ReUnion® RFX
Reversible Fracture System
Operative technique
ReUnion RFX
Reversible Fracture System

Surgical technique
Pre-operative planning and patient positioning... 8
Delto-pectoral approach .................................... 9
Surgical approach ........................................... 10

Glenoid preparation
Glenoid preparation .......................................... 13

Humeral preparation
Humeral exposure and reaming ......................... 16

Humeral stem trialing
Expandable humeral trial selection ...................... 18
Determination of initial seating height for hemi-arthroplasty procedure ..................... 19
Attachment of insertion devices to expandable humeral trial ........................................ 21
Determination of initial seating height for reverse arthroplasty procedure .................... 23
Insertion at initial seating height ......................... 25

Humeral trial adaptors
Optional utilization of humeral trial adaptors ............................................................... 27
Humeral head trial adaptors ............................. 27
Humeral cup trial adaptors ............................... 29

Procedure for hemiarthroplasty
Humeral head trialing ....................................... 32
Trial removal and final humeral preparation ............................................................... 33
Humeral fracture stem implantation .................. 34
Final humeral head trialing and implantation ............................................................... 36

Procedure for reverse shoulder arthroplasty
Humeral cup/insert trialing ............................... 40
Expanding humeral cup trialing ......................... 41
Sliding humeral cup and humeral insert trialing ....................................................... 44
Trial removal and final humeral preparation ............................................................... 46
Humeral fracture stem implantation .................... 48
Component size selection ................................. 50
Final humeral component trialing and implantation ................................................... 51
Glenosphere placement .................................... 53

Tuberosity repair/bone grafting ......................... 55

Appendix
Height markings ............................................. 60
Instrument disassembly
Humeral head trial adaptor disassembly .......... 61
Humeral cup trial adaptor disassembly ............. 61
Disassembly of ReUnion TSA glenoid reamer/planar ................................................. 61
Disassembly of ReUnion TSA spherical glenoid reamers ......................................... 63

Implant component removal
Humeral head removal ..................................... 64
Humeral poly removal ...................................... 64
Humeral cup removal ....................................... 65
Glenosphere removal ....................................... 65
Humeral stem removal ..................................... 66
This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

Follow the instructions provided in our cleaning and sterilization guide (OR-RG-1). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling. See package insert (Instructions for Use) V15203 for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient when necessary.

This document is intended to be used by healthcare professionals only.
Description and indications

Description

The Reversible Fracture Shoulder Prosthesis consists of a humeral fracture stem component. Depending on the procedure, the humeral stem component may be used in conjunction with TSA or RSA humeral and glenoid components for conventional total shoulder arthroplasty or reverse shoulder arthroplasty. It may also be used in conjunction with TSA humeral components to articulate directly with the anatomic glenoid in a hemi-shoulder application. The components are intended for implantation within the humeral and glenoid fossa preparations in cemented or cementless applications dependent upon device design (consult component package labeling for application restrictions).

Humeral Components: The Reversible fracture humeral component is available in a modular design. The selection of the appropriate TSA or RSA humeral component is dependent upon the type of arthroplasty intended, soft tissue conditions, bone geometry and the type of fixation. The modular humeral design consists of both humeral stem and interchangeable humeral head and humeral cup components.

Indications

The ReUnion RFX System includes a Reversible Fracture Stem (RFX Stem) that can utilize either the ReUnion Total Shoulder Arthroplasty (TSA) or ReUnion Reverse Shoulder Arthroplasty (RSA) humeral and glenoid components and is indicated for use as a hemi, total or reverse shoulder replacement. The ReUnion RFX stem is intended for cemented use only.

When used with ReUnion TSA Humeral and Glenoid Components

The ReUnion RFX System, when used with ReUnion TSA Humeral and Glenoid components, is indicated for use as a Hemi or Total Shoulder Replacement:

- Aseptic necrosis of the humeral head
- Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis.
- Proximal humeral fractures and/or dislocation.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.

In the case of revision, when ReUnion RFX humeral stems are well fixed, the system is indicated for conversion to a total shoulder arthroplasty. In conjunction with ReUnion TSA humeral and glenoid components, if the natural glenoid provides sufficient bone stock, ReUnion RFX humeral stems can be converted from a hemiarthroplasty to a total shoulder arthroplasty, as well as revised from an existing total shoulder arthroplasty to a secondary total shoulder arthroplasty. It is also indicated for conversion to a hemiarthroplasty. In conjunction with ReUnion TSA humeral components, ReUnion RFX humeral stems can be converted from a total or reverse shoulder arthroplasty to a hemiarthroplasty, as well as revised from an existing hemiarthroplasty to a secondary hemiarthroplasty, in treatment of previously failed shoulder arthroplasty cases where revision to a reverse shoulder arthroplasty is inappropriate.

The glenoid components are intended for cemented use only.

When used with ReUnion RSA Humeral and Glenoid Components

The ReUnion RFX System, when used with ReUnion RSA humeral and glenoid components, is intended for primary, fracture, or revision total shoulder replacement. The patient’s joint must have gross rotator cuff deficiency, a functional deltoid muscle, and be anatomically and structurally suited to receive the implant(s).
• Painful, disabling joint disease of the shoulder resulting from degenerative arthritis or rheumatoid arthritis;
• Proximal humeral fractures
• Revisions of previously failed shoulder joint replacements

In the case of revision, when ReUnion RFX humeral stems are well fixed, the system is indicated for conversion to a reverse shoulder arthroplasty. In conjunction with ReUnion RSA humeral and glenoid components, ReUnion RFX humeral stems can be converted from a hemi or total shoulder arthroplasty to a reverse shoulder arthroplasty, as well as revised from an existing reverse shoulder arthroplasty to a secondary reverse shoulder arthroplasty, in treatment of a grossly deficient rotator cuff with severe arthropathy or previously failed joint replacement with a grossly deficient rotator cuff. The patient must have a functional deltoid muscle, and be anatomically and structurally suited to receive the implant(s).

Glenoid Baseplate components are intended for cementless use with the addition of screw fixation.

**Patient counseling**

Surgeons should discuss all relevant contraindications, adverse effects and the need for post-implantation protection with their patients.

**Contraindications**

• Any active or suspected latent infection in or about the shoulder joint.
• Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
• Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
• Skeletal immaturity.
• Patients whose anticipated activities would impose high stresses on the prosthesis and its fixation.
• Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of fixation of the device or to failure of the device itself.

Additional Total and Hemi Shoulder Contraindications:

• Absent, irreparable or non-functioning rotator cuff and other essential muscles.

**MRI safety information**

Non-clinical testing has demonstrated the ReUnion Reversible Fracture (RFX) stem in a ReUnion Total Shoulder Arthroplasty (TSA) and ReUnion Reverse Shoulder Arthroplasty (RSA) construct is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

• Static magnetic field of 1.5 or 3.0 T
• Maximum spatial field gradient of 3,500 gauss/cm (35 T/m)
• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the ReUnion RFX stem in a ReUnion TSA or ReUnion RSA construct is expected to produce a maximum temperature rise of less than 4.8°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 124 mm from the ReUnion RFX stem when imaged with a gradient echo pulse sequence and a 3T MRI system.

**Warnings**

See package insert (Instructions for Use) V15203 for a complete list of warnings.
Surgical technique
Surgical technique

Pre-operative planning and patient positioning

There is a wide variation of both glenoid and humeral pathoanatomy. Accurate radiographs, CT scans, and MRI scans allow for pre-operative assessment of bone stock available to support implants, as well as the proper positioning. Templates are available for sizing.

For standard shoulder arthroplasty, the patient is positioned in a semi-fowler’s (beach chair) position. The torso is inclined 30° to 45° and the legs are padded and bent. The patient’s shoulder is brought to the edge of the table to allow full extension of the arm, thus affording exposure of the humeral shaft. A bolster may be placed beneath the involved scapula to improve exposure of the articular surface.

The head is stabilized to avoid movement during the procedure. It is recommended that anesthesia be brought to the contralateral side of the table to allow full access to the surgical field.

Tech tip: Consideration may be given to a commercially available beach chair positioner.

In most cases, the humeral component should be set in approximately 30° of retroversion. There are a number of techniques that may be employed to achieve this retroversion. By flexing the elbow 90° and aligning the forearm with a version rod set at 30°, the resulting component position will be placed in 30° of retroversion.
Surgical technique

**Delto-pectoral approach**

For most cases, an extended delto-pectoral incision will be adequate to allow exposure to all involved structures. This begins 3-4cm medial to the acromioclavicular joint coursing distally over the coracoid process and along the delto-pectoral interval. You will note that the cephalic vein is medial to the coracoid.

The incision is then taken down through subcutaneous tissue to the delto-pectoral interval. The cephalic vein is identified and usually taken laterally with the deltoid to preserve the lateral perforators.

A self-retaining or Richardson type retractor may be placed beneath the pectoralis medially and the deltoid laterally. The conjoined tendons, as they originate from the coracoid process, are identified and the interval deep to the tendons and superficial to the subscapularis is carefully developed by finger dissection. The medial retractor can be repositioned in this interval, respecting the musculocutaneous nerve and other neurovascular structures medially.
Surgical technique

A blunt retractor is then passed superiorly beneath the coracoacromial ligament and acromion and superficial to the rotator cuff tendons. This allows additional exposure of the rotator interval and the anterior capsule.

Surgical approach

Identify the biceps tendon/bicipital groove and its course as it can aid in identifying orientations of the lesser and greater tuberosities.

The lesser tuberosity is medial to the biceps tendon and the greater tuberosity is superior, lateral, and posterior to biceps tendon.

Palpate the axillary nerve on anterior/inferior aspect of subscapularis.
Surgical technique

Mobilize and secure the tuberosities with sutures. An osteotome may be used to help mobilize the tuberosities. The suture sequence is simple (red), mattress (green) and simple (blue) from superior to inferior on each tuberosity. Retract the lesser tuberosity medially and greater tuberosity laterally.

Tech tip:
Ensure that all sutures are placed through each tuberosity at the bone-tendon junction.

Remove the fractured humeral head and place it on the back table. It will be used later for humeral head measurement and/or as a source of cancellous bone graft if needed.

Remove the long head of the biceps and tenodese it to distal soft tissue.
Glenoid preparation
Glenoid preparation

Based on indication, hemi, total or reverse shoulder arthroplasty may be selected. Glenoid preparation should be done prior to proceeding with humeral preparation.

For reverse shoulder arthroplasty (RSA) procedure, please refer to the “Glenoid Preparation” section of the ReUnion RSA Operative Technique.

For total shoulder arthroplasty (TSA) procedure, please refer to the “Standard glenoid preparation” section or the “Cannulated glenoid preparation” section of the ReUnion TSA Operative Technique. After insertion of glenoid component, follow instructions for hemi-arthroplasty.

For hemi-arthroplasty procedure, proceed directly to the “humeral preparation section”
Humeral preparation
Humeral preparation

**Humeral exposure and reaming**

Assemble the 6mm starter awl and the ratcheting T-handle.

Place retractors beneath the rotator cuff tissue superiorly and medially to provide adequate exposure of the canal for reaming. A Darrach retractor along the posterior humerus can lever against the coracoid, exposing the entire humeral metaphysis. Introduce the 6mm starter awl into the IM canal to begin reaming.

Reaming should be performed manually using the quick release ratcheting T-handle and be progressive in size (i.e. 7mm, 8mm, 9mm, etc) until friction is felt as the reamer contacts cortical bone.

**Tip:**
**Ensure that the reaming forces are applied axially and do not damage the bone.**

When cortical contact is achieved, remove the cylindrical reamer with the help of the T-handle and note the final reamer size.
Humeral preparation

When utilizing the standard length ReUnion RFX humeral stem implant, the fluted cylindrical humeral reamers should be inserted to the first line above the cutting teeth [blue arrow].

If a long stem prosthesis is to be utilized, reaming depth is to the second line positioned near the top of the reamer shaft [red arrow].

**Note:**
*Fluted cylindrical reamer depth markers are based of the top of an intact humeral head. This should be accounted for when inserting reamers.*

**WARNING**
*No impaction should be done on the underside of the ratcheting T-handle for extraction or removal of the cylindrical reamer.*
Humeral stem trialing

**Expandable humeral trial selection**
Select the expandable humeral trial size that is 2mm smaller than the last reamer used during IM canal reaming. [see table below]

**For example:** if the last reamer used was 12mm, select a size 10 expandable humeral trial. The diameter of the trial will be 12 mm, accounting for 2mm of cement mantle around a 10mm stem diameter.

**Note:**
During expansion, if the selected expandable humeral trial does not lock into the humeral canal, consider selecting an expandable humeral trial that is only 1 size smaller than the last reamer used. This will result in a reduced cement mantle and must be considered to determine if adequate fixation will be achieved.

![Image of humeral stem trialing](image)

<table>
<thead>
<tr>
<th>IM canal</th>
<th>Expandable humeral trial</th>
<th>Humeral stem implant</th>
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</thead>
<tbody>
<tr>
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<td>Trial size</td>
<td>Distal diameter</td>
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For reverse arthroplasty procedure, continue to “Attachment of insertion devices to expandable humeral trial” section
Humeral stem trialing

Determination of initial seating height for hemiarthroplasty procedure

Obtain the native humeral head previously retrieved from the fracture site.

To determine humeral head diameter, place the native humeral head into the semicircular cutout of the humeral head sizing template that most closely reflects the head’s radius of curvature. Be sure to measure in the medial-lateral direction as well as anterior-posterior as they may vary.

To determine humeral head thickness, identify the hash mark that most closely approximates the height of the humeral head within the semicircular cutout of the humeral head sizing template. [Figure 18 inset]

Note:
The measured head size serves as an initial starting point. The final humeral head size will be determined upon final ROM and translation trialing.

Assemble the selected humeral head trial to the expandable humeral trial and insert the construct into the canal by hand.

Note:
The expandable humeral trial is not yet expanded at this time.
Reduce the humeral head trial into the glenoid. With the arm in the neutral position, apply slight longitudinal traction on the arm. Elevate the expandable humeral trial until the superior aspect of the humeral head trial articulates with the top of the glenoid.

Ascertain the seating height of the expandable humeral trial by noting which height marking on the anterior face of the trial corresponds to the fracture line of the humeral metaphysis.

**Tech tip:**
For very proximal fractures, the positions of the suture slots can also be used as height references to be transferred from trial to implant.

Dislocate the assembly.
Remove the expandable humeral trial and humeral head trial assembly from the canal.
Humeral stem trialing

Attachment of insertion device to expandable humeral trial

Either the Version Block or the stem/trial inserter can be attached to the expandable humeral trial to facilitate insertion of the expandable humeral trial into the IM canal.

Attach the expandable humeral trial to either the Version Block or the stem/trial inserter by making sure the locking pin (blue arrows) is engaged and the expandable humeral trial is drawn onto the alignment pins (green arrows) while closing the handle.
Humeral stem trialing

The expandable humeral trial will lock together with the Version Block and stem/trial inserter via the handle on the medial side of the instrument. It can be disengaged by releasing the same handle.

**Note:**
The face of the expanding humeral trial will be flush to the Version Block or stem/trial Inserter with no gap between the two when they are properly assembled.

**Note:**
The latch mechanism on the Version Block works optimally when the Version Block is attached to Expandable Humeral Trials, Long Stem Trials or Humeral Fracture Stems.

Fully thread the version rod in the hole corresponding to 30° of retroversion within the Version Block or stem/trial inserter. The retroversion can be adjusted to either 20° or 40° later on if needed.
Humeral stem trialing

**Determination of initial seating height for reverse arthroplasty procedure**

With the expandable humeral trial now assembled to either the Version Block or the stem/trial inserter, insert the assembly into the reamed canal. Ensure the arm is flexed 90° at the elbow and the forearm is aligned with the version rod set at 30°.

To determine the initial seating height of the expandable humeral trial, bring the greater tuberosity around the posterior aspect of the expandable humeral trial in a position that approximates its native position. The inferior greater tuberosity should fit to the superior humeral shaft, recreating the fracture line. [Figure 27]

**Note:**
The expandable humeral trial is not yet expanded at this time.

⚠️ **CAUTION**

Care should be given not to “over-reduce” the greater tuberosity too far anteriorly. This can compromise assessment of appropriate height and version.

**Tech tip:**
Understanding where the bicipital groove is can aid in proper greater tuberosity reduction as most fractures occur just lateral to the bicipital groove.

With the greater tuberosity approximately in its native position adjust the height of the expanding humeral trial such that its face is flush with the superior face of greater tuberosity.

A line can be imagined that extends from the face of the expandable humeral trial superior-laterally to the superior ridge of the greater tuberosity. This line also extends inferior-medially to the medial calcar (if calcar is intact).
Humeral stem trialing

With the face of the expandable humeral trial flush with the theoretical line extending from the medial calcar to the superior-lateral ridge of the greater tuberosity, take note of the height mark on the trial, which corresponds to the fracture line on the humeral metaphysis.

If 20° or 40° of retroversion is desired based on initial assessments of the structures, remove the expandable humeral trial with the help of the Version Block or stem/trial inserter. Thread the version rod into the hole corresponding to the desired retroversion and repeat insertion of the expandable trial assembly to the height marking previously noted.

If no version adjustments are desired, proceed to the “insertion at initial seating height” section.

If a long humeral stem is being utilized, attach Version Block or stem/trial inserter (as previously described) to appropriate long stem trial, insert long stem trial to previously determined seating height, confirm reamed canal depth is appropriate for long stem trial, remove long stem trial and continue to the “insertion at initial seating height” section with original expandable humeral trial.

Tech tip:
For very proximal fractures, the positions of the suture slots can also be used as height references to be transferred from trial to implant.

Tech tip:
Electrocautery can be used to mark exactly where on the bone the depth measurement was made.

Tech tip:
A surgical pen can also be utilized to mark the trial in the exact location corresponding to the metaphyseal fracture line.
Humeral stem trialing

**Insertion at initial seating height**

There are two hex drivers in the system. The longer driver is to be utilized with the stem/trial inserter while the shorter driver is to be used with the Version Block. Insert the long hex driver into the superior hole of either the Version Block or the stem/trial inserter.

Continue to advance the hex driver into the canal until it is fully engaged with the expansion bolt within the expandable humeral trial.

Rotate the hex driver clockwise, applying optimal torque, to expand and lock the trial in the humeral canal. If an expandable humeral trial that is only 1mm smaller than the reamed canal, apply the minimum amount of torque required to sufficiently lock the trial into the canal.

**WARNING**

*Do not excessively expand expandable humeral trials.*

While using the Version Block, grasp the Version Rod close to where it threads into the block for anti-torquing during expansion.

**CAUTION**

*Do not grasp the Version Rod too far away from where it interfaces with the Version Block so as not to create undue torque at the interface.*

When using the stem/trial inserter, use the body of the instrument for anti-torquing during expansion.

**WARNING**

*Ensure that the height and version of the expandable humeral trial are not altered during expansion with hex driver.*
Humeral stem trialing

Remove the hex driver.

Disengage the Version Block or stem/trial inserter using the handle and remove from the expandable humeral trial.

The expandable humeral trial is now locked in its initial seating position.

**Note:**
During expansion, if the selected expandable humeral trial does not lock into the humeral canal, consider selecting an expandable humeral trial that is only 1 size smaller than the last reamer used. This will result in a reduced cement mantle and must be considered to determine if adequate fixation will be achieved.
**Humeral trial adaptors**

**Optional utilization of trial adaptors**

Humeral head and humeral cup trials sit flush to the face of the expandable humeral trials, humeral broaches and humeral stems [Figure 33, Left]. In cemented applications, the morse taper adjoining the humeral head/cup implant with the humeral stem implant adds a nominal thickness of approximately 1.5mm [Figure 33, Right].

For this reason, single-use/sterile humeral head trial adaptors and humeral cup trial adaptors are available for optional utilization with ReUnion TSA humeral head trials and ReUnion RSA humeral cup trials, respectively. Utilization of the trial adaptors will account for the additional nominal 1.5mm gap introduced by the morse taper.

**Humeral head trial adaptor**

Humeral head trial adaptors mate with ReUnion TSA humeral head trials. To determine the size of the humeral head trial, please refer to the “humeral head selection and trialing” section.

Place the flat side of the humeral head trial adaptor on the bottom face of the selected humeral head trial. The protrusion/post on the humeral head trial should be pushed through the center hole in the humeral head trial adaptor.

**Note:**

*There should be no gap between the bottom face of the humeral head trial and the top side of the humeral head trial adaptor.*
Humeral trial adaptors

With the angled protrusion on the humeral head trial adaptor oriented superiorly and the pegged protrusion oriented inferiorly, place the humeral head trial on the expandable humeral trial or humeral fracture stem.

Continue trialing the humeral head, as described in the “humeral head selection and trialing” section.

If an alternate humeral head trial is desired, remove the humeral head trial adaptor from the previous humeral head trial and assemble it to the new one as previously described.

Tech tip:
The forked removal tool can aid in humeral head trial adaptor removal. See the “instrument disassembly” section.
Humeral trial adaptors

Humeral cup trial adaptor

Humeral cup trial adaptors mate with ReUnion RSA humeral cup trials and expanding cup trials.

Place the flat side of the humeral cup trial adaptor on the bottom face of the selected humeral cup trial assembly. The longer straight pin on the humeral cup trial fits through the smaller circular hole surrounded by cutouts, while the oblong pin fits through the corresponding oblong hole in the adaptor.

**Note:**
There should be no gap between the bottom face of the humeral cup trial and the top side of the humeral cup trial adaptor.

With the shorter oblong pin on the humeral cup trial oriented superiorly and the longer straight pin oriented inferiorly, place the assembled components on the expandable humeral trial or humeral fracture stem.

Continue trialing the ReUnion RSA humeral cup trial assemblies as described in the “humeral cup/insert trialing” section.

If an alternate humeral cup trial is desired, remove the humeral cup trial adaptor from the previous humeral cup trial and assemble it to the new trial as previously described.

**Tech tip:**
The forked removal tool can aid in humeral cup trial adaptor removal. See the “instrument disassembly” section.
Procedure for hemiarthroplasty
Procedure for hemiarthroplasty

Humeral head trialing

Place the selected humeral head trial onto the expandable humeral trial.

Note: If utilization of the optional humeral head trial adaptor is desired, follow instructions for attachment to humeral head trial prior to placement on expandable humeral trial.

Reduce the humeral head trial into the glenoid. An appropriate size head trial should enable 50% translation of the humeral head on the glenoid both anteriorly and posteriorly, enable external rotation with the forearm across the abdomen, and also enable 30°-40° external rotation.

With the arm placed in the neutral position, confirm that the tuberosities can be wrapped around the expandable humeral trial.

If the selected humeral head trial is deemed inappropriate, remove the humeral head trial, replace it with the newly selected humeral head trial and repeat humeral head selection and trialing.

If adjustments to the prosthesis height and/or version need to be made at this point, dislocate the shoulder, remove the humeral head trial, attach the Version Block or the stem/trial inserter, contract the expandable humeral trial and repeat steps for “expandable trial insertion at initial seating height.”

If no adjustments are required, once again confirm the height and version and proceed to the “trial removal and final humeral preparation” section.
Procedure for hemiarthroplasty

**Trial removal and final humeral preparation**

Dislocate the shoulder and remove the humeral head trial from the expandable humeral trial.

⚠️ **CAUTION**

If optional humeral head trial adaptor is being utilized, ensure that it is properly detached from the humeral head trial/expandable humeral trial and is not left in the wound.

Reattach the Version Block or stem/trial inserter to the expandable humeral trial as previously described.

Insert the long hex driver through the Version Block or stem/trial inserter, making sure to advance it until it is fully engaged with the expansion bolt within the expandable humeral trial.

Rotate the hex driver counter-clockwise to contract the expandable humeral trial and disengage it from the humeral canal.

While using the Version Block, grasp the Version Rod close to where it threads into the block for anti-torqueing during contraction.

⚠️ **CAUTION**

Do not grasp the Version Rod too far away from where it interfaces with the Version Block so as not to create undue torque at the interface.

When using the stem/trial inserter, use the body of the instrument for anti-torqueing during contraction.

Ensure the expandable humeral trial is fully contracted and remove the assembly from the humeral canal.
Procedure for hemiarthroplasty

Drill two holes medial and two holes lateral to the bicipital groove in the humeral shaft, near the fracture site.

Place sutures (black) through each hole respectively, from inside out.

Irrigate the humeral shaft and remove excess fluid with suction.

Insert cement restrictor if preferred.

Humeral fracture stem implantation

Attach the selected humeral fracture stem implant to the Version Block or stem/trial inserter as was previously described during attachment to the expandable humeral trial.

Ensure that the version rod is fully threaded into the desired 20°, 30° or 40° hole previously decided upon during trialing.

Note:
The indicator markings on the expandable humeral trial (height, suture slots) correspond to features present on the RFX humeral fracture stem.

Note:
The face of the humeral fracture stem will be flush to the Version Block or stem/trial inserter with no gap between the two when they are properly assembled.

WARNING
Take care not to damage the HA/ Ti Plasma Coating while assembling the version block/stem trial inserter to the Humeral Fracture Stem Implant.
Procedure for hemiarthroplasty

The canal should be thoroughly cleansed and dried. Varying cement techniques can be utilized per patient indications.

Pass an inferior simple tuberosity suture (yellow) through one of the medial suture holes in the RFX humeral fracture stem. Continue passage through each of the tuberosities, from inside out, at the bone junction [Figure 46, inset].

Inject/hand pack Simplex P or Simplex P SpeedSet bone cement into proximal humeral canal.

Introduce the distal tip of the RFX humeral fracture stem implant into the IM canal.

With the version rod aligned to the patients arm, lower the humeral fracture stem to the same height previously decided upon during trialing with the expandable humeral trial.

**WARNING**

Ensure that the desired height marking is clearly visible during insertion by removing any excess cement that egresses out of the IM canal.

**WARNING**

Hold the Version Block or stem/trial inserter to prevent the prosthesis from moving in the cement mantle. Ensure that the proper height and version is maintained while cement cures.

**Note:**

Care should be taken not to disturb the height and/or version of the stem when disassembling the Version Block or stem/trial inserter.
Procedure for hemiarthroplasty

**Final humeral head trialing and implantation**

Place the selected humeral head trial onto the humeral fracture stem and reduce it into the glenoid.

**Note:**
If utilization of the optional humeral head trial adaptor is desired, follow instructions for attachment to humeral head trial prior to placement on the humeral fracture stem.

Once again confirm translation, ROM and that tuberosities can be reduced around the implant as previously described.

Upon final trialing, if the humeral head trial is deemed inappropriate, replace it with the newly selected humeral head trial and repeat final humeral head trialing.
Procedure for hemiarthroplasty

Remove the humeral head trial and thoroughly clean, dry and inspect the reverse morse taper on the humeral stem.

**Note:**
If optional humeral head trial adaptor is being utilized, ensure that it is properly detached from the humeral head trial/humeral fracture stem and is not left in the wound.

**WARNING**
If optional humeral head trial adaptor is being utilized, ensure that it is disassembled and removed prior to impacting the humeral head implant.

Select the final humeral head implant of the same size decided upon during trialing and place it on the humeral fracture stem.

Using the 4-sided modular ratcheting handle and universal impactor tip, exert several mallet blows to definitively seat the humeral head. Be sure that the angle of the ratcheting handle and impactor tool is in line with the axis of the taper (90° to the face of humeral stem implant).

**CAUTION**
Excessive impaction on a properly seated humeral fracture stem may potentially cause a fracture of the medial calcar or humeral shaft.
Procedure for reverse shoulder arthroplasty
Humeral cup/insert trialing

There are 2 different methods of humeral cup/insert trialing available with the ReUnion RFX Shoulder System.

1. Expanding humeral cup trial and expanding humeral trial insert.
2. Sliding humeral cup trial and humeral insert trial

Both methods are intended to provide accurate assessment of deltoid tension for optimal range of motion and joint stability.

Tech tip:
If the initial humeral cup-trial assembly cannot be reduced into the glenosphere, consider lowering the expandable humeral trial deeper into the humeral canal by 1 height marking (2.5mm) to allow additional room for trial reduction.
Procedure for reverse shoulder arthroplasty

Expanding humeral cup trialing
Select the appropriately sized expanding insert trial [see table below]. Both small and large insert trials are color coded to match the three different diameters of glenospheres.

Tech tip:
The glenoid holder will be required to remove the glenosphere trial from the glenoid baseplate. Select a small insert trial if you anticipate a tighter joint; select a large insert trial if you anticipate a looser joint.

Constrained X3 humeral inserts are available and capture more of the glenosphere. The polyethylene walls are higher than standard bearings, but do not add any additional joint space.

Note:
The metal expandable humeral cup trials only come in one size, but are able to replicate both 4 and 10mm humeral cup options.

<table>
<thead>
<tr>
<th>Expanding humeral cup trials</th>
<th>Humeral construct size range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small (Sizes 32, 36, and 40)</td>
<td>12mm - 18mm (2mm Incr.)</td>
</tr>
<tr>
<td>Large (Sizes 32, 36, and 40)</td>
<td>16mm - 22mm (2mm Incr.)</td>
</tr>
</tbody>
</table>

Insert the selected expanding insert trial into the expanding humeral cup trial and rotate clockwise until it is in its collapsed state.

Note:
If utilization of the optional humeral cup trial adaptor is desired, follow instructions for attachment to expanding humeral cup trial prior to placement on expandable trial.

Place the assembled cup trial onto the expandable humeral trial by placing the long straight pin on the inferior hole perpendicular to the face of the expandable humeral trial. Reduce (relocate) the joint with the trial fully collapsed to facilitate the reduction maneuver.
Procedure for reverse shoulder arthroplasty

Perform an initial reduction with the collapsed trial, making sure to minimize the amount of tension on the deltoid.

As the trial is expanded and tension placed on the deltoid, the markings will correspond to the humeral cup and humeral insert thicknesses.

In the example image on the left, an 8mm thick X3 humeral insert would be used with a 10mm thick humeral cup in a left (L) shoulder.

**Note:**
The top number represents the humeral insert thickness (mm). The bottom numbers (4 and 10) represent the humeral cup thickness (mm). The L or R represents which side shoulder is being trialed.

Using the unthreaded portion of the version rod, expand the expanding insert trial until the entire construct begins to apply tension to the deltoid.

Progressively expand the trial with the shoulder reduced by turning the expanding humeral trial counterclockwise. Each turn will increase the thickness of the construct by 2mm.

⚠️ **WARNING**
*Do not overly tension the deltoid as this may cause damage to bone and soft tissue.*
Procedure for reverse shoulder arthroplasty

The trial reduction should show very limited distraction (1mm or less). In cases of extreme instability, constrained humeral bearings are available.

Constrained X3 humeral inserts capture more of the glenosphere and have polyethylene walls which are higher than the standard X3 humeral insert implants, but do not add any additional joint space.

With the arm placed in the neutral position, confirm that the tuberosities can be reduced around the expandable humeral trial.

If the appropriate amount of tension is achieved for optimal range of motion, record the component size markings on the lateral aspect of the expanding cup trial construct for final prosthesis selection.

For removal, decompress the expanding cup trial back to its original state, releasing the tension from the deltoid so that the assembly can be removed easily.

If adjustments to the height and/or version need to be made at this point, remove the humeral cup trial assembly, attach the Version Block or stem/trial inserter, contract the expandable humeral trial, repeat steps for “expandable humeral trial insertion” at “initial seating height” and repeat steps for “expanding humeral cup trialing.”
Procedure for reverse shoulder arthroplasty

**Sliding humeral cup and humeral insert trialing**

Select the appropriately sized humeral cup trial and humeral insert trial (See table below).

Engage the humeral insert trial into the humeral cup trial by sliding the insert into position and turning it by hand or using the non-threaded end of the version rod to ‘lock’ the trial insert into place.

**Note:**
If utilization of the optional humeral cup trial adaptor is desired, follow instructions for attachment to humeral cup trial prior to placement on expandable humeral trial.

Place the assembly onto the expandable humeral trial by inserting the long straight pin on the inferior hole perpendicular to the face of the expandable humeral trial.

Perform an initial reduction to determine the appropriate amount of tension on the deltoid for optimal stability and range of motion [Figure 60].

The trial reduction should show very limited distraction (1mm or less). In cases of extreme instability, constrained X3 humeral inserts are available.

**Tech tip:**
Constrained X3 humeral inserts are available and capture more of the glenosphere. The polyethylene walls are higher than standard bearings, but do not add any additional joint space.

**WARNING**
Do not overly tension the deltoid as this may cause damage to bone and soft tissue.

With the arm placed in the neutral position, confirm that the tuberosities can be reduced around the expandable humeral trial [Figure 60, inset].

### Humeral trials and size range

<table>
<thead>
<tr>
<th>Humeral trials</th>
<th>Humeral construct size range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small (Sizes 32, 36, and 40)</td>
<td>8mm - 22mm (2mm Incr.)</td>
</tr>
</tbody>
</table>
Procedure for reverse shoulder arthroplasty

If the appropriate amount of tension is achieved for optimal stability and range of motion, distract the humeral insert trial and humeral cup trial by first rotating the humeral insert trial from a “locked” position to an “unlocked” position by using the non-threaded end of the version rod.

To distract the humeral trial components, place the arm in slight abduction and external rotation to align the trial components with the glenosphere/glenoid.

Distract the trial implant by translating the humerus and humeral cup trial anteriorly until the humeral cup trial is free of the humeral insert trial. The humeral insert trial will remain engaged to the glenosphere and can then be removed separately.

If adjustments to the height and/or version need to be made at this point, remove the humeral cup trial assembly, attach the Version Block or stem/trial inserter, contract the expandable humeral trial, repeat steps for “expandable humeral trial insertion” at “initial seating height” and repeat steps for “sliding humeral cup and insert trialing.”
Trial removal and final humeral preparation

Remove either the expanding cup trial assembly or the sliding humeral cup trial assembly from the expandable humeral trial.

Note:
If optional humeral cup trial adaptor is being utilized, ensure that it is properly detached from the humeral cup trial assembly/expandable humeral trial and is not left in the wound.

Reattach the Version Block or stem/trial inserter to the expandable humeral trial as previously described.

Insert the long hex driver through the Version Block or stem/trial inserter, making sure to advance it until it is fully engaged with the expansion bolt within the expandable humeral trial.

Rotate the hex driver counter-clockwise to contract the expandable humeral trial and disengage it from the humeral canal.

While using the Version Block, grasp the Version Rod close to where it threads into the block for anti-torqueing during contraction.

⚠️ CAUTION
Do not grasp the Version Rod too far away from where it interfaces with the Version Block so as not to create undue torque at the interface.

When using the stem/trial inserter, use the body of the instrument for anti-torqueing during contraction.

Ensure the expandable humeral trial is fully contracted and remove the assembly from the humeral canal.
Procedure for reverse shoulder arthroplasty

Drill two holes medial and two holes lateral to the bicipital groove in the humeral shaft, near the fracture site.

Place sutures (black) through each hole respectively, from inside out.

Irrigate the humeral shaft and remove excess fluid with suction.

Insert cement restrictor if preferred.
Procedure for reverse shoulder arthroplasty

**Humeral fracture stem implantation**

Select a humeral fracture stem size that matches the size of the expandable humeral trial used for humeral trialing. For example, if a size 10 expandable humeral trial was utilized, select a size 10 humeral fracture stem implant.

The distal diameter of the humeral fracture stem is 2mm smaller than that of the expandable humeral trial of the same size. This allows for the 1mm (2mm circumferential) cement mantle.

Varying cement techniques may be utilized based on patient indication. Introduce the cement into the IM canal.

**Note:**
The indicator markings on the expandable humeral trial (height, suture slots) correspond to features present on the RFX humeral fracture stem.

Attach the selected humeral fracture stem implant to the Version Block or stem/trial inserter as was previously described during attachment to the expandable humeral trial.

Ensure that the version rod is fully threaded into the desired 20°, 30° or 40° hole previously decided upon during trialing.

**Note:**
The face of the humeral fracture stem will be flush to the Version Block or stem/trial inserter with no gap between the two when they are properly assembled.

![Figure 66](image)

**WARNING**
Take care not to damage the HA/Ti plasma coating while assembling the Version Block or stem/trial inserter to the humeral fracture stem implant.

![Figure 67](image)
The canal should be thoroughly cleansed and dried. Varying cement techniques can be utilized per patient indications.

Pass an inferior simple tuberosity suture (yellow) through one of the medial suture holes in the RFX humeral fracture stem [Figure 68 inset]. Continue passage through each of the tuberosities, from inside out, at the bone junction.

Introduce the distal tip of the humeral fracture stem implant into the IM canal.

Inject/hand pack Simplex P or Simplex P SpeedSet bone cement into proximal humeral canal.

With the version rod aligned to the patients arm, lower the humeral fracture stem to the same height previously decided upon during trialing with the expandable humeral trial.

⚠️ **WARNING**

Ensure that the desired height marking is clearly visible during insertion by removing any excess cement that egresses out of the IM canal.

⚠️ **WARNING**

Hold the Version Block or stem/trial inserter to prevent the prosthesis from moving in the cement mantle. Ensure that the proper height and version is maintained while cement cures.

**Note:**

Care should be taken not to disturb the height and/or version of the stem when disassembling the Version Block or stem/trial inserter.
Procedure for reverse shoulder arthroplasty

Component size selection
A large range of ReUnion RSA implant sizes is available to accommodate all ranges of glenohumeral instability and/or rotator cuff deficiency.

Note:
For assemblies of 14mm and 16mm, it is recommended to use the thicker metal humeral cup component versus a thicker X3 humeral insert.

<table>
<thead>
<tr>
<th>X3 humeral inserts [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>10</td>
</tr>
</tbody>
</table>

Figure 70

Humeral cup [mm]
**Final component trialing and implantation**

Place either the expanding cup trial or the sliding cup trial assembly previously utilized on the humeral stem implant and reduce it into the glenoid.

**Note:**
*If utilization of the optional humeral cup trial adaptor is desired, follow instructions for attachment to humeral cup trial prior to placement on humeral fracture stem.*

Once again confirm translation, ROM and that tuberosities can be reduced around the humeral fracture stem as previously described.

Upon final trialing, if the deltoid tension is deemed inappropriate, follow instructions for dislocation/removal of humeral cup assembly and follow instructions for utilizing either expanding cup or sliding cup trialing for obtaining optimal deltoid tensioning.
Dislocate and remove the humeral cup trial assembly as previously described. Thoroughly clean, dry and inspect the reverse morse taper on the humeral fracture stem.

**CAUTION**

*If optional humeral cup trial adaptor is being utilized, ensure that it is properly detached from the humeral cup trial assembly/humeral fracture stem and is not left in the wound. The humeral cup trial adaptor must be disassembled and removed prior to impacting the humeral cup implant.*

Select the final humeral cup and X3 humeral insert implants that are the same size as what was decided upon during trialing.

Place the definitive humeral cup implant into the humeral assembly block.

Position the definitive X3 humeral insert on top of the definitive humeral cup.

Attach the appropriately sized humeral insert impactor tip to the universal impactor adaptor and attach the assembly to the 4-sided handle.

While holding the humeral assembly block steady, impact the definitive X3 humeral insert into the definitive humeral cup using several sharp blows of the mallet.

The assembled definitive humeral cup and X3 humeral insert are now locked and ready to be inserted onto the definitive humeral stem.
Glenosphere placement

Engage the desired definitive glenosphere on the glenosphere holder/impactor and place the glenosphere onto the glenoid baseplate [Figure 75]. Ensure that the assembly is fully tightened and there is no gap between the glenosphere and the grey impactor tip. If using an eccentric glenosphere, use the eccentric alignment mark on the glenosphere impactor tip and align it to the laser mark on the underside of the eccentric glenosphere to place the glenosphere in the optimum orientation as trialed.

Note:
Confirm there is adequate soft tissue clearance within the envelope of the baseplate to ensure glenosphere to baseplate taper lock.

⚠️ CAUTION

The attachment between the glenosphere holder/impactor and glenosphere happens via a threaded connector. Care should be taken to make sure the axis of the instrument is parallel to the axis of the implant to avoid cross threading.

Prior to impaction, make sure the glenosphere and baseplate tapers are aligned and that there are no protruding bone ledges or interposed soft tissue that may impede full seating of the glenosphere. Definitively seat the glenosphere by placing several sharp blows on the glenosphere holder/impactor. A set screw is not needed to attach the glenosphere to the glenoid baseplate.

The design of the morse taper provides a secure mode of fixation. Ensure that the glenosphere is still fully tightened onto the glenosphere holder/impactor to make sure the taper is fully seated after impaction by gently toggling in all directions. If the morse taper has not been engaged, toggling of the handle will disengage the glenosphere from the baseplate.

Note:
It is critical to ensure that all tapers are clean, dry and clear of any debris or damage prior to assembling the glenosphere to the glenoid baseplate.

To detach the glenosphere holder/impactor from the glenosphere after it has been impacted in place, unthread the instrument counter-clockwise until it is free [Figure 76].
Procedure for reverse shoulder arthroplasty

After the removal of the glenosphere holder/impactor, inspect the glenosphere for placement and clean the articulating surface of all debris.

**Note:**

If optional humeral cup trial adaptor is being utilized, ensure that it is properly detached from the humeral cup trial assembly/humeral fracture stem and is not left in the wound.

**CAUTION**

If optional humeral cup trial adaptor is being utilized, ensure that it is disassembled and removed prior to impacting the humeral cup implant.

Place the humeral cup and insert assembly onto the taper of the implanted humeral stem.

Several sharp mallet blows are used to seat the humeral cup and X3 humeral insert assembly. Be sure the angle of the driver is in line with the axis of the trunnion (90° to humeral cup face).

**WARNING**

Excessive impaction of the humeral cup-X3 insert assembly may potentially cause a fracture of the humerus.
Tuberosity repair/bone grafting

The ReUnion RFX stem features multiple suture slots that can accommodate a number of different suturing techniques for tuberosity repair. One such technique is described below.

Prior to beginning tuberosity repair, retrieve cancellous bone graft from the native humeral head with rongeur. Pack cancellous bone graft around prosthesis, if deemed necessary. Ensure that addition of bone graft does not compromise ability to fully reduce tuberosities.

Pass each of the superior simple tuberosity sutures (red) through the most superior, anterior-lateral suture slots on the prosthesis. Continue passage of each suture through the tuberosity on the opposite side, from inside out, at the bone junction.

Pass the inferior simple tuberosity sutures (blue) through the most distal, anterior-lateral suture slots on the prosthesis. Continue passage of each suture through the tuberosity on the opposite side, from inside out, at the bone junction.

**Note:**
The number of lateral suture slots increases with stem size. See below and in appendix for more information.

<table>
<thead>
<tr>
<th>Sizes</th>
<th>Vertical suture slot options</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-7mm</td>
<td>2</td>
</tr>
<tr>
<td>8-13mm</td>
<td>3</td>
</tr>
<tr>
<td>14-15mm</td>
<td>4</td>
</tr>
</tbody>
</table>
Tuberosity repair/bone grafting

Tie the simple tuberosity sutures (red and blue).

Next, tie the mattress sutures (green) for tuberosity-to-tuberosity repair.
Tuberosity repair/bone grafting

Tie the tuberosity sutures to the shaft sutures for tuberosity to shaft repair.

Tie the circumferential suture (yellow) to finalize tuberosity repair. Check range of motion; make sure the tuberosities and shaft move as one unit.
There are five markings on the trials that correspond to implants of the same size.

**Note:**
Note that height markings, implant length as well as number of suture slot options change with trial/implant size.

Each depth marker is 2.5mm apart.

In some cases, the surgeon may decide to use a different size implant than originally trialed.
Instrument disassembly

**Humeral head trial adaptor**

Attach the forked removal tool to the 4-sided ratcheting handle.

Slide the forked removal tool between the humeral head trial and the humeral head trial adaptor. Ensure that the flat side of the forked removal tool faces the bottom side of the humeral head trial and the ramped side faces the humeral head trial adaptor.

Carefully disassemble the humeral head trial adaptor from the humeral head trial.

**Humeral cup trial adaptor**

Attach the forked removal tool to the 4-sided ratcheting handle.

Slide the forked removal tool between the humeral cup trial and the humeral cup trial adaptor. Ensure that the flat side of the forked removal tool faces the bottom side of the humeral cup trial and the ramped side faces the humeral cup trial adaptor.

Carefully disassemble the humeral cup trial adaptor from the humeral cup trial.

**Disassembly of ReUnion RSA glenoid reamer/planar**

The following disassembly instructions are applicable for all reamer styles (standard, magnetic & half-moon).

The recommended method to disassemble the glenoid reamer/planars from the cannulated straight reamer driver is by utilizing the glenoid holder to grasp around the circumference of the glenoid reamer/planar.
Instrument disassembly

By holding the reamer/planar face as shown [Figure 88] with the glenoid holder, pull the glenoid reamer/planar face away from cannulated straight reamer driver in an axial direction to disengage the quick connect feature.

Note:
Do not toggle the glenoid reamer/planar during disassembly as this has the potential to compromise the fit of the quick connect mechanism [Figure 88 inset].

If attempting to remove the glenoid reamer/planar without use of the glenoid holder, it is recommended the user utilize gauze or another material to protect their hands from blades of the reamer.
Instrument disassembly

**Disassembly of ReUnion TSA spherical glenoid reamers**

The following disassembly instructions are applicable for all reamer styles (standard, magnetic & half-moon).

The recommended method to disassemble the spherical glenoid reamers from the straight reamer driver is by utilizing the glenoid holder instrument to grasp around the circumference of the reamer.

By holding the reamer face as shown [Figure 91] with the glenoid holder, pull the reamer face away from straight reamer driver in an axial direction to disengage the quick connect feature.

⚠️ **WARNING**

Be careful not to toggle the reamer during disassembly as this has the potential to compromise the quick connect mechanism.

If attempting to remove the spherical glenoid reamer without use of the glenoid holder instrument, it is recommended the user utilize gauze or another material to protect their hands from blades of the reamer.
Implant component removal

Humeral head removal

Attach the forked removal tool to the 4-sided ratcheting handle and slide the forked humeral head removal tool under the humeral head.

Align the forked removal tool to the neck of the head and lightly tap the forked tool in with a mallet to mechanically disassociate the humeral head from the humeral stem.

If the head is in direct contact with the bone, the surgeon may need to create a small window along the edge of the resection to obtain access for insertion of the fork.

⚠️ WARNING
Be careful not to pry or lever off the cortical rim to remove head as this may cause a fracture. Excessive impaction of the forked removal tool should be avoided as this may damage the cortical rim of the humerus.

⚠️ CAUTION
The ReUnion TSA forked removal tool should only be used with the ReUnion TSA universal neck adapter or ReUnion SR heads.

Humeral poly insert removal

Dislocate the glenohumeral joint so that the X3 humeral insert is exposed.

Use the 3.1mm drill bit and drill a pilot hole into the X3 humeral insert at an oblique angle.

Drive the 3.1mm drill bit to the flat bottom surface of the humeral cup away from the sides and the locking features of the X3 humeral insert.
Implant component removal

Assemble the polyethylene removal tool to the 4-sided handle and introduce the tip of the polyethylene removal tool into the prepared pilot hole at the same oblique angle.

Drive the polyethylene removal tool into the X3 humeral insert until the insert disassociates from the humeral cup.

**Note:**
*After the X3 humeral insert has been removed, make sure that the joint space is completely clean and clear of any and all debris and polyethylene particles.*

**Humeral cup removal**

Attach the forked removal tool to the 4-sided handle and slide the forked removal tool under the humeral cup.

Align the forked removal tool to the neck of the humeral cup and lightly tap the forked removal tool in with a mallet to mechanically disassociate the humeral cup from the humeral stem.

If the humeral cup is in direct contact with the bone, the surgeon may need to create a small window along the edge of the resection to obtain access for insertion of the fork.

**Glenosphere removal**

With the glenohumeral construct distracted and the glenosphere fully exposed. Introduce the glenosphere jackscrew into the threaded hole at the top of the glenosphere.
Implant component removal

Utilizing the center screw T25 driver, begin to thread in the glenosphere jackscrew until the glenosphere distracts completely from the glenoid baseplate.

**Figure 98**

**Humeral stem removal**

Utilize the humeral stem removal tool and McReynolds slap hammer to remove the humeral stem from the humeral canal.

Attach the humeral stem extractor to the humeral stem by inserting the guide post into proximal hole of the stem. Engage the clamping arm into trunnion, then tighten the knob.

Depending on the integrity of the cement mantle or degree of humeral stem ingrowth, humeral shaft osteotomies and other techniques described in the peer reviewed literature may be justified.

**WARNING**

Do not use the broach handle or stem/trial inserter for removal of a well fixed or cemented humeral stem.

**Figure 99**
Implant component removal

Thread the McReynolds slap hammer attachment to the humeral stem extractor and apply upward thrusts in line with the long axis of the humerus and well fixed humeral stem.

⚠️WARNING
Do not apply cantilever loads while sliding the hammer to remove the stem as this may cause a fracture of the humerus.
Notes:
Notes:
Notes:
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