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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.



Surgical Technique



Reverse[®]
shoulder prosthesis

Reverse[®] shoulder prosthesis

Background

Patients presenting with a rotator-cuff-deficient shoulder and glenohumeral arthritis typically show evidence of superior migration 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 these patients.

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

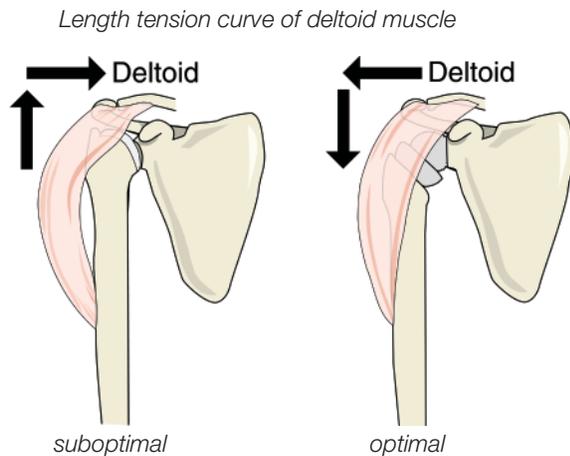


Figure 1



Postoperative

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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.

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Surgical Technique

Reverse Shoulder Prosthesis

Design Rationale

The rotator-cuff-deficient shoulder will have a variety of pathology related to the rotator cuff muscles, rotator cuff tendons, joint capsule, articular cartilage, joint congruity, and periarticular bone.

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, periarticular bone loss and loss of shoulder function.

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. 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 5.0 mm locking and/or 3.5 mm non-locking 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: 32 mm, 36 mm, and 40 mm. For each diameter, there are two offsets available, neutral and -4 mm. 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. Finally, the different glenospheres provide the ability to select a center of rotation that optimizes muscular function and avoids scapular notching.

Indications

The Reverse Shoulder Prosthesis 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 superior migration 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.

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.

CT scans will be used to determine the location of the baseplate by assessing glenoid version and bone loss.

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, and may be useful in determining the quality of the remaining rotator cuff (i.e., teres minor).

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. Consideration of the degree of preoperative instability, glenoid bone loss, and humeral bone loss is essential in anticipating the glenoid head selection, choice of socket constraint and potential need for bone graft augmentation.

Templating the humerus

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.

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.

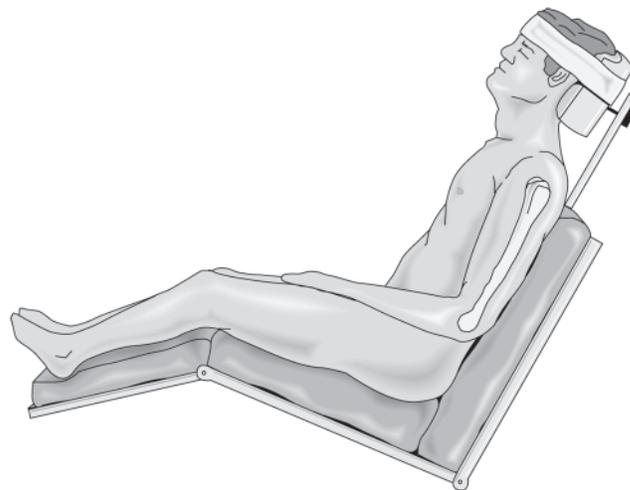


Figure 2

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.

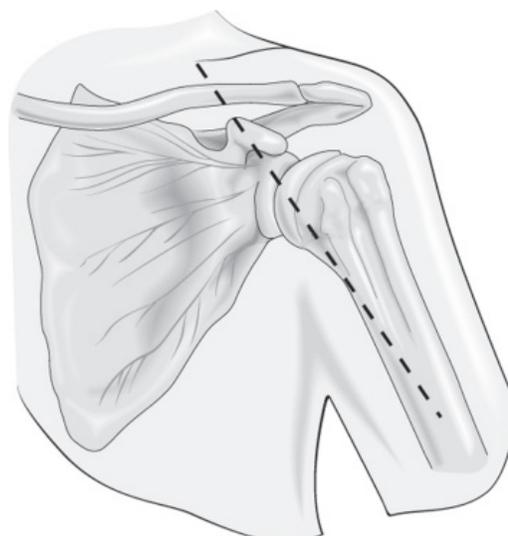


Figure 3

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.

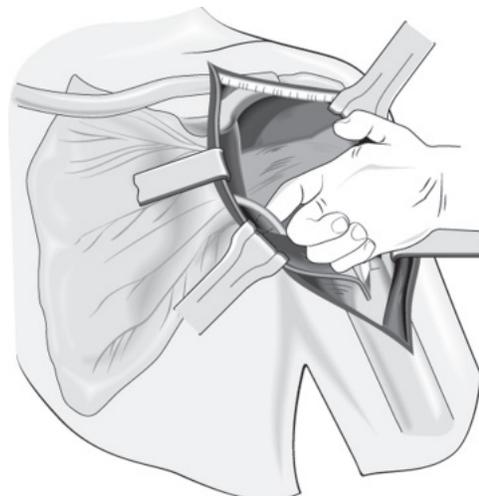


Figure 4

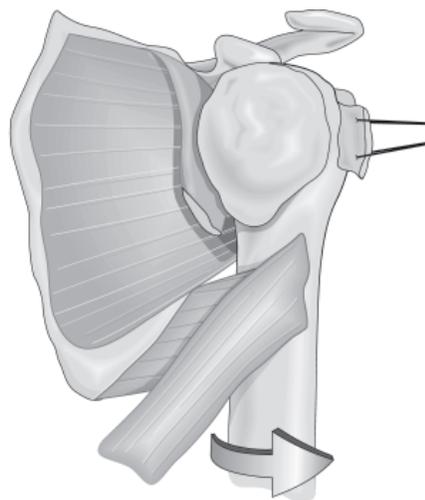


Figure 5

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 RSP 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 3.2 mm drill bit. Tap the bone pins into the prepared drill holes to secure the Osteotomy Guide to the anterior humeral shaft.



Figure 6

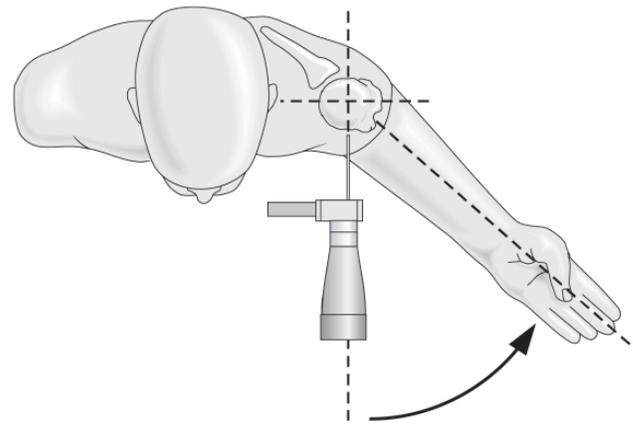


Figure 7



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 6 mm to 14 mm diameters, in 2 mm 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 14 mm 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 (6 mm) 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 depth indicator line on the lateral side of the Humeral Broach Handle lines up with 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
[804-02-055]

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, 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 baseplate insertion.



Figure 16



Figure 17

Instrumentation

RSP Humeral Socket Reamer
(Small)
[804-02-013]

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 (for the right side shoulder). 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 Meyerding 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

Assemble the Central Drill Guide Handle to the Central Drill Guide such that the handle will be held anteriorly when the drill guide is placed on the glenoid. Place the inferior edge of the drill guide on the inferior edge of the glenoid (Figure 18). The Central Drill Guide has a built-in 10 degree inferior tilt to ensure accurate placement of the RSP baseplate.

Preoperative planning helps to anticipate the tilt of the glenoid baseplate. As is common in cases of cuff-tear arthropathy, superior wear of the glenoid may be present. In those cases, the 10 degree built-in inferior tilt of the drill guide may not be sufficient in ensuring the appropriate tilt of the baseplate.

Drill the hole and exit the anterior scapula using the 2.5 mm drill bit. Measure the depth of the drill hole using the Depth Gauge to ensure that the depth of the drill hole is approximately 30 mm.

It is important to note that the length of the central screw on the baseplate is 30 mm. Therefore, the length of the drilled hole should be of the appropriate length to achieve bi-cortical fixation after the face of the glenoid has been reamed.

Seat the RSP 6.5 mm Guide Tap in the same direction and angle as that used for the 2.5 mm drill hole until it engages the anterior cortex of the scapula. The RSP 6.5 mm Guide Tap has a 30 mm depth mark to provide guidance for achieving the appropriate depth (Figure 19). Manual placement of the RSP 6.5 mm Guide Tap is achieved by connecting the manual Tap Driver Adapter to the Ratchet Handle. Power placement of the RSP 6.5 mm Guide Tap is achieved by using the PowerTap Extension. Significant resistance should be felt when the anterior cortex is engaged.

Leave the 6.5 mm Guide Tap in the glenoid (Figure 20).

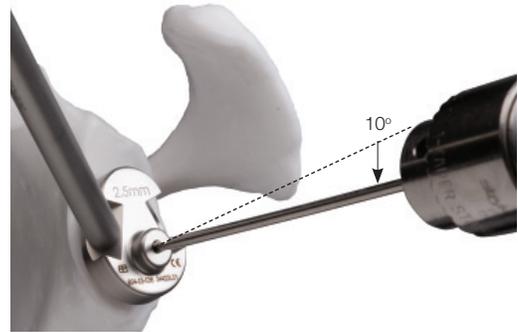


Figure 18

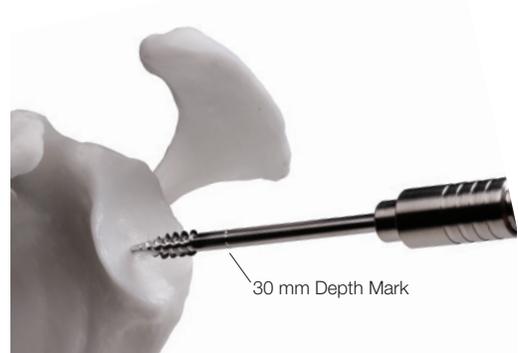


Figure 19



Figure 20

Instrumentation

2.5 mm Drill Bit
[1395-1025]

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

Central Drill Guide Handle
[804-03-037]

Depth Gauge
[804-03-003]

RSP 6.5 mm 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 6.5 mm 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 6.5 mm Guide Tap upon completion. Manual removal of the RSP 6.5 mm Guide Tap is achieved either by connecting the Quick-Coupling T-handle directly to the 6.5 mm 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

The RSP Glenoid Baseplate implant is designed with a 6.5 mm centralized bone screw that is 30 mm 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 into 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 3.5 mm Hex Driver, which mates with a hex feature on 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.

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, 5.0 mm locking bone screw implants are indicated and are available in 7 lengths (14 mm to 38 mm, in 4 mm increments). For angled placement in any direction up to 12 degrees, 3.5mm non-locking bone screw implants are indicated and are available in 13 lengths (14 mm to 38 mm, in 2 mm increments). Selection of bone screws is at the discretion of the surgeon, however, it is preferable to use 5.0 mm locking screws. The 3.5 mm non-locking screws should only be used when the perpendicular will not permit adequate bone purchase.

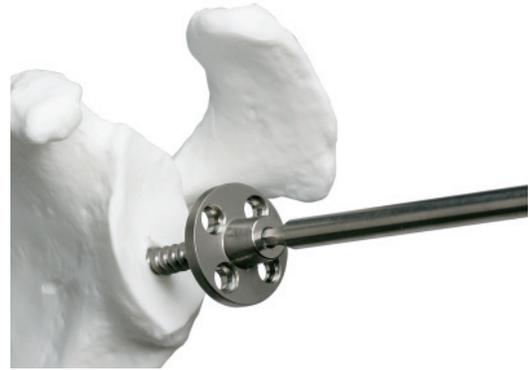


Figure 22



Figure 23

Instrumentation

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

3.5 mm Hex Driver
[803-05-167]

Surgical Technique

Reverse Shoulder Prosthesis

Peripheral bone screw insertion

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

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

Measure the depth of each predrilled screw hole using the Depth Gauge. Tap the predrilled 3.2 mm or 2.5 mm screw holes using the 5.0 mm or 3.5 mm Bone Screw Tap.

Implant the appropriate 5.0 mm locking or 3.5 mm non-locking bone screw into the RSP Glenoid Baseplate.

Manual placement of the 5.0 mm locking bone screw is achieved using the 3.5 mm Hex Driver connected to the Ratchet Handle. Power placement of the 5.0 mm locking bone screw is achieved by connecting the Power Tap Extension to the 3.5 mm Power Hex Driver.

Manual placement of the 3.5 mm non-locking bone screw is achieved using the small 2.5 mm Hex Screwdriver. Power placement of the 3.5 mm locking bone screw is achieved by connecting the Power Tap Extension to the 2.5 mm Power Hex Driver.

Obtain final seating of the bone screws using the 3.5 mm or 2.5 mm Hex Screwdriver. Screw heads should be tightened completely to prevent impingement with the RSP Glenoid Head.

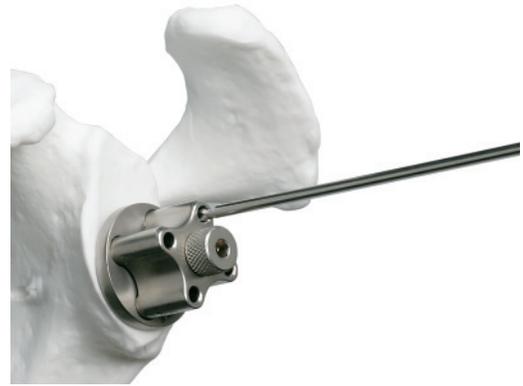


Figure 24



Figure 25

Instrumentation

3.2 mm Drill Bit
[801-01-020]

2.5 mm Drill Bit
[1395-1025]

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

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

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

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

Depth Gauge
[804-03-003]

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

3.5 mm Hex Driver
[803-05-167]

Power Driver Adaptor
[804-03-020]

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

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

Small 2.5 mm Hex Screwdriver
[1395-1030]

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

Glenoid baseplate rim planing

Position the RSP Baseplate Rim Planer over the RSP Glenoid Baseplate. Manually ream around the rim of the Glenoid Baseplate to remove any bone or soft tissue (Figure 26). This will help to prevent impingement when implanting the RSP Glenoid Head onto the RSP Glenoid Baseplate.

Final humeral preparation

Sequentially ream the proximal humerus using the Medium and Large 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

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

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

RSP Humeral Socket Reamers
(Medium/Large)
[804-02-014_015]

Trial Reduction

Reverse Shoulder Prosthesis

Shoulder trial reduction

RSP Humeral Socket Shell Trials are available in three sizes: neutral, +4 mm thickness, and +8 mm thickness. Socket Insert Trials are available in six sizes: 32 mm blue (standard and semi-constrained), 36 mm yellow (standard and semi-constrained), and 40 mm green (standard and semi-constrained). Note that the inner diameter of the Semi-Constrained 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. The Socket Insert Trials assemble to the Socket Shell Trials by lining up the tabs of the Liner Trial with the scallops of the Shell Trial (Figure 28). A clockwise $\frac{1}{4}$ turn of the Liner Trial will lock the Liner Trial to the Shell Trial. RSP Glenoid Head Trial sizes are available in six sizes: 32 mm blue (neutral and -4 mm offset), 36 mm yellow (neutral and -4 mm offset), and 40 mm green (neutral and -4 mm offset).

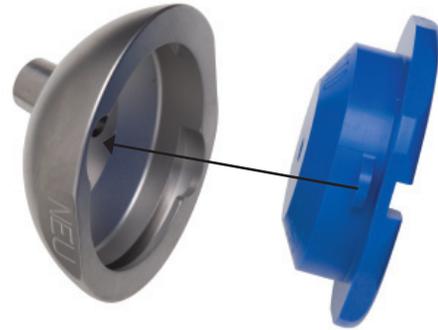


Figure 28

Select the appropriate RSP Glenoid Head Trial with the correct offset and position it onto the RSP Glenoid Baseplate. The RSP Glenoid Head Inserter is used to place the Glenoid Head Trial onto the Baseplate (Figure 29). The Glenoid Head Inserter should be impacted lightly to seat the Head Trial onto the Morse taper of the Glenoid Baseplate. If the Head Trial is not fully seated using light tapping with the Glenoid Head Inserter, then the Glenoid Head Impactor should be used to provide a greater impaction force to the Head Trial (Figure 30).



Figure 29

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

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

Instrumentation

RSP Glenoid Head Trial
[804-03-042_047]

RSP Glenoid Head Inserter
[804-03-041]

RSP Glenoid Head Impactor
[804-03-001/801-01-018]



Figure 30

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. Use the Humeral Socket Impactor to seat the Humeral Socket Trial onto the Morse taper of the Humeral Broach (Figure 31).

Reduce the shoulder by pulling laterally on the Humeral Socket Trial 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 32). If the shoulder reduces too easily, soft tissue tension is inadequate, and the RSP Humeral Socket Shell Trial with additional offset (+4 mm and +8 mm) should be considered as well as an alternate glenoid head. 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.

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.

In revision cases with proximal bone loss, bone grafting and/or use of a Humeral Socket with greater thickness will help achieve adequate soft tissue tension. In addition, a semi-constrained socket insert will improve stability.



Figure 31



Figure 32

Instrumentation

RSP Humeral Socket Shell Trials
[804-02-057_059]

RSP Humeral Socket Insert Trials
[804-02-060_065]

RSP Humeral Socket Impactor
[804-02-002, 804-02-036_037
801-01-018]

Surgical Technique

Reverse Shoulder Prosthesis

Removal of Trial Components

Once shoulder mobility and joint stability are sufficient, dislocate the shoulder to remove all RSP trial components. Rotate the RSP Socket Insert Trial counter-clockwise and remove it from the Shell Trial. If the Shell Trial cannot be removed by hand, insert the RSP Glenoid Head Distractor into the hole through the taper of the Shell Trial and rotate clockwise until the trial disengages from the Humeral Broach (Figure 33). The RSP Glenoid Head Distractor is also used to remove the Glenoid Head Trial. Position the RSP Glenoid Head Distractor into the central hole of the RSP Glenoid Head Trial and rotate clockwise until the Glenoid Head Trial disengages from the Glenoid Baseplate (Figure 34). After the trial components and the broach have been removed, clear any remaining debris from the humeral canal.



Figure 33



Figure 34

Instrumentation

RSP Glenoid Head Distractor
[804-02-035]

Glenoid Head Implantation

Reverse Shoulder Prosthesis

RSP glenoid head implant

RSP Glenoid Head Implants are manufactured with a wrought cobalt chrome articulating glenoid head surface and reverse Morse taper for fixation to the Glenoid Baseplate. RSP Glenoid Heads are available in diameters of 32 mm, 36 mm, and 40 mm, in either a neutral or -4 mm offset. The 36 mm -4 mm offset, 40 mm neutral (not hooded), and 40 mm -4mm offset Glenoid Heads are hooded on the inferior portion. All Glenoid Heads have a 5.4 mm diameter hole in the center of the glenosphere to accept a 3.5 mm titanium alloy Retaining Screw that is 16 mm long. Although the Glenoid Head is 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.

Surgical Technique

Reverse Shoulder Prosthesis

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.

As the 36 mm -4 mm offset, 40 mm neutral (not hooded), and 40 mm -4 mm offset Glenoid Heads are hooded on the inferior portion, excess bone from the medial, inferior margin of the glenoid should be removed using a high speed burr or curved rongeur to ensure that the hooded Glenoid Head sits flush within the prepared glenoid without impingement.

Select the appropriate cobalt-chrome RSP Glenoid Head implant with the correct offset. Assemble the Glenoid Head to the Glenoid Head Inserter by placing the RSP Glenoid Head inserter into the outer central hole of the Glenoid Head and rotate clockwise until tight. Position the Glenoid Head onto a clean, dry Morse taper of the RSP Glenoid Baseplate using the RSP Glenoid Head inserter (Figure 35). Light impaction on the strike plate of the inserter should be used to seat the Glenoid Head to the Glenoid Baseplate (USE ONLY LIGHT IMPACTION FORCE WITH THE INSERTER). Remove the Glenoid Head Inserter and, using the Glenoid Head Impactor, impact the cobalt-chrome Glenoid Head implant onto the Glenoid Baseplate implant using three to four firm taps (Figure 36).



Figure 35



Figure 36

Instrumentation

Glenoid Head Inserter
[804-03-041]

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

Thread the Glenoid Head Inserter onto the Glenoid Head implant and pull on the Glenoid Head Inserter to ensure the Glenoid Head is fully seated onto the Morse taper of the Glenoid Baseplate (Figure 37). A fully seated Glenoid Head implant will not move. If the Glenoid Head implant is not fully seated, soft tissue impingement may be present.

Insert the 3.5 mm titanium alloy Retaining Screw into the outer central hole of the Glenoid Head. Tighten the Retaining Screw using the RSP Torque Limiting Driver (Figure 38).



Figure 37



Figure 38

Instrumentation

Glenoid Head Inserter
[804-03-041]

RSP Torque Limiting Driver
[804-03-038]

Humeral Implantation

Reverse Shoulder Prosthesis

Humeral implantation

Using a 2 mm drill bit, drill transosseous holes into the proximal humerus. Pass No. 1 braided sutures through the pre-drilled 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. Humeral Stems are available in five primary sizes: 6 mm x 101 mm, 7 mm x 105 mm, 8 mm x 109 mm, 10 mm x 116 mm, and 12 mm x 124 mm; and 4 revision sizes: 6 mm, 8 mm, 10 mm, and 12 mm in one length of 175 mm.

RSP humeral socket implant

RSP humeral socket implants are manufactured using a titanium alloy shell. A 4mm thick compression-molded polyethylene insert snaps into the shell. 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, +4 mm and +8mm offsets, and are designed to mate with the RSP Humeral Socket Inserts. The Humeral Sockets Inserts are available in 32 mm, 36 mm, and 40 mm sizes and in either standard or semi-constrained options. The inner diameter of the Semi-Constrained 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 Glenoid 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.

RSP humeral socket assembly

Select the appropriately sized RSP Humeral Socket Shell. 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 (Figure 39). Make sure that the Socket Insert is seated all the way around the circumference of the Socket Shell.



Figure 39

Humeral stem/socket assembly

Select the appropriately sized RSP Humeral Stem implant. 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 (Figure 39).

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 40).



Figure 40

Instrumentation

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

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

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

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

Surgical Technique

Reverse Shoulder Prosthesis

Humeral stem cementation

Insert the appropriately sized cement restrictor into the humeral canal, approximately 1.5 cm 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 41).

Upon completion, remove the Humeral Socket Impactor and any remaining excess bone cement.



Figure 41

Instrumentation

Humeral Socket Impactor
[804-03-002_036_037, 800-01-018]

Humeral stem conversion

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

Lightly impact the RSP Humeral Stem Adapter Trial into the RSP Humeral Stem using three to four firm taps (Figure 42).

Humeral head trials from the Foundation Shoulder System are available in five neutral and offset head diameters (38 mm, 42 mm, 46 mm, 50 mm, 54 mm) in three neutral head heights (17 mm, 22 mm and 27 mm) and two offset head heights (22 mm and 27 mm). Select the appropriate Foundation Shoulder Humeral Head Trial with the correct diameter and height and position it onto the RSP Humeral 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 and RSP Humeral Stem Adapter height is assessed by evaluating the tension present in the rotator cuff and deltoid muscles.

Select the appropriate size RSP Humeral Stem Adapter Implant 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 (Figure 43).

Select the appropriate Foundation Shoulder Head Implant. Position the humeral head onto a clean, dry Morse taper of the RSP Humeral 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 42



Figure 43

Instrumentation

Humeral Stem Adaptor Trial
[804-02-024_025]

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

First 6 Weeks: Patient should wear a shoulder immobilizer and perform pendulum-type exercises.

Weeks 6 thru 12: Patient should wear a sling and begin supine active-assisted range of motion exercises. Active forward flexion should be performed as comfort allows.

After 12 Weeks: Patient should begin resistive exercises.

Strengthening and stretching exercises should continue, with maximal functional improvement occurring at about one year post-operatively.