EXACTECH | **EXTREMITIES**

Operative Technique

equinoxe®

Subscapularis Preserving
Total Shoulder Arthroplasty

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INTRODUCTION

Thank you for considering the Exactech Equinoxe Shoulder System and the subscapularis sparing total shoulder arthroplasty (TSA) technique. We began the Equinoxe product development process by identifying and addressing the challenges our team had been experiencing with shoulder replacement surgery. Similar to the traditional TSA technique, this procedure utilizes the deltopectoral interval. Unlike the traditional TSA technique, however, the prostheses are inserted through the rotator interval without ever violating the integrity of the subscapularis. Alternatively, the technique can be performed through a standard deltopectoral approach below the subscapularis without opening the rotator interval. These techniques build upon the work done by others, especially Dr. Laurent LaFosse and Dr. Felix Savoie, who pioneered these concepts. We extend our thanks and are grateful for the opportunity to design instrumentation that makes this approach possible.

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NYU Hospital for Joint Diseases
New York University Langone Medical Center

OPERATIVE TECHNIQUE OVERVIEW

ROTATOR INTERVAL/SUPERIOR APPROACH

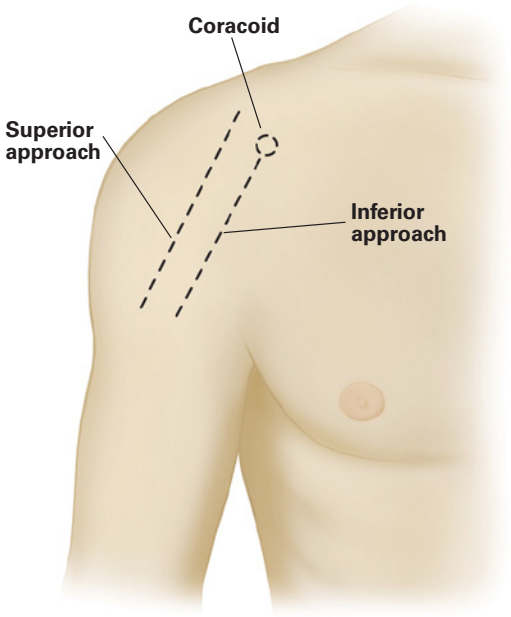

Figure A
Subscapularis Preserving TSA Incision

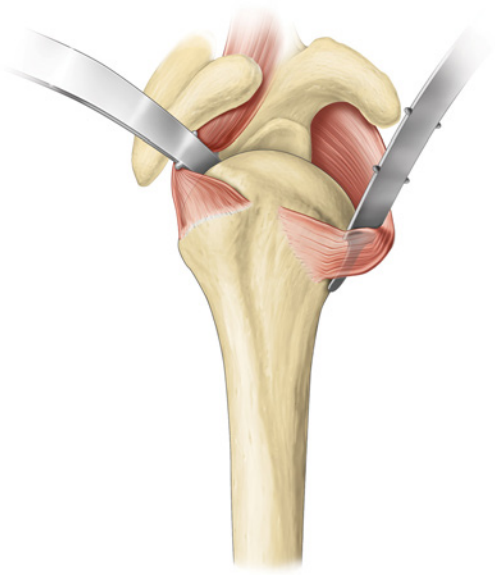

Figure B
Humeral Head Exposure

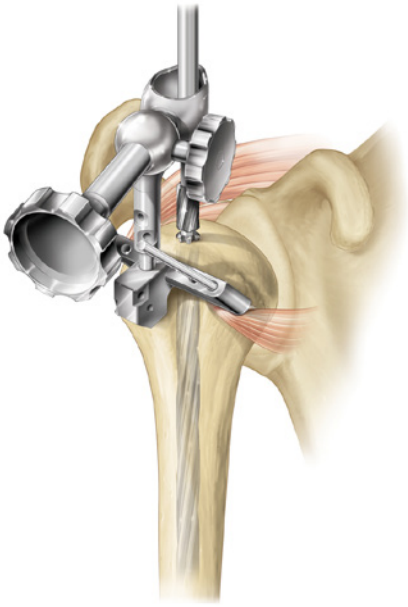

Figure C
Lateral Cut Guide with Reamer and Pins

Figure D
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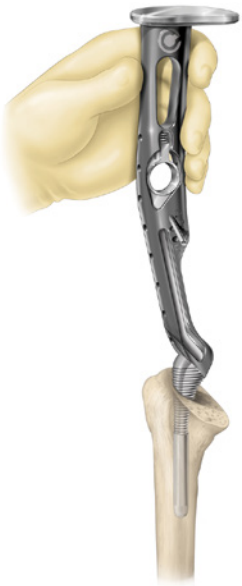

Figure E
Sequential Broaching Using the Low Profile Broach Handle

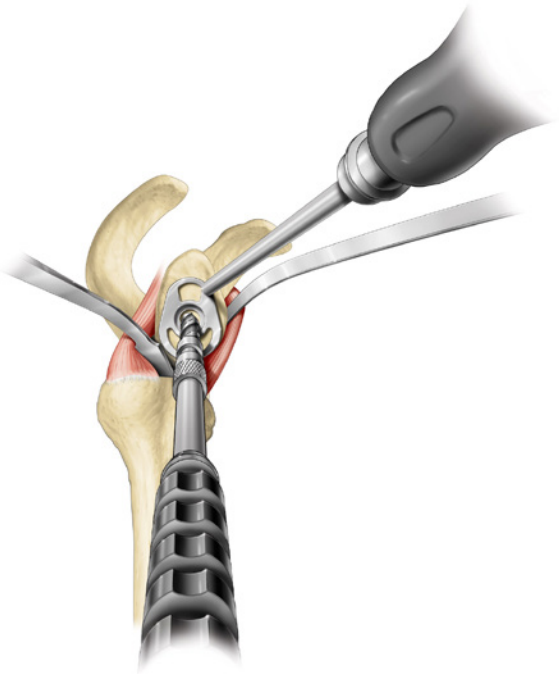

Figure F
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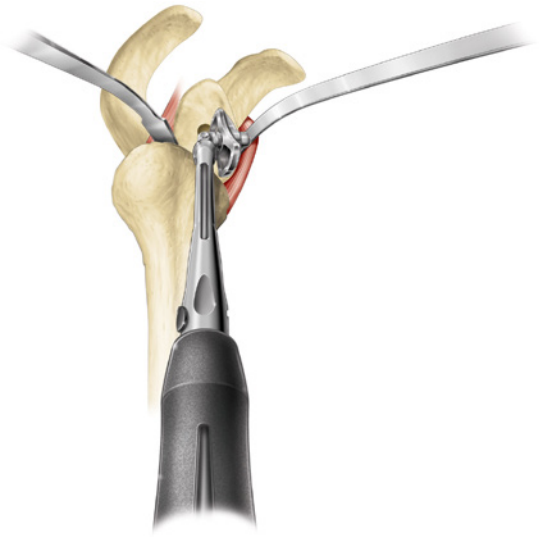

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Reaming the Glenoid Face

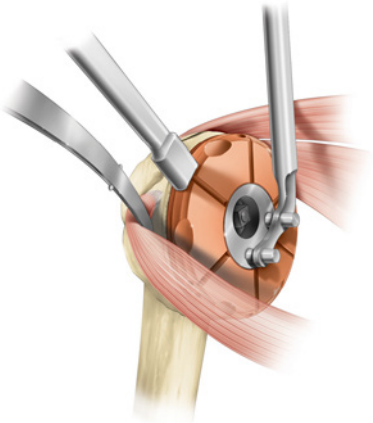

Figure H
Securing the Short Replicator Plate Adaptor into Position

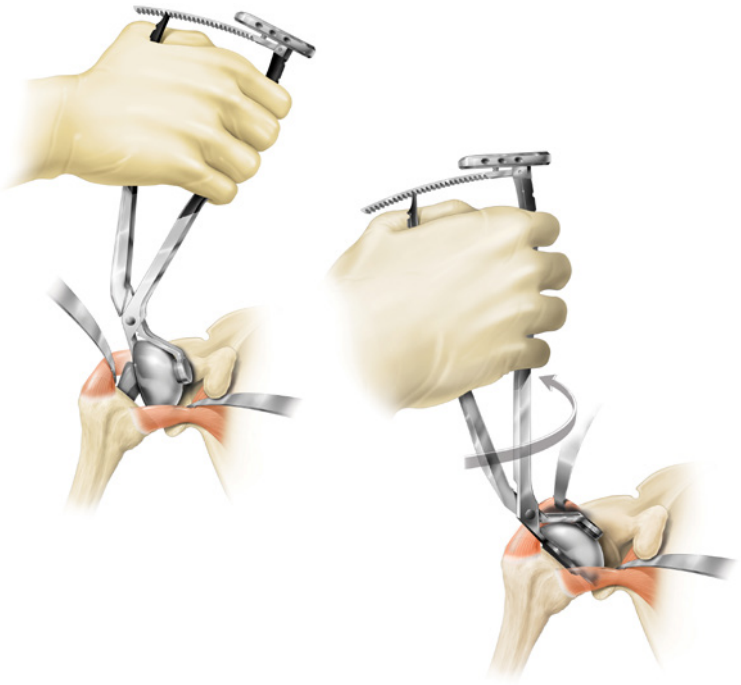

Figure I
Insertion and Impaction of the Final Humeral Implant Assembly

DETAILED OPERATIVE TECHNIQUE

ROTATOR INTERVAL/SUPERIOR APPROACH

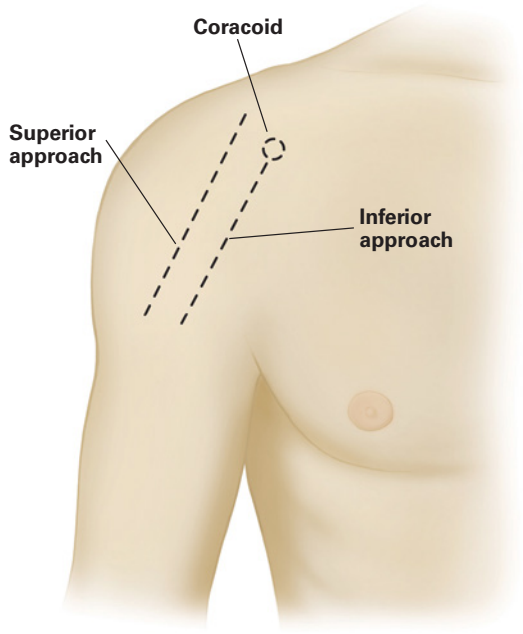

Figure 1
Subscapularis Preserving TSA Incision
(superior approach at left)
(Note the incision is ~1cm lateral to the incision for the traditional TSA technique.)

PATIENT SELECTION

While subscapularis preserving TSA technique can be considered for all patients with degenerative arthritis of the shoulder, **it is not recommended for patients who are obese or whose arthritis has resulted in significant medial erosion of the joint.** It is also not recommended in revision arthroplasty cases where a wide exposure of the joint may be required. In addition to the specially designed instrumentation supplied by Exactech, standard shoulder arthroplasty instruments will be necessary. Intra-operative imaging may also be useful.

PATIENT POSITIONING

The positioning of a patient for the subscapularis preserving TSA technique is similar to that for a traditional TSA. Therefore, the patient is placed in a beach chair position, allowing unrestricted mobility of the entire arm. **Unlike the traditional TSA, however, the patient should be positioned in a slightly more vertical position, preferably in 60-70 degrees of elevation.** The entire shoulder girdle, from the mid clavicle to the lateral third of the scapula and the entire upper extremity should be included in the operative site.

SURGICAL APPROACH

The skin incision on the anterior shoulder should be parallel, but approximately 1 cm lateral, to the standard deltopectoral incision. As depicted in *Figure 1,* the standard incision begins at the coracoid process and extends to the deltoid insertion. The incision for the subscapularis preserving

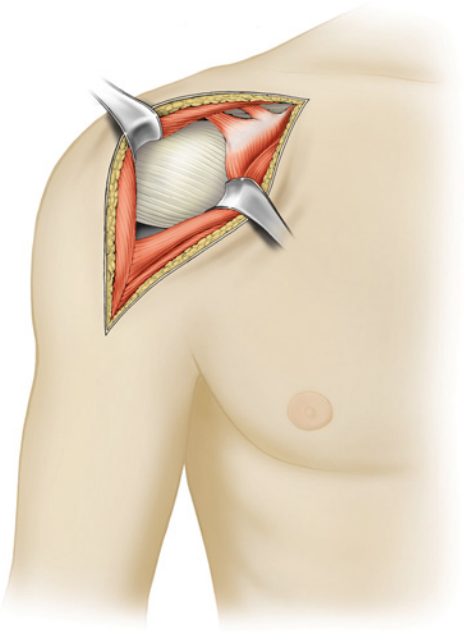

Figure 2
Dividing the Clavipectoral Fascia Longitudinally

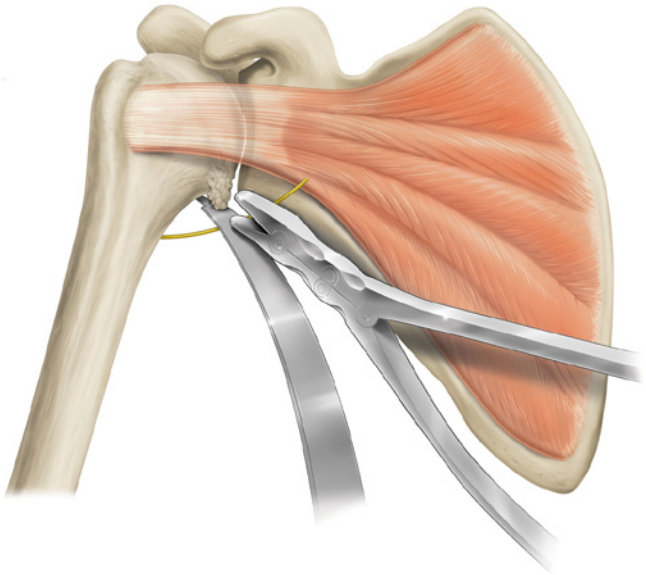

Figure 3
Removal of Humeral Osteophytes

TSA is moved 1 cm laterally. After raising skin flaps, the deltopectoral interval is developed proximally and distally. The cephalic vein can be retracted laterally or medially based upon the surgeon's preference. The subacromial space is mobilized and any preformed adhesions are released. This mobilization should be extended laterally into the subdeltoid space. The clavipectoral fascia is divided longitudinally and the conjoined tendon muscles are mobilized *(Figure 2)*. Next, the coracoacromial ligament is isolated and excised. Finally, the subscapularis tendon insertion is identified and the branches of the anterior humeral circumflex are cauterized.

HUMERAL HEAD EXPOSURE AND RESECTION

The inferior portion of the subscapularis tendon insertion into the humeral neck should be well visualized. The inferior 5 mm of the subscapularis (primarily muscular portion) is released from the humeral neck and retracted inferiorly to expose the inferior glenohumeral joint capsule. Under clear visualization, the inferior glenohumeral joint capsule is then excised. This will, in turn, provide access to the inferior portion of the glenohumeral joint. Osteophytes at the inferior humeral neck should be visible. As depicted in *Figure 3,* the osteophytes can then be removed with a rongeur, small curved osteotomes, or a combination of both. By externally rotating the humerus, posterior osteophytes can be exposed and removed. The axillary nerve is located in an extracapsular position so this dissection can be performed safely with appropriately placed retractors.

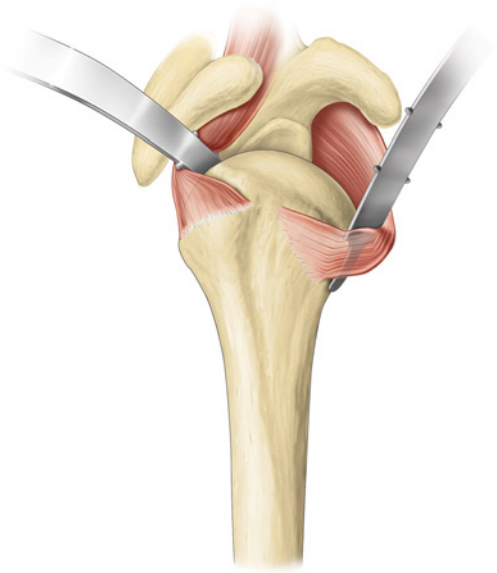

Figure 4
Humeral Head Exposure
(Be careful to avoid distal migration of the anterior retractor underneath the subscapularis.)

Next, the biceps sheath is opened at the proximal portion of the pectoralis major tendon insertion. **The biceps tendon is identified and biceps tenodesis is performed.** The biceps tendon should be secured to the pectoralis major tendon using non-absorbable sutures. The biceps tendon is divided proximal to the tenodesis site and traced into the rotator interval. The rotator interval is then opened throughout its course to the anterosuperior glenoid.

The rotator interval must be adequately developed to allow insertion of prosthesis. Therefore, all soft tissues from the "rolled" superior edge of the subscapularis to the anterior edge of the supraspinatus must be excised. Excision typically begins laterally and progresses to the superior glenoid margin. At the superior glenoid rim, the remaining biceps tendon should also be excised.

As depicted in Figure 4, spiked Hohmann retractors are then placed anteriorly underneath the subscapularis at its insertion and posteriorly underneath the posterior portion of the rotator cuff insertion. Care should be taken to avoid distal migration of the anterior retractor underneath the subscapularis, as it can potentially injure the axillary nerve. With the retractors in place, the humeral head can be visualized. The anatomic neck, as defined by the insertion of the rotator cuff should be noted.

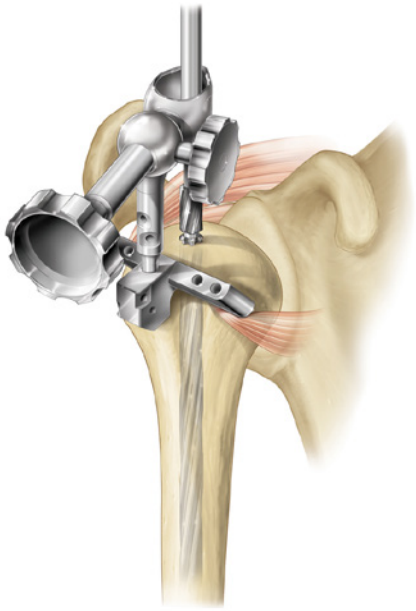

Figure 5
Securing the Lateral Cut Guide (Shown with Reamer)

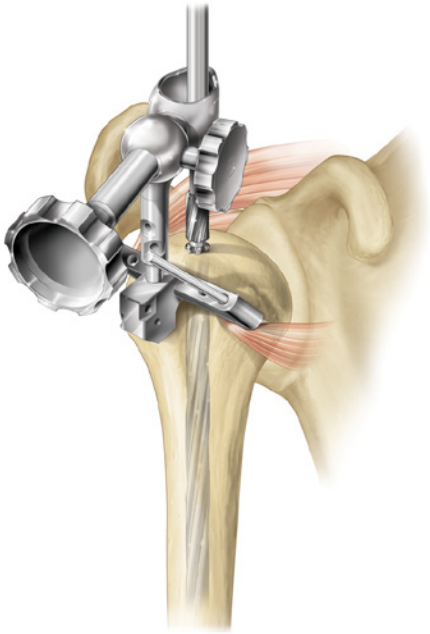

Figure 6
Lateral Cut Guide with Reamer and 3.2mm Pins

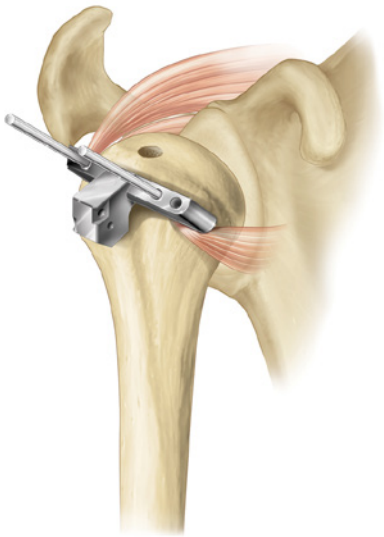

Figure 7
Lateral Cut Guide with 3.2mm Pins in Place

HUMERAL PREPARATION

There are different methods that can be used to perform the humeral head resection:

1. Intramedullary cut guide
2. Free hand technique.

The intramedullary cutting guide can be secured to the humeral head using 3.2mm diameter knee pins just distal to the anatomic neck of the humerus *(Figures 5 - 7)*. While carefully protecting the rotator cuff tendons, the initial cut into the humeral head near the rotator interval is completed using a microsagittal saw. After removing the cutting guide, the humeral head cut is completed using straight osteotomes taking care to not damage the surrounding rotator cuff. Any residual humeral head osteophytes can then be removed through the rotator interval. **After humeral head resection, the cut should be checked to ensure that there are no remaining bone fragments around the periphery.** The angle of the humeral head cut can be confirmed by palpating the cut surface through the inferior capsular exposure. Alternatively, it can also be confirmed with fluoroscopy.

Figure 8
Sequential Reaming of the Humerus

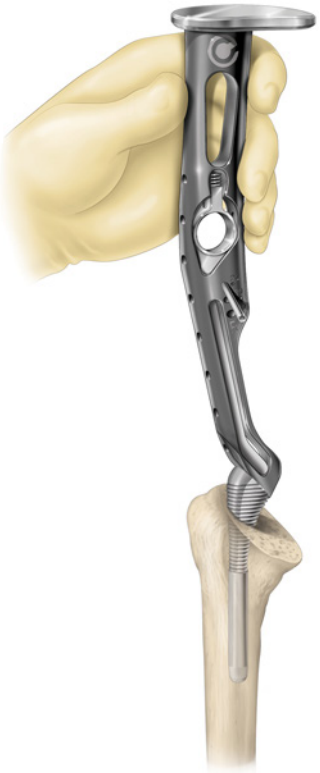

Figure 9
Sequential Broaching Using the Low Profile Broach Handle

With the humerus in an adducted and extended position, the cut surface of the humeral head can be exposed through the rotator interval for preparation of the humeral canal. The starting point is identified and the humeral canal is sequentially reamed until the appropriate size is reached *(Figure 8)*. Reaming should be continued with a larger diameter until good cortical contact is achieved. Sequential broaching is then performed using the low profile broach handle *(Figure 9)*. When broaching is completed, the broach will be left in place to trial the humeral head after glenoid preparation. Should the surgeon want to perform an in-situ humeral assembly rather than a back-table humeral assembly, the actual prosthesis can be inserted.

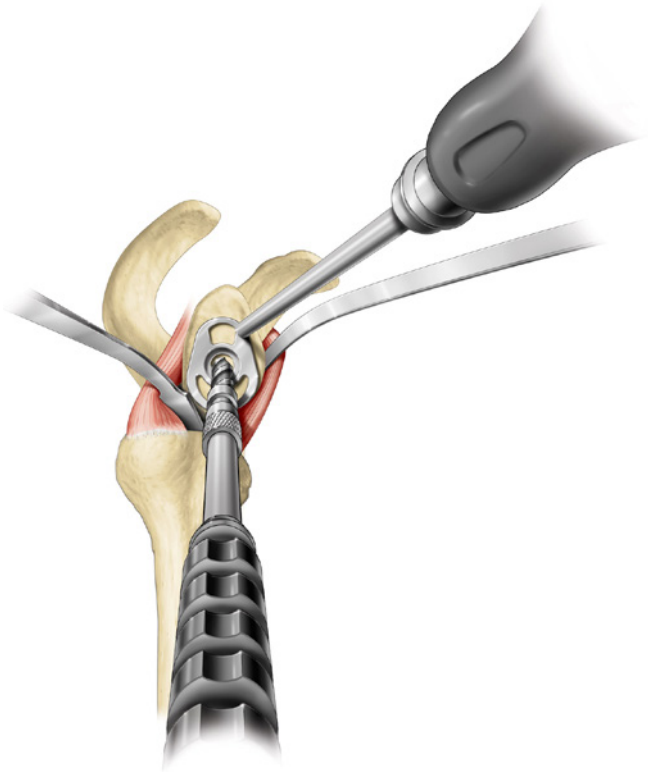

Figure 10
Drilling the Central Hole

GLENOID PREPARATION AND PROSTHESIS INSERTION

To expose the glenoid, retractors should be placed along the anterior glenoid neck and along the posterior inferior glenoid neck. A forked "Playboy" retractor may be inserted along the inferior glenoid to retract the proximal humerus posteriorly and inferiorly. A small Hohmann retractor can also be placed above the superior glenoid. **With these retractors in place, capsular release should be performed along the anterior, superior and posterior glenoid margins.** This will allow greater mobilization of the proximal humerus away from the surgical field. With the glenoid exposed, the remaining labrum should be removed circumferentially.

The central portion of the glenoid is identified based upon the preoperative imaging studies and the intraoperative visualization. The starting point is marked with the electrocautery. Finger palpation about the anterior glenoid neck can provide additional confirmation regarding the angle of the drill. Using center hole drill guide, the central drill hole is established *(Figure 10)*. If desired, cannulated drills and

Figure 11
Hinged Glenoid Reamer

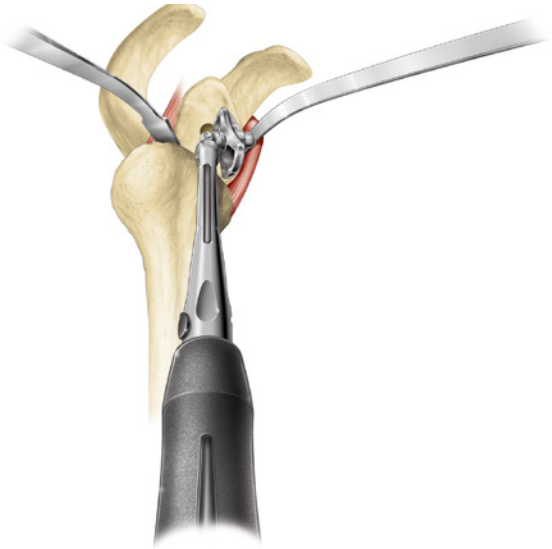

Figure 12
Hinged Glenoid Reamer

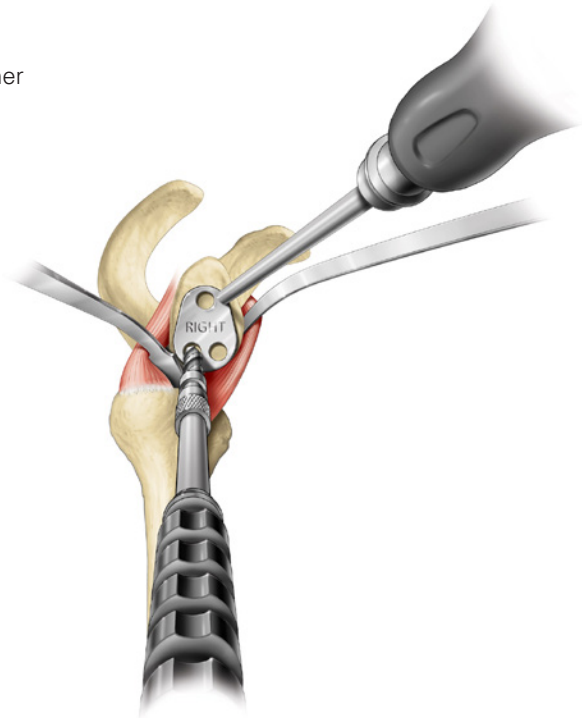

Figure 13
Drilling Glenoid Peripheral Holes

reamers that utilize a 2 mm k-wire are provided. The glenoid is then sequentially reamed to the appropriate size. A hinged glenoid reamer driver is provided for cases where access to the glenoid is limited *(Figures 11 and 12)*. Care should be taken to maintain most of the subchondral bone and to not over-ream.

Next, the peripheral hole drill guide and the peripheral peg drill is used to prepare the peripheral holes based upon whether a pegged, caged or keeled component is used *(Figure 13)*. If implanting a keeled glenoid, the 3 holes should be connected with a rongeur and then broached appropriately. After preparation is complete, confirm the appropriate size and position of the prosthesis with a trial glenoid component. The trial component should sit fully on the prepared bone without any "rocking". Finally, cementation of the glenoid component should be performed using the standard method based upon the type of glenoid component utilized. If desired, cement pressurization instrumentation can also be utilized prior to inserting the final glenoid implant.

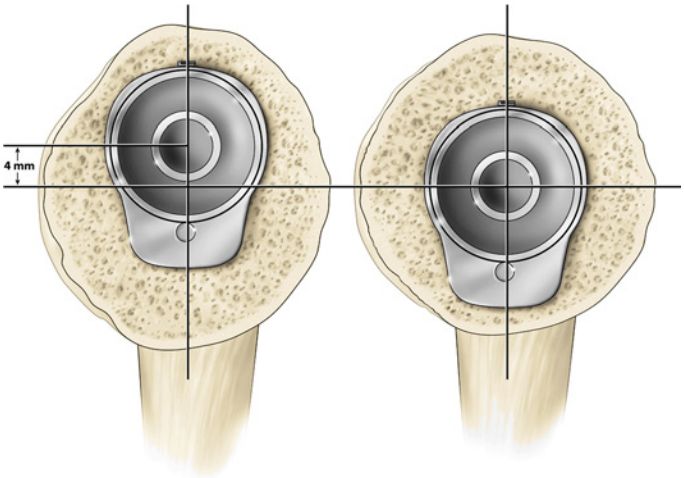

Figure 14
Determining Whether to Use a 1.5mm or 4.5mm Replicator Plate

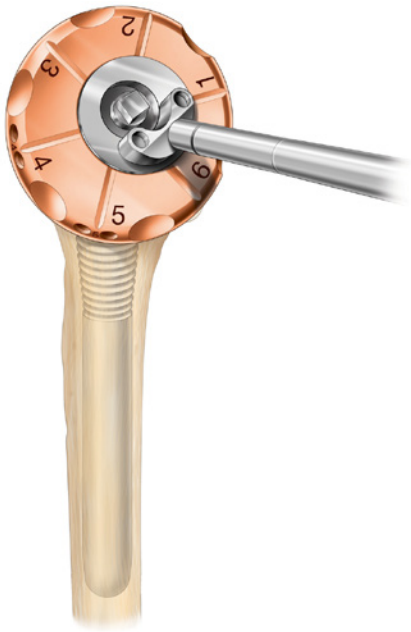

Figure 15
Humeral Plate Dial

HUMERAL PROSTHESIS INSERTION

With the arm in adduction and extension, the spiked Hohmann Retractors are used to retract the margins of the rotator cuff interval. The cut surface of the proximal humerus is evaluated to determine the offset of the humerus. A preliminary determination is made as to whether a 1.5 mm or 4.5 mm short replicator plate is appropriate *(Figure 14)*. If there is greater offset, a 4.5 mm short replicator plate is used and if there is a minimal offset, a 1.5 mm short replicator plate is used. The appropriately sized short replicator plate adaptor is then secured to the broach. As depicted in *Figures 15 - 17,* a specially designed low profile counter torque handle, angled torque screw driver and humeral plate dial adjuster are provided to secure the short replicator plate adaptor and aid the surgeon in determining the appropriate orientation and position.

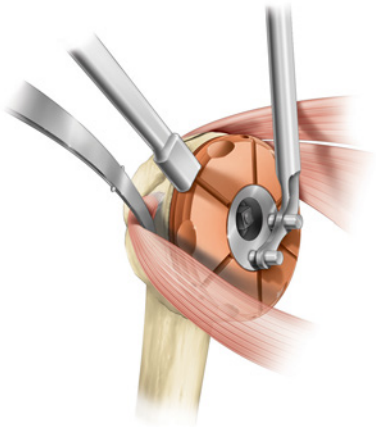

Figure 16
Adjusting the Short Replicator Plate Adaptor and Plate Dial

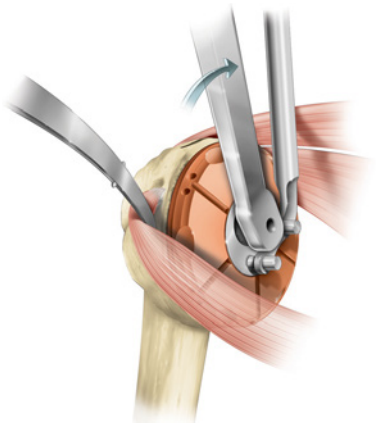

Figure 17
Securing the Short Replicator Plate Adaptor into Position

Preliminary humeral head size is determined by measuring the resected humeral head. The low profile instruments are used to rotate the short adaptor plate trial. Once the position of the short replicator plate adaptor and the low profile humeral plate dial are established, the short replicator plate adaptor is secured in position *(Figures 16 and 17)*. Finally, the humeral head trial is connected and a trial reduction is performed. Stability of the trial construct is assessed. After reduction, the offset of the humeral head relative to the offset of the replicator plate trial are noted. This dual eccentricity will be matched during assembly of the final prosthesis. The trial components are then removed.

The final implants are assembled on the back table in the same orientation and position as the trial components. The replicator plate position is matched with the definitive implants, and the replicator plate is secured to the definitive stem with a torque defining screw using the counter torque handle and angled torque screw driver. The low profile humeral insertion device is then used to insert the assembled humeral prosthesis. The arm should be placed in adduction and slight external rotation to provide maximal exposure of the humeral canal through the rotator interval. **As depicted in Figure 18, the humeral prosthesis is inserted through the rotator interval in an externally rotated position until the humeral head is deep to the coracoid process. Then, the prosthesis is internally rotated and seated.** After

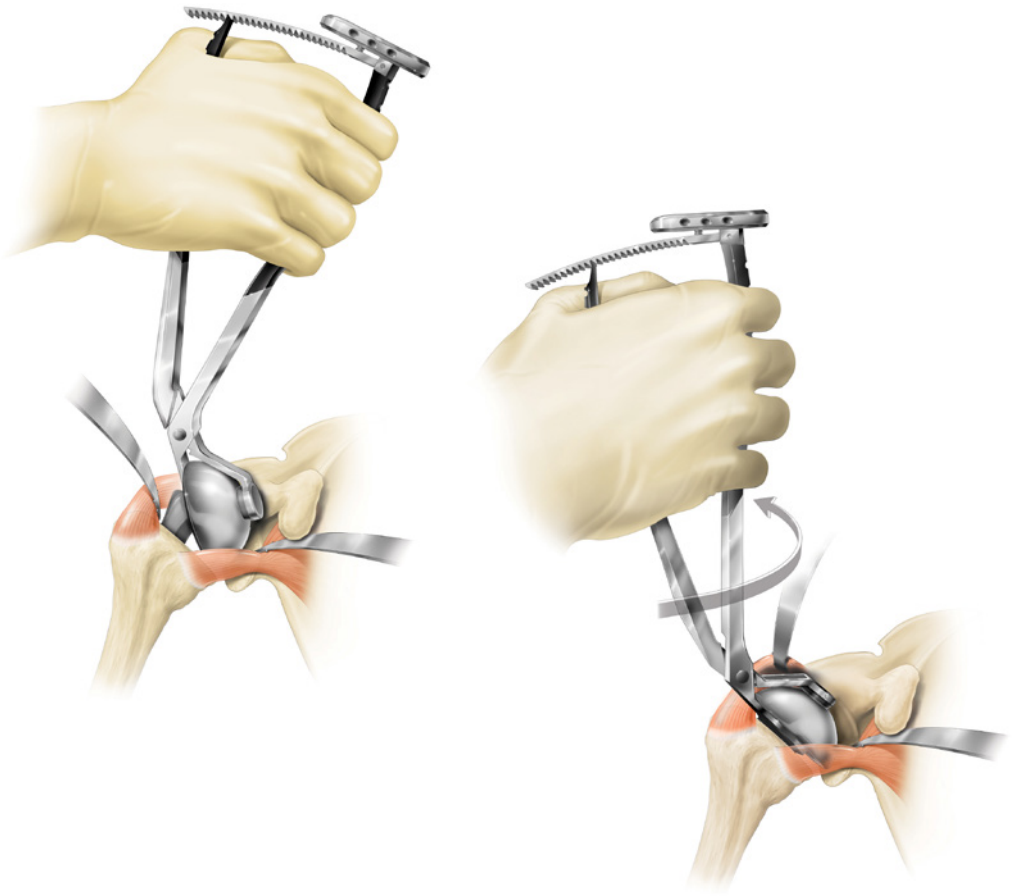

Figure 18
Insertion and Impaction of the Final Humeral Implant Assembly

confirming that the rotator cuff tissues are not impinging between the humeral cut surface and the humeral head component, the prosthesis is fully impacted into place. Stability of the final construct is once again assessed.

CLOSURE

An essential part of the closure is the rotator interval repair. After irrigation, the rotator interval is closed using non-absorbable sutures beginning laterally and progressing medially. This provides a secure repair and further enhances the stability of the construct. A Hemovac drain can be placed deep to the deltopectoral interval. The deltopectoral interval is reapproximated followed by the closure in layers. Radiographs should be obtained in the operating room. A full set of radiographs including an AP view with the humerus internally rotated, an AP view with the humerus externally rotated and an axillary view are preferred.

POST OPERATIVE REHABILITATION PROGRAM

A rehabilitation program should be initiated immediately. Although a sling is provided, it is only recommended for use when patients are moving about their environment. In our experience, other than high risk activities, the sling can be discontinued altogether 1 to 2 weeks following the surgery. Active and active assisted motion protocol are instituted immediately during their hospital stay and continued as outpatient. Resistive strengthening is added when active range of motion achieves forward elevation to 90 degrees.

OPERATIVE TECHNIQUE OVERVIEW

SUBSCAP SPLIT/INFERIOR APPROACH

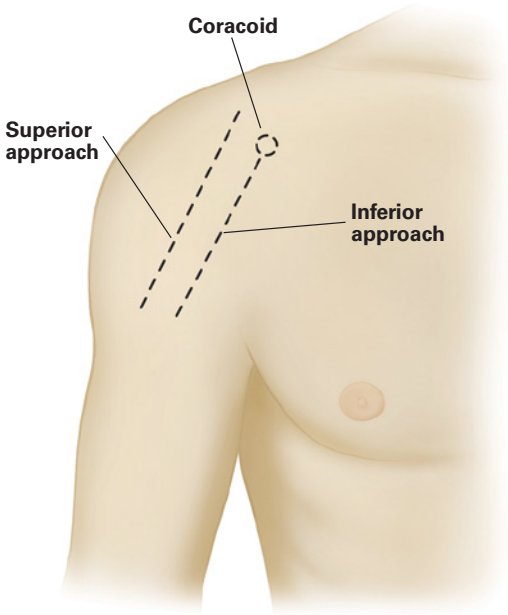

Figure A
Subscapularis Preserving TSA Incision
(Inferior approach incision at right)

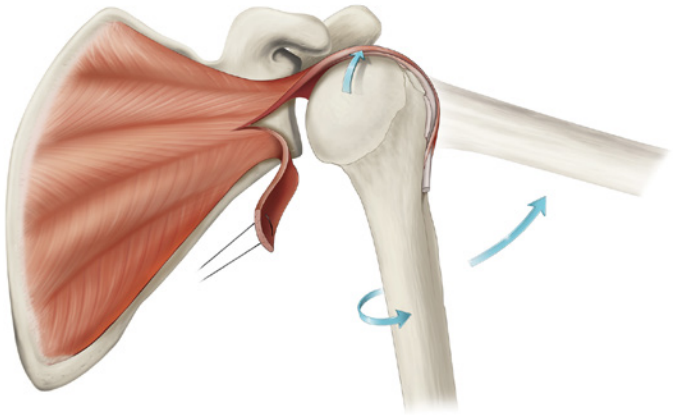

Figure B
Humeral Head Is Flipped Under the Subscapularis

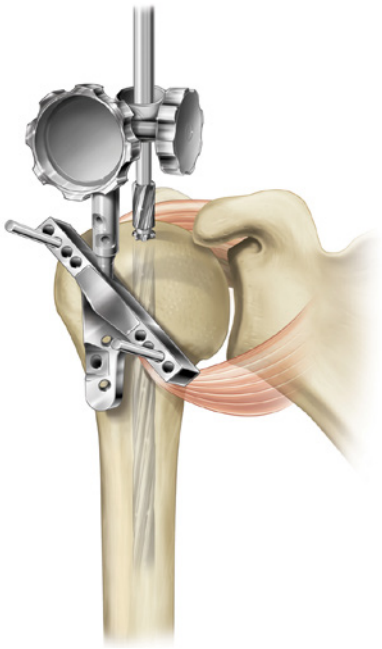

Figure C
Deltopectoral Cut Guide with Reamer and Pins

Figure D
Sequential Reaming of the Humerus

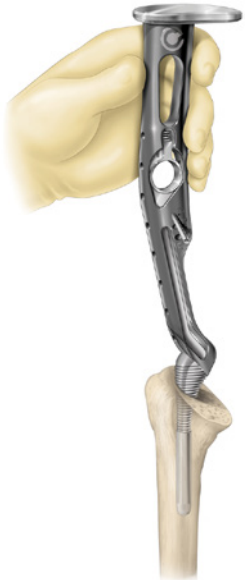

Figure E
Sequential Broaching of the Humerus

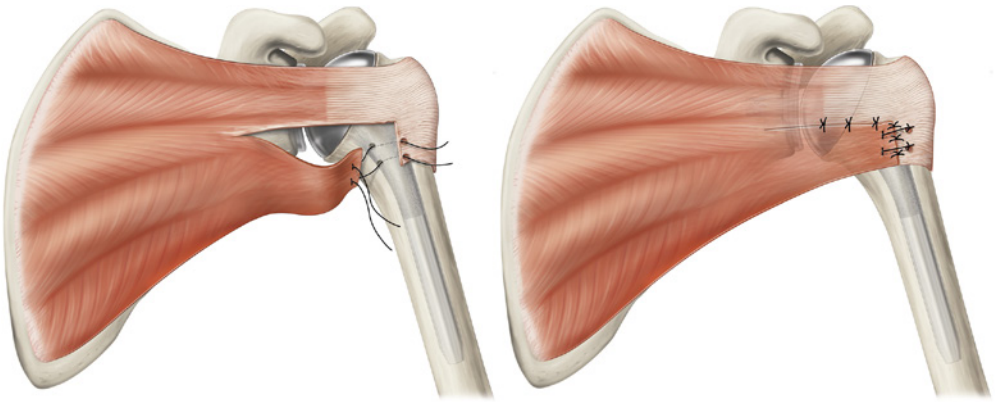

Figure F
Repairing the Horizontal Split Side to Side

DETAILED OPERATIVE TECHNIQUE

SUBSCAP SPLIT/INFERIOR APPROACH

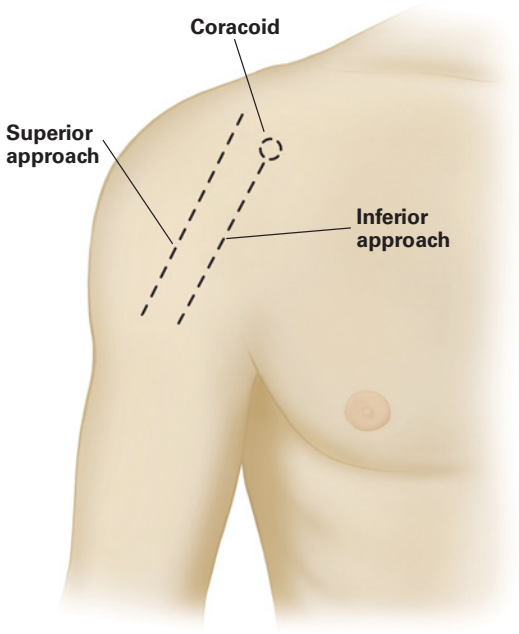

Figure 19
Subscapularis Preserving TSA Incision
(Inferior approach incision at right)

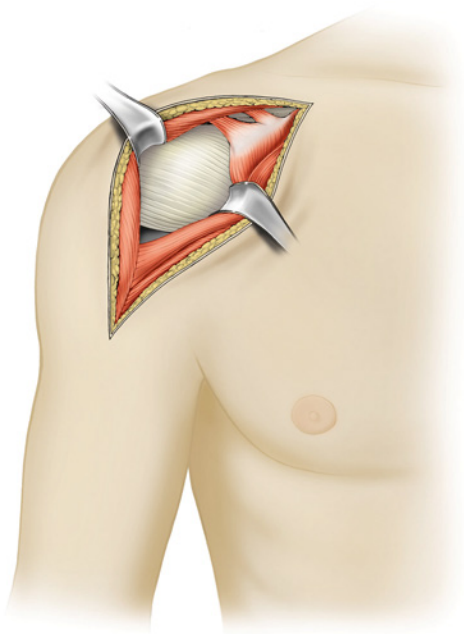

Figure 20
Dividing the Clavipectoral Fascia Longitudinally

PATIENT SELECTION

While subscapularis preserving TSA technique can be considered for all patients with degenerative arthritis of the shoulder, it is not recommended for patients who are obese or whose arthritis has resulted in significant medial erosion of the joint. It is also not recommended in revision arthroplasty cases where a wide exposure of the joint may be required. In addition to the specially designed instrumentation supplied by Exactech, standard shoulder arthroplasty instruments will be necessary. Intra-operative imaging may also be useful.

PATIENT POSITIONING

The positioning of a patient for the subscapularis preserving TSA technique is similar to that for a traditional TSA. Therefore, the patient is placed in a beach chair position, allowing unrestricted mobility of the entire arm.

SURGICAL APPROACH

The standard deltopectoral approach is utilized for this technique. As depicted in *Figure 19,* the incision begins at the coracoid process and extends to the deltoid insertion. After raising skin flaps, the deltopectoral interval is developed proximally and distally. The cephalic vein can be retracted laterally or medially based upon the surgeon's preference. The subacromial space is mobilized and any preformed adhesions are released. This mobilization should be extended laterally into the subdeltoid space. The clavipectoral fascia is divided longitudinally and the conjoined tendon muscles are mobilized *(Figure 20).* Next, the coracoacromial ligament is isolated and excised. Finally, the subscapularis tendon insertion is identified and the branches of the anterior humeral circumflex are cauterized.

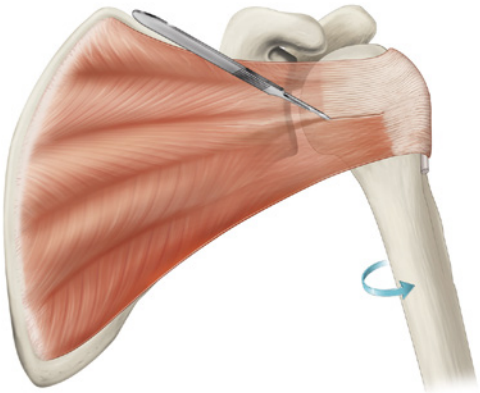

Figure 21
Releasing Middle Glenohumeral and Coracohumeral Ligaments

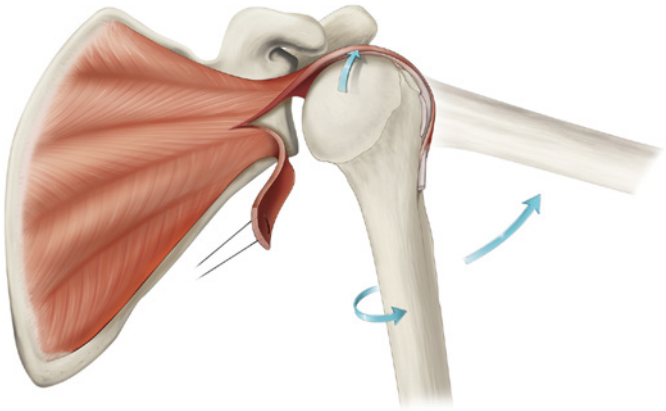

Figure 22
Humeral Head Is Flipped Under the Subscapularis

HUMERAL HEAD EXPOSURE

The long head of the biceps is located at the top of the pectoralis major tendon and followed up through the rotator interval, which is released between the supraspinatus and subscapularis, thus allowing the biceps to be released off the superior labrum. The subscapularis tendon is identified, and a split is made in the lower muscle tendon raphe, which is located in the lower one-half to lower one-third of the muscle tendon. Electrocautery is used to follow a line straight down the humerus on the medial ridge of the biceps groove to the pectoralis major insertion. This leaves the tissue along the lateral groove as a potential anchor for future soft tissue repair. The inferior one-third to one-half of the subscapularis is elevated off the lesser tuberosity and a soft tissue sleeve continues around the inferior humerus subperiosteally. It is important to continue the release medially under and around any inferior humeral spurs in order to protect the axillary nerve.

The humerus is externally rotated allowing the capsule to be released from the inferior humeral neck as far as possible. The middle glenohumeral and coracohumeral ligaments are released *(Figure 21)*. A curved rotator cuff retractor is then inserted along the anatomic neck posteriorly as the arm is abducted and externally rotated and the humeral head is flipped under the subscapularis *(Figure 22)*. A Chandler retractor can be used medially to lever the humerus anteriorly. All osteophytes are removed with a rongeur, small curved osteotomes, or a combination of both.

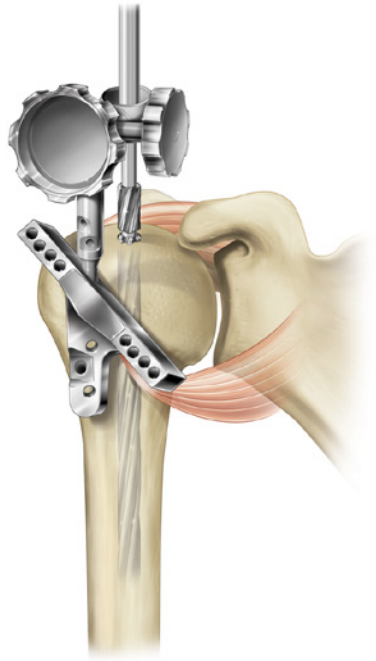

Figure 23
Securing the Deltopectoral Cut Guide (Shown with Reamer)

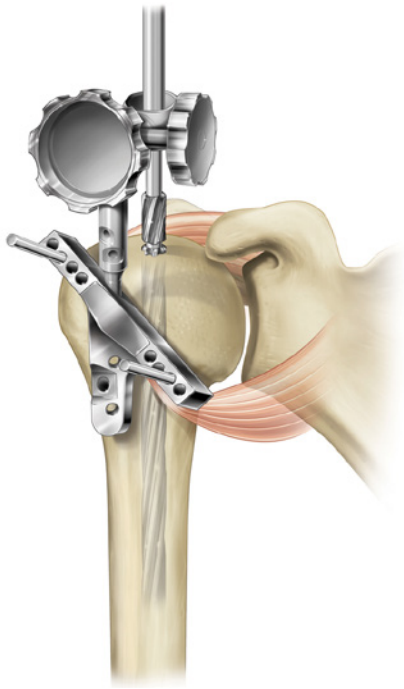

Figure 24
Deltopectoral Cut Guide with Reamer and 3.2mm Pins

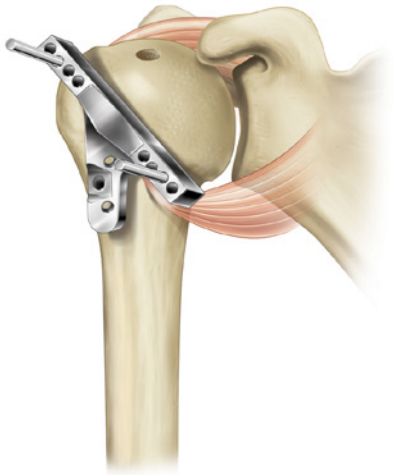

Figure 25
Deltopectoral Cut Guide with 3.2mm Pins in Place

HUMERAL PREPARATION

There are different methods that can be used to perform the humeral head resection:

1. Intramedullary cut guide
2. Fixed angle resection guide
3. Free hand technique

While carefully protecting the rotator cuff tendons, the initial cut into the humeral head is completed using a microsagittal saw. The intramedullary cutting guide can be secured to the humeral head using 3.2mm diameter pins just distal to the anatomic neck of the lumens *(Figures 23 - 25)*.

Figure 26
Sequential Reaming of the Humerus

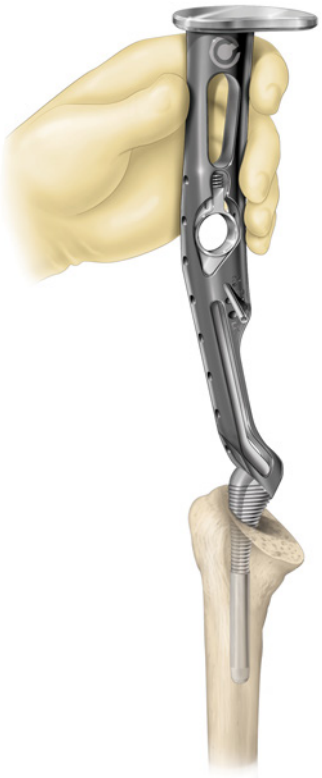

Figure 27
Sequential Broaching of the Humerus

The starting point is identified and the humeral canal is sequentially reamed using the standard Equinoxe® instrumentation until the appropriate size is reached *(Figure 26)*. Reaming should be continued with a larger diameter until good cortical contact is achieved. Sequential broaching is then performed using the low profile broach handle *(Figure 27)*. When broaching is completed, the broach will be left in place to trial the humeral head after glenoid preparation. Should the surgeon want to perform an in-situ humeral assembly rather than a back-table humeral assembly, the actual prosthesis can be inserted.

GLENOID PREPARATION AND PROSTHESIS INSERTION

Retractors are provided to aid in glenoid exposure. A **Posterior Glenoid Retractor** (such as S-bend of offset Wolfe) should be used to displace the humerus posteriorly while the **Single Point Glenoid Retractor** or **Dual Point Glenoid Retractor** is placed anteriorly to retract the superior subscapularis and pectoralis major medially. The arm is placed in abduction and externally rotated. A low profile **Spiked Hohmann Retractor** is placed superiorly and used to retract the upper subscapularis superiorly.

The glenoid is prepared in the standard fashion and the glenoid component is inserted into the glenoid. *Please refer to the superior approach section in this operative technique for detailed steps of this portion of the procedure.

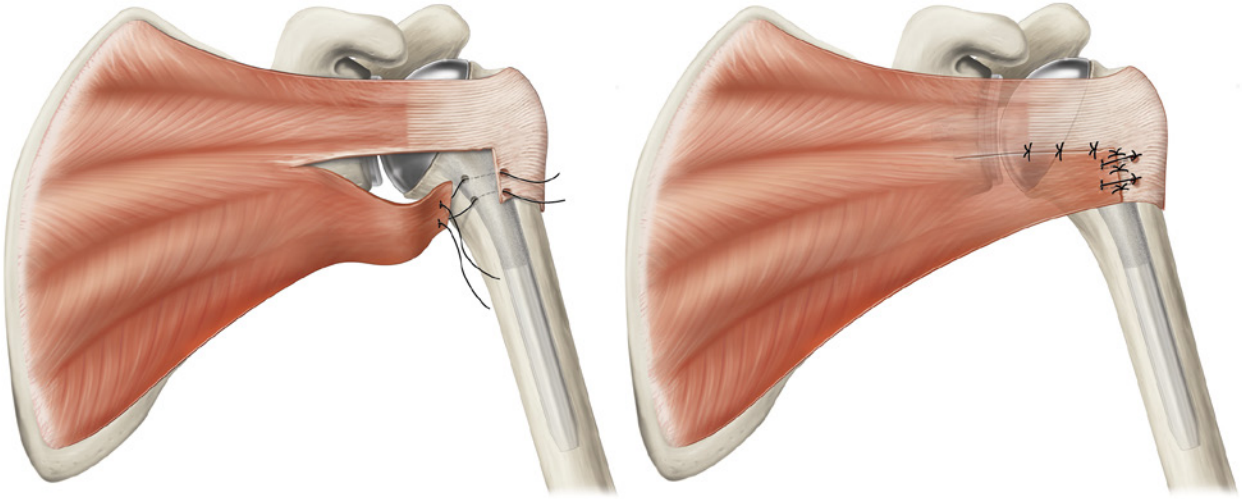

Figure 28
Repairing the Horizontal Split Side to Side

HEAD POSITIONING

A **Chandler Retractor** is used to lever the humerus anteriorly and the humerus is assessed to position the **Replicator Plate** and **Humeral Head** to the desired position per the standard primary operative technique (Page 26). Once the definitive implants have been impacted, the humerus is reduced and stability of the final construct is once again assessed.

CLOSURE

Closure is performed beginning with the inferior subscapularis which is repaired using suture anchors or using sutures previously passed through bone tunnels with a modified Mason-Allen stitch. The horizontal split between the inferior and superior subscapularis is repaired side to side with a #2 braided suture *(Figure 28)*. A Hemovac drain can be placed deep into the deltopectoral interval. The deltopectoral interval is reapproximated followed by the closure in layers.

POST OPERATIVE REHABILITATION PROGRAM

A rehabilitation program should be initiated immediately. Although a sling is provided, it is only recommended for use when patients are moving about their environment. In our experience, other than high risk activities, the sling can be discontinued altogether 1 to 2 weeks following the surgery. Active and active assisted motion protocol are instituted immediately during their hospital stay and continued as outpatient. Resistive strengthening is added when active range of motion achieves forward elevation to 90 degrees. Patients may use the arm for activities of daily living 6 weeks following surgery.

INSTRUMENT LISTING

CATALOG NUMBER	PART DESCRIPTION
311-01-11	IM Humeral Cutting Guide
311-01-12	Deltopectoral IM Resection Guide
311-01-13	Superiolateral IM Resection Guide
311-31-38	Stainless Steel Humeral Head Trial - 38mm Short
311-31-41	Stainless Steel Humeral Head Trial - 41mm Short
311-31-44	Stainless Steel Humeral Head Trial - 44mm Short
311-31-47	Stainless Steel Humeral Head Trial - 47mm Short
311-31-50	Stainless Steel Humeral Head Trial - 50mm Short
311-31-53	Stainless Steel Humeral Head Trial - 53mm Short
331-00-01	Offset Broach Handle
331-00-03	Quick Snap Version Bar
331-00-07	Female Broach - 7mm
331-00-09	Female Broach - 9mm
331-00-11	Female Broach -11mm
331-00-13	Female Broach - 13mm
331-00-15	Female Broach - 15mm
331-01-15	Fixed Angle Replicator Plate Adapter - 1.5mm
331-01-45	Fixed Angle Replicator Plate Adapter - 4.5mm
331-04-01	Offset Wolfe Retractor - Left
331-04-02	Offset Wolfe Retractor - Right
331-04-03	Mini Spiked Hohmann Retractor
331-04-04	S-Bend Retractor
331-04-05	Subscap Sparing Retractor
331-07-10	Stem Assembly Inserter
331-10-30	Counter Torque Handle
331-10-31	Angled Torque Screw Driver
331-11-01	Humeral Plate Dial Adjuster
331-11-38	Low Profile Flush Humeral Plate Dial - 38mm
331-11-41	Low Profile Flush Humeral Plate Dial - 41mm
331-11-44	Low Profile Flush Humeral Plate Dial - 44mm
331-11-47	Low Profile Flush Humeral Plate Dial - 47mm
331-11-50	Low Profile Flush Humeral Plate Dial - 50mm
331-11-53	Low Profile Flush Humeral Plate Dial - 53mm
331-25-00	Pivot Reamer Driver
331-25-11	aTSA Butterfly Reamer - XS
331-25-12	aTSA Butterfly Reamer - SM
331-25-13	aTSA Butterfly Reamer - MD
331-25-14	aTSA Butterfly Reamer - LG
331-25-15	aTSA Butterfly Reamer - XL
331-27-02	CSA Center Drill Guide - Left
331-27-03	CSA Center Drill Guide - Right
331-27-04	CSA Peripheral Drill Guide - Left
331-27-05	CSA Peripheral Drill Guide - Right

PRIMARY & REVERSE SHOULDER SYSTEM

INDICATIONS

The Equinoxe Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemi-arthroplasty is determined by the surgeon to be the preferred method of treatment.

- The cemented primary humeral stem, long/revision stem, fracture stems and all Equinoxe glenoids are intended for cemented fixation.
- The press-fit humeral stems are intended for press-fit applications but may be used with bone cement at the discretion of the surgeon.
- The reverse humeral components are intended to be used in cemented applications or in revision cases when the humeral component is well-fixed/stable, as deemed by the orthopaedic surgeon.
- Humeral Heads are intended for use in cemented and press-fit applications.

Clinical indications for the PRIMARY (P), LONG/REVISION (L), and FRACTURE (F) humeral components are as follows:

P	L/R	F	Indications
✓	✓		Rheumatoid arthritis, osteoarthritis, osteonecrosis or post-traumatic degenerative problems
✓	✓		Congenital abnormalities in the skeletally mature
✓			Primary and secondary necrosis of the humeral head
✓		✓	Humeral head fracture with displacement of the tuberosities
✓	✓		Pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
✓	✓		Revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved)
		✓	Displaced three-part and four-part upper humeral fractures
	✓		Spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases)
	✓		Revision of failed previous reconstructions when distal anchorage is required
✓	✓		To restore mobility from previous procedures (e.g. previous fusion)

The Equinoxe Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

The Equinoxe Platform Fracture Stem is indicated for use in skeletally mature individuals with acute fracture of the proximal humerus and displacement of the tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is indicated for cemented use only.

CONTRAINDICATIONS

Use of the Equinoxe Shoulder System is contraindicated in the following situations:

- Osteomyelitis of the proximal humerus or scapula; if a systemic infection or a secondary remote infection is suspected or confirmed, implantation should be delayed until infection is resolved.
- Inadequate or malformed bone that precludes adequate support or fixation of the prosthesis.
- Neuromuscular disorders that do not allow control of the joint.
- Significant injury to the brachial plexus.
- Non-functional deltoid muscles.
- Patient's age, weight, or activity level would cause the surgeon to expect early failure of the system.
- The patient is unwilling or unable to comply with the post-operative care instructions.
- Alcohol, drug, or other substance abuse.
- Any disease state that could adversely affect the function or longevity of the implant.

NOTES

NOTES

Exactech, Inc. is proud to have offices and distributors around the globe. For more information about Exactech products available in your country, please visit www.exac.com

For additional device information, refer to the Equinoxe Shoulder System–Instructions for Use for a device description, indications, contraindications, precautions and warnings. For further product information, please contact Customer Service, Exactech, 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

Exactech, as the manufacturer of this device, does not practice medicine, and is not responsible for recommending the appropriate surgical technique for use on a particular patient. These guidelines are intended to be solely informational and each surgeon must evaluate the appropriateness of these guidelines based on his or her personal medical training and experience. Prior to use of this system, the surgeon should refer to the product package insert for comprehensive warnings, precautions, indications for use, contraindications and adverse effects.

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