DePuy Synthes
JOINT RECONSTRUCTION
COMPANIES OF Johnson & Johnson

GLOBAL®
UNITE®

Platform Shoulder System

SURGICAL TECHNIQUE

GLOBAL® | UNITE®
PLATFORM SHOULDER SYSTEM

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PLATFORM SHOULDER SYSTEM

Introducing the GLOBAL® UNITE® Platform Shoulder Arthroplasty System, a modular shoulder system that provides surgeons principled adaptability within the Operating Room without compromising recognized biomechanical principles.

Every shoulder fracture presents a unique challenge. That is why DePuy Synthes Joint Reconstruction created the GLOBAL UNITE System, a next-generation platform system. The modular proximal bodies allow the surgeon to restore joint height in press-fit applications, while the modular suture collar allows for anatomic reconstruction of the tuberosities.

In the event that the GLOBAL UNITE System requires conversion to a reverse shoulder, it does so without compromising biomechanics. Removal of the proximal body allows the epiphysis to attach to a well-fixed distal stem within the humerus at the proper height and version to optimize deltoid function as demonstrated by Professor Paul Grammont.

The GLOBAL UNITE System truly provides the surgeon *Principled Adaptability* within the Operating Room.

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(FRANCE)

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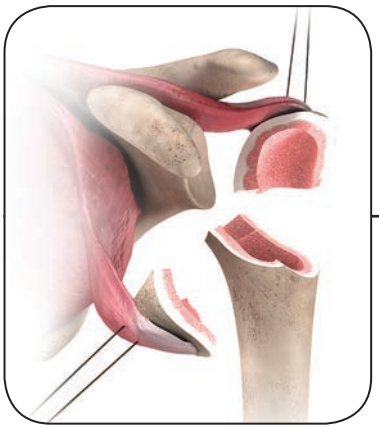
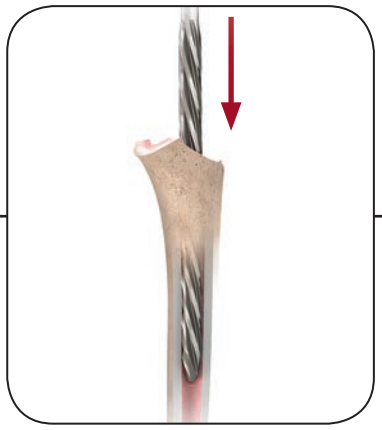
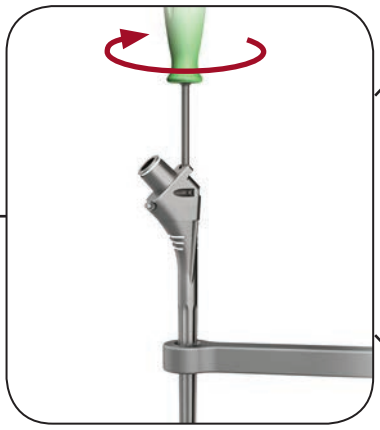
KEY SURGICAL STEPS



Remove Humeral Head and
Tag Tuberosities

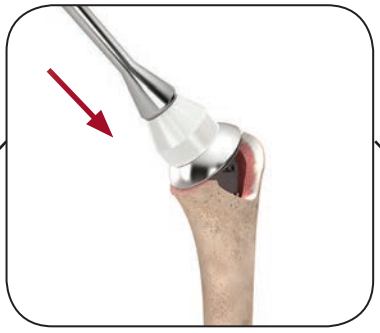


Ream Humeral Canal

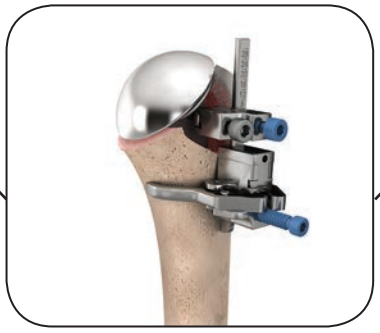


Assemble Trial Components (0 Body)

PRESS-FIT FIXATION

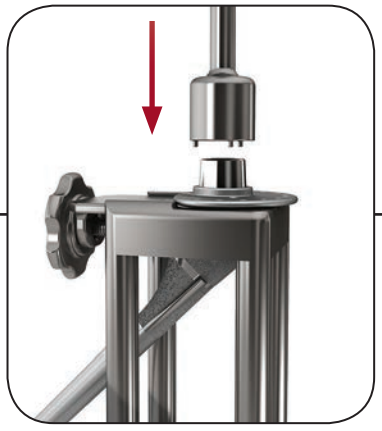


Insert Implant and Impact

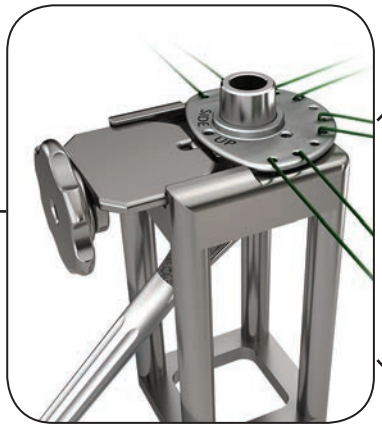


Insert Implant with Jig

CEMENTED FIXATION

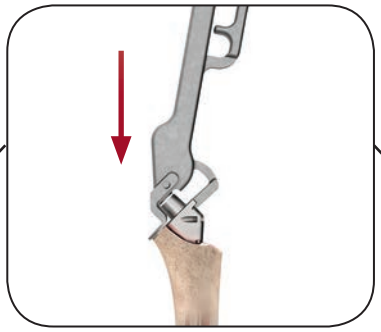


Impact Collar

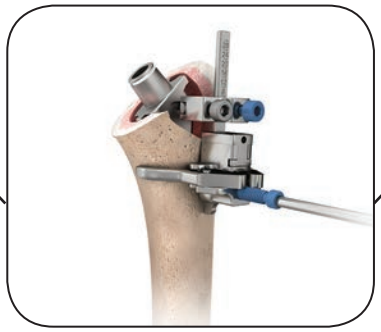


Place Suture Through Collar and
Impact Head

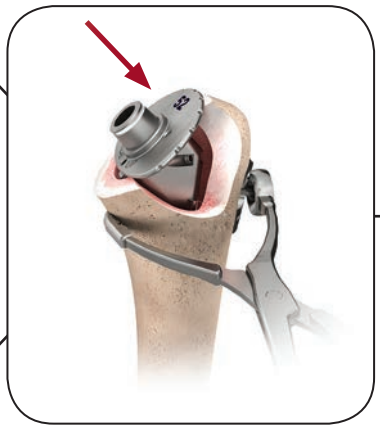
PRESS-FIT FIXATION



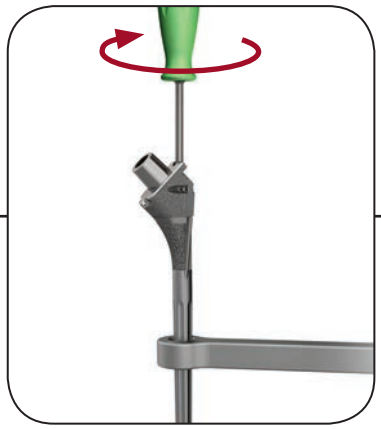
Trial Insertion with Trial Inserter



Trial Insertion with Positioning Jig

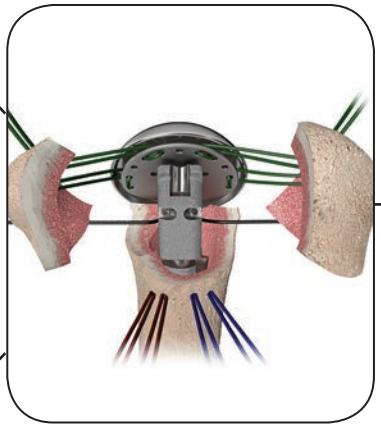


Attach Trial Collar Component and Reduce Tuberosities

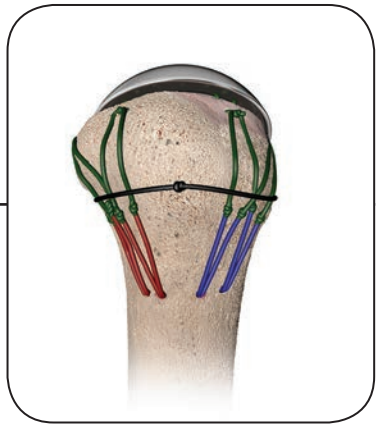


Create Final Construct

CEMENTED FIXATION



Suture Tuberosities



Finished Tuberosity Reconstruction

PRE-OPERATIVE TEMPLATING AND PATIENT POSITIONING

Pre-operative Templating
Pre-operative planning should be carried out using AP and Lateral shoulder radiographs of known magnification and the available GLOBAL UNITE Implant template to help the surgeon determine the size and alignment of the implant (Figure 1). The final decision should be made intraoperatively.

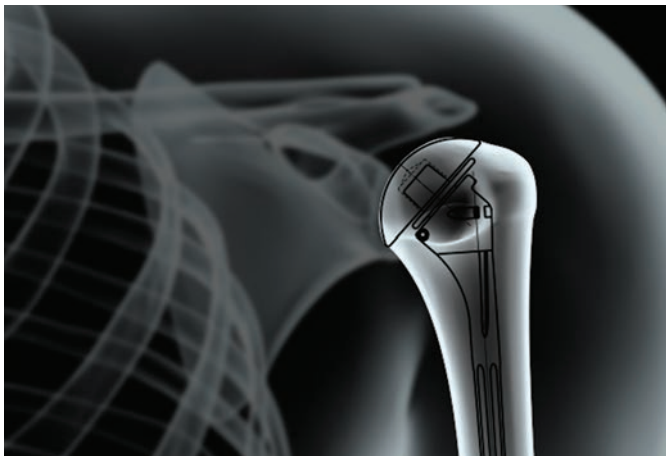


Figure 1

Patient Positioning
Place the patient in 30 – 60 degree beach chair position. The knees should be flexed approximately 30 degrees and the involved shoulder should extend over the side of the surgical table (Figure 2). Some surgeons prefer to use an operating table specifically designed for shoulder surgery.

Secure the patient's head (Figure 3). Use a drape to isolate the anaesthesia equipment from the sterile field. A sterile arm holder and positioning device can also be used.

Figure 2

Figure 3

SOFT TISSUE DISSECTION

Deltopectoral Incision
The initial incision line runs from the mid-clavicle, over the top of the coracoid and extends in a straight line down the anterior aspect of the arm (Figure 4). It should follow the path of the cephalic vein along the interval between the deltoid and the pectoralis major. The length of the initial incision along this line can be varied; depending on the exposure needed to provide adequate access and visualization of the joint, and is determined by patient body habitus.

Please refer to the GLOBAL® ENABLE® Glenoid Exposure System surgical technique (0612-44-510) for detailed information regarding exposure.

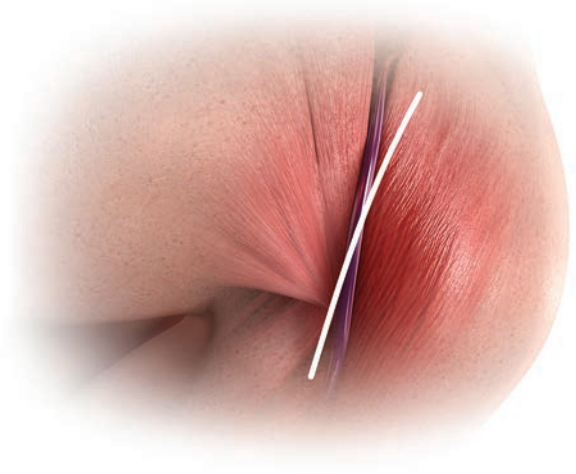


Figure 4

SOFT TISSUE DISSECTION

Releasing the Pectoralis Major Tendon and Clavipectoral Fascia
Cut the upper portion of the pectoralis major tendon.

Retract and separate the deltoid and pectoralis interval thereby defining the clavipectoral fascia. Divide the clavipectoral fascia just lateral to the conjoined tendon superiorly to the level of the coracoacromial ligament, which is preserved. Ligate or cauterize the anterior humeral circumflex vessels.

Musculocutaneous Nerve Identification
In fracture cases, it is important to identify and protect the musculocutaneous nerve. Palpate the musculocutaneous nerve as it comes from the brachial plexus into the posteriomedial aspect of the conjoined tendon. The nerve usually penetrates the muscle 2 to 5cm inferior to the tip of the coracoids process. In some instances, the nerve has a higher penetration into the conjoined muscle tendon unit. Remember the nerve location when retracting the conjoined tendon.

Greater and Lesser Tuberosity Identification
The biceps tendon is an excellent landmark to identify the interval between the lesser and greater tuberosity. The fracture line in a four part fracture is usually lateral to the bicipital groove.

Axillary Nerve Identification
Place the arm in neutral abduction with internal rotation. Identify the upper border of the latissimus dorsi tendon and bluntly dissect above the tendon into the axillary pouch keeping the instrument on the inferior capsule. In most cases you can palpate the axillary nerve and then place a reverse Hohman retractor between the nerve and capsule to retract the nerve and protect it during inferior dissection of the capsule.

Greater and Lesser Tuberosity Mobilization
Mobilize the greater and lesser tuberosities from adhesions and attached hematoma. Leave any capsule or healthy soft tissues attached to the proximal humerus. Pass #2 ORTHOCORD® Sutures at the tendon bone interface as traction sutures. This step should result in normal mobility of these tissues (Figure 5).

With the greater and lesser tuberosities mobilized and retracted out of the way by the stay sutures, use a clamp to retrieve the fractured humeral head. Remove any portion of articular humeral head that may remain on the tuberosity fragments. Open the sheath of the biceps tendon and divide the transverse humeral ligament. Remove the long head of the biceps and tenodese it distally to local soft tissue and resect the proximal portion to the superior glenoid tubercle. After removal of the biceps tendon examine the glenoid fossa for fracture or arthritic changes that may need to be surgically treated.

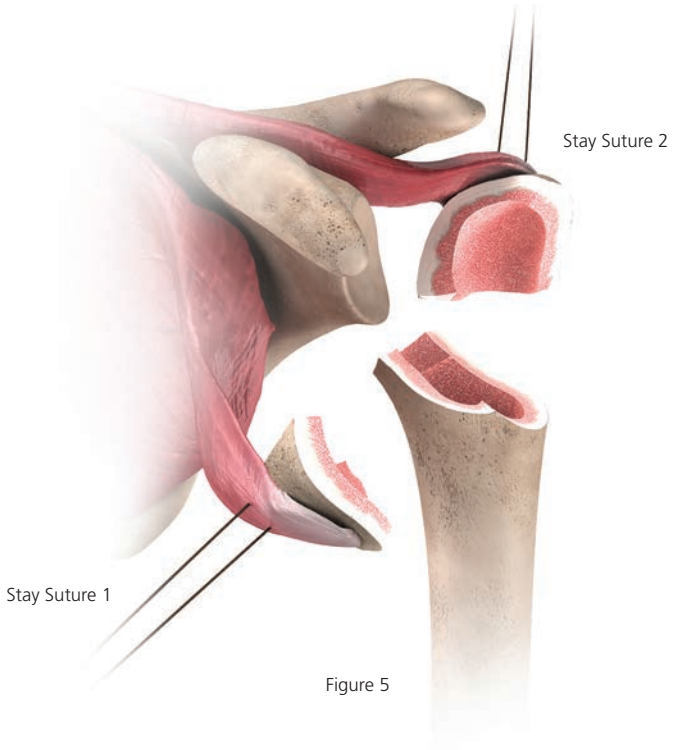


Figure 5

Removal and Measurement of the Head
The selected humeral head component should be approximately 3mm smaller in height than the resected humeral head because of the suture collar. The radius of curvature should be approximately the same. Measure the resected humeral head for height and diameter using the Humeral Head Template. The template takes into account the thickness of the prosthetic head and the suture collar; together these two components represent the volume of the native humeral head (Figure 6). Two styles of humeral head trials are available for the fracture set ranging from 12, 15, 18 and 21mm heights and 40, 44, 48, 52 and 56mm diameters.

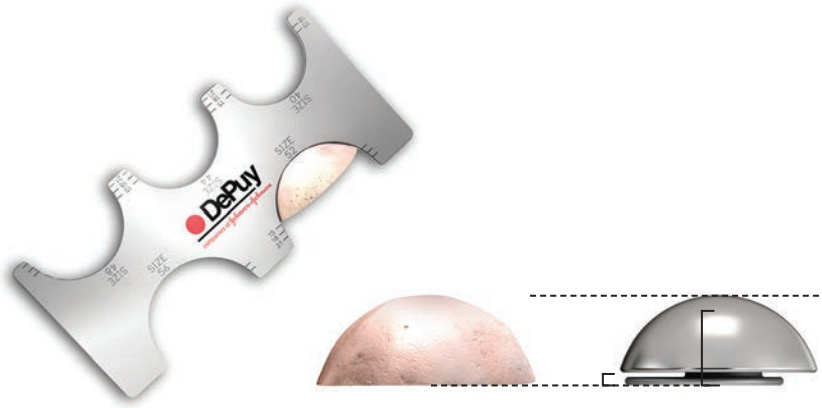


Figure 6

After selecting the desired humeral head size, select the corresponding trial suture collar size. The selected head size and trial collar are color coded and should match (Figure 7).

NOTE: The diameter of the suture collar must never be larger than the diameter of the head.

Figure 7

HUMERAL PREPARATION

Cancellous Bone Removal
After selecting the humeral head component, place the humeral head on the back table to be used later if necessary as a source for cancellous bone graft.

Humeral Shaft Preparation
Place the arm in extension, adduction and external rotation. The arm and elbow should extend off the side of the table, which delivers the shaft out of the wound.

Starting with a 6mm reamer, sequentially ream the medullary canal to determine the humeral stem size (Figure 8). For press-fit fixation of standard length stems, ream to the largest size obtaining distal cortical contact such that the proximal edge of the cutting flutes reach the anatomic height of the detached greater tuberosity. For long stemmed implants, the reamers are advanced distally until the laser mark located superior on the reamer shaft reaches the same estimated level of the greater tuberosity. In some cases this will need to be estimated by approximating the greater tuberosity to the proximal part of the humeral shaft fracture line or the height of the greater tuberosity fragment(s) is measured with a ruler.

Figure 8

PRESS-FIT FIXATION

Trial Assembly and Positioning
Assemble the selected stem with the corresponding proximal body size 0 trial. The stem and proximal component are color coded. Utilize the female hex screwdriver (green handle) and distal stem wrench to connect the two components (Figure 9).

Restoring Proper Retroversion and Height
With the inserter, place the stem assembly into the intramedullary canal so that it is firmly fixed within the canal. The horse shoe collar of the stem inserter represents the final location of the suture collar and can be used as a reference to the medial calcar for the correct height placement (Figure 10). An alignment rod may be attached to the inserter at the desired retroversion. The alignment rod is inserted into the desired version hole on the inserter and is then aligned to the forearm (Figure 11). Native version varies within the normal population with an average retroversion of approximately 20 to 30 degrees with respect to the axis of the forearm when the elbow is in 90 degrees of flexion.

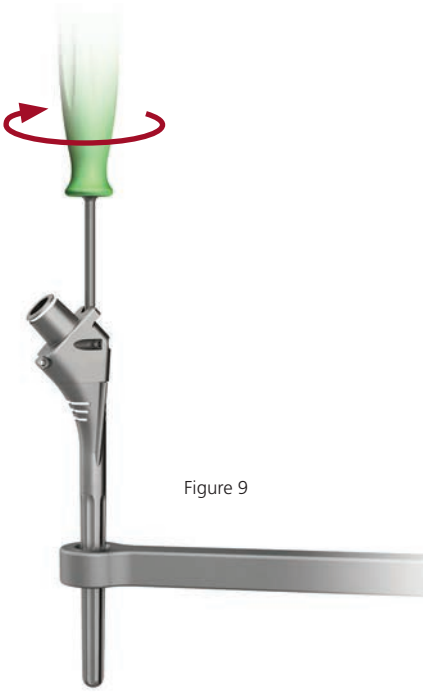


Figure 9

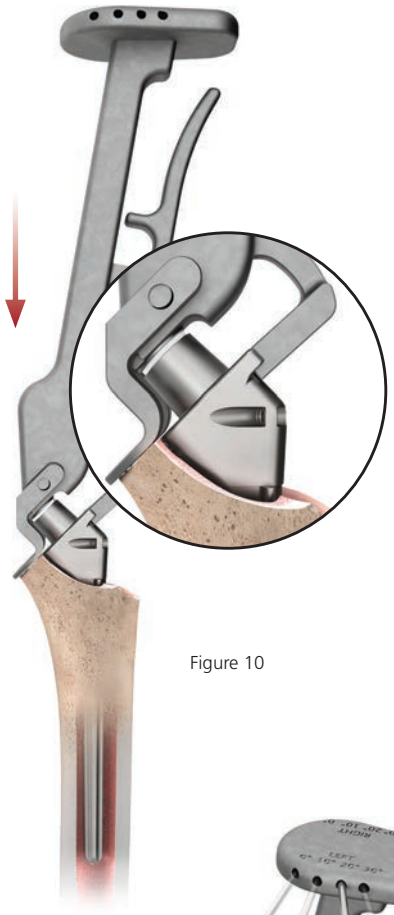


Figure 10

Retroversion Alignment

Figure 11

TRIAL IMPLANTATION AND TUBEROSITY REDUCTION:

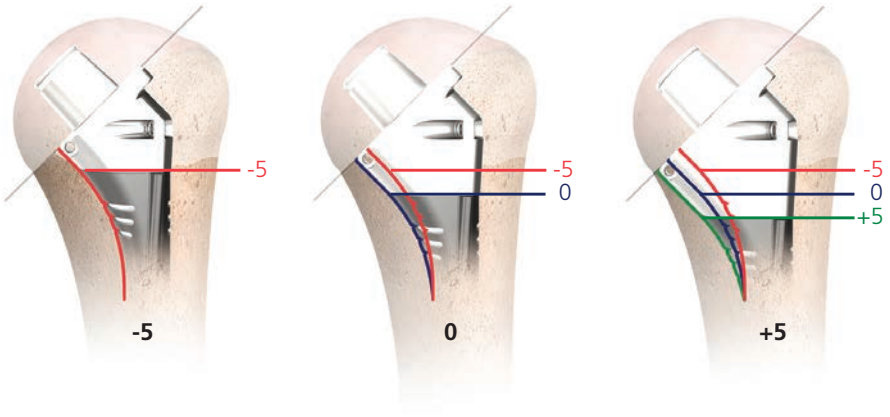
PRESS-FIT FIXATION

Assemble the trial collar onto the epiphysis and reduce the greater tuberosity. The desired height of the stem is achieved when the greater tuberosity (supraspinatus rotator cuff insertion) is located under the collar and the distal portion of the tuberosity is anatomically reduced to the humeral shaft.

If the stem is stable in the canal and the tuberosity is above the collar by 5mm or more, the stem is too low. Remove the 0mm proximal body component and attach the +5mm proximal component. If the trial collar is still too low then trial a larger stem or use the positioning jig and utilize bone cement to place the originally selected stem at the desired height.

If the trial stem and collar are too high, then remove the 0mm proximal body and replace it with the – 5mm proximal body component. Minor corrections of 1-2mm can be achieved by impacting the trial stem further into the humerus. If the trial collar is s till too high, then down size the stem and use the positioning jig and cement the stem (Figure 12).

Stem Height Adjustment



Proximal Body Sizes

Figure 12

PRESS-FIT FIXATION

Trial Reduction of Tuberosities
After determining the correct implant sizing, height and version reduce and hold the greater tuberosity in its anatomic position using the Greater Tuberosity Forceps provided in the instrument set (Figure 13). If the greater tuberosity is displaced away from the stem then remove some of the cancellous bone from the tuberosity.

If the tuberosity is close to the stem but is not aligned with the edge of the centered suture collar replace it with an eccentric collar and rotate it to optimize the alignment of the edge of the suture collar and the cuff insertion on the greater tuberosity. This should not result in an overhang of the collar with either of the tuberosities. Overhang can result in compromise or injury to the rotator cuff. If an eccentric collar is used then an eccentric head is also needed and positioned in the same orientation as the collar.

Figure 13

PRESS-FIT FIXATION

Place the correct sized head (centered or eccentric) as measured by the sizing gauge onto the stem. Reduce the humeral head into the glenoid and bring the lesser tuberosity around the stem to check its position and tension (Figure 14). Check soft tissue tensioning by performing a gentle range of motion.

It is recommended to perform an intra-operative x-ray or fluoroscopic examination to verify final prosthetic height and tuberosity position. The trial heads are barium infused and illuminate brightly under fluoroscopy.

NOTE: There are no holes in the trial collar. Notches on the collar identify the hole locations of the final implant.

Figure 14

CEMENTED FIXATION

Trial Assembly and Positioning:
Using a Positioning Jig

Assemble the chosen stem with the corresponding proximal body size 0 trial. The stem and proximal component are color coded. Utilize the female hex screwdriver (green handle) and distal stem wrench to connect the two components.

Insert the trial stem using the inserter. The horse shoe collar of the stem inserter represents the final location of the suture collar and can be used as a reference to the medial calcar for the correct height placement. Use the positioning jig to then hold the trial stem in the desired position.

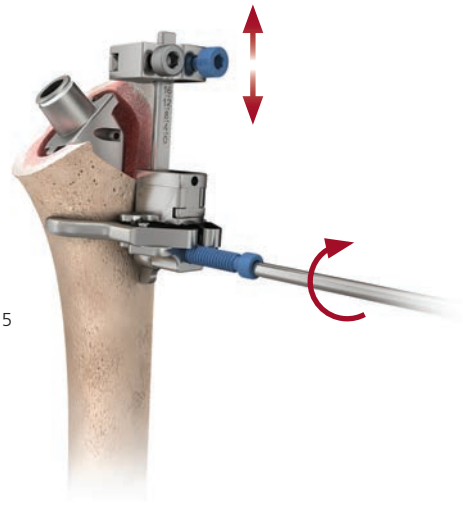


Figure 15

Positioning Jig

Loosely attach the positioning jig around the humeral shaft approximately 1 to 2cm distal to the fracture on the shaft (Figure 15). Align and attach the fin clamp to the anterior fin of the trial prosthesis assuring that the letter L or R is facing up denoting the side being operated upon (Figure 16). Rotate the stem and it's attached positioning jig around the humeral shaft so that the alignment rod of the jig is in line with the forearm resulting in 30 degree retroversion of the stem to the forearm. Once the trial prosthesis is at the proper height and version, secure the positioning jig to the proximal humerus by tightening the large anterior screw using the 3.5mm hex screwdriver (yellow handle) (Figure 17).

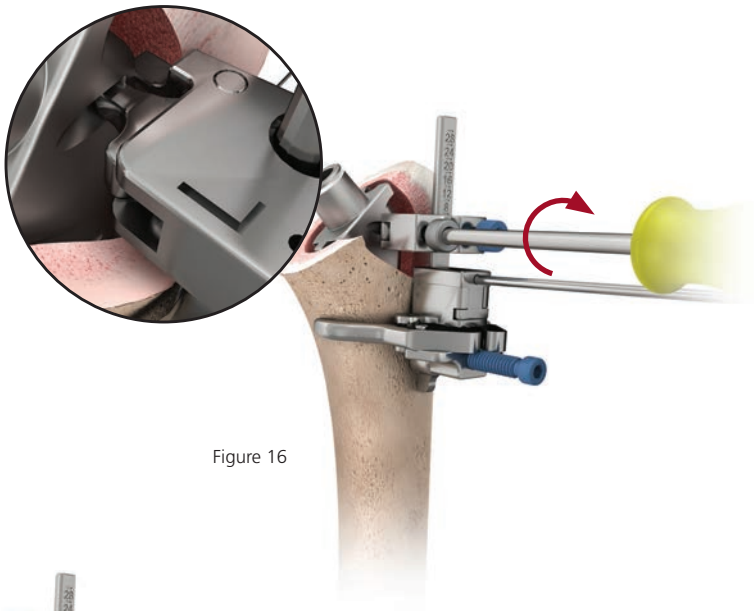


Figure 16

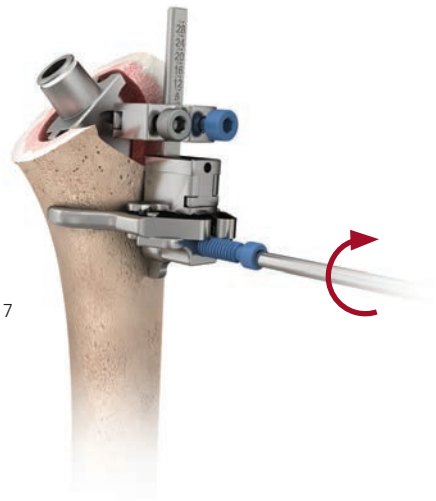


Figure 17

CEMENTED FIXATION

Assemble the selected trial collar on the proximal body (Figure 18).

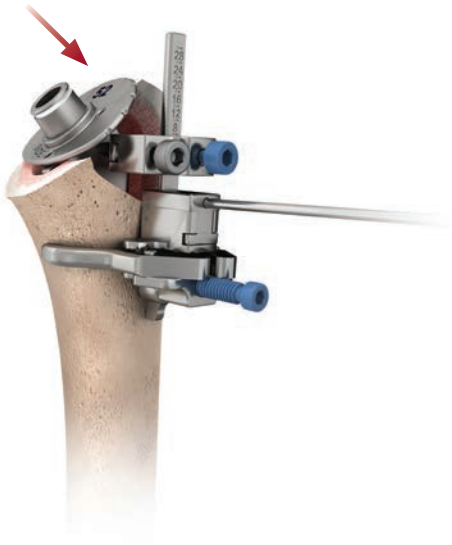


Figure 18

The positioning jig holds the trial implant securely to perform trial reduction and test the range of motion and stability. One of the most important advantages of the positioning jig is to allow for reduction of the tuberosities. It also allows for range of motion testing with the trial prosthesis in place without a press fit stem. During range of motion testing, the trial implant should remain in the glenoid fossa and the head should not ride high in the glenoid.

Adjust the stem height by sliding the fin clamp up or down the vertical height gauge so that the greater tuberosity is located under the collar and is reduced to the humeral shaft. To do this, use Greater Tuberosity Forceps provided in the instrument set or a towel clip to hold the greater tuberosities reduced around the prosthesis (Figure 19).

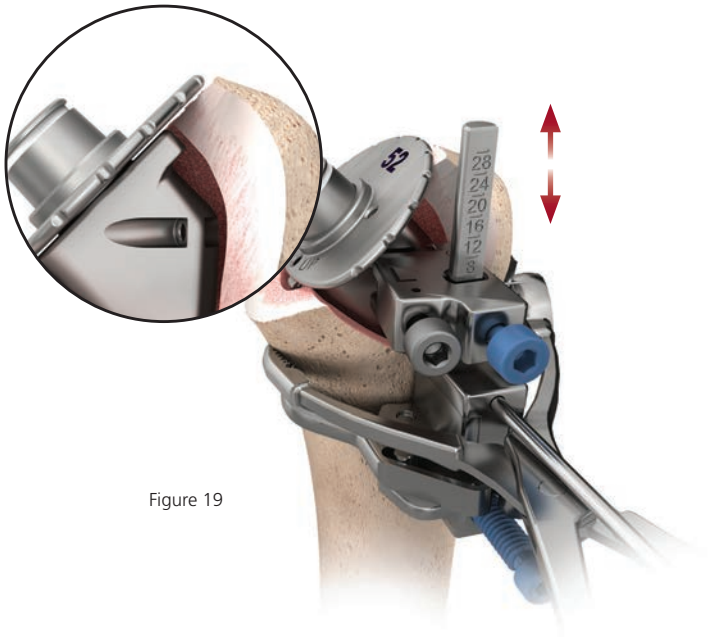


Figure 19

CEMENTED FIXATION

If the greater tuberosity is displaced away from the stem then remove some of the cancellous bone from the tuberosity.

If the tuberosity is close to the stem but is not aligned with the edge of the centered suture collar replace it with an eccentric collar and rotate it to optimize the alignment of the edge of the suture collar and the cuff insertion on the greater tuberosity. This should not result in an overhang of the collar with either of the tuberosities. Overhang can result in compromise or injury to the rotator cuff. If an eccentric collar is used then an eccentric head is also needed and positioned in the same orientation as the collar.

Place the correct sized head (centered or eccentric) as measured by the sizing gauge onto the stem (Figure 20). Reduce the humeral head into the glenoid and bring the lesser tuberosity around the stem to check its position and tension. Check soft tissue tensioning by performing a gentle range of motion.

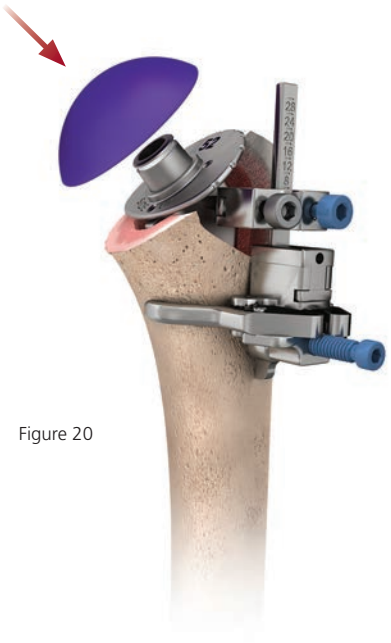


Figure 20

It is recommend to take an intra-operative x-ray or fluoroscopic examination to verify final prosthetic height and tuberosity position. The trial heads are barium infused and illuminate brightly under fluoroscopy.

NOTE: There are no holes in the trial collar. Notches on the collar identify the hole locations of the final implant.

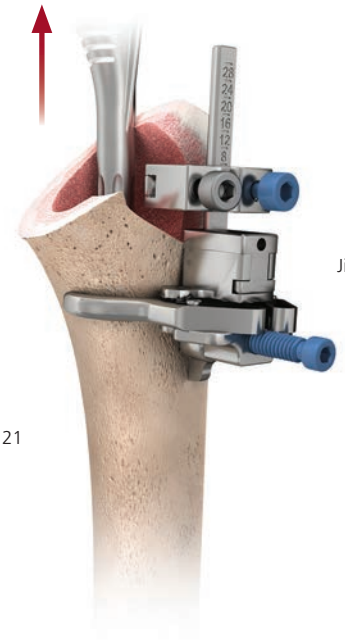
HUMERAL SHAFT PREPARATION FOR TUBEROSITY FIXATION

CEMENTED AND PRESS-FIT FIXATION

Prior to removal of the stem for cemented or cementless technique note the position of the stem for version and height based upon bone landmarks on the proximal shaft. Mark the cortex with an electrocautery knife.

For the cemented technique, loosen the anterior fin clamp from the anterior fin of the implant and **leave the positioning jig in place. Be sure to check that it is securely attached to the shaft.** Remove the trial implant from the humerus (Figure 21).

Drill two suture holes through the anterior lateral portion of the shaft 2cm below the fracture line. Drill two suture holes through the posterior lateral portion of the shaft 2cm below the fracture line. Pass four strands of #2 ORTHOCORD Suture or larger non-absorbable suture through the newly created holes. Both the anterior and posterior set of holes will have two sets of suture passing from inside the canal to the outside in a mattress suture technique. These will be utilized later as vertical suture fixation of the tuberosities (Figure 22).



Jig in Fixed Position

Figure 21

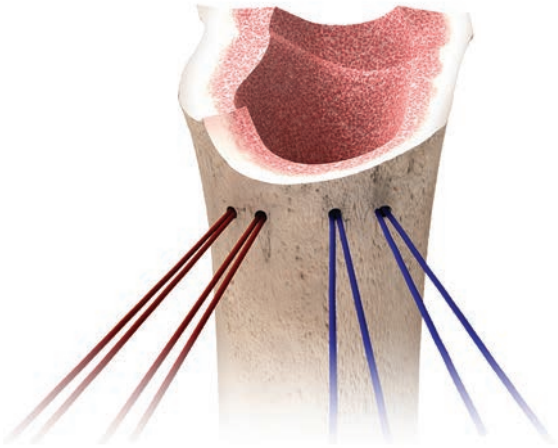


Figure 22

FINAL STEM AND PROXIMAL COMPONENT ASSEMBLY AND IMPLANTATION

CEMENTED FIXATION

Assemble the appropriate sized stem and proximal component with the female hex screwdriver (green handle) and the modular implant locking wrench (Figure 23).

Place the implant into the impaction stand and impact the suture collar onto the neck in the intended position with the words "Side Up" facing up. Pass #2 ORTHOCORD Suture through the superior two holes of the suture collar to be used to reattach the supraspinatus and another #2 ORTHOCORD Suture through the suture collar more posterior to be used through infraspinatus, teres minor.

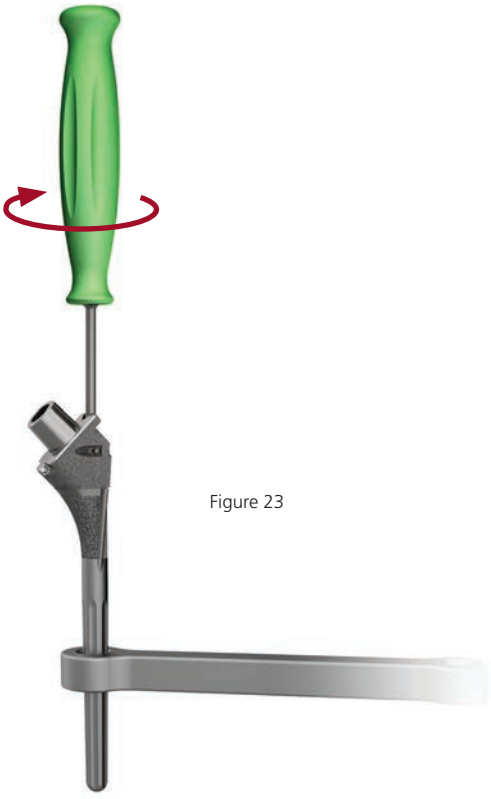


Figure 23

FINAL STEM AND PROXIMAL COMPONENT ASSEMBLY AND IMPLANTATION

CEMENTED FIXATION

Two #2 ORTHOCORD Sutures are placed in the anterior portion of the collar for reattaching the lesser tuberosity. All sutures should be placed so that the loose ends are exiting the top portion of the collar creating a loop on the bottom side of the collar (Figure 24).

Place a #2 ORTHOCORD Suture or larger non-absorbable suture through the medial hole of the proximal component of the assemble stem. When all sutures have been passed through the suture collar and implant the humeral head can be impacted in the impaction stand or later when the stem has been implanted

Thoroughly irrigate the medullary canal to remove blood and other debris and dry the canal.

Insert a cement restrictor distally to the final implant location to prevent migration of cement distally towards elbow.

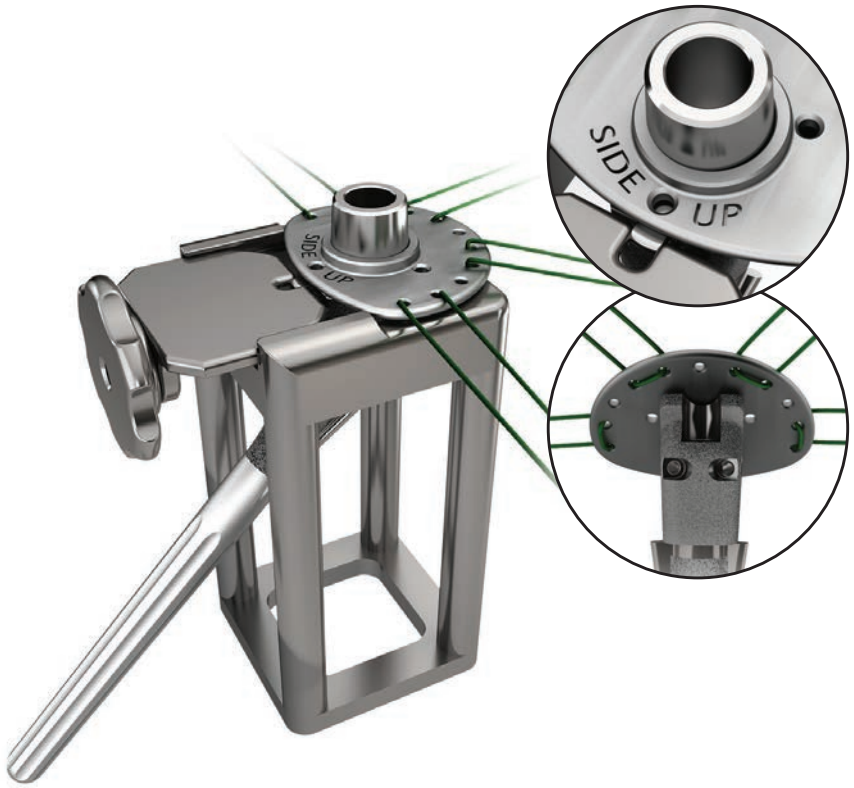


Figure 24

FINAL STEM AND PROXIMAL COMPONENT ASSEMBLY AND IMPLANTATION

CEMENTED FIXATION

Digitally insert bone cement such as DePuy's SMARTSET® HV Bone Cement into the medullary canal. If a cement gun is used fill the canal from distal to proximal and avoid pressurization that could fracture the humeral shaft.

Insert the assembled final component into the cement to the height determined during the trialling process and hold in place via the positioning jig. With the positioning jig still in its original position secure the clamp to the anterior fin of the prosthesis to ensure that the final prosthetic is in the same position as the trial (Figure 25).

Before the bone cement hardens, remove the excess to a level just below the proximal body portion of the stem. This will allow placement of cancellous bone material as well as easy exchange of the proximal body component if the stem height needs to be adjusted using the 0 or +5 component. In addition not cementing the proximal body component will aid in the removal of this part of the stem in the event of revision surgery for conversion to a reverse total shoulder.

Figure 25

FINAL STEM AND PROXIMAL COMPONENT ASSEMBLY AND IMPLANTATION

PRESS-FIT FIXATION

Assemble the appropriate sized stem and proximal body component with the female hex screwdriver (green handle) and the modular implant locking wrench (Figure 26).

Place the implant into the impaction stand and impact the suture collar onto the neck in the intended position with the words "Side Up" facing up. Pass #2 ORTHOCORD Suture through the superior two holes of the suture collar to be used to reattach the supraspinatus and second set of #2 ORTHOCORD Suture through the suture collar more posterior to be used through infraspinatus and teres minor. Two #2 ORTHOCORD Sutures are placed in the anterior portion of the collar for reattaching the lesser tuberosity. All sutures should be placed so that the loose ends are exiting the top portion of the collar creating a loop on the bottom side of the collar (Figure 27).

Place a #2 ORTHOCORD Suture or larger non absorbable suture through the medial hole of the proximal body component of the assemble stem.

When all sutures have been passed through the suture collar and implant the humeral head can be impacted in the impaction stand or later when the stem has been implanted.

Implant the final construct into the Humerus with the implant holder. Utilize the orientation pin placed into the proper alignment hole on the implant holder to assure that the implant is in the proper retroversion and impact the implant down to the proper height.

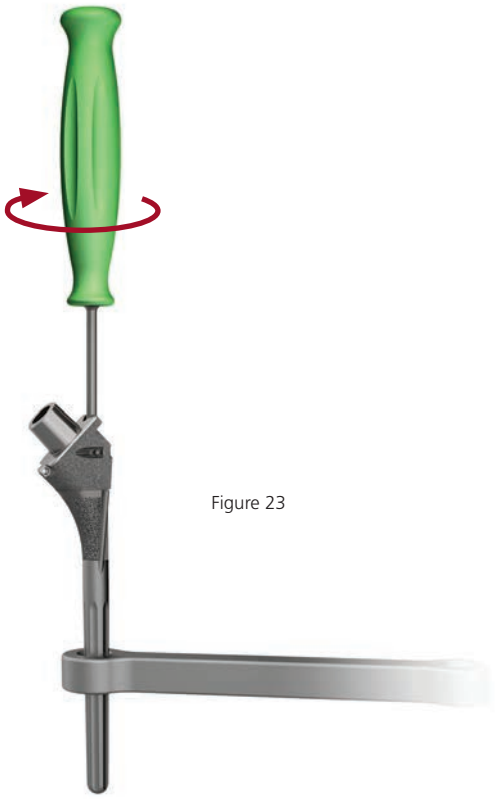


Figure 23

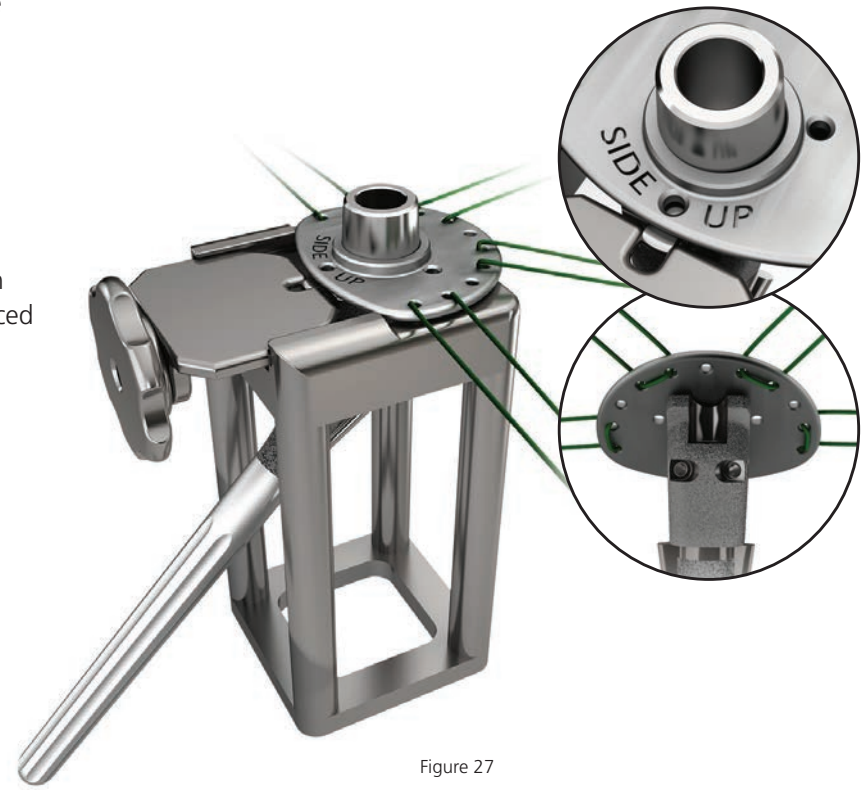


Figure 27

FINAL TUBEROSITY ATTACHMENT

Reattaching the Greater and Lesser Tuberosities to Suture Collar

Pass the suture of the medial stem hole through the cuff insertion on the greater tuberosity from inside out, and one through the insertion point of the subscapularis also in an inside to out fashion (suture 1 & 2 of Figure 28). These two ends are clamped and tied later.

Take posterior suture (E of Figure 29) in the collar and place it through the insertion of the infraspinatus from inside to out fashion. It is important to place the needle very close to the bone tendon junction.

The superior suture (D of Figure 29) for the supraspinatus is placed from inside to out in the same fashion. Tie the superior suture first and then the posterior suture. Do not cut off the ends of the suture after tying. These sutures will be used for the vertical tension band repair.

If the head has not been impacted, do so now with the head impactor.

The two anterior sutures are placed through the subscapularis tendon from an inside to out fashion close to the bone-tendon junction (F & G of Figure 29).

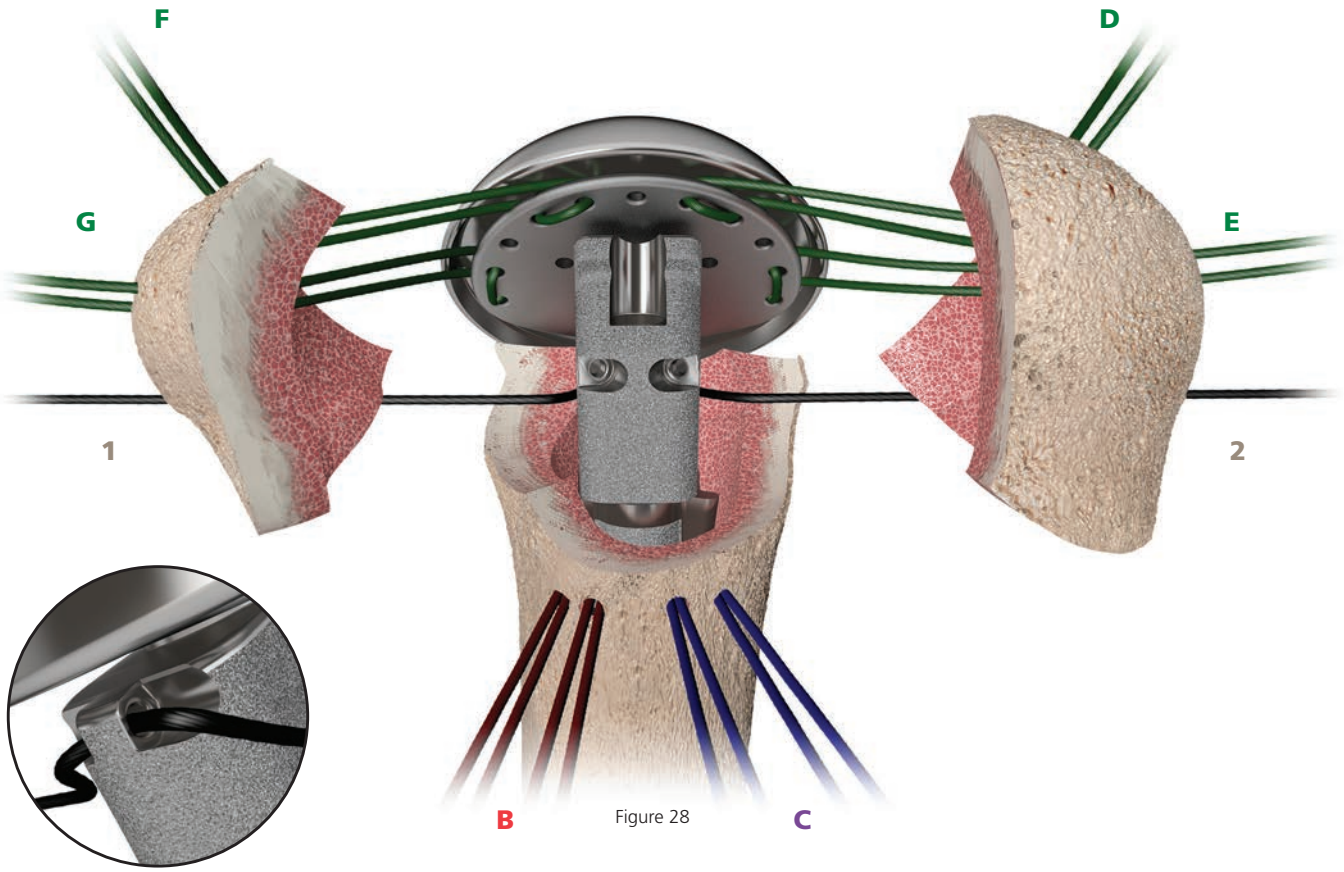


Figure 28

Medial/Proximal Body Suture

FINAL TUBEROSITY ATTACHMENT

To assure proper placement of the sutures a trial reduction should be performed and verified via fluoroscopy. Once verification has been achieved the sutures can be tied.

The tuberosities are now attached to the suture collar. The loose ends of the two greater tuberosity sutures are tied to the lateral sutures in the humeral shaft in a vertical figure eight fashion (D & E to C, Figure 30).

This step will reduce the greater tuberosity into an anatomic position. The same process is performed with the sutures through the subscapularis (G & F to B, Figure 30) to create an anatomic reduction of the lesser tuberosity. These eight strands of suture create a tension band fixation of the tuberosities.

The final step is to tie the horizontal sutures running through the medial hole of the implant (1 & 2) in a cerclage fashion to provide addition strength/stability to the tuberosity fixation.

Please note the previously described suturing technique is one method of anatomically repairing the tuberosities. It is understood that additional methods can be utilized that incorporate the use of the suture collar in vertical and horizontal repair of the tuberosities. On the following pages you will find a step by step diagram of an alternative method of repairing the tuberosities using the suture collar. Variations of both techniques can be modified to better suit a surgeons preference.

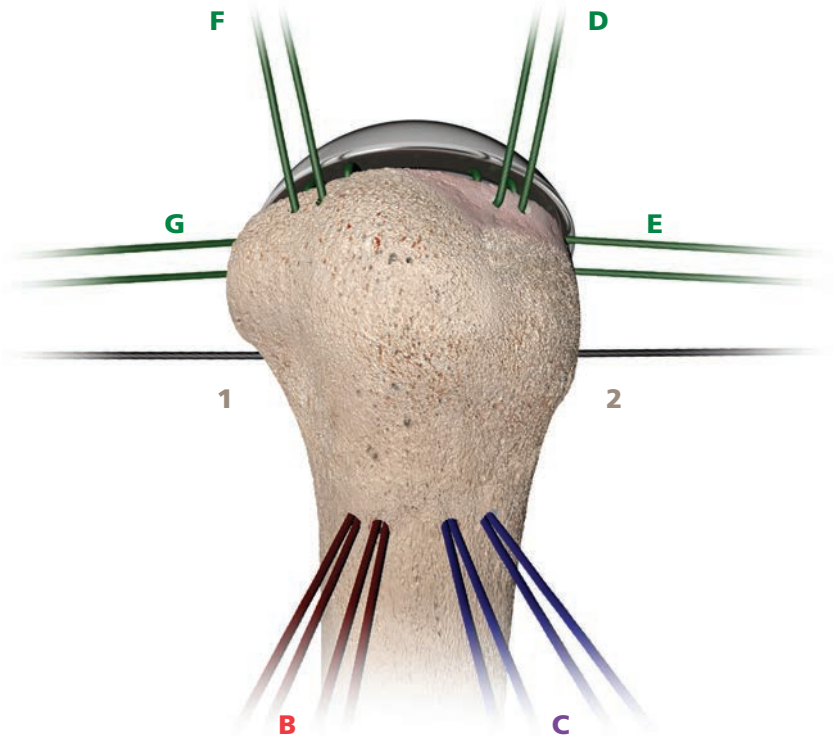


Figure 29

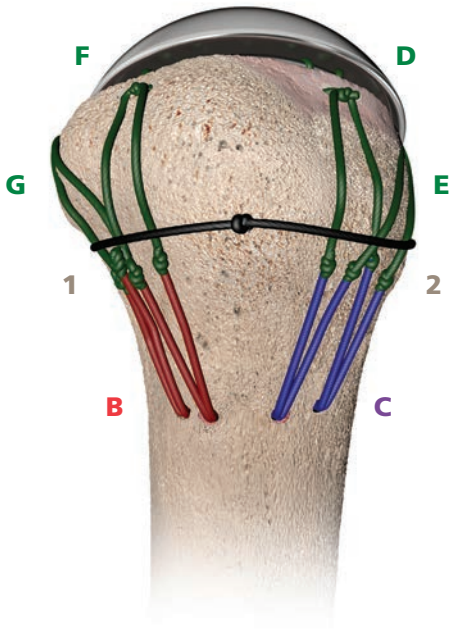
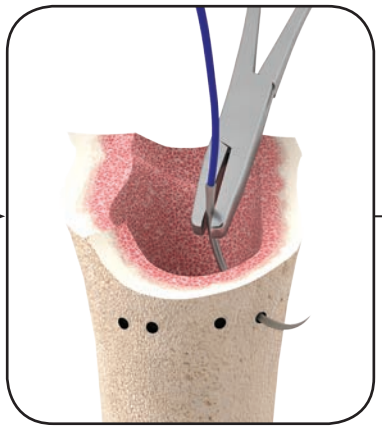


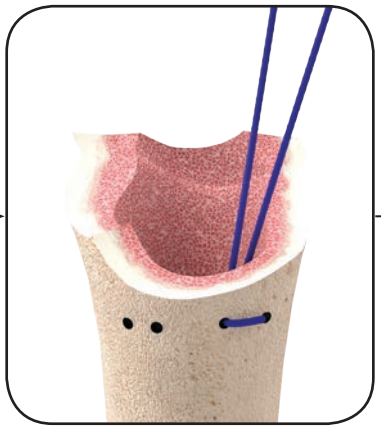
Figure 30

QUICK SUTURE GUIDE – ADDENDUM 1

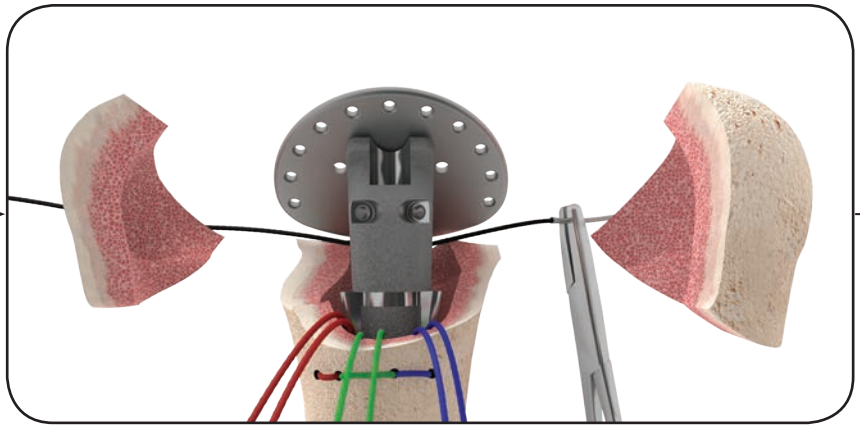
Drill four holes in humerus



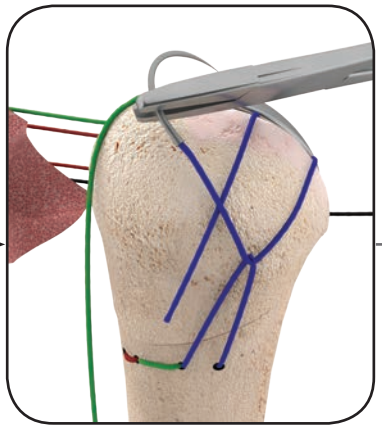
Pass suture from inside humerus to outside



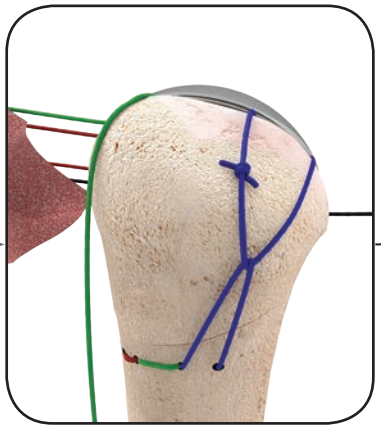
Pass leg of suture back inside humerus creating suture loop on exterior of humerus



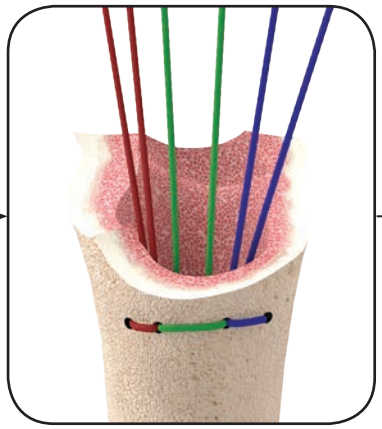
Pass suture from the medial hole of the implant through greater and lesser tuberosity at the bone/tendon interface



Pass one leg of the suture down underneath the suture loop and tension it upwards

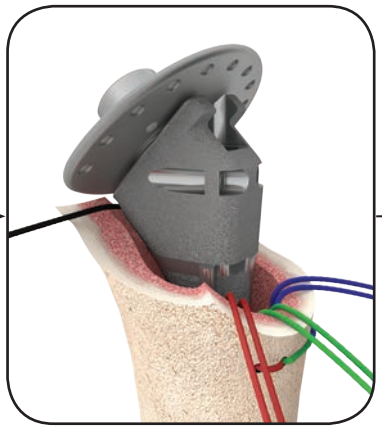


Tie the suture to the other mating limb of the suture

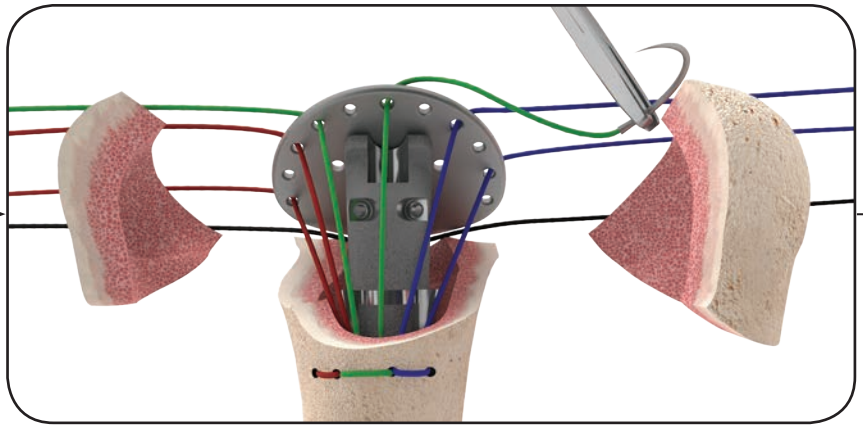


Repeat the process two additional times creating three suture loops on exterior of humerus

Impact collar onto stem and pass suture through medial hole of implant

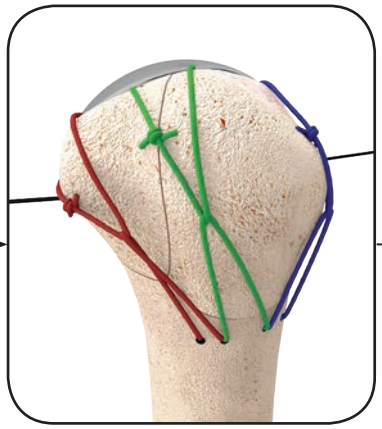


Insert stem into the humerus at the proper height

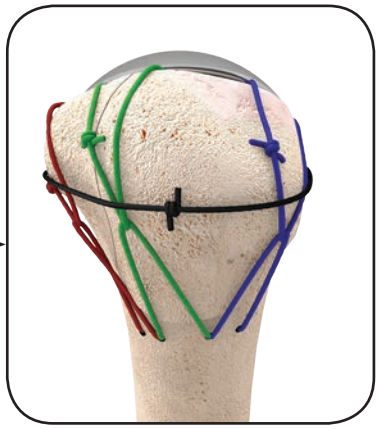


Pass the legs of the distal shaft suture up through the suture collar and from inside to outside through the tuberosity at the bone/tendon interface

Repeat the process with the remaining suture from the distal shaft



Repeat the process with the remaining limbs of the suture to complete the vertical repair of the tuberosities



Finalize the repair by tying the horizontal suture from the medial hole of the implant

SOFT TISSUE AND WOUND CLOSURE

Soft Tissue Closure
Close the rotator interval between the subscapularis and the supraspinatus tendons.

Wound Closure
Thoroughly irrigate the wound with an antibiotic solution. Use a portable wound evacuation unit, such as the HEMO-DRAIN® LC Wound Drainage System, to prevent formation of a postoperative hematoma. Infiltrate the soft tissues with 0.25 percent Marcaine solution, which helps reduce immediate postoperative pain and facilitates passive shoulder motion on the same day as surgery. One option for wound closure is using a 2.0 VICRYL® Suture in the deep subcutaneous layer, closing the skin with a running subcuticular nylon suture. If the posttraumatic skin is swollen and ecchymotic, interrupted skin sutures or skin clips may be preferred. After the dressing and shoulder immobilizer are in place, use a shoulder ice wrap. Place the prefrozen ice wrap on the shoulder in the operating room and replace it as needed. The combination of local anesthetic infiltration with Marcaine® injection and immediate cooling from the ice wrap markedly helps reduce postoperative pain.

Removing the humeral head and proximal component
Remove the head and suture collar using the head distractor.

Remove each component (head, collar) independently from each other starting by removing the head first and then followed by the suture collar.

Angle the head distractor so that both fingers of the instrument engage the collar (humeral head removal) or the proximal component (collar). This is important to assure that the appropriate mechanical forces are generated to remove the head and collar (Figure 31).

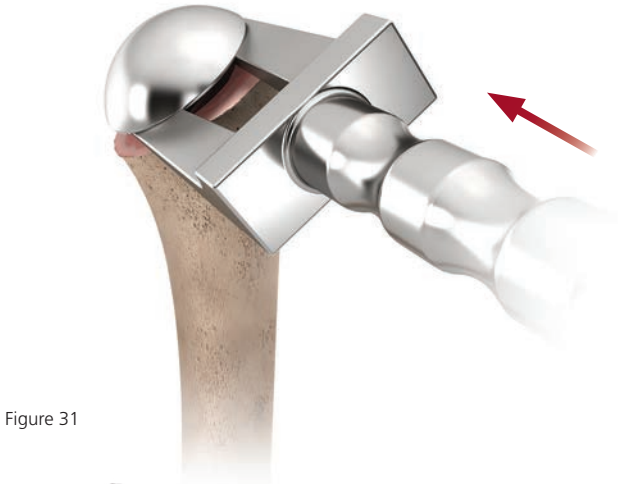


Figure 31

Removing the Proximal Component
Use appropriately sized thin osteotomes to remove the bone on-growth surrounding the proximal component.

Once the fixation between bone and proximal component has been broken, utilize the female hex screwdriver (green handle) to unscrew the proximal bolt (Figure 32).

Grasp proximal component with rongeur or similar device and remove it from the distal stem.

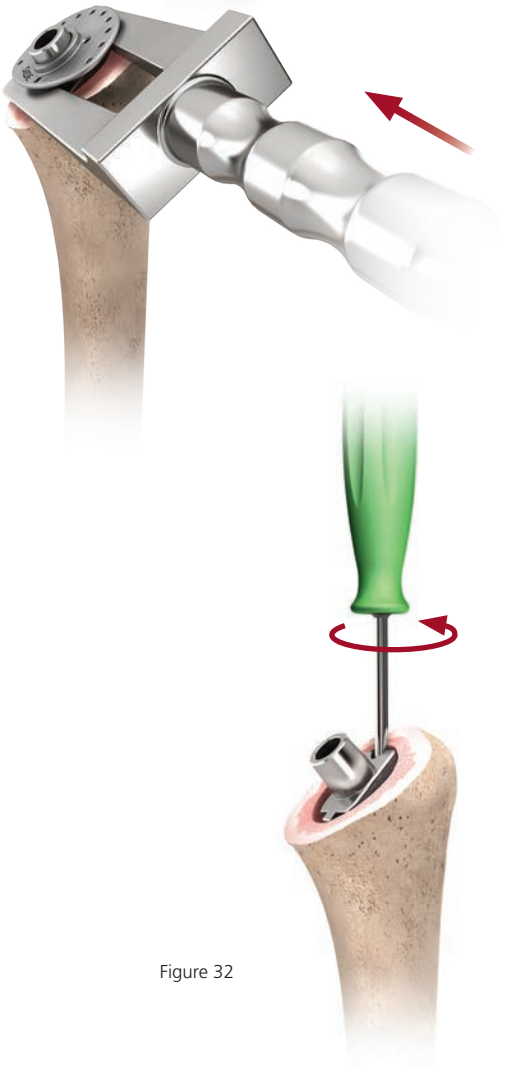


Figure 32

Humeral Reaming
Position the orientation pin through the reaming guide at the desired reversed epiphysis version (Figure 33).

(0°: reversed epiphysis will be parallel to the shoulder axis, non anatomic version)

(20°: reverse epiphysis will be 20° retroverted, anatomic version)

Place the assembled reaming guide and orientation pin on the stem by aligning the pin to the forearm while keeping the reaming guide on the stem spigot (Figure 33).

The maximum version range for the reverse epiphysis is +/-30°, therefore it may not be possible to align the pin to the forearm for a stem positioned at more than 30° of version. If this is the case, we recommend using the maximum reaming guide position.

Tighten the reaming guide screw to the stem using the 3.5mm male hex screwdriver (yellow handle). Place the sizing guides on the reaming guide in order to determine the correct reverse epiphysis size. The correct size will be contained within the cortical wall (Figure 34). If the smaller size (size 1) is still out of the cortical wall, the version may need to be changed.

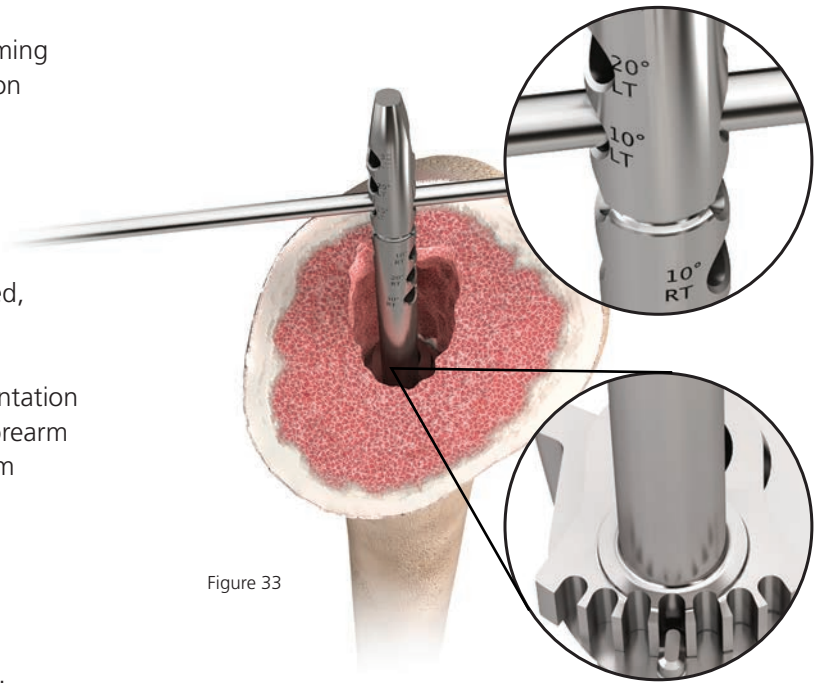


Figure 33

Figure 34

Select the color coded reamer (Red or Green) determined during the sizing exercise and prepare the humeral canal by using power (Figure 35). Once the reaming process has been completed the reamer guide can be removed utilizing the 3.5mm hex screwdriver (yellow handle).

Utilize an Osteotome or ronguers to remove any bone that may remain around the proximal portion of the distal stem that may prevent the proximal component from completely engaging with the stem (Figure 36).

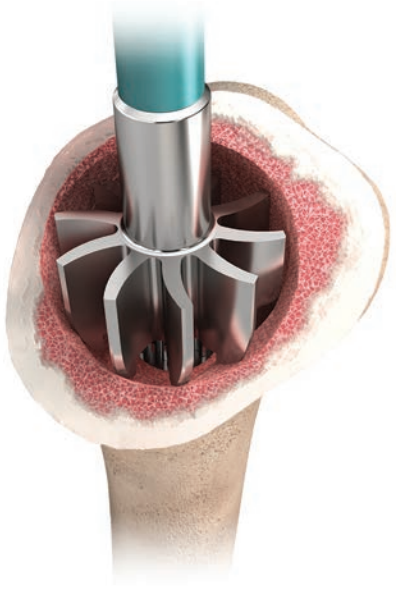


Figure 35

Figure 36

Attaching the Trial Epiphysis Component to Distal Stem

Attach the DELTA XTEND Reverse Shoulder System Trial Epiphysis to the reverse epiphysis holder by squeezing the distal portion and placing it within the epiphysis. Align the pins on the outside of the epiphyseal holder with the notches on the implant and release the holder, this will lock the two components together (Figure 37).

Figure 37

Place the orientation guide pin through the retroversion hole that was originally determined during the reaming process (Figure 38). Align the trial epiphysis to the stem and align the pin to the forearm.

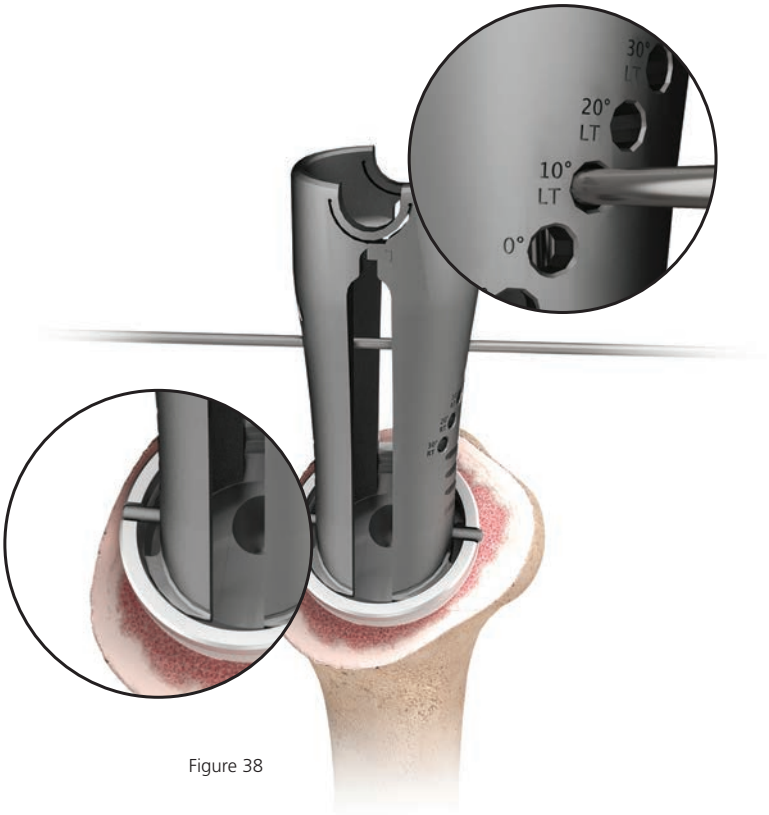


Figure 38

Once the component is in proper orientation, place the 3.5mm hex screwdriver (yellow handle) through the inner portion of the proximal holder and securely tighten the bolt. Remove the reverse epiphyseal holder when this step has been completed (Figure 39).

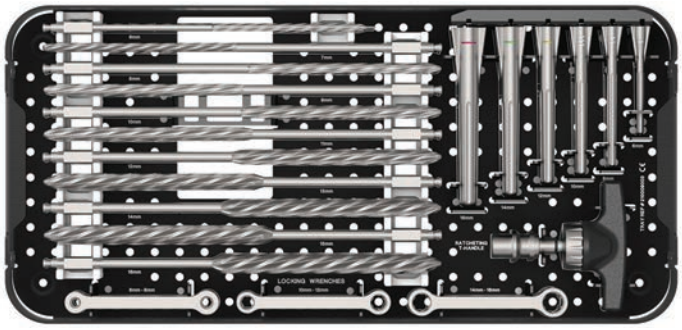
Remove any bone on the superior aspect of the trial epiphysis that could cause impingement. This can be done with an oscillating saw and using the trial epiphysis as a guide.

Once the proximal component has been secured to the stem, all other steps of the procedure are consistent with DELTA XTEND Reverse Shoulder System.

Please refer to DELTA XTEND System Surgical Technique (0612-53-505) for the remaining portion of procedure.

Figure 39

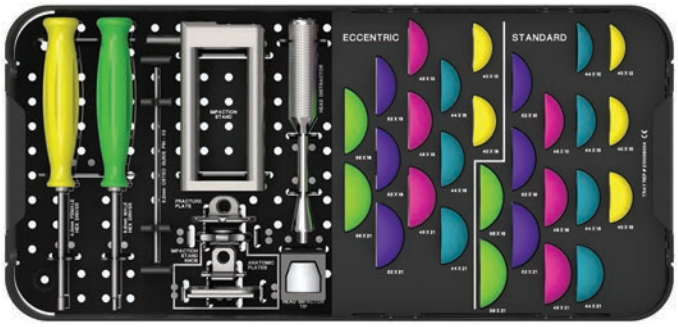
INSTRUMENT ORDERING INFORMATION
COMMON CASE



Top Tray – Humeral Preparation

2128-11-006	Bullet Tip Reamer 6mm
2128-11-007	Bullet Tip Reamer 7mm
2128-11-008	Bullet Tip Reamer 8mm
2128-11-009	Bullet Tip Reamer 9mm
2128-11-010	Bullet Tip Reamer 10mm
2128-11-011	Bullet Tip Reamer 11mm
2128-11-012	Bullet Tip Reamer 12mm
2128-11-013	Bullet Tip Reamer 13mm
2128-11-014	Bullet Tip Reamer 14mm
2128-11-015	Bullet Tip Reamer 15mm
2128-11-016	Bullet Tip Reamer 16mm
2128-61-070	Ratchet T-Handle
2307-84-001	Stem Wrench 10 – 12mm
2307-84-002	Stem Wrench 14 – 16mm
2307-84-003	Stem Wrench 6 – 8mm
2100-06-100	Humeral Stem 6mm Trial
2100-08-100	Humeral Stem 8mm Trial
2100-10-100	Humeral Stem 10mm Trial
2100-12-100	Humeral Stem 12mm Trial
2100-14-100	Humeral Stem 14mm Trial
2100-16-100	Humeral Stem 16mm Trial

INSTRUMENT ORDERING INFORMATION
COMMON CASE



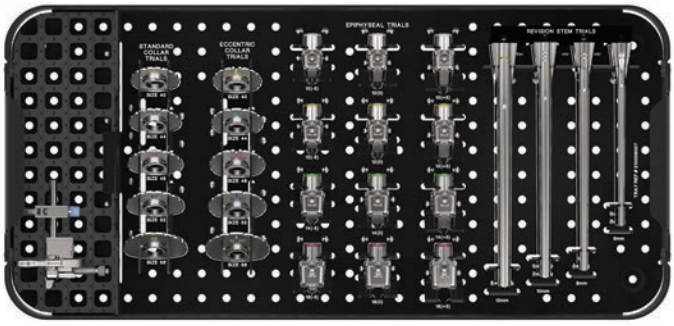
Bottom Tray – Trial Heads

2130-20-000	3.2mm Osteotomy Guide Pin – Long
2100-70-155	4.0mm Female Hex Screwdriver
2100-70-150	3.5mm Hex Screwdriver
2011-65-000	Humeral Head Impactor
2100-01-022	Impaction Stand
2100-40-500	Humeral Head 40 x 15 Trial
2100-40-510	Humeral Head 40 x 18 Trial
2100-44-500	Humeral Head 44 x 15 Trial
2100-44-510	Humeral Head 44 x 18 Trial
2100-44-520	Humeral Head 44 x 21 Trial
2100-48-500	Humeral Head 48 x 15 Trial
2100-48-510	Humeral Head 48 x 18 Trial
2100-48-520	Humeral Head 48 x 21 Trial
2100-52-500	Humeral Head 52 x 15 Trial
2100-52-510	Humeral Head 52 x 18 Trial
2100-52-520	Humeral Head 52 x 21 Trial
2100-56-510	Humeral Head 56 x 18 Trial
2100-56-520	Humeral Head 56 x 21 Trial
2100-40-600	Humeral Head 40 x 15 Eccentric Trial
2100-40-610	Humeral Head 40 x 18 Eccentric Trial
2100-44-600	Humeral Head 44 x 15 Eccentric Trial
2100-44-610	Humeral Head 44 x 18 Eccentric Trial
2100-44-620	Humeral Head 44 x 21 Eccentric Trial
2100-48-600	Humeral Head 48 x 15 Eccentric Trial
2100-48-610	Humeral Head 48 x 18 Eccentric Trial
2100-48-620	Humeral Head 48 x 21 Eccentric Trial
2100-52-600	Humeral Head 52 x 15 Eccentric Trial
2100-52-610	Humeral Head 52 x 18 Eccentric Trial
2100-52-620	Humeral Head 52 x 21 Eccentric Trial
2100-56-610	Humeral Head 56 x 18 Eccentric Trial
2100-56-620	Humeral Head 56 x 21 Eccentric Trial

Common Trial Heads

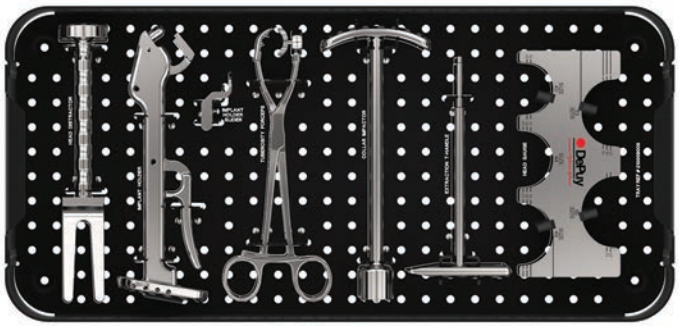
2100-11-400	Common Humeral Head 40 X 12 Trial
2100-11-401	Common Humeral Head 40 X 15 Trial
2100-11-402	Common Humeral Head 40 X 18 Trial
2100-11-440	Common Humeral Head 44 X 12 Trial
2100-11-441	Common Humeral Head 44 X 15 Trial
2100-11-442	Common Humeral Head 44 X 18 Trial
2100-11-443	Common Humeral Head 44 X 21 Trial
2100-11-481	Common Humeral Head 48 X 15 Trial
2100-11-482	Common Humeral Head 48 X 18 Trial
2100-11-483	Common Humeral Head 48 X 21 Trial
2100-11-521	Common Humeral Head 52 X 15 Trial
2100-11-522	Common Humeral Head 52 X 18 Trial
2100-11-523	Common Humeral Head 52 X 21 Trial
2100-11-562	Common Humeral Head 56 X 18 Trial
2100-11-563	Common Humeral Head 56 X 21 Trial
2100-22-401	Common Humeral Head 40 X 15 Eccentric Trial
2100-22-402	Common Humeral Head 40 X 18 Eccentric Trial
2100-22-441	Common Humeral Head 44 X 15 Eccentric Trial
2100-22-442	Common Humeral Head 44 X 18 Eccentric Trial
2100-22-443	Common Humeral Head 44 X 21 Eccentric Trial
2100-22-481	Common Humeral Head 48 X 15 Eccentric Trial
2100-22-482	Common Humeral Head 48 X 18 Eccentric Trial
2100-22-483	Common Humeral Head 48 X 21 Eccentric Trial
2100-22-521	Common Humeral Head 52 X 15 Eccentric Trial
2100-22-522	Common Humeral Head 52 X 18 Eccentric Trial
2100-22-523	Common Humeral Head 52 X 21 Eccentric Trial
2100-22-562	Common Humeral Head 56 X 18 Eccentric Trial
2100-22-563	Common Humeral Head 56 X 21 Eccentric Trial

INSTRUMENT ORDERING INFORMATION FRACTURE CASE



Top Tray – Trials

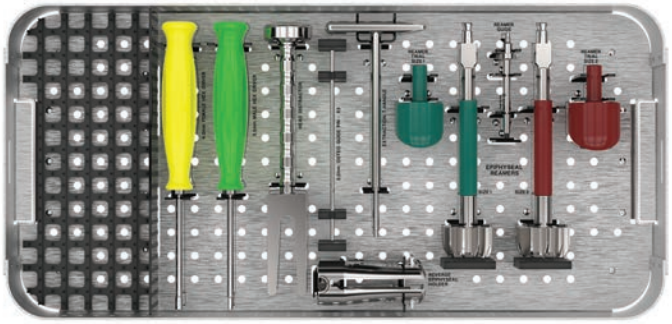
2100-30-000	Proximal Body 10 (-5) Trial
2100-30-010	Proximal Body 10 (0) Trial
2100-30-020	Proximal Body 10 (+5) Trial
2100-40-000	Proximal Body 12 (-5) Trial
2100-40-010	Proximal Body 12 (0) Trial
2100-40-020	Proximal Body 12 (+5) Trial
2100-50-000	Proximal Body 14 (-5) Trial
2100-50-010	Proximal Body 14 (0) Trial
2100-50-020	Proximal Body 14 (+5) Trial
2100-60-000	Proximal Body 16 (-5) Trial
2100-60-010	Proximal Body 16 (0) Trial
2100-60-020	Proximal Body 16 (+5) Trial
2100-20-100	Suture Collar 40mm Trial
2100-20-200	Suture Collar 44mm Trial
2100-20-300	Suture Collar 48mm Trial
2100-20-400	Suture Collar 52mm Trial
2100-20-500	Suture Collar 56mm Trial
2100-06-600	Long Humeral Stem 6mm Trial
2100-08-600	Long Humeral Stem 8mm Trial
2100-10-600	Long Humeral Stem 10mm Trial
2100-12-600	Long Humeral Stem 12mm Trial
2100-20-110	Suture Collar 40mm Eccentric Trial
2100-20-210	Suture Collar 44mm Eccentric Trial
2100-20-310	Suture Collar 48mm Eccentric Trial
2100-20-410	Suture Collar 52mm Eccentric Trial
2100-20-510	Suture Collar 56mm Eccentric Trial
2100-01-036	Fracture Positioning Jig



Bottom Tray - Instruments

2100-01-019	Global UNITE Head Gauge
2100-01-035	Implant Holder
2100-70-250	Collar Impactor
2100-70-300	Greater Tuberosity Forceps
2130-01-120	Humeral Head Distractor
2307-99-002	Extraction T-Handle

INSTRUMENT ORDERING INFORMATION
REVISION CASE



Top Tray

2100-70-500	Epiphyseal Sizer 1
2100-70-510	Epiphyseal Sizer 2
2100-70-600	Epiphyseal Reamer 1
2100-70-610	Epiphyseal Reamer 2
2100-70-410	Epiphyseal Reamer Guide
2100-70-700	Reverse Epiphyseal Holder
2130-01-120	Humeral Head Distractor
2307-99-002	Extraction T-Handle
2130-20-000	3.2mm Osteotomy Guide Pin – Long
2100-70-155	4.0mm Female Hex Screwdriver
2100-70-150	3.5 Male Hex Screwdriver

IMPLANT ORDERING INFORMATION

Standard Humeral Stem Components

1100-06-100	Standard Humeral Stem 6mm x 83mm
1100-08-100	Standard Humeral Stem 8mm x 107mm
1100-10-100	Standard Humeral Stem 10mm x 113mm
1100-12-100	Standard Humeral Stem 12mm x 121mm
1100-14-100	Standard Humeral Stem 14mm x 130mm
1100-16-100	Standard Humeral Stem 16mm x 138mm

Humeral Long Stem Components

1100-06-600	LONG Humeral Stem 6mm x 143mm
1100-08-600	LONG Humeral Stem 8mm x 177mm
1100-10-600	LONG Humeral Stem 10mm x 183mm
1100-12-600	LONG Humeral Stem 12mm x 191mm

Suture Collar Components

1100-20-100	Suture Collar 40mm
1100-20-200	Suture Collar 44mm
1100-20-300	Suture Collar 48mm
1100-20-400	Suture Collar 52mm
1100-20-500	Suture Collar 56mm
1100-20-110	Suture Collar 40mm Eccentric
1100-20-210	Suture Collar 44mm Eccentric
1100-20-310	Suture Collar 48mm Eccentric
1100-20-410	Suture Collar 52mm Eccentric
1100-20-510	Suture Collar 56mm Eccentric

Proximal Bodies

1100-30-100	Proximal Body 10 (-5)
1100-30-110	Proximal Body 10 (0)
1100-30-120	Proximal Body 10 (+5)
1100-40-100	Proximal Body 12 (-5)
1100-40-110	Proximal Body 12 (0)
1100-40-120	Proximal Body 12 (+5)
1100-50-100	Proximal Body 14 (-5)
1100-50-110	Proximal Body 14 (0)
1100-50-120	Proximal Body 14 (+5)
1100-60-100	Proximal Body 16 (-5)
1100-60-110	Proximal Body 16 (0)
1100-60-120	Proximal Body 16 (+5)

Humeral Head Components

1100-40-500	Humeral Head 40 x 15
1100-40-510	Humeral Head 40 x 18
1100-44-500	Humeral Head 44 x 15
1100-44-510	Humeral Head 44 x 18
1100-44-520	Humeral Head 44 x 21
1100-48-500	Humeral Head 48 x 15
1100-48-510	Humeral Head 48 x 18
1100-48-520	Humeral Head 48 x 21
1100-52-500	Humeral Head 52 x 15
1100-52-510	Humeral Head 52 x 18
1100-52-520	Humeral Head 52 x 21
1100-56-510	Humeral Head 56 x 18
1100-56-520	Humeral Head 56 x 21
1100-40-600	Humeral Head 40 x 15 Eccentric
1100-40-610	Humeral Head 40 x 18 Eccentric
1100-44-600	Humeral Head 44 x 15 Eccentric
1100-44-610	Humeral Head 44 x 18 Eccentric
1100-44-620	Humeral Head 44 x 21 Eccentric
1100-48-600	Humeral Head 48 x 15 Eccentric
1100-48-610	Humeral Head 48 x 18 Eccentric
1100-48-620	Humeral Head 48 x 21 Eccentric
1100-52-600	Humeral Head 52 x 15 Eccentric
1100-52-610	Humeral Head 52 x 18 Eccentric
1100-52-620	Humeral Head 52 x 21 Eccentric
1100-56-610	Humeral Head 56 x 18 Eccentric
1100-56-620	Humeral Head 56 x 21 Eccentric

DNI and Templates

2100-10-101	Humeral Stem DNI 10mm
2100-30-001	Proximal Body DNI 10 (-5)
2100-30-011	Proximal Body DNI 10 (0)
2100-30-021	Proximal Body DNI 10 (+5)
2100-48-511	Humeral Head DNI 48 x 18
2100-20-301	Suture Collar DNI 48mm
2100-52-621	Humeral Head DNI 52 x 21 Eccentric
2100-20-411	Suture Collar DNI 52mm Eccentric
2100-22-000	X-Ray Templates

IMPLANT ORDERING INFORMATION

Metaglene Component

1307-60-000	Metaglene

Glenosphere Component

1307-60-138	Glenosphere 38mm
1307-60-142	Glenosphere 42mm
1307-60-038	Glenosphere 38mm Eccentric
1307-60-042	Glenosphere 42mm Eccentric

Metaglene Screw Components

1307-70-018	Non Locking Metaglene Screw 4.5mm x 18mm
1307-70-024	Non Locking Metaglene Screw 4.5mm x 24mm
1307-70-030	Non Locking Metaglene Screw 4.5mm x 30mm
1307-70-036	Non Locking Metaglene Screw 4.5mm x 36mm
1307-70-042	Non Locking Metaglene Screw 4.5mm x 42mm
1307-90-024	Locking Metaglene Screw 4.5mm x 24mm
1307-90-030	Locking Metaglene Screw 4.5mm x 30mm
1307-90-036	Locking Metaglene Screw 4.5mm x 36mm
1307-90-042	Locking Metaglene Screw 4.5mm x 42mm
1307-90-048	Locking Metaglene Screw 4.5mm x 48mm
1307-60-042	Glenosphere 42mm Eccentric

Polyethylene Cup and Humeral Spacer

1307-38-203	Humeral Polyethylene Cup 38mm +3mm
1307-38-206	Humeral Polyethylene Cup 38mm +6mm
1307-38-209	Humeral Polyethylene Cup 38mm +9mm
1307-42-203	Humeral Polyethylene Cup 42mm +3mm
1307-42-206	Humeral Polyethylene Cup 42mm +6mm
1307-42-209	Humeral Polyethylene Cup 42mm +9mm
1307-38-106	Humeral Polyethylene Cup 38mm +6mm Retentive
1307-42-106	Humeral Polyethylene Cup 42mm +6mm Retentive
1307-38-703	High Mobility Premieron® X-Linked Humeral Cup 38mm +3mm
1307-38-706	High Mobility Premieron® X-Linked Humeral Cup 38mm +6mm
1307-38-709	High Mobility Premieron® X-Linked Humeral Cup 38mm +9mm
1307-42-703	High Mobility Premieron® X-Linked Humeral Cup 42mm +3mm
1307-42-706	High Mobility Premieron® X-Linked Humeral Cup 42mm +6mm
1307-42-709	High Mobility Premieron® X-Linked Humeral Cup 42mm +9mm
1307-30-009	Humeral Spacer +9mm
1307-60-042	Glenosphere 42mm Eccentric

IMPORTANT

This Essential Product Information sheet does not include all of the information necessary for selection and use of the device. Please see full labeling for all necessary information.

INDICATIONS

Total shoulder or hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head;
3. Deformity and/or limited motion.

When used in a total shoulder replacement, the GLOBAL UNITE Implants are to be used with DePuy Synthes Joint Reconstruction's glenoids. The glenoids are for cemented use only.

When well-fixed, the GLOBAL UNITE Humeral Stems, in conjunction with existing Delta Xtend Epiphyseal Components, are also indicated for conversion to a reverse, in treatment of a grossly deficient rotator cuff joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary. The Delta Xtend Met aglene is HA-coated and is intended for uncemented use with the addition of screws for fixation. The Delta Xtend Epiphyseal Components are HA-coated and are intended for uncemented use.

CONTRAINDICATIONS

The following conditions are contraindications for total shoulder and hemi-shoulder arthroplasty:

1. Active local or systemic infection
2. Poor bone quality, such as osteoporosis, where there could be considerable migration of the prosthesis and/or a chance of fracture of the humerus or glenoid
3. Inadequate bone stock in the proximal humerus or glenoid fossa for supporting the components (Note: This contraindication does not apply when converting to a reverse)
4. Absent, irreparable or nonfunctional rotator cuff or other essential muscles (Note: This contraindication does not apply when converting to a reverse.)

Please review the full labeling for Delta Xtend System Metaglene when converting to a reverse.

WARNINGS AND PRECAUTIONS

- Implants and trial components from different manufacturers should never be used together.
- DePuy's single use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.
- Always use a trial prosthesis for trial purposes. Trials should never be used as an implant.
- Do not alter or modify implants in any way.
- Global Unite System Standard and Eccentric Humeral Heads are intended to be used with either Global Unite or Global AP Humeral Components.
- The use of a glenoid prosthesis in patients with cuff tear arthropathy could increase the risk of glenoid component loosening due to non-anatomic loading conditions.
- When used with multiple components of a total shoulder replacement system, the MR compatibility and safety of the entire system of implants has not been evaluated and the entire system of implants has not been tested together for heating or migration in the MR environment. The risks of exposure to MR include heating and/or displacement of a metallic implant. Image artifacts including dead zones and distortion may occur, especially in the immediate area around the implant, requiring optimization of imaging parameters. In line with the recommendations of the American College of Radiology, DePuy Synthes Joint Reconstruction recommends that a professional familiar with the specific MRI apparatus to be used assess the patient prior to any MRI examination or therapy.

The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity, thereby placing the patient at higher risk for failure of the shoulder arthroplasty:

1. Obesity or excessive patient weight.
2. Manual labor.
3. Active sports participation.
4. High levels of patient activity.
5. Likelihood of falls.
6. Alcohol or drug addictions.
7. Other disabilities, as applicable.

ADVERSE EVENTS AND COMPLICATIONS

The following events are generally the most frequently encountered adverse events and complications in total and hemi shoulder arthroplasty:

1. Change in position of the prosthesis, often related to factors listed in the Warnings and Precautions
2. Early or late infections
3. Early or late loosening of the prosthetic component(s), often related to factors listed in the Warnings and Precautions

Limited Warranty and Disclaimer: DePuy Synthes Joint Reconstruction products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

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