosphere which is available in varying offsets to minimize scapula notching.

Sterility

All implants have been sterilized by gamma radiation and are sterile in the unopened, undamaged package. If either the implant or the package appears damaged or has been opened, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize this product.

Adverse Events

• Potential adverse events include early or late postoperative infection, allergic reaction, intraoperative or postoperative bone fracture and/or postoperative pain. In case of arthroplasty after fracture: malunion or nonunion.
• Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
• Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, and/or excessive activity.
• Surgical intervention may be required to treat adverse effects.
• MDR Reporting Reminder: Medical device manufacturers and users are required by law and regulation to report serious injuries and death.

Surgical Procedure

A Surgical Technique brochure is available which outlines the basic procedure for device implantation and use of the specialized surgical instrumentation. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience.

Meticulous preparation of the implant site and selection of the proper size implant increase the potential for successful reconstruction. A complete set of instruments for each type of implant is available to aid bone preparation and reduce the operative time. It is suggested that the proper size implant be removed from its sterile package only after the implant site has been prepared and properly sized.

Training

Surgeons may obtain training from a qualified instructor prior to implanting the Titan™ Reverse Shoulder System to ensure thorough understanding of the implantation techniques and the instrumentation.
Instruments

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**Long Stem NOT Pictured**

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<td>4.5</td>
<td>2.5</td>
</tr>
<tr>
<td>SCW-0961-046-55</td>
<td>55</td>
<td>4.5</td>
<td>2.5</td>
</tr>
</tbody>
</table>

### Locking Screw Cap Dimensions (mm), Ti

<table>
<thead>
<tr>
<th>Locking Screw Cap Catalog Number</th>
<th>Height</th>
<th>Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>SLC-0961-045-01</td>
<td>3</td>
<td>6</td>
</tr>
</tbody>
</table>

### Baseplate Dimensions (mm), Ti

<table>
<thead>
<tr>
<th>Glenoid Baseplate Catalog Number</th>
<th>Height</th>
<th>Width</th>
<th>Thickness</th>
<th>Spherical Diameter</th>
<th>Central Peg Length</th>
<th>Central Peg Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>GBP-0961-094-S</td>
<td>27.3</td>
<td>22.8</td>
<td>2</td>
<td>15.3</td>
<td>10.4</td>
<td></td>
</tr>
</tbody>
</table>

**Long Stem NOT Pictured**

### Baseplate, Screw and Locking Screw Cap Dimensions

**Height**

**Width**

**Spherical Diameter**

**Central Peg Diameter**

**Central Peg Length**

**Major Diameter**

**Minor Diameter**

**Length**

**Height**

**Ø**