

EXACTECH | SHOULDER

Operative Technique



equinox[®]
SHOULDER SYSTEM

Humeral Reconstruction Prosthesis





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INTRODUCTION

The Equinoxe® Humeral Reconstruction Prosthesis is designed for challenging cases with significant humeral bone loss. This platform humeral stem integrates with the entire Equinoxe® Shoulder System and allows the surgeon to have intra-operative flexibility to choose between a hemiarthroplasty, primary total shoulder or reverse total shoulder. Due to the varying levels of possible humeral resections, the midsections and proximal bodies have numerous soft tissue attachments as well as a range of sizes to reconstruct the length in 12.5mm increments from 50 to 222.5mm in length. The anatomically shaped^{1,2} proximal bodies are designed to help restore the locations of the rotator cuff muscle insertions and increase deltoid wrapping³⁻⁵ to improve joint stability. In addition, the offset distal stem and collars are designed to provide external fixation and rotational stability while the offset distal stem allows for optimal fit within the intramedullary canal. Finally, while we have taken a comprehensive approach to this operative technique, we would be remiss if we failed to make it clear that shoulder reconstructions are challenging procedures and should be performed by surgeons with significant experience.

If you are new to challenging shoulder revisions or orthopaedic oncology cases involving bone loss of the proximal humerus, please consider observing a shoulder specialist, watching a shoulder surgical DVD, performing a sawbone and/or implanting in a cadaver to ensure you are comfortable with the surgical technique. We would be happy to facilitate any aspect of this training to ensure a positive Exactech experience.

Respectfully,

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OPERATIVE TECHNIQUE OVERVIEW

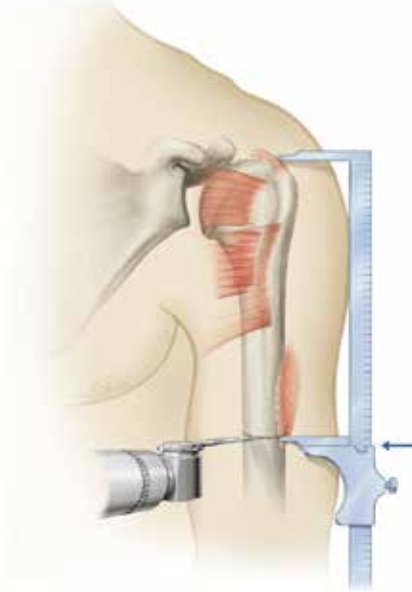


Figure A
Humeral Resection



Figure B
Reaming of Humeral IM Canal

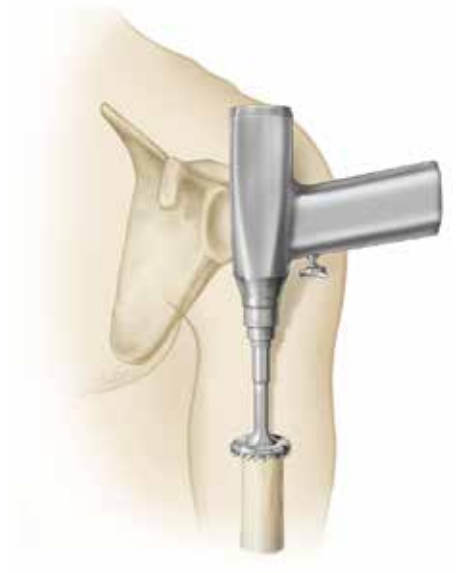


Figure C
Humeral Planing



Figure D
Trial Collar Diameter
(Mark Bone at Best Fit)



Figure E
Align Collar to Mark on Bone from
Previous Step (Use Actual Stem or
Trial Stem to Determine Offset that
Centers the Stem in the Canal)

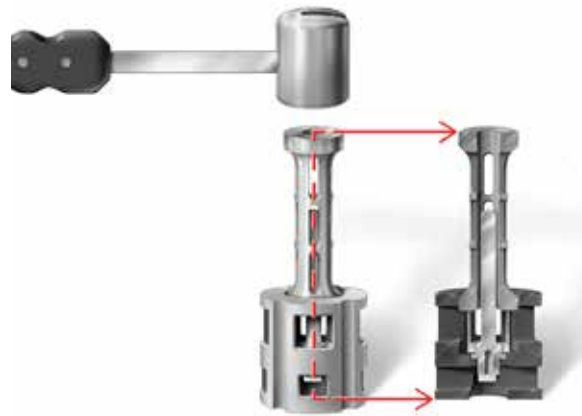


Figure F
Impact Collar in the Correct 'Clocked Position'



Figure G
Cementing the Distal Humeral Stem
in the Intramedullary Canal

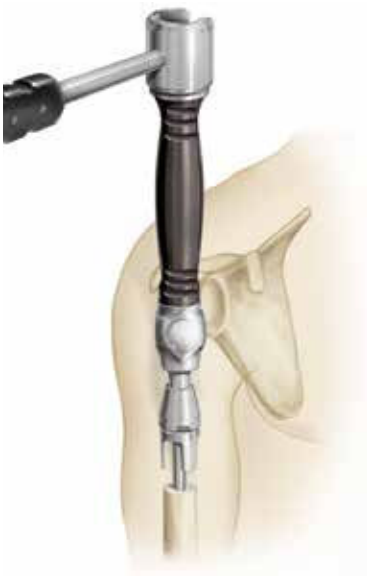


Figure H
Positioning the Assembled Distal Stem/Collar in the Humeral IM Canal



Figure I
First Trial Is Attached to Distal Stem with Captured Screw



Figure J
Using Middle and Proximal Segments to Reconstruct the Humerus to its Original Height Following Resection



Figure K
Backtable Impaction of Middle and Proximal Segment Tapers

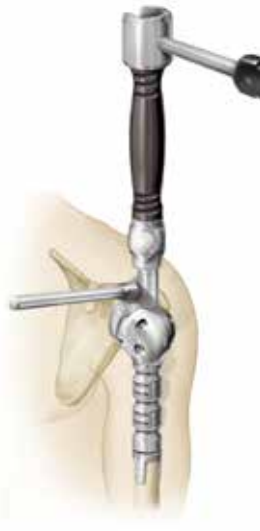


Figure L
Impaction of Proximal Segment and Middle Segment Tapers to the Distal Stem Taper with aTSA

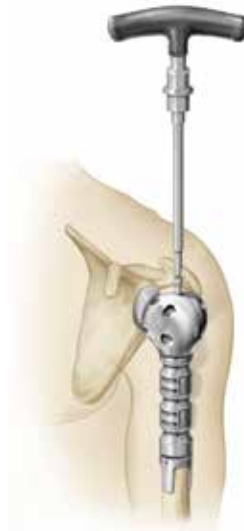


Figure M
Securing the Taper Locking Screw with aTSA; place the Screw before Implantation of the Humeral Head or Reverse Tray



Figure N
Finish Procedure with either Replicator Plate or Humeral Head Implantation or Reverse Tray and Liner Implantation

DETAILED OPERATIVE TECHNIQUE

PRE-OPERATIVE EVALUATION

After a careful history and physical examination, radiographs with size markers should be obtained to assess osseous deformities and estimate humeral canal size. For revision applications or primary cases with significant bone loss, the following three radiographic views should be obtained: 1) a true A/P view of the glenohumeral joint (30 degrees external oblique – Grashey view), 2) a scapular lateral view and 3) an axillary lateral view. In patients with osteoarthritis, varying amounts of posterior glenoid wear (with posterior subluxation of the humeral head) are common. If significant glenoid wear is a concern, a CT scan may be helpful to further define the bony anatomy. For oncology applications, a full-length MRI should be obtained to assess the length of resection, presence of skip metastases, soft tissue involvement, and any potential intra-articular disease. To aid in pre-operative planning, radiographic templates are available for each mating implant component to approximate the required sizes.

STEP 1: PATIENT POSITIONING

The patient should be placed on an operating table in a supine position. The head of the operating table should be elevated approximately 30 degrees in a modified beach chair position. A small bolster can be placed laterally behind the involved shoulder at the lateral edge of the operating table in order to protract the scapula to facilitate glenoid exposure. The patient should be moved to the side of the table so that the upper extremity can be placed into maximum extension without obstruction by the operating table. Alternatively, a Captain's chair or similar positioning device can be used for proper patient positioning. The patient should be secured to the operating table to minimize any changes in position intra-operatively. Once the patient is secure, the arm is examined to assess the range of motion, with particular attention to external rotation with the arm at the side. If external rotation is restricted (i.e., internal rotation contracture) the need for more extensive subscapularis mobilization or lengthening procedures may be necessary. The entire arm should be prepped and draped to allow complete access to the operative area and full mobility during the procedure.

STEP 2: SURGICAL APPROACH

For oncology applications, a modified deltopectoral approach to the proximal humerus is most often utilized. This approach should facilitate removal of the biopsy tract en bloc with the resection specimen and most often includes a portion of the anterior third of the deltoid. This incision can be extended distally into an extended anterior lateral approach should tumor extent dictate (*Figure 1*). Subsequent resection work is at the discretion of the operating surgeon and dictated by

the extent of the tumor. A cuff of normal tissue should be retained about the resection specimen to ensure an adequate margin in malignant tumors. Care should be taken to preserve the axillary nerve as it courses posterior to the proximal humerus through the quadrilateral space innervating the deltoid. Similarly, care should be taken to protect the radial nerve as it courses from medial to lateral anterior to the teres major and latissimus dorsi. It then courses posterior to the humerus approximately at the level of the deltoid insertion and is at the greatest risk when performing the distal osteotomy.

For revision applications or primary cases with significant bone loss, a traditional deltopectoral approach is made beginning inferior to the clavicle and passing over the coracoid process and extending distally toward the deltoid insertion. The length of the incision should depend upon the amount of resection required (*Figure 1*). Medial and lateral subcutaneous flaps are created, and the deltopectoral interval is identified. In revision procedures or primary cases with significant bone loss, the deltopectoral interval may be difficult to identify. The cephalic vein is often no longer present. In these situations, it may be easier to identify the proximal origin of the interval where the deltoid and pectoralis first join to form the interval. This overlies the coracoid process. The interval can then be developed in a proximal to distal direction using the electrocautery. Once this is complete, the next step is to mobilize the subdeltoid space. This can be accomplished with blunt dissection and should be extended into the subacromial space. The conjoined tendon should also be carefully mobilized from the deeper tissues—specifically the subscapularis if it is intact. The exposure of the implant and proximal humerus must be individualized since each revision situation will be different. All efforts should be directed at preserving the subscapularis and any rotator cuff tendons that may be intact. Careful exposure of the proximal humerus should include release of superior and lateral adhesions. This should be followed by release of the inferior capsular attachments to the humeral neck to allow the humerus to be externally rotated to 90 degrees. As this release is performed it is important to be aware of the close proximity of the axillary nerve. At this point, the humerus should be placed in extension and external rotation to expose the humeral implant. If this position cannot be easily accomplished then additional releases should be performed so that the existing implant can be removed by axial extraction (with or without a vascularized humeral window osteotomy).

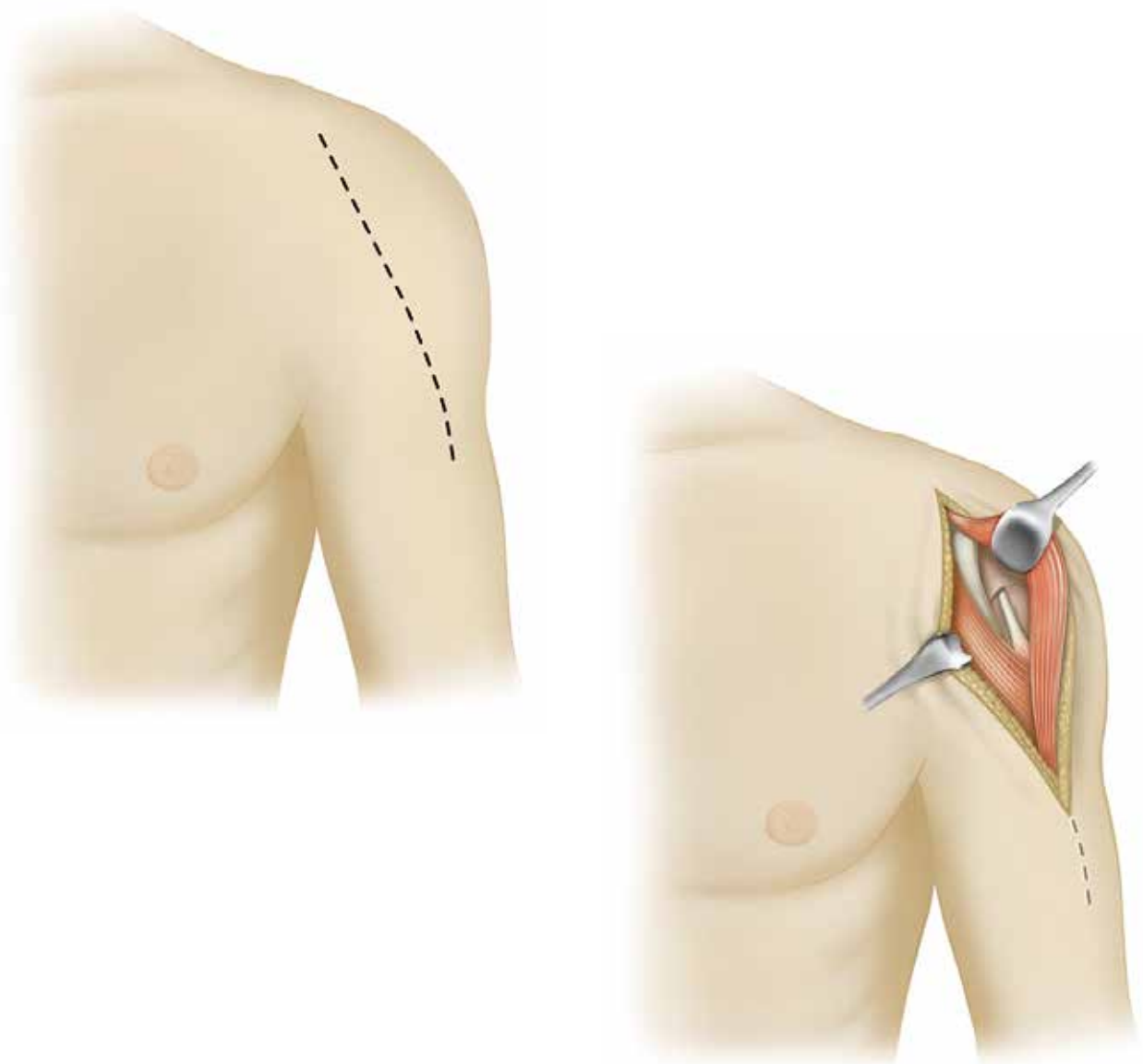


Figure 1
Deltopectoral Incision

DETAILED OPERATIVE TECHNIQUE

APPROACH AND PATIENT POSITIONING

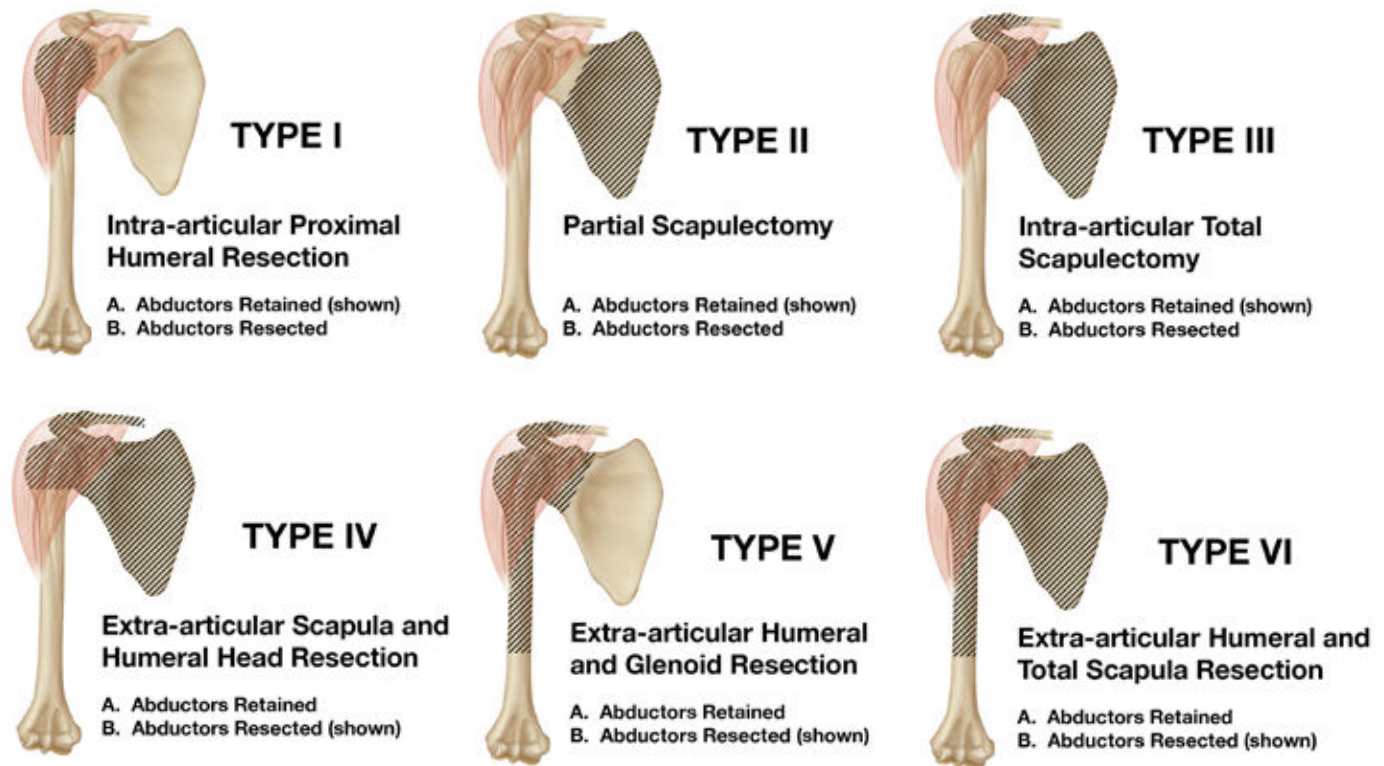


Figure 2

Malawer Classification of Resections

STEP 3: HUMERAL RESECTION

Prior to the humeral resection, the tissues surrounding the resection site should be completely exposed, and any osteophytes should be removed using a rongeur. If the humeral head is resected, the amount of retroversion (usually 20-40 degrees) should be determined by positioning the humerus in external rotation before the resection is made.

Resections of the shoulder girdle have been classified in six types according to Malawer (*Figure 2*). The Equinox Humeral Reconstruction Prosthesis is used for both Type I intrarticular and for certain Type V resections of the proximal humerus. The vast majority of resections of the proximal humerus are intra-articular Type I resections. In rare occasions there is

intra-articular tumor extent and a Type V resection is needed. In these instances, we recommend using the Equinox Humeral Reconstruction Prosthesis only if sufficient glenoid bone is preserved to achieve implant fixation. The Equinox Humeral Reconstruction Prosthesis also requires an intact axillary nerve and an innervated deltoid. The majority of humeral resections do not require an osteotomy distal to the deltoid insertion to obtain clean margins; therefore, the deltoid insertion is not compromised and does not need to be reattached. However, in a minority of cases, the required humeral resection is distal to the deltoid insertion and must be taken down; thus, the deltoid tendon will require reattachment to the prosthesis as described in Step 15.

With the Equinox Humeral Reconstruction Prosthesis, resection heights between 50 and 222.5mm from the top of the humeral head (Figure 3) can be accommodated using different combinations of proximal and middle humeral stem segments (Table 1). As described in Table 1, **anatomic shoulder resection heights are 1:1 with the resection whereas reverse shoulder resection heights are approximately 10mm more than the resection (due to the inferior-medial shift in the position of the center of rotation and humerus inherent to reverse shoulder arthroplasty);** however it should be noted that patient-to-patient soft tissue tension differences may result in an additional ± 5 mm variation for reverse shoulder applications. The resection height should be marked at the desired location and resected using a sagittal saw; a resection guide is provided to facilitate the resection measurement.

If performing the humeral osteotomy for a primary malignancy of bone, it is advisable to determine with the pathologist that the intramedullary margin is indeed clear prior to reaming the distal canal. This helps to confirm the adequacy of the margin and avoids contamination of the distal canal during subsequent reaming or introduction of the prosthetic humeral stem.

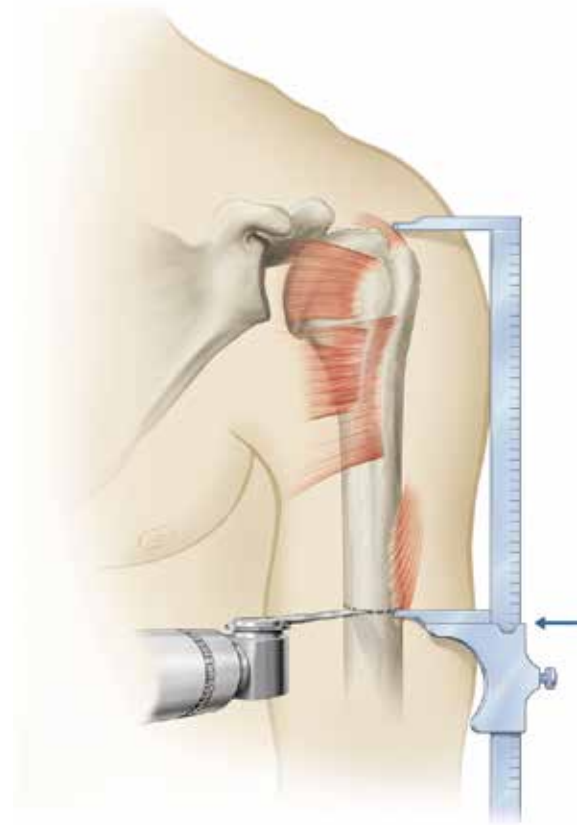


Figure 3

Humeral Resection

Table 1

Comparison of Humerus Resection Height for Anatomic and Reverse Arthroplasty Using the Equinox Humeral Reconstruction Prosthesis

HUMERAL RESECTION AND SCREW SELECTION CHART

Actual Resection (mm)	PRIMARY Reconstruction Length (mm)	REVERSE Reconstruction Length (mm)	Recommended Implant Combination				
			Proximal Body	Middle Segment 1	Middle Segment 2*	Screw Size	Screw Catalog Number (Length Color on Package Labeling)
50	50	60	+0mm	-	-	0	308-15-01 (Black)
62.5	62.5	72.5	+12.5mm	-	-	12.5	308-15-12 (Black-White)
75	75	85	+0mm	25mm	-	25	308-15-25 (Orange)
87.5	87.5	97.5	+12.5mm	25mm	-	37.5	308-15-37 (Orange-White)
100	100	110	+0mm	50mm	-	50	308-15-50 (Blue)
112.5	112.5	122.5	+12.5mm	50mm	-	62.5	308-15-62 (Blue-White)
125	125	135	+0mm	75mm	-	75	308-15-75 (Red)
137.5	137.5	147.5	+12.5mm	75mm	-	87.5	308-15-87 (Red-White)
150	150	160	+0mm	25mm	75mm	100	308-16-00 (Green)
162.5	162.5	172.5	+12.5mm	25mm	75mm	112.5	308-16-12 (Green-White)
175	175	185	+0mm	50mm	75mm	125	308-16-25 (Yellow)
187.5	187.5	197.5	+12.5mm	50mm	75mm	137.5	308-16-37 (Yellow-White)
200	200	210	+0mm	75mm	75mm	150	308-16-50 (Purple)
212.5	212.5	222.5	+12.5mm	75mm	75mm	162.5	308-16-62 (Purple-White)

* When two middle segments are used, always secure the longer middle segment in the most distal position. Do not use more than two middle segments. Using implant combinations other than those listed above may result in failure under load.

DETAILED OPERATIVE TECHNIQUE

APPROACH AND PATIENT POSITIONING



Figure 4
Reaming of Humeral IM Canal - Manual

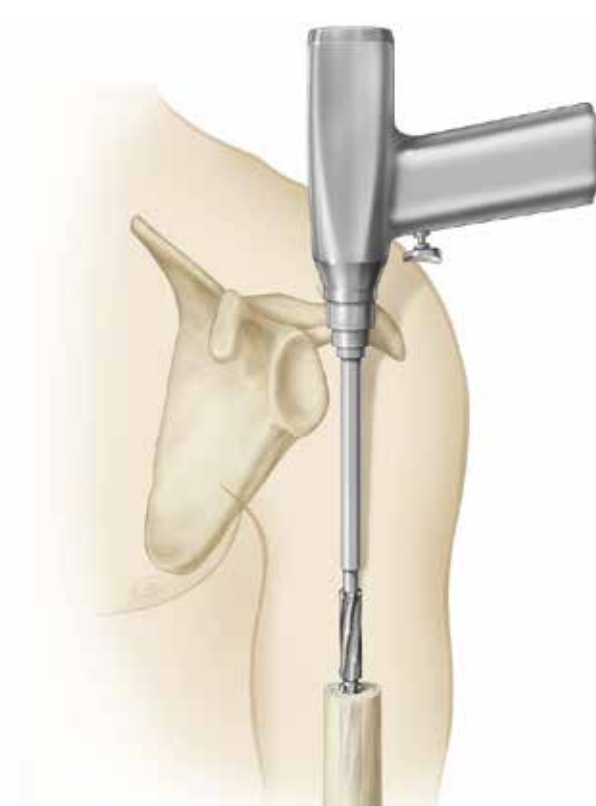


Figure 5
Reaming of Humeral IM Canal - Powered

STEP 4: PREPARE THE GLENOID

If the orthopaedic surgeon deems total shoulder arthroplasty to be the most appropriate treatment option, please refer to the Equinox[®] Platform Shoulder System operative technique (718-01-30) for preparation of the glenoid for anatomic and reverse total shoulder arthroplasty. If glenoid augments are necessary, please refer to Equinox Posterior Augment Glenoid and Augmented Reverse Glenoid Implants operative technique addenda (718-01-32 and 718-04-37, respectively) for use of glenoid augments with anatomic and reverse total shoulder arthroplasty.

STEP 5: REAMING THE HUMERAL SHAFT

Humeral straight reamers are provided in 1mm increments from 6 to 14mm to facilitate sequential reaming of the IM

canal. Reaming prepares the IM canal for the distal stem diameter and determines the final diameter of the definitive cemented stem, which is 1mm smaller than the final reamer used. Reaming can be performed manually with attachment to a T-handle or carefully with power (*Figures 4 and 5*). The humeral reamer is inserted into the IM canal to the appropriate depth as indicated by the depth markers; sequential reaming should occur until endosteal cortical contact is obtained. Depth markers are provided on each humeral reamer to the depth of each humeral stem length; the depth marker should be sunk completely into the canal. As stated above, the diameter of the definitive distal humeral stem should be 1mm smaller than the largest reamer selected to ensure a 1mm cement mantle (minimum of 0.5mm on each side of the stem).



Figure 6
Humeral Planing

Larger diameter straight reamers (up to 17mm) are provided in the standard Equinox® Platform Shoulder System instrument cases as described in operative technique (718-01-30) if the surgeon desires a thicker cement mantle for the largest diameter humeral stems.

Note: Since the reamer is the only instrument that prepares the distal canal, do not attempt to implant a distal stem that is the same size or larger than the largest fully seated reamer.

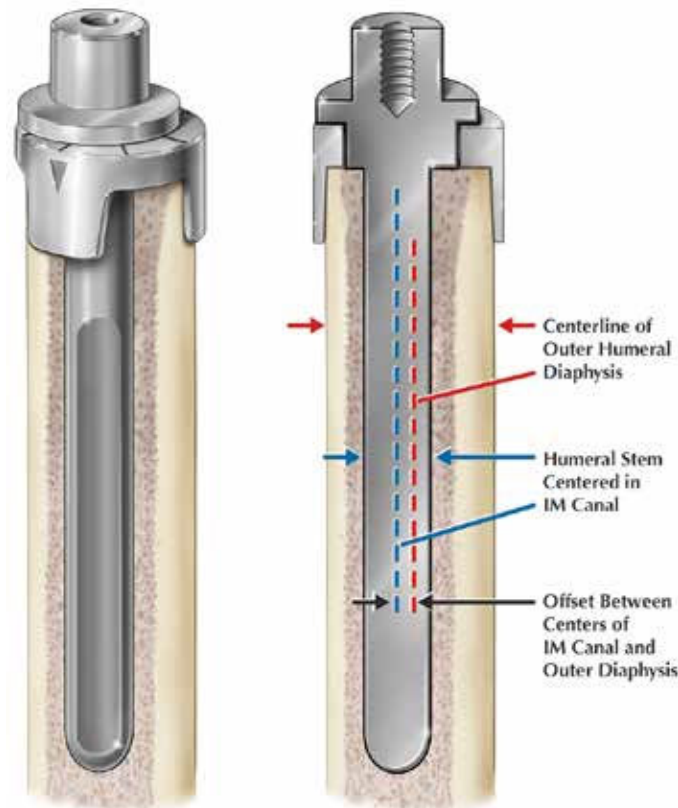
STEP 6: PLANING THE HUMERAL OSTEOTOMY

A 34mm diameter humeral planar is provided to ensure that the humeral osteotomy is perpendicular to the IM canal in order to prepare for impaction of the distal collar onto the distal stem. Humeral planing can be performed manually

with attachment to a T-handle or with power (*Figure 6*). An 80mm threaded guide connects to the humeral planar and is provided in sizes corresponding to each distal humeral stem (6, 7, 8, 9, 11, 13mm) to maintain planing on-axis.

DETAILED OPERATIVE TECHNIQUE

APPROACH AND PATIENT POSITIONING



Dual offset of stem and collar necessary to position the humeral stem in the center of IM canal to ensure a uniform cement mantle thickness

Figure 7

Trialing of distal collar and distal stem offset (1mm each) to account for the positional differences between the outer and inner diameters of the humeral diaphysis; these dual eccentricities permit for anatomic differences from 0 to 2mm and help to ensure a uniform cement mantle with the humeral stem in the IM canal

STEP 7: TRIALING THE DISTAL COLLARS

To improve distal fixation, collars are provided to fit around the humeral diaphysis. **Trial distal collars are provided in 1mm increments from 17.5 to 33.5mm and are diametrically sized to account for the plasma and HA coating of the definitive implant.** Each size collar is trialed over the diaphysis to determine which size distal collar and which rotational orientation of the collar best fits the resected bone. Care should be taken at this step to ensure the best fit of the trial collar by rotationally positioning it in a manner that achieves outer-diaphyseal contact with all 3 collar tines. If collar tine contact is suboptimal, consider changing the collar size and/or rotational alignment. It should be noted that the cross sectional humeral geometry is roughly triangular and

varies greatly from patient to patient. After determining the best rotational position and diameter size, mark the bone to use as a reference for stem trial and implantation alignment. To encourage a best fit, both the distal collar and distal stem are offset by 1mm to account for the positional differences between the outer and inner diameters of the humeral diaphysis; therefore, these **dual eccentricities permit for anatomic differences from 0 to 2mm and help to ensure a uniform cement mantle with the humeral stem in the IM canal.** A uniform cement mantle thickness will increase the fatigue strength of the reconstructed device (*Figure 7*). The tines of the trial distal collars are approximately $\frac{1}{2}$ the length of the definitive distal collars; as an interference fit of the distal collar around the diaphysis is desired, we recommend



Figure 8

Trial Distal Collar is Line to Line with Actual Implant. Select Trial Collar Size which Achieves An Adequate Interference Fit with the Humeral Diaphysis as shown. Do Not Fully Seat As It Will Be Difficult To Remove.

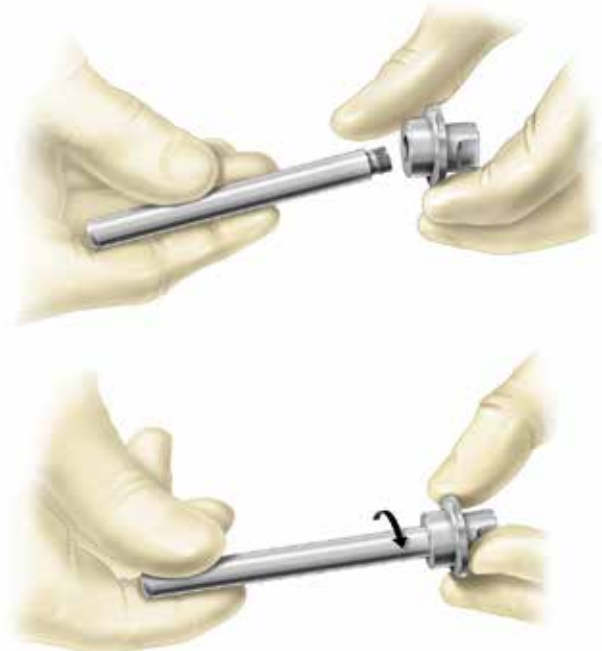


Figure 9

Trial Shaft Adapter Threaded onto Threaded Guides to Create a Provisional Stem Trial

selecting a collar size that only partially seats around the outer diaphysis as the implants (and not the trials) should have an interference fit with the outer humeral diaphysis (*Figure 8*).

At this stage, the definitive distal humeral stem implant should be selected and opened. **The definitive distal humeral stem should be 1mm smaller than the largest reamer to ensure a 1mm cement mantle (minimum of 0.5mm of cement on each side of the stem).** If a larger cement mantle is desired, select a definitive distal humeral stem that is 2 or 3 sizes smaller than the largest reamer used. To trial the stem position within the collar choose a collar one size larger than the definitive collar diameter. This will allow the collar to sit flat on the cut during the trialing

process. Align the larger collar with the bone mark that was during the collar diameter trial. The surgeon can now use the definitive stem or the planer shaft adapter to trial the stem's position. The trial shaft adapter can be threaded onto the threaded guides referenced in Step 6 to create a provisional stem trial (*Figure 9*).

DETAILED OPERATIVE TECHNIQUE

APPROACH AND PATIENT POSITIONING



Figure 10

Note the Position of the Exactech "e"
in Reference to the Collar



Figure 11

Align Collar to Mark on Bone from Previous Step.
Use Actual Stem or Trial Stem to Determine Offset
that Centers the Stem in the Canal



Figure 12

Assessment of Offset Position Using the 1mm Over-
sized Diameter trial distal collar and the Definitive Distal
stem; Offset Orientation Can Not Be Accurately Assessed
without Using the Oversized 1mm Trial Distal Collar

Place the Exactech "e" laser mark (that is on the trial or definitive stem) in the direction opposite of the offset canal. Then rotate within the collar until the stem is able to sit flush and achieve a uniform cement mantle. Once the orientation is confirmed, make note of the position of the "e" in reference to the collar in order to recreate it with the definitive stem and collar (*Figure 10*). **It is critical that a distal collar trial one size larger than the actual implant be used so that the trial collar can sit flat against the planed surface, otherwise, the trialing of the dual offsets may not be accurate** (*Figure 11, 12*).

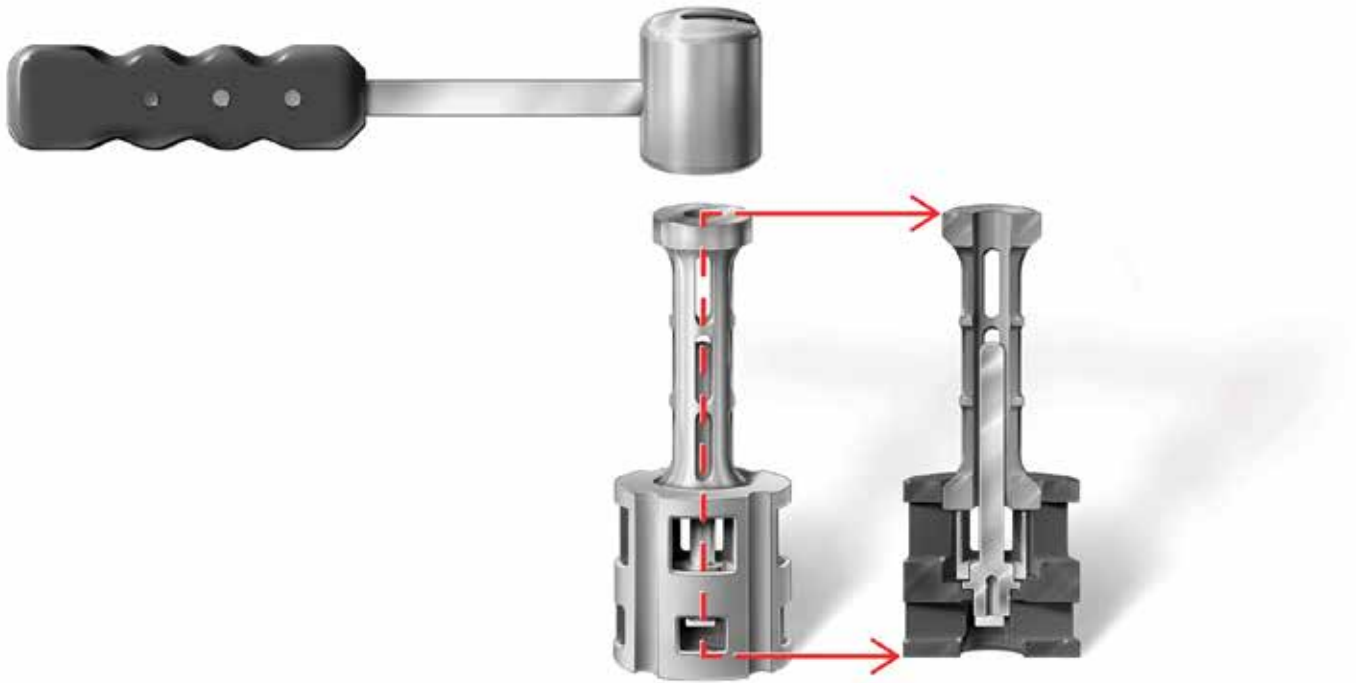


Figure 13

Backtable Assembly of the Distal Collar and Distal Humeral Stem Tapers Using the Backtable Assembly Base and Hammer

STEP 8: BACKTABLE ASSEMBLY OF THE DISTAL HUMERAL STEM AND DISTAL COLLAR

The distal collar implant should be assembled to the taper on the humeral stem implant on the backtable using the backtable assembly base and hammer. Prior to impaction of the tapers, clean and dry the stem and collar tapers to ensure engagement. Position the distal stem and then the distal collar in the backtable assembly base so that the tapers are aligned and in the orientation identified in the previous trialing step.

After the position/orientation of the stem and collar is confirmed within the backtable assembly base, the backtable hammer is then placed over the distal stem so that it contacts the distal surface of the distal collar tines. The humeral stem

and distal collar tapers are engaged with impaction of a mallet against the backtable hammer impaction surface (*Figure 13*).

It is critical that the tapers be contacted just hard enough to engage the tapers; do not over-impact as over-impaction can cause distal collar tine deformation. After impaction, the tapers should be manually extracted to ensure adequate engagement prior to implantation.

DETAILED OPERATIVE TECHNIQUE

APPROACH AND PATIENT POSITIONING

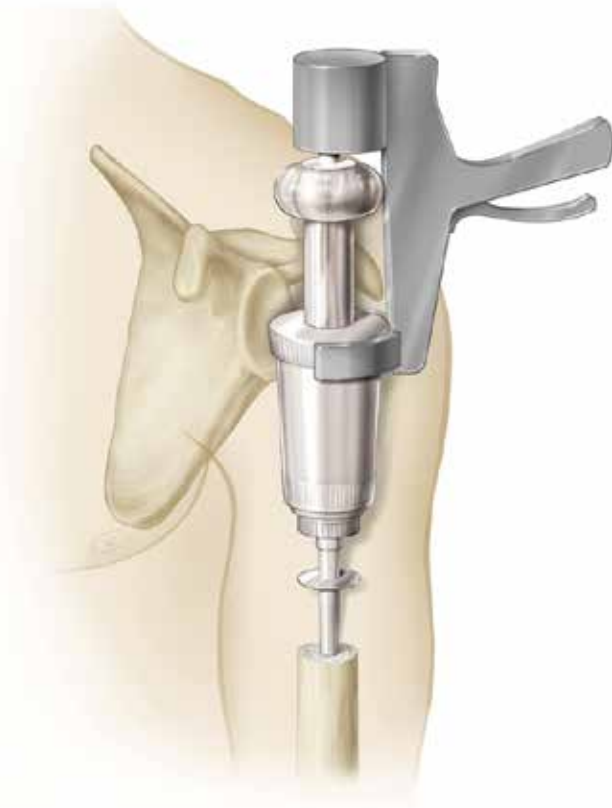


Figure 14
Cementing the distal humeral stem in the intramedullary canal

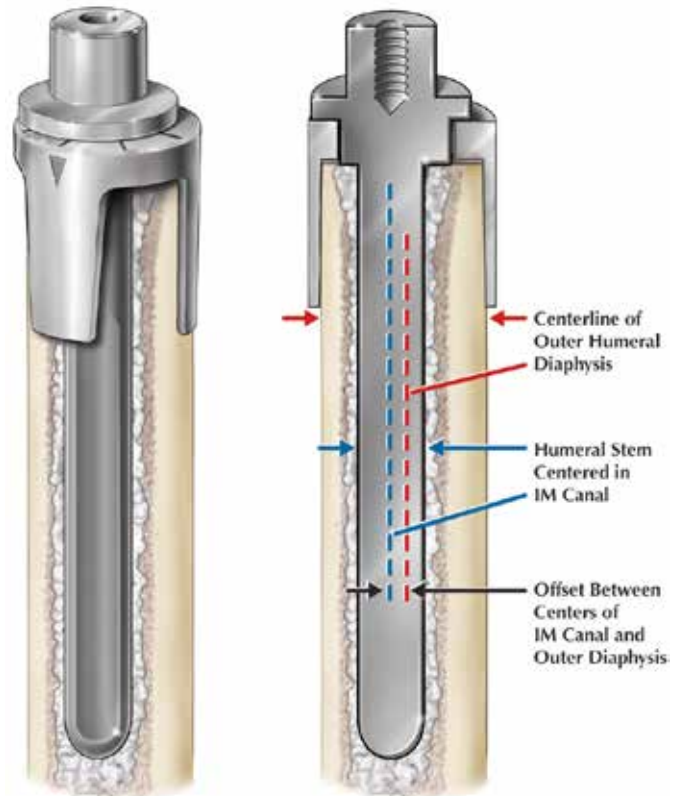


Figure 15
Dual offset of stem and collar necessary to position the humeral stem in the center of IM canal to ensure a uniform cement mantle thickness

Figure 15
Alignment of the Distal Stem/
Collar to the Bone Mark Ensures a
Uniform Cement Mantle

STEP 9: CEMENT THE DISTAL HUMERAL STEM

Prior to cementing the distal humeral stem, the IM canal should be packed with a sponge to prepare a dry interface for cementing. Once the canal is prepared, the PMMA bone cement is mixed and injected into the canal (*Figure 14*). **The use of a cement restrictor is recommended since it is crucial to improve cement distribution and pressurization within the canal.**

The cement is pressurized with a gloved thumb. The proximal cement is removed with a freer for about 1 cm so as to allow for cement displacement when the stem is placed. Any excess extruded cement should be meticulously removed from the area around the collar.

STEP 10: IMPACTION OF THE DISTAL STEM/COLLAR ASSEMBLY TO HUMERAL DIAPHYSIS

As the PMMA bone cement is polymerizing, the assembled distal stem/collar should be oriented along the humeral diaphysis as determined in the previous trialing step. Alignment of the distal stem/collar assembly to the bone mark will ensure a uniform cement mantle, achieved through the dual eccentricities in the collar and stem (*Figure 15*).

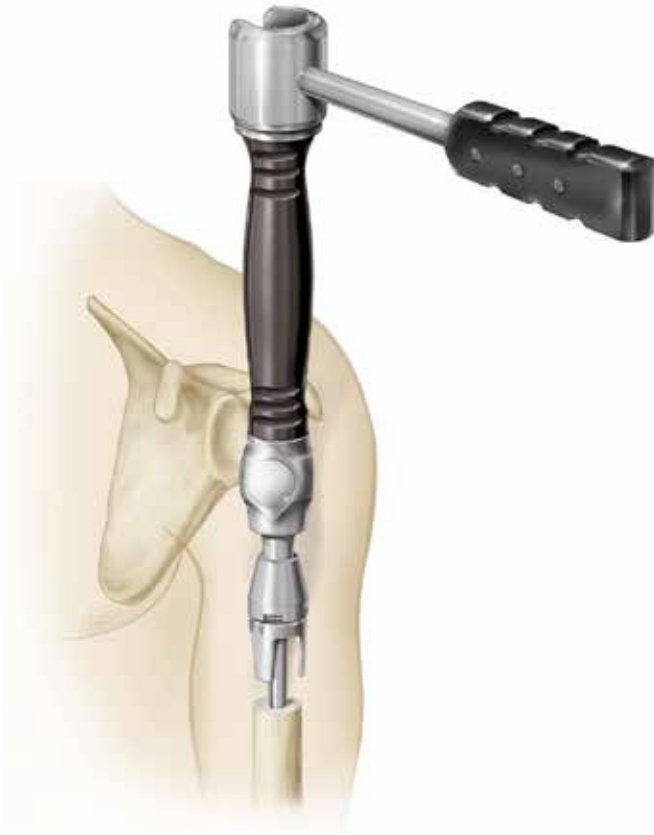


Figure 16
Positioning the Assembled Distal Stem/
Collar in the Humeral IM Canal

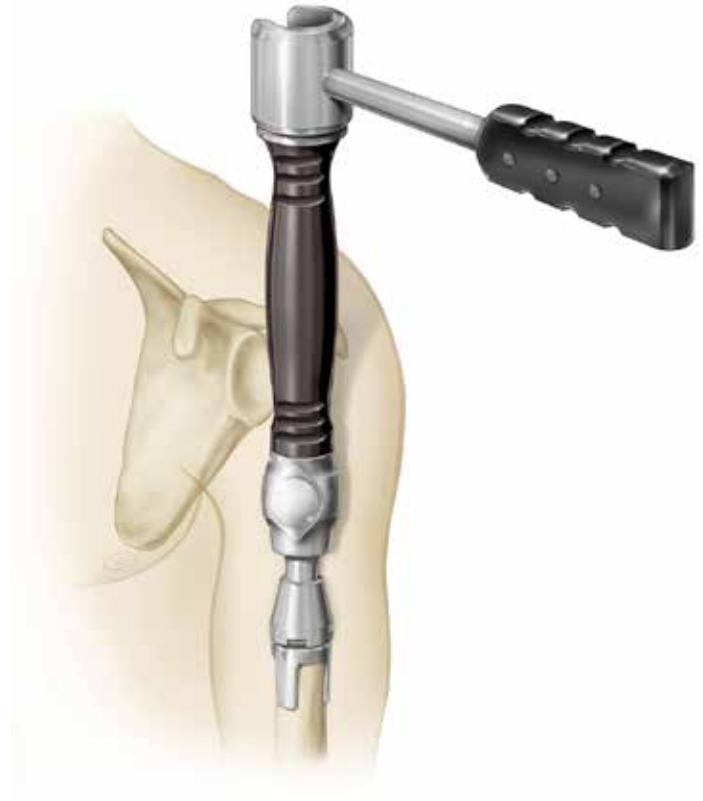


Figure 17
Impaction of the Assembled Distal Stem/
Collar in the Humeral IM Canal. Excess
Cement Should be Removed After Impaction.

The impactor should then be secured to the modular handle and positioned over the top of the distal stem (*Figure 16*).

A Mallet should then be used to impact the assembled distal stem/collar on the humerus until the assembly is fully seated on the bone (*Figure 17*). After the assembly is fully seated, pressure should be applied to the distal humeral stem/collar construct until cement polymerization is complete.

Any excess bone cement around the humerus should be removed. The Distal Humeral stem is grit blasted and the Distal Collars are plasma coated with HA to improve fixation. Care should be taken to avoid cement extrusion during implantation of the humeral stem to limit interference with the bone/HA-coated implant interface.

DETAILED OPERATIVE TECHNIQUE

APPROACH AND PATIENT POSITIONING

Middle Segment Height	Color
25mm	Black
50mm	Blue
75mm	Orange

Table 2

Color Coding of Middle Segments



Figure 18

Using Middle and Proximal Segments to Reconstruct the Humerus to its Original Height Following Resection (Note that a 25 and 50mm trial segment is shown; these trials are equivalent to a 75mm segment which should be used when the final implant is selected if this length is deemed appropriate for the particular patient)

STEP 11: TRIAL OF PROXIMAL AND MIDDLE SEGMENTS

Color coded trials (*Table 2*) are provided in various heights to reconstruct the humerus to the resected height (*Figure 18*).

Three sizes of middle segments are provided in 25mm increments (25, 50, and 75mm) and two proximal segments are provided in 12.5mm increments (0 and 12.5mm). No more than two middle segments should be used. When two middle segments are used, always secure the longer middle segment in the most distal position to minimize the torque on the modular interfaces. As described in *Table 1*, combining proximal and middle segments provides for up to 162.5mm of buildup from the resection in 12.5mm increments.

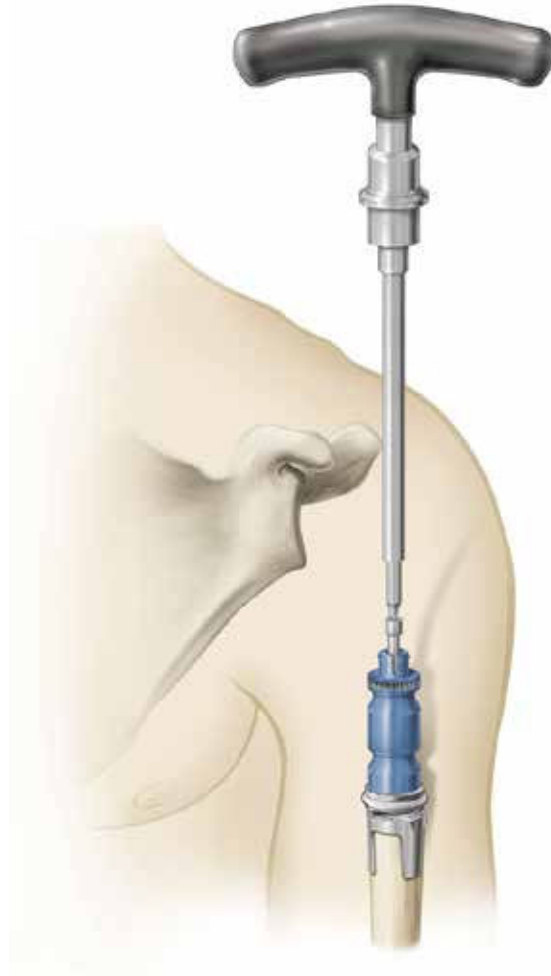


Figure 19
 Securing Middle Segment Trials to
 Distal Stem with Captured Screw

Trial screws are provided and are captured within the proximal and middle trial components, to secure the trial component to the distal stem (*Figure 19*). As stated above, no more than two middle segments should be used.

When two middle segments are used, always secure the longer middle segment in the most distal position to minimize the torque on the modular interfaces. Additional middle or proximal trials are secured together by axial compression to engage the snap-locking mechanism and the anti-rotation ring. Prior to engagement of this anti-rotation ring, the orientation of the trial middle segments can be rotated 360° to align the cutout segments on the trial with the desired soft tissue location. The cutout segments on the middle segment trials correspond to the cpTi plasma coated regions of the

definitive implants that are used to secure soft tissue to the device with sutures (**#5 suture or equivalent reinforced suture**). Numerous suture holes and grooves are provided in the definitive middle segments and in the definitive proximal body implants to facilitate soft tissue attachment and protect the sutures from abrasion with the plasma coated regions of the implants. Trial segments can be separated manually after trial reduction and selection of definitive implant height by raising the anti-rotation ring.

DETAILED OPERATIVE TECHNIQUE

APPROACH AND PATIENT POSITIONING

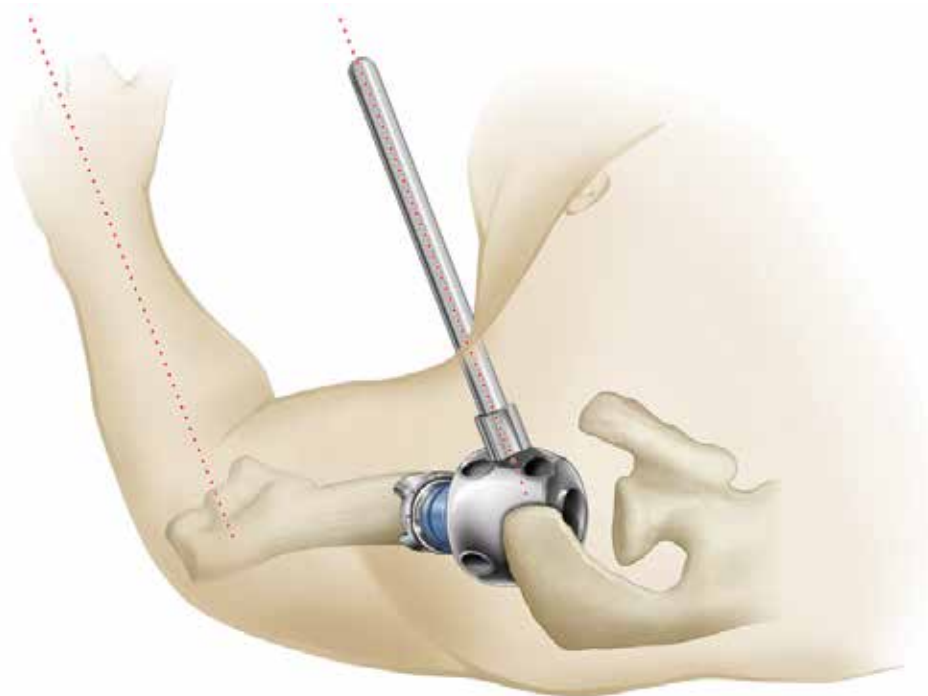


Figure 20

Assessing humeral retroversion using the Retroversion Handle Secured to the Proximal Body Trial; 20 degrees of humeral retroversion is achieved when the retroversion handle/planar shaft is aligned with the forearm

If humeral resection necessitates removal of any muscular insertions, reattachment of those muscles is possible by passing sutures (**#5 suture or equivalent reinforced suture**) through the suture holes which strategically surround the multiple cpTi plasma coated regions on the prosthesis, compressing the tissue against the coating to facilitate on-growth. These cpTi plasma coated regions may also be used to transfer a particular muscle, if deemed appropriate by the surgeon to improve function. To aid in this planning during the trial reduction, the cpTi plasma coated regions on the definitive prosthesis are indicated as machined recessed regions on the corresponding middle and proximal segment trials. Please refer to Step 15 for instructions specific to deltoid reattachment.

The proximal body can be oriented in 20 degrees of humeral retroversion by using a visual check to assess version. A threaded hole is provided on the left and right sides of the proximal body trial for attachment of the retroversion handle (or planar shaft) which indicates 20 degrees retroversion when aligned with the patient's forearm (assuming the patient has a stable elbow) (*Figure 20*). If the clinical situation indicates the need for a different amount of retroversion, the handle can be used as a guide for this adjustment.



Figure 21

Selection of One of Four Different Sizes of Lateralized Proximal Bodies



Figure 22

Lateralizing the Proximal Body is an Alternative Way to Improve Joint Stability by Increasing Wrapping of the Deltoid Around the Proximal Humerus

STEP 12: TRIAL REDUCTION/DELTOID TENSIONING

The Equinoxe Humeral Reconstruction Prosthesis provides multiple proximal body segments (Small, Medium, Large, and Extra Large) that are built-up laterally in 4 to 5mm increments as an alternative method to tension the joint (rather than building in the plane of the resection with thicker humeral heads/humeral trays or by building vertically with longer middle segments or proximal bodies) (Figure 21). **Lateralizing the humerus increases stability by increasing deltoid wrapping around the proximal humerus** (Figure 22).

Multiple sizes of lateralized proximal bodies can be trialed until appropriate tension is achieved. In the absence of glenoid wear, the size of the proximal body segment should be selected to reproduce the size of the patient's resected humeral head in order to recreate the patient's anatomic wrapping of the deltoid.

DETAILED OPERATIVE TECHNIQUE

APPROACH AND PATIENT POSITIONING

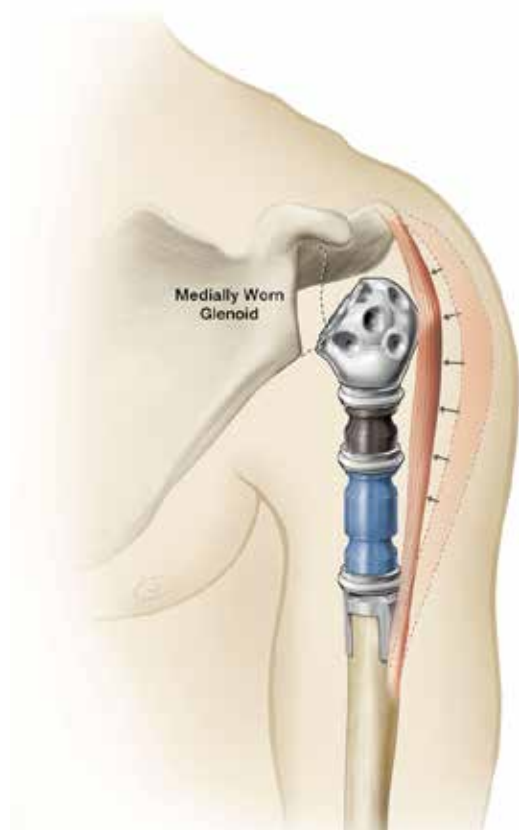


Figure 23
Reduced Deltoid Wrapping with Medial
Glenoid Wear; Additional Proximal Body
Lateralization will Restore Deltoid Wrapping
to Improve Joint Stability

In the presence of glenoid wear, the joint should be lateralized until the greater tuberosity is lateral to the lateral edge of the acromion; if the greater tuberosity is medial to the acromion, deltoid wrapping is minimized and the deltoid vector may cause a destabilizing laterally-directed distraction force (*Figure 23*). A larger size may be selected to lateralize the humerus and facilitate greater deltoid wrapping. Alternatively, a smaller size is provided to facilitate deltoid closure for smaller anatomies or if the anterior deltoid and/or pectoralis is deficient.

Trialing For Anatomic Shoulder Arthroplasty

If trialing for an anatomic shoulder arthroplasty, secure the 0mm (nonoffset) replicator plate or 0mm replicator plate trial to the proximal body trial and select the appropriately sized diameter (38, 41, 44, 47, 50, and 53mm) and thickness (short, tall, expanded) humeral head trial until desired joint tension is achieved. A smaller diameter humeral head size is recommended to prevent any damage to the surrounding soft tissue by an oversized humeral head. Note that the humeral heads have variable offset between 0mm (for the 38 and 41mm diameters) and 1.5mm (for the 44, 47, 50, and 53mm diameters) so they need to be dialed to the preferred orientation. Assessment of stability is performed in a step-wise sequence. First, the articulation is assessed with the arm at the side. The arm is rotated internally and externally; rotation should be smooth, and the humeral head should maintain a reduced position on the glenoid component. Second, with the arm at the side, anterior, posterior and inferior translation should be assessed. Up to 50 percent posterior and inferior translation is acceptable; up to 25 percent anterior translation is acceptable. Third, range of motion is assessed. The arm should internally rotate to the chest wall without limitation. At 90 degrees of abduction, the shoulder should internally rotate 70 degrees. If these tissues are intact and available for repair the stability of the implant can be enhanced by the rotator cuff interval closure and subscapularis repair. Varying the thickness of the modular humeral head can improve stability but may decrease range of motion. If soft-tissue laxity is excessive, a taller humeral head may be necessary but only after the above soft tissue closure has been optimized. Conversely, if soft-tissue tension is excessive, a shorter humeral head may be necessary. In general, the thinnest humeral head that provides adequate stability should be used to avoid overstuffing the joint. If the surgeon desires to further adjust the positioning of the head, simply loosen the torque defining screw one-half rotation to loosen the replicator plate and repeat the previous steps.

Please refer to the Equinoxe Platform Shoulder System operative technique (718-01-30) for additional information related to the preparation of the glenoid and replicator plate/humeral head components for anatomic total shoulder arthroplasty.

Trialing For Reverse Shoulder Arthroplasty

If trialing for a reverse shoulder arthroplasty, secure the appropriate offset humeral tray and humeral liner. The +0mm Humeral Adapter Tray Trial is attached to the humeral stem by threading the Humeral Adapter Tray Captured Screw into the Humeral Stem’s screw hole (+10mm is also attached this way). **It is critical that the Humeral Adapter Tray be oriented such that the laser mark line on the Adapter Tray aligns with the midline of the proximal body.** The +5mm trial tray can be added as needed. For a +10mm offset and greater, remove the +0mm Humeral Adapter Tray Trial and insert the +10mm tray trial. To obtain a +15mm offset and larger, the +5mm tray trial will need to be added. Combinations of humeral trays and liners can achieve the following offsets: +0, +2.5, +5.0, +7.5, +10.0, +12.5, +15, and +17.5mm. It is important to note that the assembled humeral component will have a humeral neck angle of 145 degrees because the liner adds 12.5 degrees to the proximal body’s 132.5 degree neck angle. Constrained humeral liner options are also provided if additional constraint is needed. To insert the Humeral Liner Trial into the Trial Tray, the underside asymmetric-connecting feature should be appropriately aligned and the liner/tray trials should be pressed together until the C-spring engages. To disengage the trials, the tip of the removal pliers is inserted into the recessed region of the trial tray and the instrument is squeezed until the spring that connects the Humeral Liner Trials and plate trials is disengaged, thereby freeing the Humeral Liner.

Assessment of stability is performed during a trial reduction. The shoulder should be placed through a range of motion to assess the stability of the construct. While each surgeon may have their own system to assess stability, we approach the trial reduction as follows:

- 1) With reduction and arm by the side, the lateral deltoid and conjoined tendon should be under reasonable tension. The expectation is that the reduction should require more distraction to achieve than reduction of non-constrained implants.
- 2) Forward elevation and abduction should be assessed to determine that the construct is stable and the components do not impinge on bony structures.

- 3) Internal and external rotation should be assessed with the humerus at 0 and 90 degrees to assess stability. Although maximal ranges of external rotation may produce some impingement posteriorly, it should not result in instability.
- 4) With the arm at the side, there should be no evidence of impingement that results in distraction of the implants.
- 5) As these motions occur, the implant should be carefully observed for any camming which indicates contact between the humeral tray and bone or soft tissue. If the implant cams throughout these motions, the site of impingement with bone should be removed.

If additional stability is required based upon the trial reduction, use of larger diameter glenospheres or more laterally offset glenospheres is recommended. Increasing humeral liner offset (up to 17.5mm) may also be used to improve stability. Constrained liner options are also provided in the same diameter and offset as the standard liners; however, while constrained liners will provide better stability, it is important to note they will also reduce the potential range of motion that can be achieved. As a result, constrained liners are recommended only when other options fail to achieve stability. In addition, the optimal situation for using a constrained liner is with a lateralized glenosphere as impingement is less likely in this construct. Alternatively, if additional stability is required, a unique method to the Equinox Humeral Reconstruction Prosthesis to improve stability is by lateralizing the proximal humerus with the use of thicker proximal segments. The more lateralized the proximal segment, the greater the deltoid wrapping and the greater stability (*Figures 19 and 20*). If trial components are changed, additional closed reductions and assessments should be performed to confirm that the desired stability has been obtained. In the unusual situation in which the +0mm liner is too tight, the humeral component should be removed and the proximal body or middle segments should be shortened. **Please refer to the Equinox Platform Shoulder System operative technique (718-01-30) for additional information related to the preparation of the glenoid and humeral components for reverse total shoulder arthroplasty.**

DETAILED OPERATIVE TECHNIQUE

APPROACH AND PATIENT POSITIONING



Figure 24
Impaction of Middle
Segments on the Backtable



Figure 25
Backtable Impaction of Middle and
Proximal Segment Tapers

STEP 13: IMPLANTATION OF DEFINITIVE HUMERAL RECONSTRUCTION PROSTHESIS STEM IMPLANTS

After a stable trial reduction is achieved with either anatomic or reverse shoulder arthroplasty, the trial segments should be disassembled and the definitive middle segments and proximal bodies should be selected based upon the final trials.

The tapers of the middle segments and proximal bodies should be impacted and engaged on the back-table. **We do not recommend impaction of the modular proximal and middle segments in situ to minimize damage to the distal stem cement mantle, only the fully assembled proximal segment should be impacted in situ to the distal stem. When performing the backtable assembly, place the**

largest/most inferior middle segment on the backtable assembly base and place the next middle segment (if a second middle segment is required), aligning the two segments appropriately to each other according to the desired soft tissue insertion positions. Clean and dry the tapers and align the four grooves of the impactor/impactor handle with the four grooves on the proximal portion of the middle segment. Next, impact the strike surface of the impactor handle with a mallet two to three times (*Figure 24*). After impaction, the tapers should be manually extracted to ensure adequate engagement prior to implantation. Then secure the proximal body impactor to the inferior end of the impactor handle and impact the proximal body to the middle segment according to the same process (*Figure 25*).

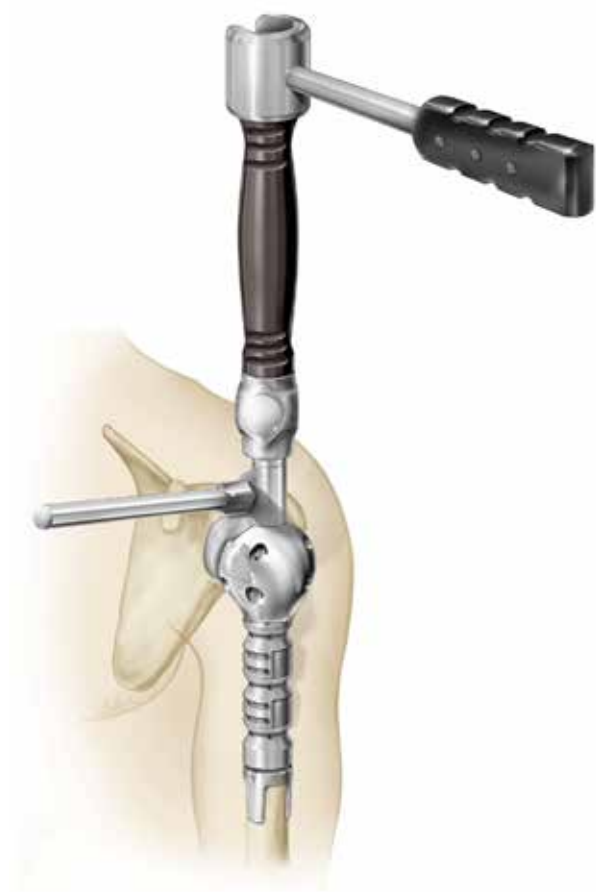


Figure 26

Impactation of Proximal Segment and Middle Segment Tapers to the Distal Stem Taper with aTSA

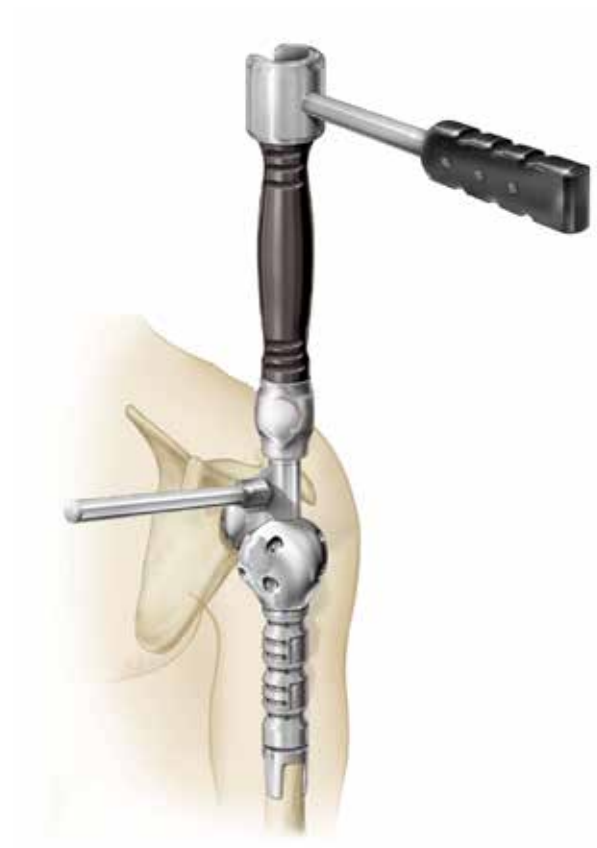


Figure 27

Impactation of Proximal Segment and Middle Segment Tapers to the Distal Stem Taper with rTSA

Finally, the back-table constructed assembly is taken in situ and oriented in 20 degrees of retroversion. The impactor handle will engage the proximal body and allow for the version rod to be threaded into the impactor. This will allow for rotational control and for implantation at the recommended 20 degrees of retroversion. The proximal body impactor and impactor handle are used to impact the back-table constructed assembly to the distal humeral stem taper. As before, clean and dry the tapers and impact the strike surface of the impactor handle with a mallet two to three times (*Figures 26 and 27*).

Never secure the middle and proximal segments to the distal segment until after the distal stem cement polymerization is completed. **Care should be made to not over-impact the tapers at this step to minimize damage to the distal stem cement mantle.** After impactation, confirm that the tapers between the proximal body/middle segment have engaged with the distal stem taper by manually extracting the reconstructed device.

DETAILED OPERATIVE TECHNIQUE

APPROACH AND PATIENT POSITIONING

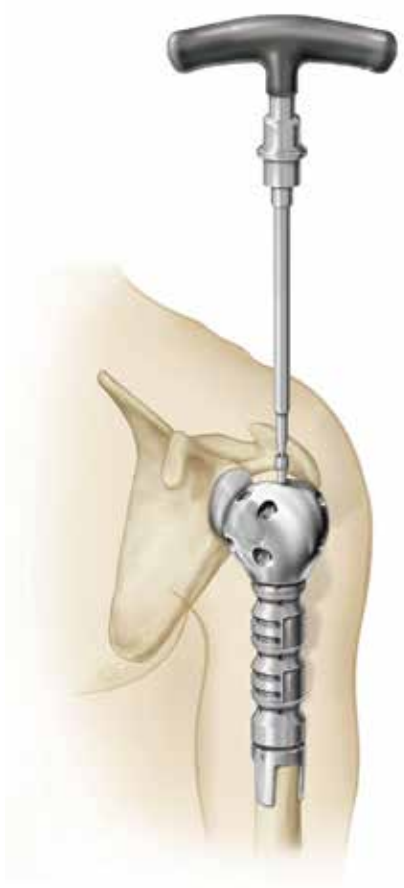


Figure 28
Securing the Taper Locking
Screw with aTSA

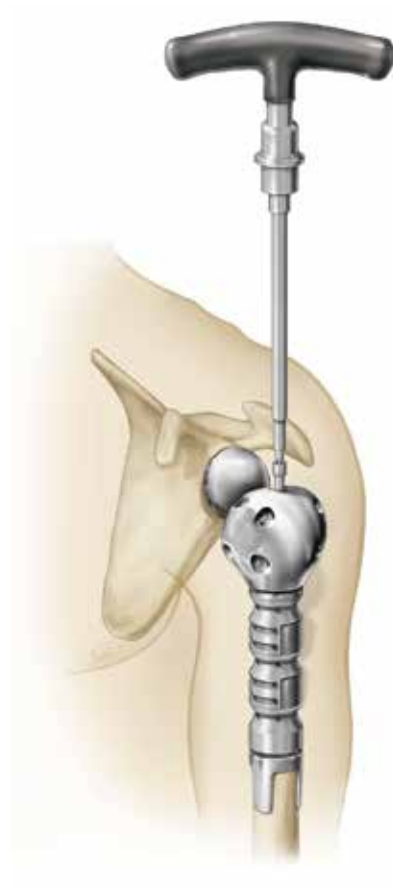


Figure 29
Securing the Taper Locking
Screw with rTSA

After confirming that all tapers are engaged, these implants should be added together to determine the total build up in order to select the final locking screw length. As described previously in *Table 1*, taper locking screws are provided in 12.5mm increments up to 162.5mm in length and are used to secure the proximal body to the distal stem after all taper segments have been individually impacted and engaged. The appropriate length of taper locking screw is secured through the proximal body to the distal stem using the 3.5mm hex drive and t-handle (*Figures 28 and 29*).

Secure the taper locking screw until tight; ensure that the taper locking screw is fully threaded/seated and that the screw is not cross-threaded.

Note: Place the screw before implanting the humeral head or reverse tray.



Figure 30
Securing the Replicator
Plate to the Proximal Body

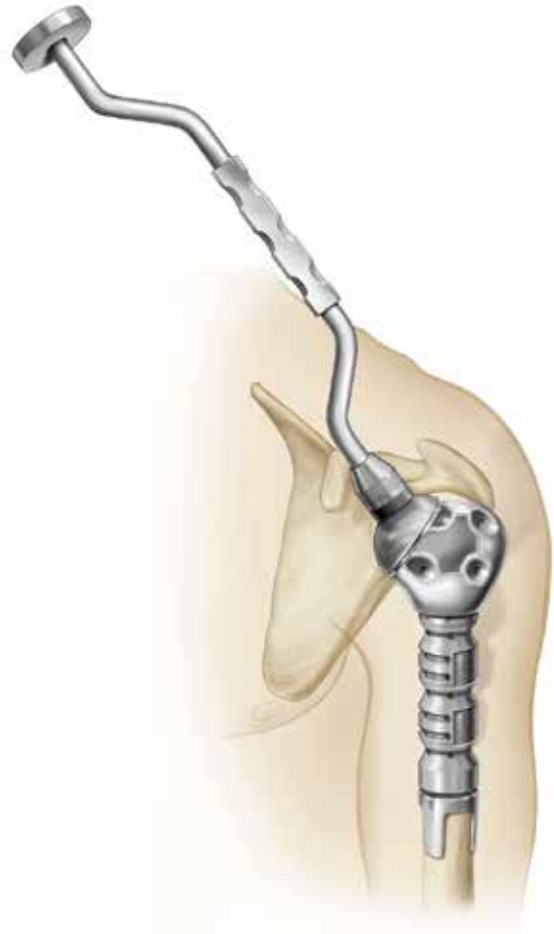


Figure 31
Impacting the Humeral Head
to the Replicator Plate

**STEP 14A: SECURING THE REPLICATOR PLATE
AND HUMERAL HEAD**

As described in Equinox Platform Shoulder System operative technique (718-01-30), attach the 0mm replicator plate to the proximal body by hand tightening the primary torque defining screw with the torque defining screw drive. Next, insert the replicator handle into the holes located on the surface of the plate. The replicator handle is used to provide counter-torque as the torque defining screw is tightened. Attach the t-handle to the torque defining screw drive and with one hand, use the t-handle to tighten the screw until the superior portion disengages, which will occur at an applied torque of 11 N*m. A counter-torque must be simultaneously applied using the replicator handle (*Figure 30*).

The superior portion of the screw that remains in the torque defining screw drive (both of which are disposable) will leave a square head on the implant that the surgeon can use to loosen the screw using the torque defining screw removal instrument should the replicator plate ever need to be removed (e.g. revision of hemi to a TSA or reverse).

Next, clean and dry the visible portion of the replicator plate and place the definitive humeral head implant on the replicator plate using the numbers on the bottom of the implant to replicate the head trial orientation. Using the head impactor and a mallet, strike the head directly in line with the taper to ensure proper taper engagement (*Figure 31*). Ensure the head impactor tip is fully threaded to the impactor before striking. Hand-test to ensure proper seating.

DETAILED OPERATIVE TECHNIQUE

APPROACH AND PATIENT POSITIONING



Figure 32

Securing the Reverse Shoulder Humeral Tray to the Proximal Body



Figure 33

Impaction of the Humeral Liner to the Reverse Shoulder Humeral Tray

STEP 14B: SECURING THE HUMERAL TRAY AND HUMERAL LINER

As described in Equinox Platform Shoulder System operative technique (718-01-30), the definitive humeral adapter tray is attached to the proximal body using the reverse torque defining screw. It is critical that the humeral adapter tray be oriented properly, which requires aligning the indicator mark on the tray with the midline of the proximal body. The humeral adapter tray is locked to the stem by applying 11 N*m torque to the screw with the supplied torque defining screw driver while countering the torque to the arm with the replicator handle (*Figure 32*). The superior portion of the screw that remains in the torque defining screw drive (both of which are disposable) will leave a square head on the implant that the surgeon can use to loosen the screw using the torque

defining screw removal instrument should the humeral tray ever need to be removed (e.g. revision of a reverse).

The final humeral liner is attached to the humeral adapter tray by orienting the asymmetric connecting features and sliding the lip of the liner under the superior rim of the humeral tray. As with the trial insertion, it is important to note that the assembled humeral component will have a humeral neck angle of 145 degrees because the humeral liner adds 12.5 degrees to the proximal body's 132.5-degree neck angle. Finally, the apical mushroom of the humeral liner is engaged to the apical lock of the humeral adapter tray by impacting the humeral liner with the appropriately sized humeral liner impactor tip. The humeral liner should be impacted until it sits flush on the humeral adapter tray (*Figure 33*).

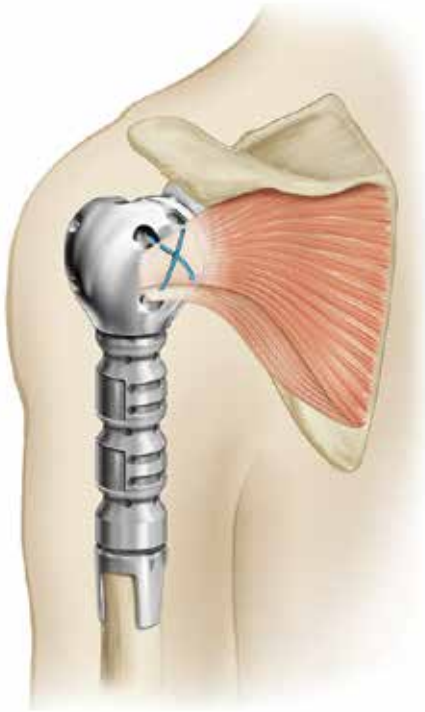


Figure 34

Securing the Infraspinatus and Teres Minor to the Plasma Coated Region of the Posterior Side of the Proximal Body Using Reinforced Sutures with aTSA

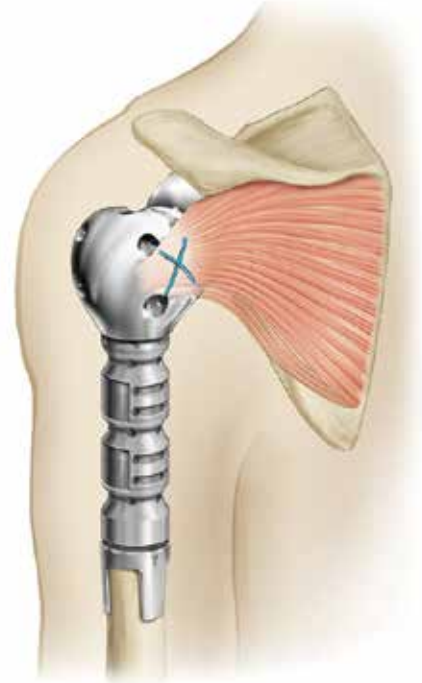


Figure 35

Securing the Infraspinatus and Teres Minor to the Plasma Coated Region of the Posterior Side of the Proximal Body Using Reinforced Sutures with rTSA

STEP 15: SOFT TISSUE ATTACHMENT

After all implants have been assembled, available soft tissue can be repaired to improve function and stability. Numerous suture holes are machined into the proximal and middle segments, both of which have regions that are plasma coated with cpTi to facilitate repair. **If possible, the surgeon should repair the infraspinatus and teres minor tendons to maximize external rotation function** (Figures 34 and 35).

DETAILED OPERATIVE TECHNIQUE

APPROACH AND PATIENT POSITIONING

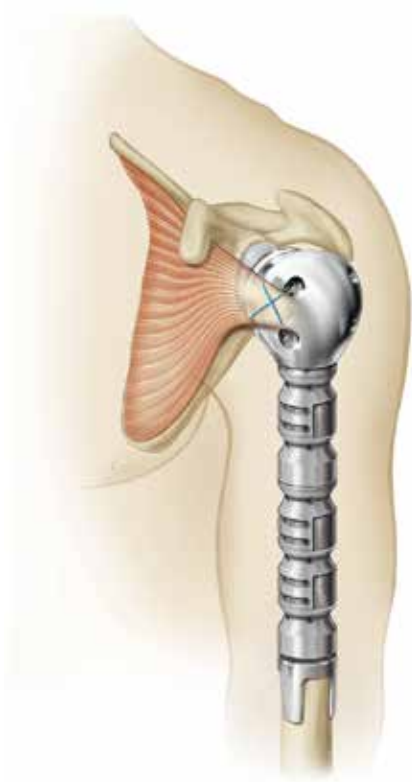


Figure 36

Securing the Subscapularis to the Plasma Coated Region of the Anterior Side of the Proximal Body Using Reinforced Sutures with aTSA



Figure 37

Securing the Subscapularis to the Plasma Coated Region of the Anterior Side of the Proximal Body Using Reinforced Sutures with rTSA

Repair of the subscapularis tendon can sometimes be performed if sufficient tissue is available (*Figures 36 and 37*).

The surgeon should balance the functional benefit of subscapularis re-attachment with potential loss of range of motion if the cuff is deficient.

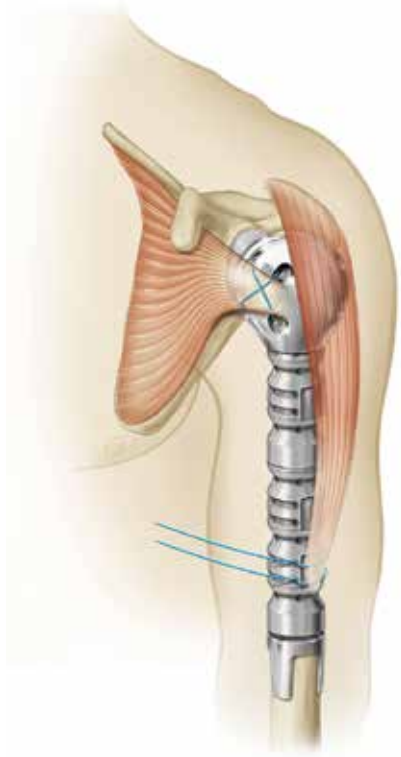


Figure 38

Securing the Footprint of the Deltoid Tendon to the Plasma Coated Region of the Middle Segment is Mandatory (If Detached) with aTSA; It Should Be Circumferentially Secured with Reinforced Sutures



Figure 39

Securing the Footprint of the Deltoid Tendon to the Plasma Coated Region of the Middle Segment is Mandatory (If Detached) with rTSA; it Should be Circumferentially Secured with Reinforced Sutures

The deltoid, if detached distally during oncologic or revision resection must be repaired by attachment to the prosthetic body to allow proper function (*Figure 38 and 39*). Primary closure of the deltopectoral interval is recommended to complete the wrap of the deltoid around the prosthesis and close the joint to maximize stability and function.

At this point, the humeral component should be reduced onto the glenoid component if total shoulder arthroplasty (aTSA or rTSA) is deemed by the surgeon to be the most appropriate treatment option; otherwise the hemiarthroplasty should be reduced to the glenoid bone. Range of motion and stability should be assessed to confirm the findings from the trial reduction. Once this assessment has been made, closure can be performed.

STEP 16: CLOSURE

For revision applications or primary cases with significant bone loss, closure should begin after repair of the rotator cuff muscles to the proximal body of the Humeral Reconstruction Prosthesis humeral stem. External rotation should be checked at the closure. The deltopectoral interval is closed followed by closure of the subcutaneous tissue and the skin; a robust deltopectoral closure will facilitate stability. The upper extremity is then placed in a sling and swathe. For oncology applications, closure is performed by closing the deep tissues as available in layers. Often, the remaining deltoid can be approximated to the pectoralis major for anterior coverage. A drain may be placed deep and brought out lateral to the incision. Superficial closure should be performed at the discretion of the surgeon.

DETAILED OPERATIVE TECHNIQUE

APPROACH AND PATIENT POSITIONING

STEP 17: POST-OPERATIVE REHABILITATION

It is recommended to initiate the rehabilitation program on the same day as surgery. Rehabilitation should be customized depending upon the specific soft tissue reattachments performed and physician preference. If the deltoid requires repair, an abduction pillow for a minimum of 6 weeks is recommended. In general, all patients begin active range of motion of the elbow, wrist and hand. Range of motion of the shoulder consists of passive forward elevation, external rotation based on the assessment following subscapularis repair and internal rotation to the chest wall. It is very important that caregivers do not pull up on the operated arm of the patient in an effort to assist the patient from bed or a chair as this might compromise soft tissue repair and cause instability. The sling is typically discontinued after four to six weeks. A longer period of sling use may be necessary if there is concern about the soft tissue repair. When the sling is discontinued, active range of motion should begin followed by isometric strengthening. Resistive strengthening generally begins at 12 weeks.

REVISION

IMPLANTING A GLENOID: CONVERSION OF HEMIARTHROPLASTY TO TOTAL SHOULDER ARTHROPLASTY

Gaining exposure to the glenoid after a hemiarthroplasty, while rarely easy, is facilitated with the Equinox System's removable replicator plate. Using the head removal tool, lever the head off the replicator plate. When the torque defining screw was initially torqued, the portion that snapped off left a square that can be used to remove the screw. Attach the torque defining screw removal instrument to the asymmetric t-handle and loosen the screw. The replicator plate can now be removed and discarded and the **glenoid can be implanted according to the Equinox Platform Shoulder System operative technique (718-01-30) for preparation of the glenoid for anatomic total shoulder arthroplasty.** After glenoid implantation, a new replicator plate, screw, and humeral head should be used to ensure proper engagement of the taper.

CHANGING PROSTHESIS HEIGHT

Should the Equinox Humeral Reconstruction Prosthesis need to be revised and the height need to be modified, the joint should be dislocated and the humeral liner/humeral adapter tray or humeral head/replicator plate should be removed as described previously along with the torque defining screw. If a reverse shoulder was performed, the glenosphere may also need to be removed. Use the 3.5mm hex drive to remove the glenosphere locking screw. After screw removal, the glenosphere removal instrument can be

used to hook into the anterior and posterior recesses on the underside of the glenosphere to lever it off of the baseplate.

Next, the taper locking screw should be removed from the humeral components using the 3.5mm hex drive and t-handle. After removal of the taper locking screw, the taper disengagement wedge should be connected to the impactor handle. The taper disengagement wedge should be placed perpendicular to the modular segments that are desired to be modified. Impaction of the strike surface of the impactor handle with a mallet will cause taper disengagement (*Figure 40*).

Multiple taper disengagement wedges are provided per set to facilitate use. The joint should be re-trialed and implanted according to the method described above.

When revising the Humeral Reconstruction Prosthesis, soft tissues should be sharply elevated from the prosthesis in order to preserve as much length as possible. Doing so maximizes the potential for reattachment of the soft tissues to the new prosthetic body.

Additionally, care should be taken to protect the radial nerve as it often is trapped in the scar tissue immediately adjacent to the posterior prosthesis body.

EXTRACTING THE DISTAL HUMERAL STEM

Should the distal humeral stem need to be revised, the taper locking screw and modular middle and proximal segments should first be removed as described above. After removal, the stem extractor connector threads into the distal humeral stem. It is critical that the connector completely thread into the humeral stem until it bottoms out on the distal stem taper (*Figure 41*).

The slap hammer then secures to the stem extractor connector and the integrated telescopic Slap Hammer can be used to extract both the distal stem and distal collar at the same time (*Figures 42 and 43*).

Note that it is not possible to remove the distal collar from the humeral stem independently.

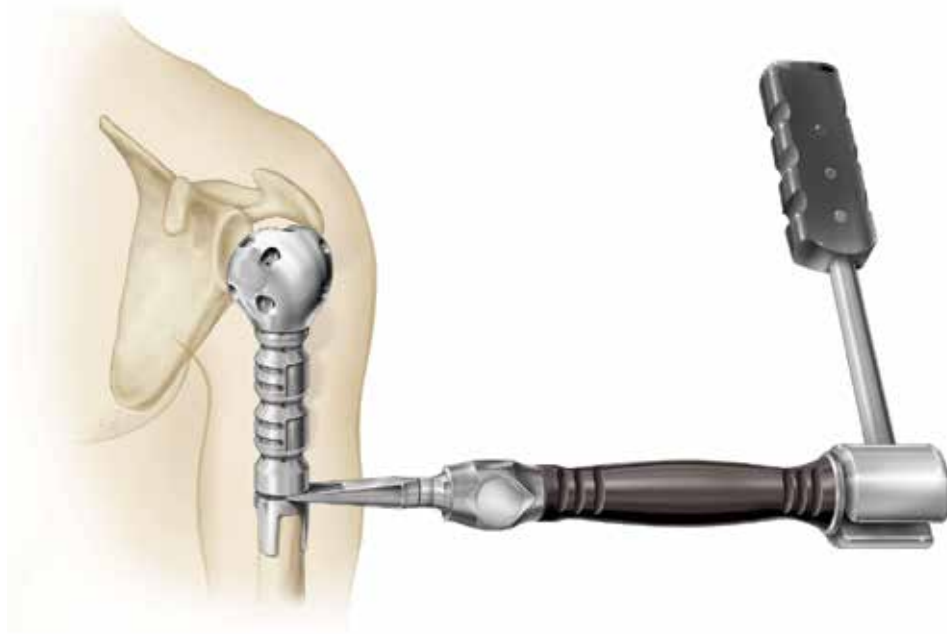


Figure 40

Using Taper Disengagement Wedge and Impactor Handle to Disengage Tapers After Removal of the Taper Locking Screw



Figure 41

Securing the Stem Extractor Connector to the Distal Stem



Figure 42

Securing the Slap Hammer to the Stem Extractor Connector



Figure 43

Extraction of the Distal Stem and Distal Collar From the Humeral Diaphysis Using the Slap Hammer

IMPLANT PART NUMBERS

Catalog #	Description	Catalog #	Description
308-01-06	6x80mm Distal Stem	308-15-25	Taper Locking Screw 25
308-02-06	6x120mm Distal Stem	308-15-37	Taper Locking Screw 37.5
308-01-07	7x80mm Distal Stem	308-15-50	Taper Locking Screw 50
308-02-07	7x120mm Distal Stem	308-15-62	Taper Locking Screw 62.5
308-01-08	8x80mm Distal Stem	308-15-75	Taper Locking Screw 75
308-02-08	8x120mm Distal Stem	308-15-87	Taper Locking Screw 87.5
308-03-08	8x200mm Distal Stem	308-16-00	Taper Locking Screw 100
308-01-09	9x80mm Distal Stem	308-16-12	Taper Locking Screw 112
308-02-09	9x120mm Distal Stem	308-16-25	Taper Locking Screw 125
308-01-11	11x80mm Distal Stem	308-16-37	Taper Locking Screw 137
308-02-11	11x120mm Distal Stem	308-16-50	Taper Locking Screw 150
308-01-13	13x80mm Distal Stem	308-16-62	Taper Locking Screw 162.5
308-02-13	13x120mm Distal Stem	308-05-17	Distal Stem Collar 17.5
308-10-25	25mm Middle Segment	308-05-18	Distal Stem Collar 18.5
308-10-50	50mm Middle Segment	308-05-19	Distal Stem Collar 19.5
308-10-75	75mm Middle Segment	308-05-20	Distal Stem Collar 20.5
308-08-00	0mm Proximal Body Extra Small	308-05-21	Distal Stem Collar 21.5
308-08-12	12.5mm Proximal Body Extra Small	308-05-22	Distal Stem Collar 22.5
308-09-00	0mm Proximal Body Small	308-05-23	Distal Stem Collar 23.5
308-09-12	12.5mm Proximal Body Small	308-05-24	Distal Stem Collar 24.5
308-10-00	0mm Proximal Body Medium	308-05-25	Distal Stem Collar 25.5
308-10-05	0mm Proximal Body Large	308-05-26	Distal Stem Collar 26.5
308-10-10	0mm Proximal Body Extra Large	308-05-27	Distal Stem Collar 27.5
308-12-00	12.5mm Proximal Body Medium	308-05-28	Distal Stem Collar 28.5
308-12-05	12.5mm Proximal Body Large	308-05-29	Distal Stem Collar 29.5
308-12-10	12.5mm Proximal Body Extra Large	308-05-30	Distal Stem Collar 30.5
308-15-01	Taper Locking Screw 0	308-05-31	Distal Stem Collar 31.5
308-15-12	Taper Locking Screw 12.5	308-05-32	Distal Stem Collar 32.5
		308-05-33	Distal Stem Collar 33.5

INSTRUMENT PART NUMBERS

Catalog #	Description	Catalog #	Description
309-01-06	6mm Planar Shaft	309-07-05	Universal Impactor Handle
309-01-07	7mm Planar Shaft	309-07-08	Retroversion Impactor
309-01-08	8mm Planar Shaft	309-07-09	Middle Segment Impactor
309-01-09	9mm Planar Shaft	309-07-11	Backtable Assembly Base
309-01-11	11mm Planar Shaft	309-07-12	Backtable Assembly Hammer
309-01-13	13mm Planar Shaft	309-08-00	Proximal Body Trial 0 Extra Small
309-01-32	34mm Planar	309-08-12	Proximal Body Trial 12.5 Extra Small
309-03-00	Humeral Resection Guide	309-09-00	Proximal Body Trial 0 Small
309-05-17	17.5mm Collar Trial	309-09-12	Proximal Body Trial 12.5 Small
309-05-18	18.5mm Collar Trial	309-10-00	Proximal Body Trial 0 Medium
309-05-19	19.5mm Collar Trial	309-10-05	Proximal Body Trial 0 Large
309-05-20	20.5mm Collar Trial	309-10-10	Proximal Body Trial 0 Extra Large
309-05-21	21.5mm Collar Trial	309-10-25	Middle Segment Trial 25
309-05-22	22.5mm Collar Trial	309-10-50	Middle Segment Trial 50
309-05-23	23.5mm Collar Trial	309-10-75	Middle Segment Trial 75
309-05-24	24.5mm Collar Trial	309-12-00	Proximal Body Trial 12.5 Medium
309-05-25	25.5mm Collar Trial	309-12-05	Proximal Body Trial 12.5 Large
309-05-26	26.5mm Collar Trial	309-12-10	Proximal Body Trial 12.5 Extra Large
309-05-27	27.5mm Collar Trial	309-15-06	Shaft Reamer 6mm
309-05-28	28.5mm Collar Trial	309-15-07	Shaft Reamer 7mm
309-05-29	29.5mm Collar Trial	309-15-08	Shaft Reamer 8mm
309-05-30	30.5mm Collar Trial	309-15-09	Shaft Reamer 9mm
309-05-31	31.5mm Collar Trial	309-15-10	Shaft Reamer 10mm
309-05-32	32.5mm Collar Trial	309-15-11	Shaft Reamer 11mm
309-05-33	33.5mm Collar Trial	309-15-12	Shaft Reamer 12mm
309-07-01	Taper Disengage Wedge	309-15-13	Shaft Reamer 13mm
309-07-03	Slaphammer	309-15-14	Shaft Reamer 14mm
309-07-04	Stem Extractor Connector	309-20-00	Planar Shaft Adaptor

INDICATIONS FOR USE

INDICATIONS

The Equinox® Humeral Reconstruction Prosthesis System is intended for use in hemi or total shoulder arthroplasty where proximal humeral resection is deemed necessary in cases of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Revision where other devices or treatments have failed
- Correction of functional deformity
- Treatment of acute or chronic fracture with humeral head involvement, which are unmanageable using other treatment
- Traumatic arthritis
- Oncology applications including bone loss due to tumor resection.
- Significant humeral resection which are unmanageable using other treatment methods

The Equinox Humeral Reconstruction Prosthesis System can be used in either primary or revision arthroplasty procedures.

The Equinox Humeral Reconstruction Prosthesis System is indicated for proximal humeral replacement in conjunction with reverse shoulder arthroplasty in which significant resection of the proximal humerus is necessary, the rotator cuff is irreplaceable and grossly deficient, and a functional deltoid muscle is present.

In the USA, the Equinox Humeral Reconstruction Prosthesis System is not indicated for use with the Equinox Reverse Shoulder System components in oncology applications.

The Equinox Humeral Reconstruction Prosthesis Distal Stems are for cemented use only, while the HA coated Equinox Humeral Reconstruction Prosthesis Distal Stem Collars are only for uncemented, press-fit use.

CONTRAINDICATIONS

Use of the Equinox Humeral Reconstruction Prosthesis 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

Lined writing area with 20 horizontal lines.



Exactech 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 Exactech Shoulder System—Instructions for Use for a device description, indications, contraindications, precautions and warnings. For further product information, please contact Customer Service, Exactech, Inc., 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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