



Reverse[®]
shoulder prosthesis

Reverse[®] shoulder prosthesis

Background

Patients presenting with a rotator-cuff-deficient shoulder and glenohumeral arthritis typically show evidence of upward displacement of the humeral head (rides high) with respect to the glenoid and loss of the glenohumeral joint space.

Conventional surgical methods, such as hemiarthroplasty, bipolar and total shoulder arthroplasty are often unreliable in improving comfort and function in patients whose shoulders have the above pathology. The prosthetic humeral head "rides high" and/or subluxes antero-superiorly with respect to the glenoid and leads to an unstable joint. The length-tension curve of the deltoid muscle is suboptimal and cannot provide a stable fulcrum for elevation (Figure 1). As a result, the patient may experience pain, joint instability, and undesirable range of motion.

The goal of the Encore Reverse[®] Shoulder Prosthesis (RSP) is to provide orthopedic surgeons with a prosthetic surgical alternative for the above problem when the patient's shoulder is disabled.



Preoperative



Postoperative

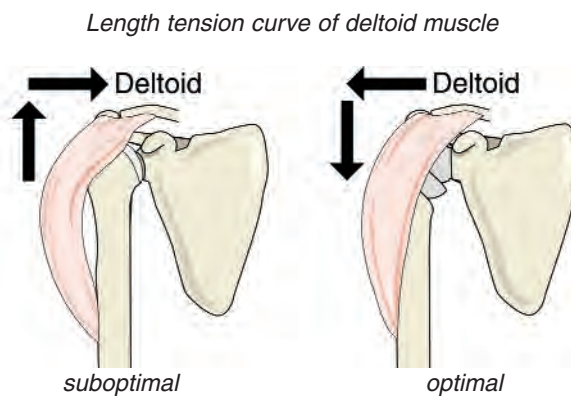


Figure 1

Design Surgeon

Mark A. Frankle, MD

Associate Clinical Professor
University of South Florida
Tampa, FL

Chief of Orthopedics
Department of Orthopedic Surgery
University Community Hospital
Tampa, FL

Chief of Shoulder & Elbow Surgery
Florida Orthopaedic Institute
Tampa, FL

Encore Medical, L.P.
9800 Metric Boulevard
Austin, TX
(800) 456-8696
www.encoremed.com
www.encorereverse.com

This brochure is presented to demonstrate the surgical technique utilized by the surgeon listed above. Encore, as the manufacturer of this device, does not practice medicine and cannot recommend this or any other surgical technique for use on a specific patient. The choice of the appropriate surgical technique is the responsibility of the surgeon performing the operation.

Table of Contents

| | |
|---------------------------------------|-----------|
| Design rationale | 2 |
| Range of motion | 3 |
| Indications | 3 |
| Contraindications | 3 |
| Preoperative Planning | 4 |
| Initial examination | 4 |
| Templating the humerus and glenoid | 4 |
| Humeral Preparation | 5 |
| Patient preparation and positioning | 5 |
| Deltpectoral surgical approach | 5 |
| Humeral exposure | 6 |
| Humeral head osteotomy | 7 |
| Humeral canal reaming | 9 |
| Humeral canal broaching | 10 |
| Proximal humeral preparation | 11 |
| Glenoid Preparation | 12 |
| Glenoid exposure | 12 |
| Glenoid drill guide placement | 13 |
| Glenoid reaming | 14 |
| Glenoid Baseplate Implantation | 15 |
| RSP glenoid baseplate implant | 15 |
| Glenoid baseplate insertion | 15 |
| Peripheral bone screw implants | 15 |
| Peripheral bone screw insertion | 16 |
| Glenoid baseplate rim planing | 17 |
| Final humeral preparation | 17 |
| Trial Reduction | 18 |
| Shoulder reduction | 18 |
| Assessment of mobility | 19 |
| Assessment of joint stability | 19 |
| Glenoid Head Implantation | 20 |
| RSP glenoid head implant | 20 |
| Glenoid head insertion | 20 |
| Humeral Implantation | 21 |
| RSP humeral stem implant | 21 |
| RSP humeral socket implant | 22 |
| Humeral stem/socket assembly | 22 |
| Humeral stem cementation | 23 |
| Closure | 24 |
| Final reduction and closure | 24 |
| Postoperative management | 24 |

Surgical Technique

Reverse Shoulder Prosthesis

Design Rationale

The rotator-cuff-deficient shoulder will have consistent pathology of the rotator cuff muscles, rotator cuff tendons, joint capsule, articular cartilage, joint congruity, and periarticular bone to varying degrees. A spectrum of clinical problems arises from the altered biomechanics and resultant pathophysiology. The progression of symptoms may not be linear. In fact, at some point, loss of sufficient rotator cuff function will lead to joint instability, synergistically causing greater dysfunction than muscle loss alone. The unopposed vertical pull of the deltoid further destabilizes the joint resulting in glenohumeral subluxation, which can lead to progressive articular cartilage breakdown and periarticular bone loss.

A reverse ball and socket is selected because it provides the most mechanically efficient method to neutralize the vertical forces of the unopposed deltoid and maintain joint stability. The RSP is designed to provide enhanced stability of the glenohumeral joint by increasing constraint of the artificial articulation. There are substantial forces present from the more-constrained devices, demanding stable fixation until adequate bone ingrowth occurs. Fixation of the glenoid baseplate is achieved by using a fixed central screw and four peripheral screws. The central screw is attached to the baseplate at a fixed angle, providing significant compression at the prosthesis bone interface. The compression imparted by the central screw, in conjunction with the contour of the ingrowth surface of the baseplate (which is plasma sprayed with a hydroxyapatite coating), provides an ideal environment for bone ingrowth into the prosthesis. Additional fixation is achieved through four peripheral screws that allow for insertion of either 5.0mm locking and/or 3.5mm nonlocking bone screws. The design of the four peripheral baseplate holes provides additional resistance to shear and torsional forces.

The variability in the degree of soft tissue deficiency, periarticular bone loss and quality, instability, and overall pathoanatomy experienced in rotator-cuff-deficient shoulders requires an array of reconstructive options to optimize surgical outcomes. The modularity of the Encore RSP provides the surgeon with this needed versatility. For example, there are three different glenosphere diameters available: 32mm, 36mm, and 40mm. For each diameter, there are two offsets available, neutral and -4mm. The humeral socket is available in two different levels of constraint depending on the depth of the socket chosen. Note that the inner diameter of the more-constrained humeral socket insert will have 10 degrees more articular arc than will the inner diameter of the standard humeral socket, providing more articular contact with the glenosphere for additional stability. The potential range of motion from these combinations varies with a more-constrained construct providing less motion but more stability and vice versa. Finally, the different glenospheres provide the ability to select a center of rotation that optimizes muscular function and avoids scapula notching.

Range of motion

The Reverse Shoulder Prosthesis is designed to address gross rotator cuff deficiencies. However, owing to the inherent constraints built into its design, there may be limitations surrounding the patient's achievable range of motion. Additionally, a risk of impingement and/or additional wear is also possible.

The range of motion measurements listed below are based on in vitro testing. Clinical results may vary according to the individual patient's skeletal and soft tissue characteristics. Additionally, the total arc of motion achieved may be greater or less than the degrees measured in vitro, since these arcs of motion are influenced by other body kinematics.

| | | |
|-------------------|---|----------------|
| Forward Flexion | > | No impingement |
| Adduction | > | -9° to 8° |
| Abduction | > | 71° to 98° |
| External Rotation | > | 10° to 30° |
| Internal Rotation | > | 26° to 53° |

NOTE: Surgeons implanting the Reverse Shoulder Prosthesis should be highly familiar with the surgical technique described and well-versed in shoulder replacement surgery.

Indications

The Reverse Shoulder Prosthesis Shoulder is indicated for use in patients with:

- Grossly deficient rotator cuff shoulder joints with severe arthropathy
- Failed joint replacement with a grossly deficient rotator cuff shoulder joint
- Evidence of upward displacement of the humeral head with respect to the glenoid
- Loss of glenohumeral joint space

NOTE: Patients must have a functional deltoid muscle to receive this implant device.

Contraindications

Total joint replacement is contraindicated whenever there is:

- Nonfunctional deltoid muscle
- Active sepsis
- Excessive glenoid bone loss
- Pregnancy
- Muscular, neurologic, or vascular deficiencies that compromise the affected extremity
- Conditions that place excessive demand on the implant (Charcot's joints, muscle deficiencies, refusal to modify postoperative physical activities, skeletal immaturity)
- Known metal allergy (jewelry)

Preoperative Planning

Reverse Shoulder Prosthesis

Initial examination

It is suggested that the case history, examination, radiographs, and CT scans be performed as part of the preoperative plan.

Objectives:

- Determine the quality of bone in the superior and inferior aspects of the glenoid.
- Determine the quality of bone in the proximal and distal aspects of the humerus.
- Determine the implant size and appropriate position/alignment for the humeral stem, humeral socket, glenoid baseplate, and glenoid head.
- Determine the level of humeral head resection.
- Determine appropriate location of the four bone screws in the glenoid.
- Determine the anatomic humeral socket/glenoid head offset to balance the soft tissue, optimize stability, and restore function.

For primary cases, a detailed case history confirmed by A/P and lateral radiographs indicating shoulder arthritis and an irreparable rotator cuff tear must be present to perform a reverse shoulder surgery. A CT scan of the shoulder provides effective evaluation of glenoid version and quality of bone stock. An MRI is occasionally helpful in equivocal cases.

Preoperative planning also enables identification of any bone abnormalities and potential problems before surgery, which will help determine the proper selection of the prostheses, instrumentation required, and any variables that will need to be dealt with intraoperatively.

Templating the humerus and glenoid

To determine the humeral implant size and appropriate position, select the humeral template size that best fits the proximal and distal humerus. Move the template proximally and distally until the axis of the neck of the humeral stem is in line with the axis of the patient's humeral neck. Locate the center of the humeral head using the humeral socket template. Center the geometry of the reverse shoulder humeral stem in the humeral canal, and fill the canal to the medial cortical wall. Verify that the stem size chosen in the A/P plane also fits the lateral plane.

To determine the humeral socket implant size and appropriate offset, select the humeral socket template size that provides the best offset to balance the soft tissue, optimize stability, and restore function.

To determine the glenoid head implant size and appropriate offset, select the glenoid head/baseplate template size that provides the best offset to balance the soft tissue, optimize stability, and restore function. Verify the location of the 5.0mm locking and/or 3.5mm nonlocking bone screws.

Reverse Shoulder Prosthesis templates include radiograph templates for the humeral stem, humeral socket, and glenoid head/baseplate. Note that the templates incorporate 10% magnification for greater accuracy when using A/P and lateral radiographs.

Instrumentation

RSP X-ray templates
[804-88-001/015]

Humeral Preparation

Reverse Shoulder Prosthesis

Patient preparation and positioning

General endotracheal anesthesia combined with an interscalene nerve block is preferable prior to positioning.

Place the patient in an upright beach chair position with the head firmly secured with the arm draped free (Figure 2). The operative arm must be sufficiently off to the side of the bed to allow for unobstructed movement of the shoulder in adduction and hyperextension.

Deltopectoral surgical approach

An extended deltopectoral approach is used (Figure 3).

In a primary case, prepare the incision 5cm medial to the acromioclavicular joint and extend it down the anterior arm, distal and lateral to the axillary fold.

Identify and preserve the cephalic vein. Free the deltoid muscle from the cephalic vein, ligating the lateral tributaries and leaving the vein medial with the pectoralis major muscle.

Release a portion of the pectoralis major tendon insertion. Care should be taken to not damage the long head of the biceps tendon underneath.

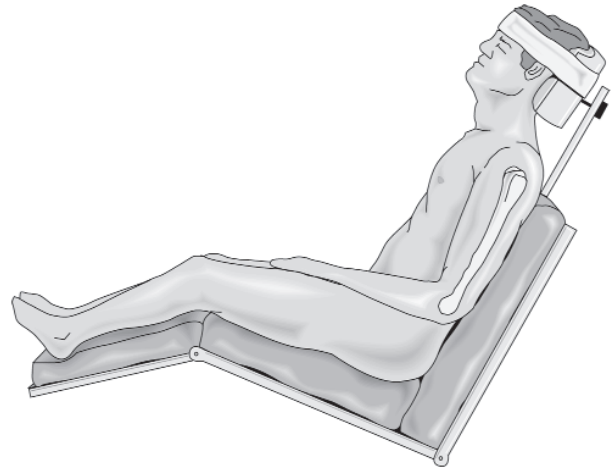


Figure 2

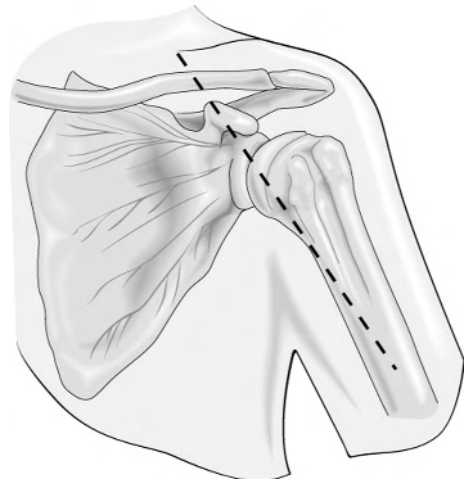


Figure 3

Surgical Technique

Reverse Shoulder Prosthesis

Humeral exposure

Expose the subdeltoid, subacromial, and subcoracoid spaces. Open the subdeltoid space using blunt and electrocautery dissection.

Excise the subacromial bursa to allow placement of a deltoid retractor. Any remaining posterior rotator cuff insertion can be appreciated. Palpate the tip of the coracoid and identify the conjoined tendon.

Incise the clavipectoral fascia superficially with electrocautery on the lateral border of the conjoined tendon. Avoid medial retractors on the conjoined tendon to prevent a musculocutaneous nerve traction injury.

Palpate the axillary nerve proximally between the conjoined tendon and the lower subscapularis muscle and distally on the undersurface of the lateral deltoid muscle. Confirm its location by performing the tug test (Figure 4).

Expose the long head of the biceps tendon and completely open the rotator interval to the superior rim of the glenoid. Ligate the anterior humeral circumflex vessels at the lower portion of the subscapularis. Release the remnant subscapularis tendon from the lesser tuberosity and proximal humerus. Externally rotating the arm will place tension on the muscle and facilitate its release from bone.

Atraumatically dislocate the shoulder anteriorly using gentle external rotation and extension (Figure 5). The humerus is often osteopenic and can be fractured, if overzealous force is used to dislocate the shoulder.

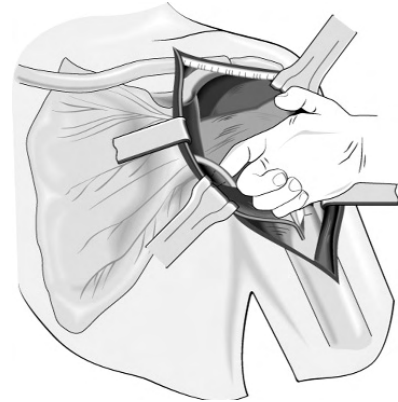


Figure 4

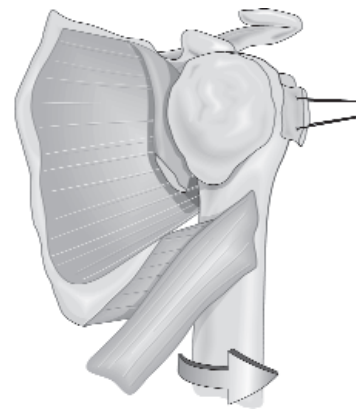


Figure 5

Humeral head osteotomy

Measure the level of the humeral head resection intraoperatively by reviewing the preoperative plan. Trim any osteophytes from the proximal humerus as needed using a straight rongeur to improve visualization of the anatomic neck of the humerus.

Position the osteotomy guide onto the anterior humeral shaft to determine the varus-valgus angle of the humeral head osteotomy (Figure 6).

Humeral retroversion is determined by using the forearm as a reference point to the flexed elbow. Externally rotate the forearm, and align the retroversion alignment rod parallel to the forearm to recreate a preferred humeral neck resection in 30 degrees of humeral retroversion (Figure 7). Note that the height of the osteotomy should be above the anatomic neck so that resection is no larger than a tablespoon (Figure 8). A minimal amount of bone should be removed.

Drill 2 holes through the osteotomy guide using a 3.2mm drill bit. Tap the bone pins into the prepared drill holes to secure the osteotomy guide to the anterior humeral shaft.



Figure 6

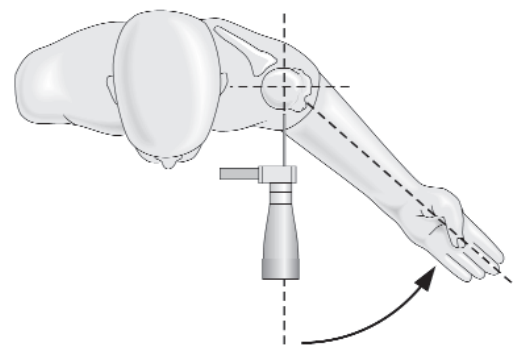


Figure 7



Figure 8

Instrumentation

Osteotomy Guide, Right/Left
[804-00-046/047]

Bone Pins, 3-inch
[800-01-048]

Retroversion Alignment Rod
[803-01-057]

3.2mm Drill Bit
[801-01-020]

Surgical Technique

Reverse Shoulder Prosthesis

Humeral head osteotomy

Place Hohmann retractors medially around the proximal humerus to protect the axillary nerve. Aim the oscillating saw parallel to the sagittal plane of the body through the proximal humerus. Begin the humeral head resection by cutting parallel to the top of the osteotomy guide until the humeral head is completely resected (Figure 9).

Pull out the bone pins using the bone pin puller/extractor, and remove the osteotomy guide (Figure 10).



Figure 9



Figure 10

Instrumentation

Bone Pin Puller/Extractor
[800-01-035]

Humeral canal reaming

The humeral reamers are cylindrical and self-centered, with blunt tips, proportionally sized in 6mm to 14mm diameters, in 2mm increments. It is recommended to always manually hand-ream the intramedullary humeral canal.

Extend and adduct the humerus to allow access to the medullary canal. Remove a small amount of lateral cortical bone to allow straight access down the humeral shaft and prevent varus reaming.

Enter the intramedullary canal where the supraspinatus tendon normally would attach to the greater tuberosity lateral to the humeral head cut surface. Begin reaming with the small T-handle starter reamer and then advance with the 6mm reamer (Figure 11).

Attach the smallest size (6mm) humeral reamer to the detachable T-handle. Orient the humeral reamer laterally against the cortical bone to ensure proper alignment of the reamer along the long axis of the humeral shaft for correct component positioning.

Use the proximal level of the humeral osteotomy as the point of reference, and sequentially ream the intramedullary canal to the size templated in the preoperative plan or until cortical bone chatter resistance is encountered (Figure 12).



Figure 11



Figure 12

Instrumentation

T-Handled Starter Reamer (6mm)
[804-00-002]

Detachable T-Handle
[803-00-047]

Humeral Reamers
(6mm/8mm/10mm/12mm/14mm)
[804-00-029/037]

Surgical Technique

Reverse Shoulder Prosthesis

Humeral canal broaching

RSP humeral broaches are symmetrically designed and available from 6mm to 14mm diameters in 1mm increments. Each broach is precisely matched with the RSP humeral stems. To allow for an adequate cement mantle, a stem smaller than the final broach size should be selected. Attach the smallest size (6mm) RSP humeral broach, to the humeral broach handle (Figure 13).

As a guide for proper alignment and retroversion, attach the retroversion alignment rod to the right or left hole in the humeral broach handle. Externally rotate the forearm, and align the retroversion alignment rod parallel to the patient's forearm to maintain approximately 30 degrees of humeral retroversion (Figure 14).

Gently impact the humeral broach handle using a mallet until the notch on the humeral broach handle contacts the lateral humeral cortex to ensure that the RSP humeral broach has been countersunk into the metaphysis of the proximal humerus (Figure 15).

Continue to sequentially broach, increasing in size, until a firm and stable fit is achieved. The final RSP broach size obtained is generally equivalent to, or is one size smaller than, the last humeral reamer size used.

Remove the humeral broach handle, and leave the final countersunk RSP humeral broach in the humerus.

Instrumentation

Humeral Broach Handle
[804-02-011]

Retroversion Alignment Rod
[803-01-057]

RSP Humeral Broach, (6mm-14mm)
[804-02-006/019]



Figure 13



Figure 14



Figure 15

Proximal humeral preparation

RSP humeral socket reamers are designed with cross-cut teeth to effectively prepare a proximal cup of bone support that will surround the RSP humeral socket. They are available in three sizes: small, medium, and large.

Using the small-sized RSP humeral socket reamer only, position the tip into the opening of the countersunk RSP humeral broach in the humeral metaphysis. Ream the humeral metaphysis using power (Figure 16).

Remove excess bone from the medial margin of the humeral metaphysis using a burr or curved rongeur (Figure 17).

Leave the final countersunk RSP humeral broach in the humeral canal while preparing the glenoid to minimize the risk of deforming or fracturing the proximal humerus.

Final preparation of the proximal humerus will be performed after glenoid head implantation.



Figure 16



Figure 17

Instrumentation

RSP Humeral Socket Reamers
(Small, Medium, Large)
[804-02-013/014/015]

Glenoid Preparation

Reverse Shoulder Prosthesis

Glenoid exposure

Abduct the arm on a free-standing Mayo stand or arm holder to relax the deltoid, and allow the humerus to retract posteriorly. Extensive soft tissue releases may be necessary to gain optimal visualization and access to the glenoid.

Place a glenoid retractor on the posterior inferior rim of the glenoid to displace the humerus posteriorly.

Release the coracohumeral ligament from the lateral coracoid to free the subscapularis and visualize the lateral coracoid base.

Release the glenohumeral ligaments, capsule, and labrum, and excise them from the glenoid beginning at the 12 o'clock position and ending between the 6 and 7 o'clock positions. Excise the inferior capsule to ensure excellent visualization of inferior glenoid. Note that the axillary nerve is at risk for injury near the posterior-inferior resection of the capsule. When using electrocautery, care must be taken to remain on the bone of the glenoid neck while performing these releases to help minimize this risk.

Place a Meyerdinger or blunt Hohmann retractor on the anterior glenoid neck to retract the subscapularis and facilitate releases around the glenoid to minimize traction on the anterior structures to avoid brachial plexus traction injuries.

Glenoid drill guide placement

To determine proper drill hole location, draw a circle onto the glenoid based on the approximate size of the glenoid baseplate, using the inferior glenoid rim as the bottom of the circle. Mark the starting point for the drill bit at the center of the circle.

Position the 2.5mm drill bit onto the glenoid with a downward inferior vertical tilt of 10-15 degrees using the 2.5mm central drill guide to ensure accurate placement and version of the RSP glenoid baseplate (Figure 18).

Drill the hole and exit the anterior scapula. Measure the depth of the drill hole using the depth gauge to ensure that the depth of the drill hole is approximately 30mm.

Seat the RSP 6.5mm guide tap in the same direction/angle as that used for the 2.5mm drill hole until it engages the anterior scapula. The RSP 6.5mm guide tap is calibrated, using depth markings that range from 25mm to 40mm, in 5mm increments (Figure 19). Significant resistance should be felt when the far cortex is engaged.

Leave the 6.5mm guide tap in the glenoid (Figure 20). Manual placement of the RSP 6.5mm guide tap is achieved by connecting the manual tap driver adaptor to the ratchet handle. Power placement of the RSP 6.5mm guide tap is achieved by using the power driver adaptor.

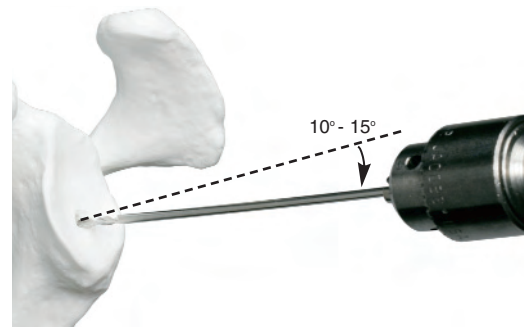


Figure 18

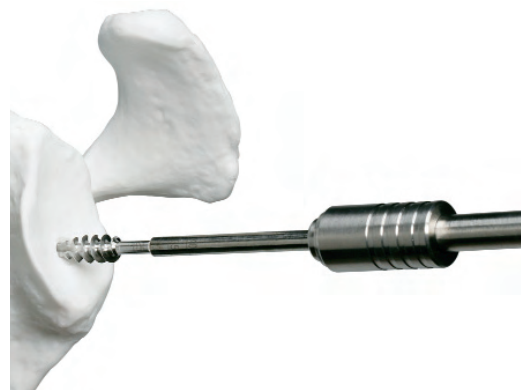


Figure 19



Figure 20

Instrumentation

2.5mm Drill Bit
[1395-1025]

2.5mm Central Drill Guide
[804-03-036]

Depth Gauge
[804-03-003]

RSP 6.5mm Guide Tap
[804-03-008]

Ratchet Handle (black)
[803-05-163]

Manual Tap Driver Adaptor
[804-03-016]

Power Driver Adaptor
[804-03-020]

Surgical Technique

Reverse Shoulder Prosthesis

Glenoid reaming

RSP glenoid reamers are cannulated and designed to create a concave glenoid surface that is congruent with the RSP glenoid baseplate. They are designed for power use and available in 4 sizes: starter, small, medium, and large.

Connect the smallest-sized starter RSP glenoid reamer to the RSP glenoid reamer driver for power use. Place the hole of the cannulated starter RSP glenoid reamer onto the RSP 6.5mm guide tap and begin to ream the glenoid surface using power. Ream the glenoid surface using the small RSP glenoid reamer (Figure 21). Medium and large RSP glenoid reamers are available based on surgeon preference.

Ream to expose subchondral bone. Continue reaming to violate the subchondral bone on the inferior 50% of the prepared glenoid until bleeding bone is exposed.

Remove the RSP 6.5mm guide tap upon completion. Manual removal of the RSP 6.5mm guide tap is achieved either by connecting the quick-coupling T-handle directly to the 6.5mm guide tap or by connecting the manual tap driver adaptor to the ratchet handle.



Figure 21

Instrumentation

RSP Glenoid Reamer Driver
[804-03-011]

RSP Glenoid Reamer, Starter
[804-03-012]

RSP Glenoid Reamer
(Small/Medium/Large)
[804-03-013/014/015]

Ratchet Handle (Black)
[803-05-163]

Manual Tap Driver Adaptor
[804-03-016]

Quick-Coupling T-Handle
[804-03-019]

Glenoid Baseplate Implantation

Reverse Shoulder Prosthesis

RSP glenoid baseplate implant

RSP glenoid baseplate implant is designed with a 6.5mm centralized bone screw that is 30mm long with 4 peripheral holes for bone screws. The baseplate is made of titanium alloy with hydroxyapatite (HA) coating plasma sprayed over the 3DMatrix® porous coating on the backside of the baseplate to promote bony ingrowth.

Glenoid baseplate insertion

Implant the RSP glenoid baseplate onto the prepared glenoid by purchasing the tip of the 6.5mm central bone screw into the anterior cortex of the scapula for secure fixation (Figure 22). Manual placement of the RSP glenoid baseplate is achieved by connecting the ratchet handle to the 3.5mm hex driver, which mates with the Morse taper of the RSP glenoid baseplate.

When fully seated, the RSP glenoid baseplate should sit flush with the glenoid, and the scapula should rotate slightly when attempting to tighten it down onto the glenoid surface (Figure 23). The purchase of the central screw when the baseplate is fully seated **MUST BE VERY SECURE** so that the attempted further advancement of the screw will cause the entire scapula to rotate. If any bony defects remain superiorly on the glenoid surface, cancellous bone graft from the humeral head or metaphysis can be used.

Peripheral bone screw implants

Four peripherally mounted bone screws are used to provide additional fixation of the RSP glenoid baseplate to the glenoid surface. For perpendicular placement, 5.0mm locking bone screw implants are indicated and are available in 7 lengths (14mm to 38mm in 4mm increments). For angled placement in any direction up to 12 degrees, 3.5mm nonlocking bone screw implants are indicated and are available in 13 lengths (14mm to 38mm, in 2mm increments). Selection of bone screws is at the discretion of the surgeon. It is preferable to use 5.0mm locking screws. The 3.5mm nonlocking screws should only be used when the perpendicular will not permit adequate bone purchase.

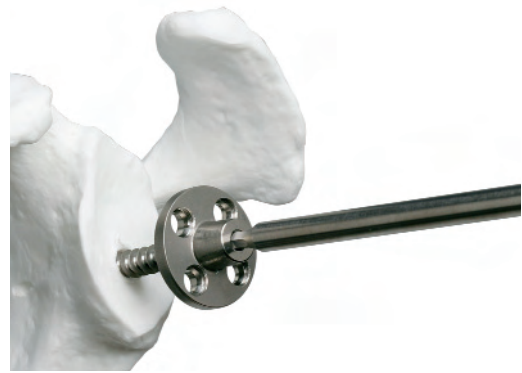


Figure 22

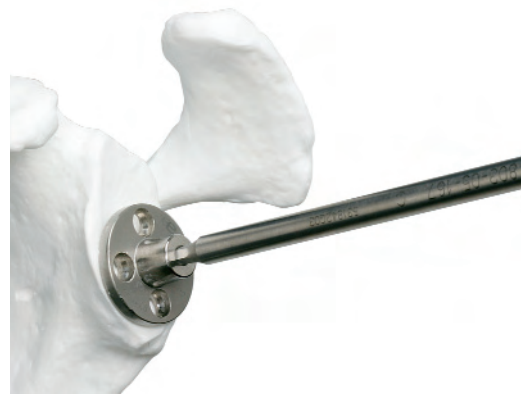


Figure 23

Instrumentation

Ratchet Handle (Black)
[803-05-163]

3.5mm Hex Driver
[803-05-167]

Surgical Technique

Reverse Shoulder Prosthesis

Peripheral bone screw insertion

For placement of the 5.0mm locking bone screws, attach the RSP 3.2mm 4-hole drill guide onto the RSP glenoid baseplate. Using the 3.2mm drill bit, drill all 4 screw holes through the RSP 3.2mm 4-hole drill guide perpendicular to the RSP glenoid baseplate (Figure 24). Remove the RSP 3.2mm 4-hole drill guide.

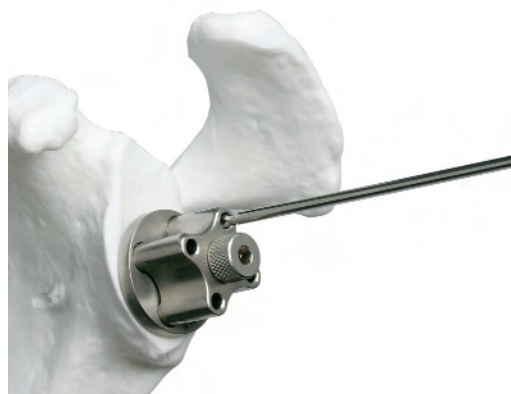


Figure 24

Occasionally, there may be an inadequate amount of bone stock and/or poor quality of bone for perpendicular placement of the 5.0mm locking bone screws. Under these circumstances, the 3.5mm nonlocking bone screws can be used to angle the bone screw placement using the 2.5mm drill bit and the 2.5mm drill guide for improved bone purchase (Figure 25).

Measure the depth of each predrilled screw hole using the depth gauge. Tap the predrilled 3.2mm or 2.5mm screw holes using the 5.0mm or 3.5mm bone screw tap.

Implant the appropriate 5.0mm locking or 3.5mm nonlocking bone screw into the RSP glenoid baseplate.

Manual placement of the 5.0mm locking bone screw is achieved using the 3.5mm hex driver connected to the ratchet handle. Power placement of the 5.0mm locking bone screw is achieved by connecting the power driver adaptor to the 3.5mm power hex driver.

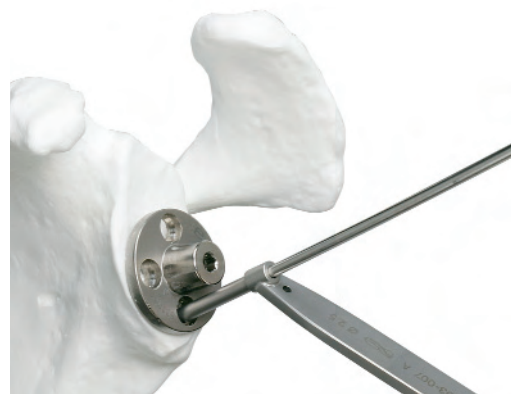


Figure 25

Manual placement of the 3.5mm nonlocking bone screw is achieved using the small 2.5mm hex screwdriver. Power placement of the 3.5mm locking bone screw is achieved by connecting the power driver adaptor to the 2.5mm power hex driver.

Obtain final seating of the bone screws using the 3.5mm or 2.5mm hex screwdriver. Screw heads should be tightened completely to prevent impingement with the RSP glenoid head.

Instrumentation

3.2mm Drill Bit
[801-01-020]

2.5mm Drill Bit
[1395-1025]

RSP 3.2mm 4-Hole Drill Guide
[804-03-009]

2.5mm/3.2mm Drill Guide
[804-03-007]

5.0mm Bone Screw Tap
[804-03-017]

3.5mm Bone Screw Tap
[804-03-018]

Depth Gauge
[804-03-003]

Ratchet Handle (Black)
[803-05-163]

3.5mm Hex Driver
[803-05-167]

Power Driver Adaptor
[804-03-020]

3.5mm Power Hex Driver
[804-03-022]

2.5mm Power Hex Driver
[804-03-021]

Small 2.5mm Hex Screwdriver
[1395-1030]

Large 3.5mm Hex Screwdriver
[801-01-042]

Glenoid baseplate rim planing

Position the correct size RSP baseplate rim planer (available in 32mm, 36mm, and 40mm) over the RSP glenoid baseplate. Plane around the rim of the glenoid baseplate to remove any bone or soft tissue to prevent impingement during implantation of the RSP glenoid head to the RSP glenoid baseplate (Figure 26).

Final humeral preparation

Sequentially ream the proximal humerus using the medium and large-sized RSP humeral socket reamers.

Position the tip of the RSP humeral socket reamer into the opening of the countersunk RSP humeral broach in the humeral metaphysis. Ream the humeral metaphysis using power (Figure 27).

Leave the final countersunk RSP humeral broach in the humeral canal for trial reduction.



Figure 26



Figure 27

Instrumentation

RSP 32mm Baseplate Rim Planer
[804-03-010]

RSP 36mm Baseplate Rim Planer
[804-03-034]

RSP 40mm Baseplate Rim Planer
[804-03-035]

RSP Humeral Socket Reamers
(Small, Medium, Large)
[804-02-013/014/015]

Trial Reduction

Reverse Shoulder Prosthesis

Shoulder reduction

RSP humeral socket trials are available in nine standard and nine semiconstrained sizes: 32mm blue (neutral, +4mm offset, +8mm offset), 36mm yellow (neutral, +4mm offset, +8mm offset), and 40mm green (neutral, +4mm offset, +8mm offset). Note that the inner diameter of the semiconstrained humeral socket insert will have 10 degrees more articular arc than the inner diameter of the standard humeral socket, providing more articular contact with the head for additional stability.

RSP glenoid head trial sizes are available in six sizes: 32mm blue (neutral, -4mm offset), 36mm yellow (neutral, -4mm offset), and 40mm green (neutral, -4mm offset).

Select the appropriate RSP glenoid head trial with the correct offset and position it onto the RSP glenoid baseplate.

As the 36mm -4mm offset, 40mm neutral, and 40mm -4mm offset glenoid heads are hooded on the inferior portion, excess bone from the medial, inferior margin of the glenoid should be removed using the glenoid punch to ensure that the hooded glenoid head sits flush within the prepared glenoid without impingement.

Pull the proximal humerus laterally while extending and externally rotating the arm to deliver the proximal humerus anteriorly.

Position the taper of the RSP humeral socket trial into the opening of the countersunk RSP humeral broach to ensure that it sits flush against the prepared metaphysis without any impingement from osteophytes, labrum, or soft tissue.

Reduce the shoulder by pulling laterally on the humeral socket and proximal humerus to clear it from the glenoid head trial, while flexing and internally rotating the arm, until a gentle, but appreciable "clunk" occurs (Figure 28).

If the shoulder reduces too easily, soft tissue tension is inadequate, and the RSP humeral socket trial with additional offset (+4mm and +8mm) should be trialed.

If the shoulder cannot be reduced, there may be soft tissue impingement, the patient may not be completely relaxed, or additional reaming of the proximal humerus may be required.



Figure 28

Instrumentation

RSP Humeral Socket Trials:
32mm (Blue)
[804-02-026/028 and -038/040]

36mm (Yellow)
[804-02-029/031 and -041/043]

40mm (Green)
[804-02-032/034 and -044/046]

RSP Glenoid Head Trials:
32mm (Blue)
[804-03-005/006]

36mm (Yellow)
[804-03-030/031]

40mm (Green)
[804-03-032/033]

Trial Reduction

Reverse Shoulder Prosthesis

Assessment of mobility

In primary cases, ideal soft tissue tension of the shoulder will allow for "near" full elevation.

In revision cases, elevation is dependent on several variables due to the altered native anatomy. However, 120 degrees of elevation is often achieved.

Assessment of joint stability

Initial assessment of stability is performed with the arm at the side. If there is excessive laxity, additional humeral insert thickness may be selected. The positions most associated with instability are internal rotation, adduction, and extension of the humerus. Patients with severe deficiency of the infraspinatus and teres minor may be more apt to be unstable, and either selection of a larger head with a more constrained socket or increasing anteversion of the humeral component may be helpful.

In revision cases with proximal bone loss, bone grafting and/or use of a humeral socket with greater offset will help achieve adequate soft tissue tension.

Once shoulder mobility and joint stability are sufficient, remove all RSP trial components, dislocate the shoulder, and clear any remaining debris from the humeral canal.

Glenoid Head Implantation

Reverse Shoulder Prosthesis

RSP glenoid head implant

RSP glenoid head implants are manufactured using a wrought cobalt chrome articulating glenoid head surface and reverse Morse taper fixation to the glenoid baseplate. The glenoid head is designed to deliver a force of resistance against the humeral socket/glenoid head combination to help prevent superior escape of the humerus. Available in diameters of 32mm, 36mm, and 40mm, in either a neutral or -4mm offset. The 36mm -4mm offset, 40mm neutral, and 40mm -4mm offset glenoid heads are hooded on the inferior portion. All glenoid heads have a 5.4mm diameter hole in the center of the glenosphere to accept a 3.5mm titanium alloy retaining screw that is 16mm long. Although the glenoid head is still attached to the glenoid baseplate via a Morse taper connection, the retaining screw is designed to be tightened into the central part of the glenoid baseplate to provide an additional measure of security.



Figure 29

Glenoid head insertion

Clear any soft tissue around the circumference of the RSP glenoid baseplate. Irrigate the glenoid baseplate surface including the Morse taper and dry thoroughly.

Select the appropriate cobalt-chrome RSP glenoid head implant with the correct offset. Position the glenoid head onto a clean, dry Morse taper of the RSP glenoid baseplate using a light rotational movement until firmly seated.

Using the glenoid head impactor, lightly impact the cobalt-chrome glenoid head implant onto the glenoid baseplate implant using three to four firm taps (Figures 29).

Insert the 3.5mm titanium alloy retaining screw into the center of the glenoid head and glenoid baseplate. Tighten the retaining screw until it is fully seated using the large 3.5mm hex screwdriver.

As the 36mm -4mm offset, 40mm neutral, and 40mm -4mm offset glenoid heads are hooded on the inferior portion, excess bone from the medial, inferior margin of the glenoid should be removed using the glenoid punch to ensure that the hooded glenoid head sits flush within the prepared glenoid without impingement.

Pull on the implanted glenoid head to confirm that it is locked onto the glenoid baseplate. If it does not seat properly, soft tissue or screw head impingement is present.

Instrumentation

Glenoid Head Impactor
[804-03-001, 800-01-018]

Punch/Drill Guide, 36mm/40mm
[804-03-024/025]

Punch, 36mm/40mm
[804-03-026/027]

Glenoid Punch Driver
[804-03-029]

3.2mm Stop Drill
[804-03-028]

Humeral Implantation

Reverse Shoulder Prosthesis

Humeral implantation

Using a 2mm drill bit, drill transosseous holes into the proximal humerus. Pass No. 1 braided sutures through the predrilled holes for reattaching any remaining subscapularis after final humeral implantation.

RSP humeral stem implant

RSP humeral stem implants are manufactured using titanium alloy and designed with a 150-degree head/neck angle, anatomic-shaped proximal body, and cylindrical-shaped distal segment with cement flutes. The cemented RSP humeral stems are precisely matched with the RSP humeral reamers and broaches, size for size, in all dimensions. To allow for an adequate cement mantle, a stem smaller than the final broach size should be selected. Available in five primary sizes: 6mm x 101mm, 7mm x 105mm, 8mm x 109mm, 10mm x 116mm, and 12mm x 124mm; and 4 revision sizes: 6mm, 8mm, 10mm, and 12mm in one length of 175 mm.

RSP humeral socket implant

RSP humeral socket implants are manufactured using a titanium alloy shell that snaps into a 4mm thick compression-molded polyethylene insert. Connected to the humeral stem via Morse taper fixation, the lateralized humeral socket design stabilizes the superior pulling force of the deltoid muscle to help restore joint mobility and minimize the risk of bone erosion caused by impingement of the humeral socket against the inferior aspect of the glenoid.

The RSP humeral socket shells are available in neutral and +4mm and +8mm offsets, and are designed to mate with the RSP humeral socket inserts, available in 32mm, 36mm, and 40mm, in either standard or semiconstrained options. The inner diameter of the semiconstrained humeral socket insert will have 10 degrees more articular arc than the inner diameter of the standard humeral socket, providing more articular contact with the head for additional stability. Any humeral socket shell can be combined with any humeral socket insert, but the size of the insert must match the size of the glenoid head.

Surgical Technique

Reverse Shoulder Prosthesis

RSP humeral socket assembly

Select the appropriately sized RSP humeral socket shell with the correct offset. Position the socket shell into the humeral stem/socket impaction fixture.

Select the appropriately sized RSP humeral socket insert based on the last trial reduction performed. Carefully align the humeral socket insert into the opening of the humeral socket shell.

Lightly impact the RSP humeral socket insert into the RSP humeral socket shell using three to four firm taps. Make sure that the socket insert is seated all the way around the circumference of the socket shell (Figure 30).

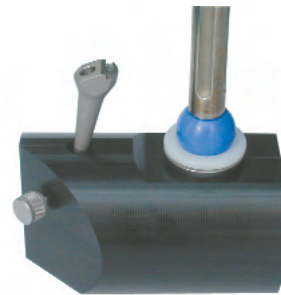


Figure 30

Humeral stem/socket assembly

Select the appropriately sized RSP humeral stem implant with the correct offset. Note that the humeral stem implant should be smaller than the final RSP humeral broach size used. Position and lock the humeral stem into the humeral stem/socket impaction fixture.

Mate the Morse taper of the assembled RSP humeral socket implant into the opening of the RSP humeral stem implant using a light rotational movement until firmly seated. Determine the correct orientation of the two components by aligning the black-etched markings on the inferior aspect of the humeral socket to the medial aspect of the humeral stem.

Lightly impact the humeral socket implant into the humeral stem implant using three to four firm taps (Figure 31).

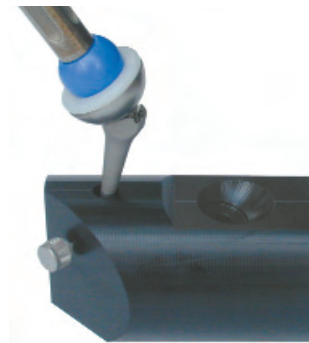


Figure 31

Instrumentation

Humeral Stem/Socket Impaction Fixture
[804-02-053]

32mm Humeral Socket Impactor (Blue)
[804-03-002, 800-01-018]

36mm Humeral Socket Impactor (Yellow)
[804-02-036, 800-01-018]

40mm Humeral Socket Impactor (Green)
[804-02-037, 800-01-018]

Humeral stem cementation

Insert the appropriately sized cement restrictor into the humeral canal, approximately 1.5cm below the distal tip of the RSP humeral stem implant. Brush, irrigate, and dry the humeral canal before bone cement is pressurized into the humeral canal.

Mix the bone cement according to the manufacturer's instructions. Extrude the bone cement into the humeral canal by filling the humeral canal, distal to proximal, using a retrograde technique. This technique is critical to avoid embolization of the intramedullary humeral canal with debris such as air and bone marrow. Pressurize the bone cement using a pressurizing nozzle or a digit.

When the bone cement has reached a dough like consistency, insert the assembled RSP humeral prosthesis into the humeral canal in the established 30 degrees of retroversion. Lightly tap the prosthesis into the humeral canal using the appropriate humeral socket impactor (Figure 31).

Upon completion, remove the humeral socket impactor and any remaining excess bone cement.

RSP Head/Neck Stem Adapters are designed to convert the RSP Humeral Stem from a reverse shoulder prosthesis to a hemiarthroplasty prosthesis. RSP Head/Neck Stem Adapters are available in 6mm and 12mm head/neck heights.

Select the appropriate size RSP Head/Neck Stem Adapter and position it into the taper of the RSP Humeral Stem. Lightly impact the RSP Head/Neck Stem Adapter into the RSP Humeral Stem using three to four firm taps.

Humeral head trials from the Foundation Shoulder System are available in five neutral and offset head diameters (38mm, 42mm, 46mm, 50mm, 54mm) in three neutral head heights (17mm, 22mm and 27mm) and two offset head heights (22mm and 27mm). Select the appropriate Foundation Shoulder Humeral Head Trial with the correct diameter and height and position it onto the RSP Head/ Neck Stem Adapter. Perform trial reduction. The height of the humeral prosthesis above the greater tuberosity and degree of retroversion of the head are examined before reduction. The appropriateness of the chosen humeral head thickness is assessed by evaluating the tension present in the rotator cuff and deltoid muscles.

Select the appropriate Foundation Shoulder Head Implant. Position the humeral head onto a clean, dry Morse taper of the RSP Head/Neck Stem Adapter using a light rotational movement until firmly seated. Assemble the Impactor Handle to the Humeral Head Impactor. Lightly impact the humeral head implant onto the humeral stem implant using three to four firm taps. Pull on the implanted humeral head to confirm that it is locked on to the humeral stem. If it is not seated properly, soft tissue impingement may be present.

Perform final trial reduction and inspection of the joint to ensure that no residual material or osteophytes are present. Final closure should be performed at this time.



Figure 31

Closure

Reverse Shoulder Prosthesis

Final reduction and closure

With the patient relaxed, reduce the humeral prosthesis onto the glenoid head prosthesis. If the prosthesis cannot be reduced, soft tissue impingement may be present.

Gently examine the shoulder while the bone cement is still curing to confirm the previously established motion and joint stability.

Examine the axillary nerve again using the "tug" test.

Place the arm in about 30 degrees of abduction and slight external rotation.

Reattach any remaining subscapularis to the previously prepared sutures in the proximal humerus.

Perform the final range of motion to ensure a safe range for postoperative therapy.

Final routine closure is performed in layers.

Place the arm in an immobilizer.

Postoperative management

The day after surgery, the patient should begin supine passive range of motion with assistance from a physical therapist. Ninety degrees of elevation and zero degrees of external rotation should be accomplished.

At 4 weeks, the patient should wear a shoulder immobilizer and perform passive range of motion exercises.

During the next 4 weeks, the patient should wear a sling and perform assisted active range of motion exercises.

After 8 weeks, the patient should perform active range of motion.

Resistive exercises are delayed until the remnant subscapularis tendon insertion has healed, which usually occurs at 12 weeks.

In revision cases, it is not unusual for therapy to be delayed based on a variety of circumstances.

Encore Medical, L.P.
9800 Metric Blvd.
Austin, Texas 78758
512-832-9500
www.encoremed.com


© 2005 Encore Medical, L.P.
Cat. # 030302-001 rev. C June 2005


Encore, Reverse and 3DMatrix are
registered trademarks of Encore
Medical Corporation or its affiliates.

US Patent No. 6,790,234

CAUTION: Federal Law (USA) restricts
this device to sale by or on the order
of a physician.

See package insert for a complete listing
of indications, contraindications, warnings,
and precautions.

 Shoulder Instruments

⁰¹²³ Shoulder Implants and Instruments