



**GLOBAL | AP™**  
ADJUSTABLE PROSTHESIS

## Surgical Technique





## RECOVERY FUNCTION SURVIVORSHIP

DePuy believes in an approach to total shoulder replacement that places equal importance on recovery, function and survivorship.



# GLOBAL | AP™

ADJUSTABLE PROSTHESIS



## ***“Power-Tower”*** *Technology*

### **The Design**

The Global AP™ prosthesis combines fixed and variable humeral neck geometry with over 15 years of Global Shoulder clinical experience. Its fully anatomic design and straightforward surgical technique assist the surgeon to achieve appropriate joint biomechanics, implant stability and range of motion for their patients. Variability of plus or minus 15 degrees in both neck angle and version allow the surgeon to restore individual patient anatomy with increased accuracy without sacrificing implant integrity.

This adds up to a shoulder system that helps surgeons treat more patients effectively.

### **The System**

The Global AP humeral implant achieves versatility through its three parts: the body, the head and the neck. A total of six body sizes are available with stem diameters ranging from 6 to 16 mm, in 2 mm increments. The collarless humeral body is constructed

of high strength titanium alloy, which affords exceptional biocompatibility. The body is also offered in a proximally coated Porocoat finish and in long stem version for revisions.

The Global AP head assortment includes 13 standard and 13 eccentric components that fit most body configurations. When impacted on the humeral body/neck assembly, the Global AP humeral head sits flush to the humeral osteotomy to provide a true anatomic replacement. The Global AP humeral head is constructed of cobalt chrome alloy, leveraging the proven clinical results of the Global Advantage™ system.

The neck options provide a fixed 135 degree neck or a two piece adjustable neck. These components are designed to allow the head on a well-fixed humeral component to be revised without removing the stem.

### **The Technique**

Recognizing that a successful shoulder arthroplasty is critically dependent on soft tissue balancing, this document provides a detailed guide to the techniques of tendon lengthening and capsular releases, which are integral parts of the procedure. These steps cannot be affected with jigs and guides, but rather require an understanding of the principles of shoulder mechanics.

Recognizing that each shoulder arthroplasty needs to be adapted to the patient's unique combination of soft tissue and bone anatomy, the system maximizes the surgeon's flexibility in matching a wide variety of anatomic requirements. Because patients have high expectations of the function and durability of the arthroplasty, a premium has been placed on secure fixation, conservation of bone and optimization of biomechanics. Surgical technique is a critical variable in the success of any arthroplasty. This document seeks to optimize surgical technique through detailed technique descriptions and advanced instrumentation.

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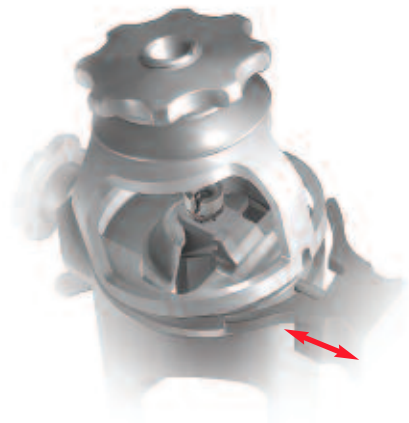
*A note within this surgical technique in red denotes a point that should be considered vital to a successful surgery.*



# Key Instrument Steps for Adjustable Neck



**Step 1:** Mount the broach/trial ball cylinder assembly into the impaction block and tighten the front slide to secure in place. Place eccentric head trial on ball cylinder, if applicable, and note position of eccentricity relative to number on face of impaction stand.



**Step 2:** Withdraw the locking mechanism and mount the orientation device on top of the impaction stand.



**Step 5:** Remove the broach and insert the humeral stem implant into the impaction stand. Seat the stem insert and place the ball taper loosely on top of the insert.



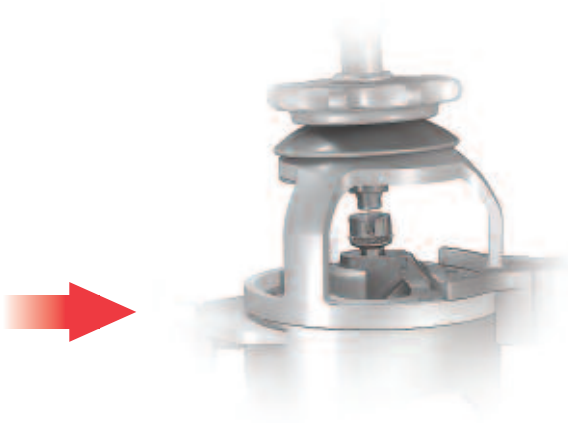
**Step 6:** Reposition the orientation device with its recorded position. Re-insert the taper impactor and engage the tip of the impactor with the ball taper implant.



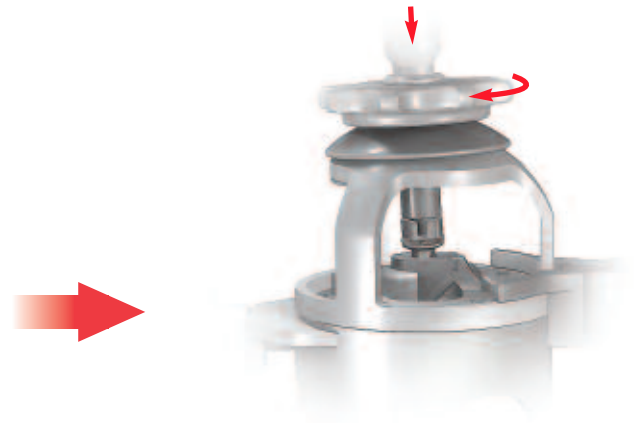
**Step 8:** Remove the orientation device and place the selected head onto the impacted ball taper. If using an eccentric head, position the indicator on the underside of the head with the appropriate numeral on the face of the impaction stand.



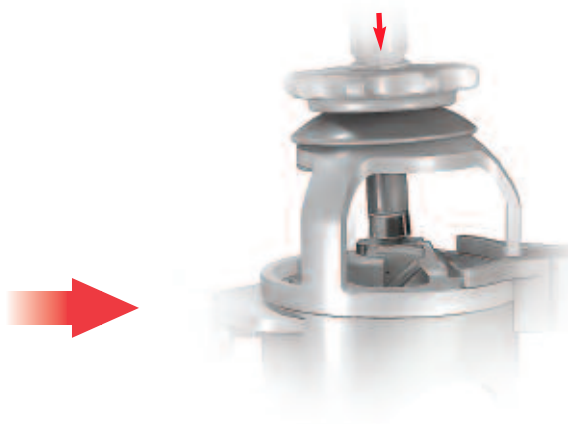
**Step 9:** With the end of the perforated head impactor over the center of the head, firmly impact the head 3-4 times using the slotted mallet.



**Step 3:** With the shells of the orientation device loose, carefully engage the taper impactor into the trial ball cylinder.

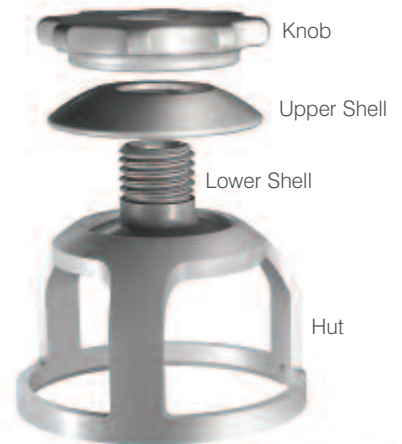


**Step 4:** Apply light palm pressure to the fully engaged taper impactor while locking the shells together by tightening the knob. Remove the orientation device from the impaction stand. **DO NOT** loosen the knob-shell assembly.

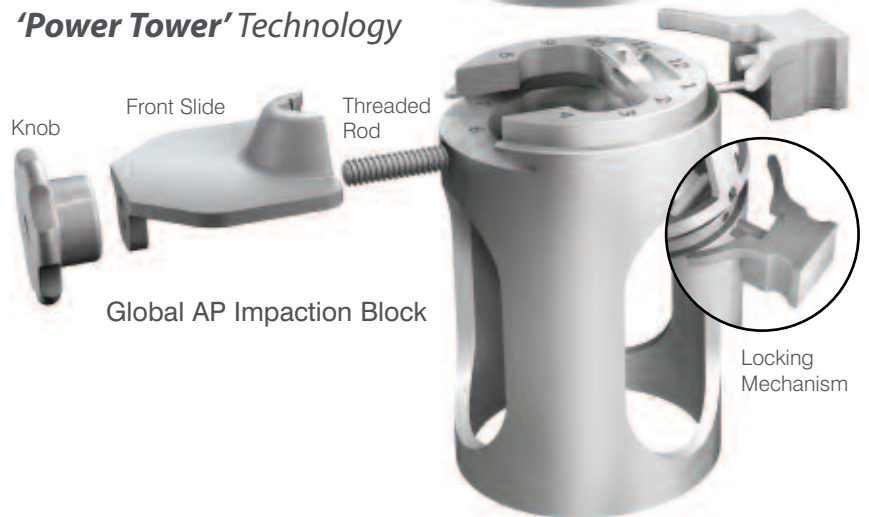


**Step 7:** Strike the taper impactor with the slotted mallet 5-6 times. Make light impactions for the first few times followed by controlled impactions.

**Global AP Orientation Device**



**'Power Tower' Technology**



# Preoperative Templating and Patient Positioning



Figure 1

## Preoperative Templating

Preoperative evaluation of the humerus using the Global AP™ shoulder template system helps determine the size of the prosthesis and level of the head resection. The goal is to remove the humeral head at the anatomic neck using the patient's own neckshaft angle and humeral version (Figure 1).



Figure 2

## Patient Positioning

Remove the standard headrest from the operating table and replace it with a headrest such as the Mayfield or the McConnell. Place the patient on the operating table in a semi-Fowler position with the head inclined at approximately 30 degrees, the legs at around 20 degrees and the knees in approximately 20 degrees of flexion (Figure 2).



Figure 3

Ensure that the involved shoulder extends laterally over the top corner of the table so that the arm can be brought into extension and abduction (this is essential for good exposure of the humeral head) (Figure 3). Use an intraoperative arm or positioner and post attached to the table to help keep the patient on the table and avoid traction on the body. Secure the patient's head with tape and drape the shoulder to isolate the anesthesia equipment from the sterile field.



# Exposure

## Initial 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.

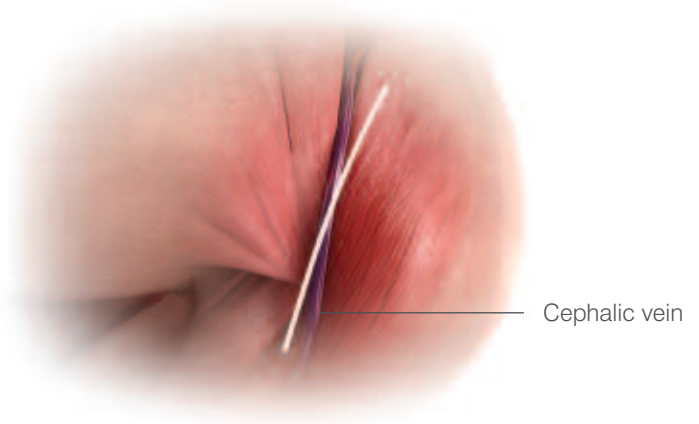


Figure 4

## Exposure

Once the initial incision has been made, undermine the fatty layer, expose, incise and release the fascia. Locate the cephalic vein at the delto-pectoral interval. Separate the deltoid and pectoralis major muscles so that the deltoid muscle is completely free from its origin to its insertion, especially along its deep surface (Figure 5).

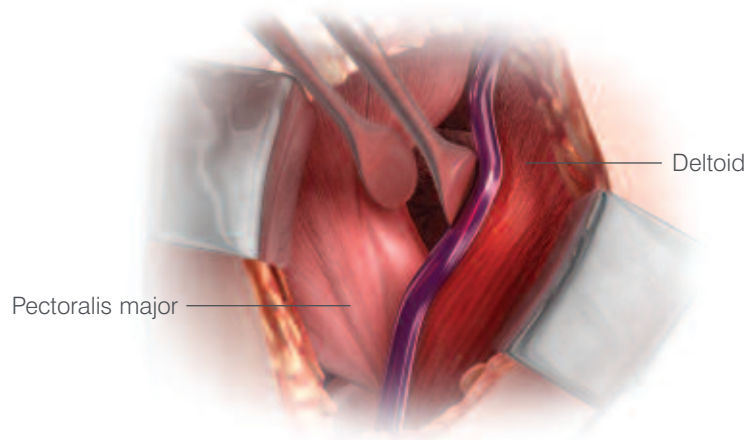


Figure 5

Abduct and externally rotate the arm. Gently retract laterally the cephalic vein along with the deltoid muscle (Figure 6).

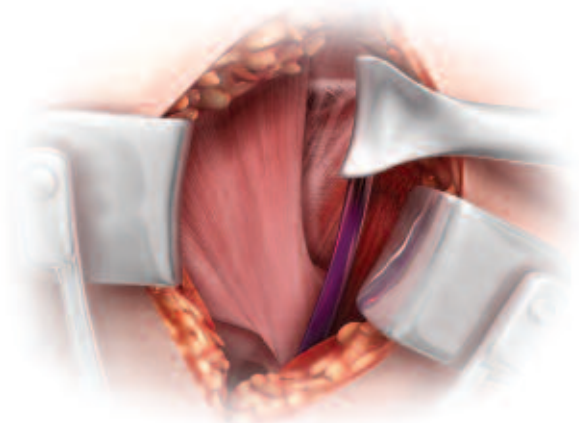


Figure 6

# Exposure

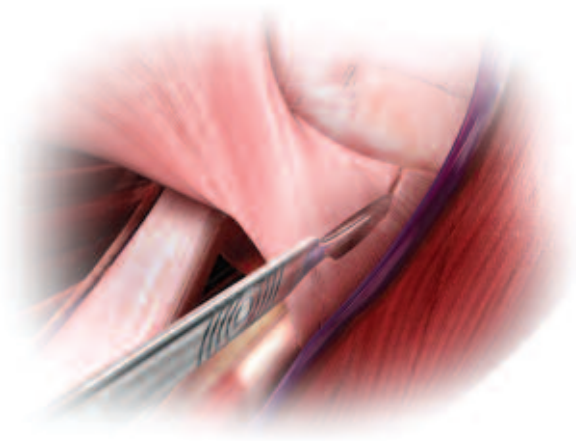


Figure 7

Incise the clava-pectoral fascia to expose the conjoined tendon. Release the upper 25 percent of the pectoralis major tendon from its insertion on the humerus, using an electrocautery cutting blade (Figure 7). This will improve exposure of the inferior aspect of the joint and will not require repair during closure.

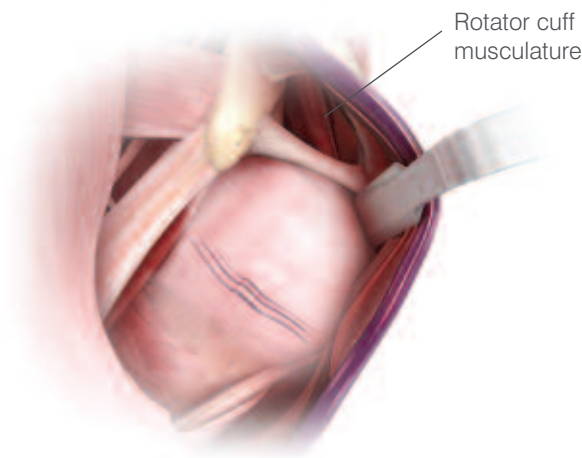


Figure 8

Now place a reverse or Hohmann retractor over the top of the humeral head, pulling the upper part of the deltoid posteriorly. Check that the rotator cuff tendons are intact (Figure 8).

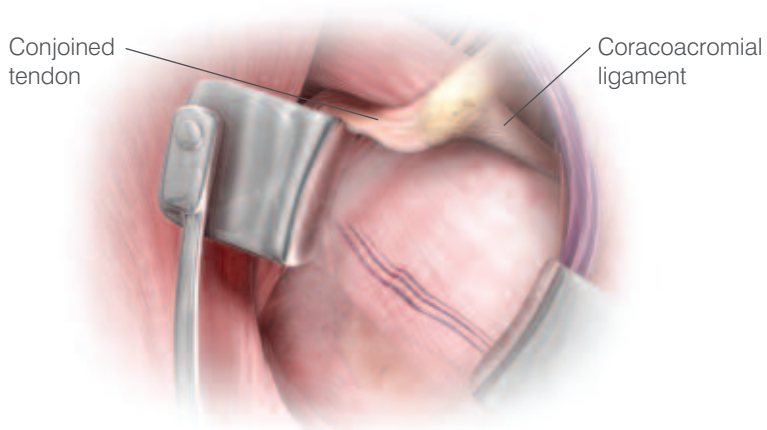


Figure 9

Introduce a Kobel retractor underneath the conjoined tendon and underneath the middle deltoid (Figure 9). It is important to save the coracoacromial ligament and only sacrifice it if the rotator cuff is intact, or if extra exposure is needed.

At this stage, the biceps tendon can be released from the bicipital groove and along the rotator interval down to its glenoid attachment (Figure 10). Resect the long head of the biceps at the origin of the superior glenoid. Tenodesis the biceps tendon to soft tissue, distal to the bicipital groove.

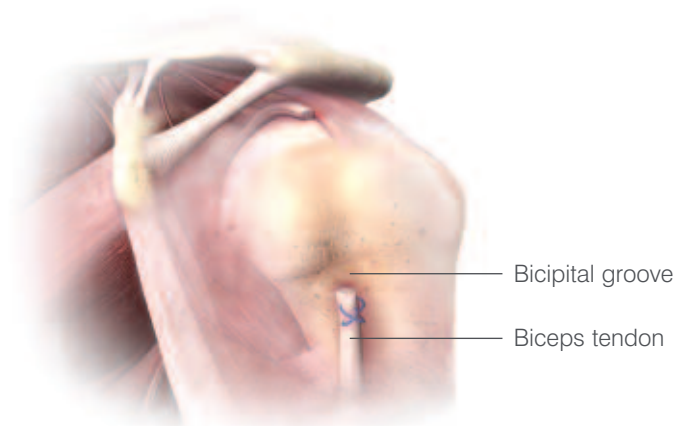


Figure 10

#### Management of the Anterior Humeral Circumflex Vessels

Isolate, clamp and ligate or coagulate the anterior humeral circumflex vessels lying across the anterior/inferior third of the subscapularis tendon (Figure 11).

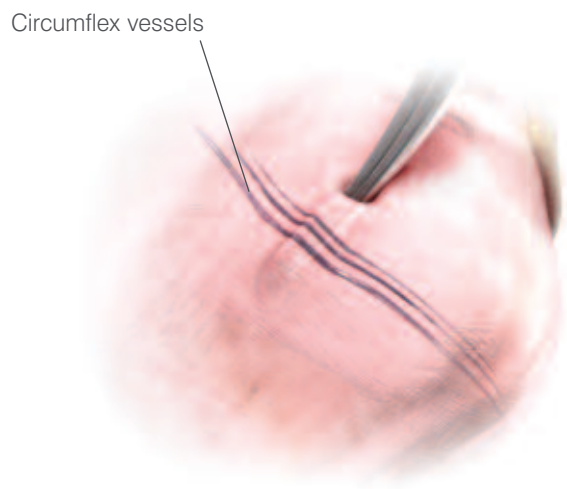


Figure 11

#### Management of the Musculocutaneous and Axillary Nerves

It is important to be aware of the musculocutaneous nerve, which penetrates the coracobrachialis muscle 1 to 2 inches distally from the coracoid. The nerve may not be palpable within the surgical field, but remember its proximity to the conjoined tendon (Figure 12). Digitally locate the axillary nerve. Introduce a reverse Hohmann retractor and carefully retract the nerve along with the latissimus dorsi tendon. This is especially important as it will protect the delicate axillary nerve and will define and expose the inferior capsule.



Figure 12

# Subscapularis Tendon Release

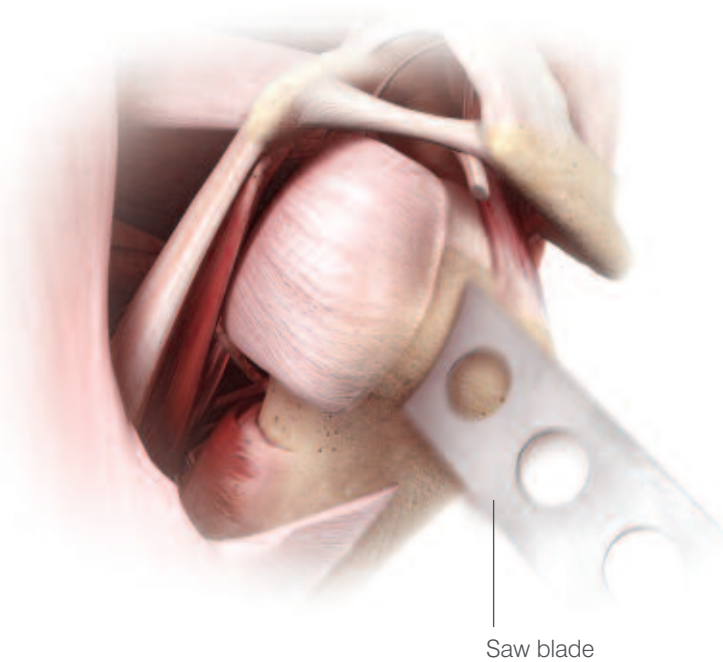


Figure 13

There are different methods of taking down the subscapularis. Some surgeons prefer to perform a tenotomy while others prefer a lesser tuberosity osteotomy. Typically, a z-plasty is only performed in the event that the subscapularis was shortened by prior surgery.

When performing a lesser tuberosity osteotomy, first move the arm into internal rotation to improve access to the lesser tuberosity. Introduce the saw blade (as shown) or a sharp curved 1/2 inch osteotome at the interval created at the insertion side of the subscapularis and resect approximately 4-5 mm of the lesser tuberosity (Figure 13).

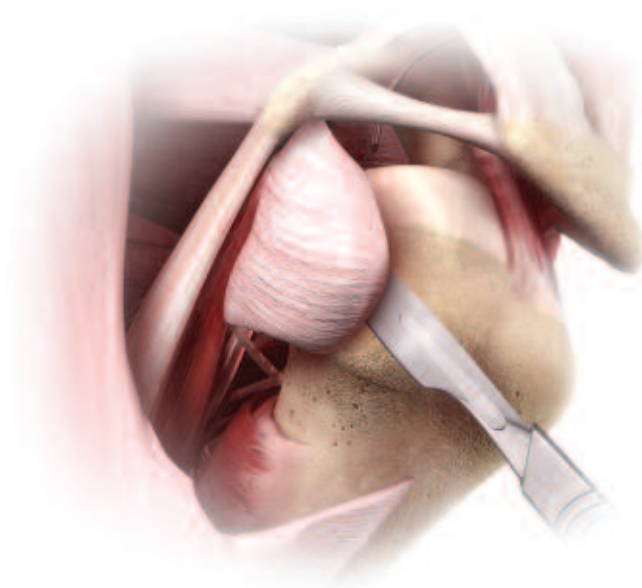


Figure 14

When performing a release of the subscapularis tendon without an osteotomy, the tendon is removed from its insertion with a cautery or scalpel (Figure 14).

# Capsule Release and Humeral Head Dislocation

Using a blunt dissection (Cobb) separate the capsule from the subscapularis, inferiorly and medially, using a scalpel. Release the rest of the anterior capsule from the subscapularis to the glenoid rim.

Release the coracohumeral ligament from the base of the coracoid (Figure 15).

*Note: Failure to sufficiently release the capsule from the humeral neck to its posterior inferior area will make it very difficult to bring the head up and out of the glenoid fossa.*

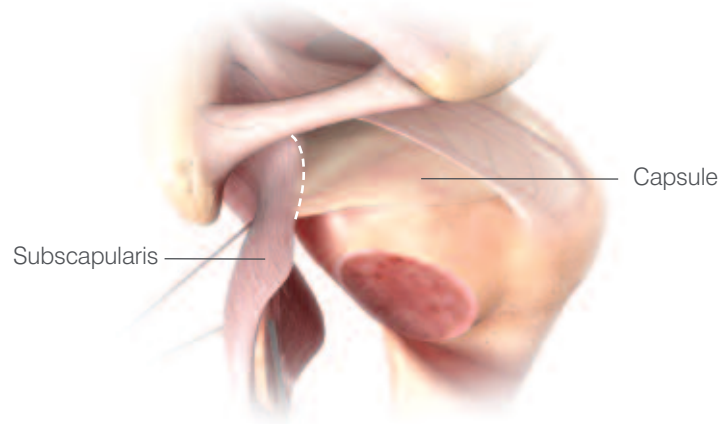


Figure 15

Place a Bankart retractor between the capsule and the subscapularis. Resect the anterior capsule in its entirety from the glenoid insertion sites (Figure 16).

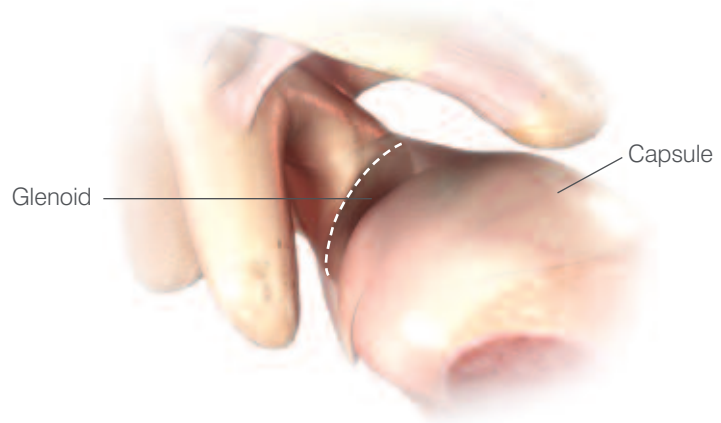


Figure 16

Place a large Darrach retractor underneath the upper part of the humeral head and dislocate the humerus. Put a medium size retractor on the inferior part of the humeral head and continue to bring the arm into full external rotation. The entire humeral head should now be in vision, with all capsular tissues removed from around the neck to provide excellent exposure (Figure 17).

*Note: It is important to fully visualize the rotator cuff insertion site superiorly and posteriorly since this and the humeral neck will define the true, anatomic resection angle for the humeral head. Using a large rongeur, remove any osteophytes circumferentially.*

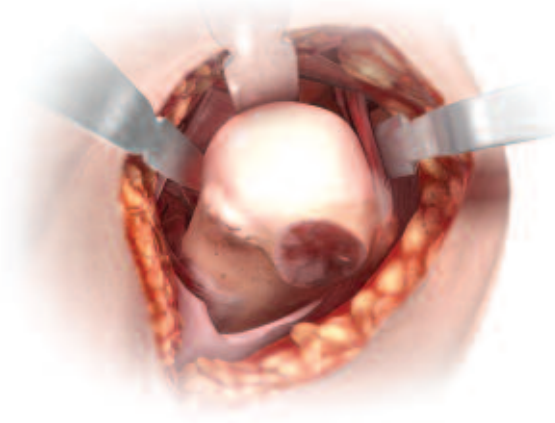


Figure 17



# Humeral Head Preparation and Resection

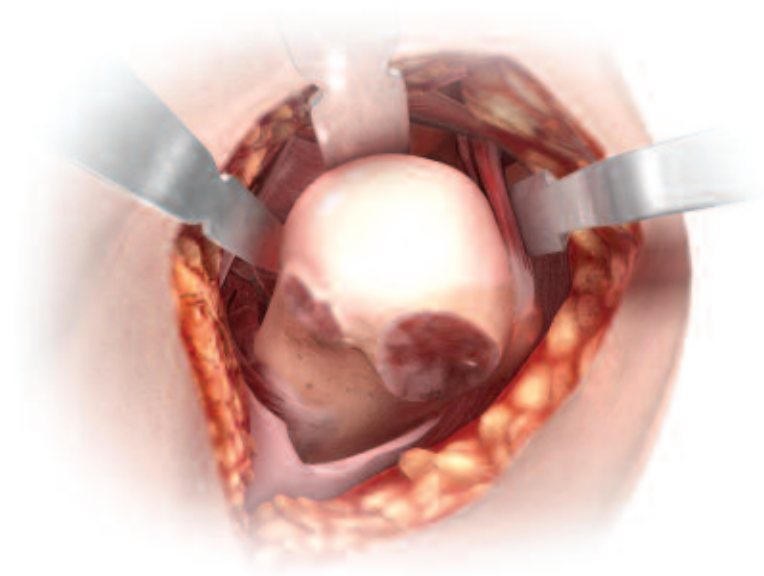


Figure 18

## Assessing the Head Size

Place a curved Crego or reverse Hohmann retractor along the anatomic neck superiorly to protect and retract the posterior-superior rotator cuff (Figure 18).

*Note: Using a rongeur or other instrument, remove any unwanted osteophytes to return proximal humerus to near native anatomy.*

## Free-Hand Resection Technique

Use an oscillating power saw to remove the humeral head at the anatomic neck. The saw should enter the anterior surface of the humerus along the line of the anatomic neck and exit 2-3 mm proximal to the posterior cuff attachment. In this way, the native neckshaft angle and humeral retroversion can be approximated. Once complete, the resection should be at the level of the articular surface of the supraspinatus insertion site (Figure 19).

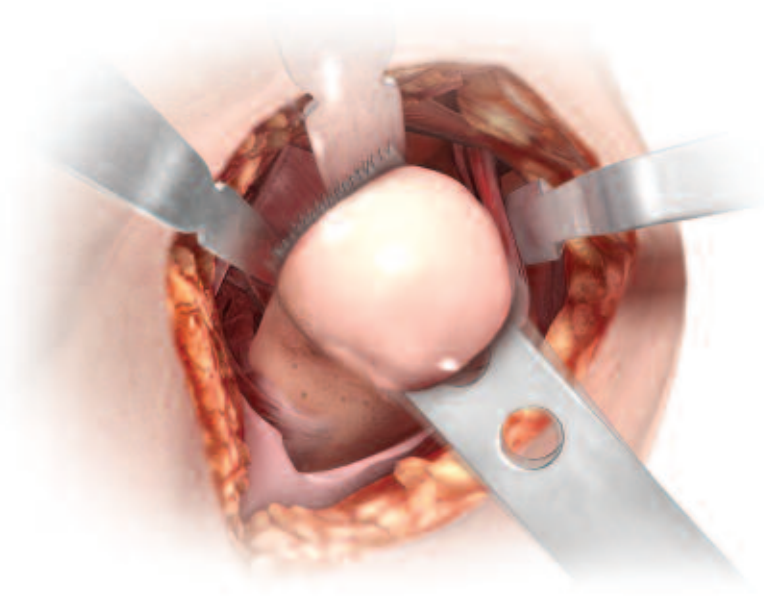


Figure 19

### Alternative Head Resection with a Cutting Guide

Verify the humeral head diameter and thickness with the flat head gauge (Figure 20).

Once the head size and thickness has been determined, assemble the humeral head sizer with the appropriate diameter to the sizer/drill guide handle. Use the head sizer to find the center of the head and the plane of the anatomic neck in both neck shaft angle and version (Figure 21).

*Note: There is only one plane that is exactly in alignment with the anatomic neck. It is therefore critical that the periphery of the hooded template be parallel to the anatomic neck and then the pin is drilled into the center of the head.*



Figure 20

### Identifying the Center of the Humeral Head

Mark the superior-inferior and anterior-posterior axes of the humeral head using electrocautery or a marking pen through the round windows in the sizer (Figure 22). Remove the sizer and complete the axes.

Visually assess the intersection to ensure positioning is appropriate and in the center of the head. If not, repeat the previous steps.

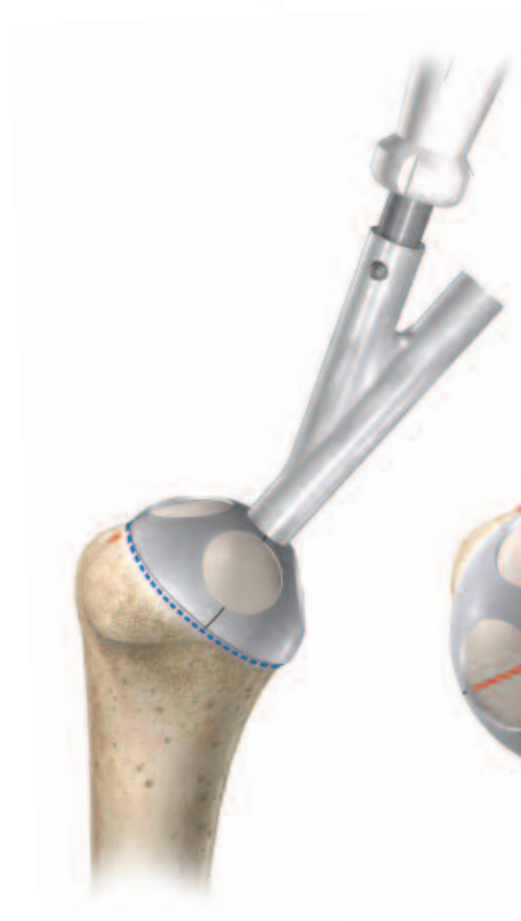


Figure 21



Figure 22

# Humeral Head Preparation and Resection

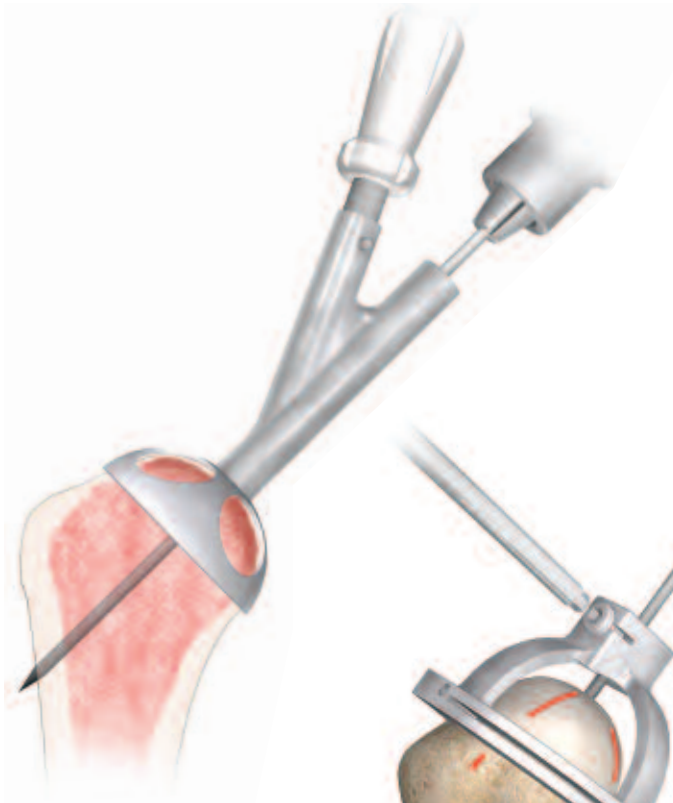


Figure 23

Replace and center the humeral sizer over the humeral head. Drill the long threaded pin through the center of the cannulated sizer and into the humeral head (Figure 23).

The tip of the threaded guide pin should penetrate the lateral cortex of the humerus to prevent the pin from migrating in cancellous bone. Remove the humeral sizer leaving the guide pin in place.



Figure 24

## Humeral Head Resection

Pass the resection guide down the guide pin to the level of the anatomic neck. If the guide pin placement procedure was performed correctly then the saw capture slot must be in alignment with the anatomic neck. So the only adjustment to be made is the height of the cut.

Engage the T-handle with the locking screw and secure the resection guide in position on the guide pin (Figure 24). Stabilize the guide by placing the two short pins through the peripheral holes.

Pass an oscillating saw (1.2 mm x 20 mm blade) through the guide capture and resect the humeral head, following the rim of the articular surface around the humeral head until approximately 50 - 80 percent of the resection is complete, leaving a wedge of bone. Remove the resection guide and pin and complete the cut (Figure 25).

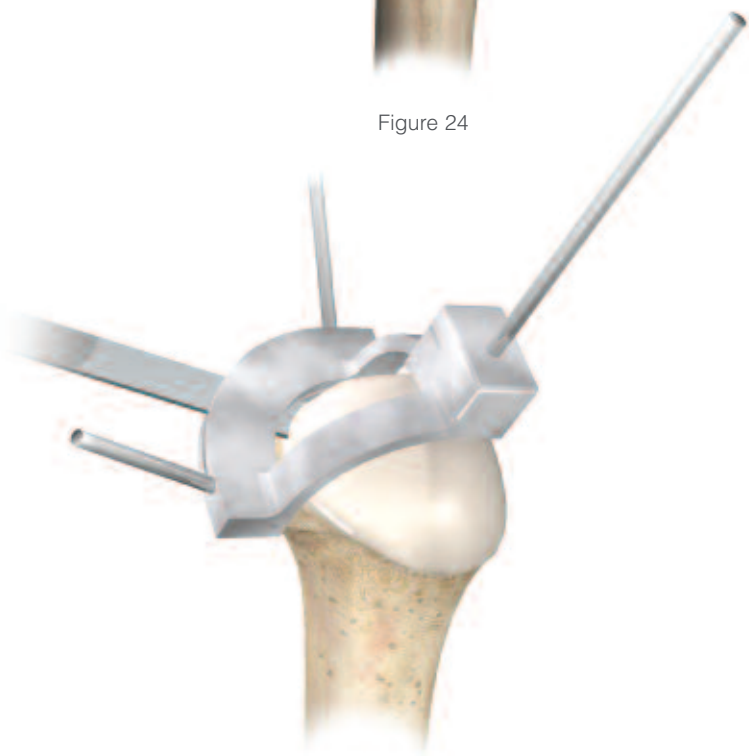


Figure 25

Use the sizer template to measure the resected head diameter and height to confirm the humeral head selection. The resected humeral head can now be used to provide cancellous bone graft if required later in the procedure.

# Humeral Canal Preparation

## Humeral Reaming

Attach the T-handle to the 6 mm reamer. Place the tip of the reamer at the most superior point on the resected humerus just behind the long head of the biceps groove, so that it is aligned with and ready to pass directly down the intramedullary canal (Figure 26). Create a pilot hole and then ream the medullary canal in line with its long axis. For the standard length of prosthesis, stop reaming when the circular mark on the reamer is at the level of the resected bone (Figure 27). When using the long stem prosthesis, pass the entire length of the cutting flutes down the intramedullary canal.

*Note: Power reaming of the humeral canal should be avoided as it may remove more bone than necessary.*

Continue sequential reaming, following the path created through the intramedullary canal, increasing the reamer diameter in 2 mm increments until a reamer begins to bite on cortical bone. Note the final reamer diameter. This will determine the stem size of the body sizing osteotome, the final broach and the implant.



Figure 26



Figure 27

# Humeral Canal Preparation



Figure 28



Figure 29

## Proximal Humeral Preparation

The surgeon should assess cancellous bone quality using digital pressure on the center of the cancellous cut surface of the humerus. If with firm digital pressure the humeral cancellous bone can be indented then it is recommended to not use the box osteotome and move directly to the humeral broach. Using the broach without the osteotomy will result in the impaction of this poor quality bone and improving the rotational stability of the final implant. If this technique is used and the broach can not be fully seated with a few attempts at impaction and disimpaction sequences then a small amount of the impacted cancellous bone may need to be removed from the medial area of the metaphysis using a burr or rongeur.

If a box osteotome is necessary, select the box osteotome that matches the diameter of the final reamer. Place the orientation pin through the lower hole of the osteotome. Use the pin to guide rotation. Pass the osteotome down the medullary canal. When the pin sits flat against the resected humeral surface, version is correct (Figure 28).

Carefully remove the pin, without disrupting the rotational position. The side of the osteotome is etched with a V indicator laser mark. Using a mallet, tap the osteotome down until the apex of the mark reaches the resected surface. If the resection plane lies within the lateral or open end of the mark, the cut has been made within the osteotomy range of the system (Figure 29). If it does not, the box osteotomy must be removed. The osteotomy must be readjusted to bring into system limits.

Drive the box osteotome down to create space for the proximal body of the implant. After removal of the box osteotome, there may be some residual bone in the humeral canal that requires removal. This can be saved for bone graft at a later time.



# Broach/Trial Stem Insertion

Select the broach that matches the diameter noted for the final reamer size. Attach the broach to the broach handle, making sure the broach face is flush with the locking surface. Lock the broach to the broach handle (Figure 30).

Carefully drive the broach into the proximal humerus so that the fins on the broach follow the tracks created by the box osteotome. (The broach is approximately 1 mm smaller than the corresponding humeral prosthesis, to obtain a proximal press-fit.) Seat the broach until the rocker bar on the broach handle sits on the resected surface both front and back (Figure 31).

*Note: Be cautious if cancellous bone is soft. Do not drive the broach handle rocker bar into soft bone, the rocker bar should just touch or sit slightly above the osteotomy.*

At this point the broach itself is seated approximately 2 mm below the resection and is ready to act as the trial stem. Release the locking arm and remove the broach handle.

*Note: If the broach handle rocker bar does not just touch or sit slightly above the cut osteotomy surface, do not try to aggressively drive it down. Rather, remove the broach and then pass the reamer deeper into the canal (further cutting with the osteotome may be needed). Then seat the broach again and remove any osteophytes.*

*Note: If utilizing the impaction bone grafting technique, it is important that it is done at the time the trial/broach is inserted into the humerus. This will ensure proper positioning of the stem and head trials and will translate correctly to the final implant. Impaction bone grafting at the point of final implant insertion can force the implant into an incorrect position.*



Figure 30



Figure 31

# Glenoid Preparation and Implantation

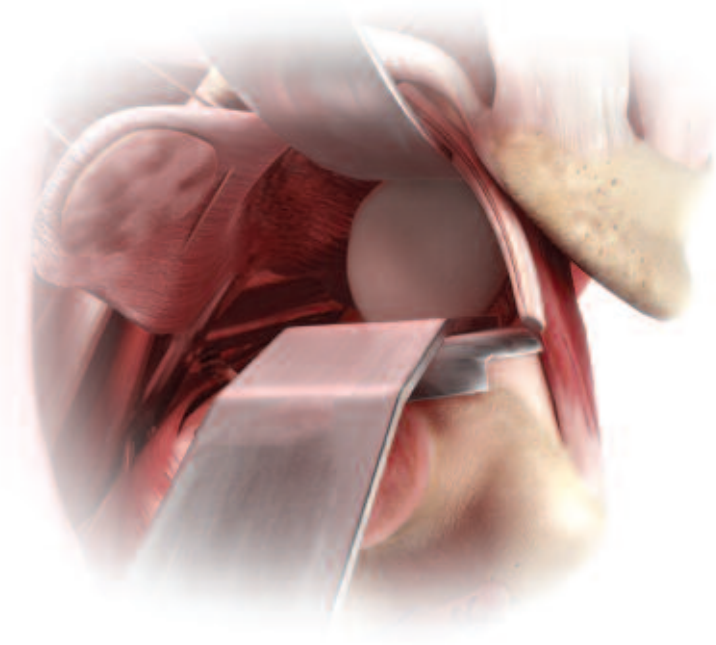


Figure 32

*Note: The Global glenoid components (Anchor Peg or Keel) can be used with the Global AP humeral stem. The surgical technique for implantation of the glenoid with the Global AP humeral stem is not significantly different from previously described technique manuals. In general, the goals of glenoid resurfacing are to place the glenoid component in normal glenoid version against a concentrically reamed surface. Although decreasing humeral retroversion has been used in combination with uncorrected posterior glenoid deficiency, this technique does not affect glenohumeral stability. Therefore, correction of any glenoid version abnormalities or deficiencies (unless they are deemed to be congenital) through a combination of asymmetrical reaming and bone grafting is preferred.*

*Note: Protecting the humeral osteotomy prior to initiating glenoid preparation, cover the humeral osteotomy surface with an osteotomy cover. This will help avoid damaging the proximal humerus.*

## Glenoid Exposure

With the resected humerus protected by the osteotomy cover, place a standard Fukuda retractor posterior to the glenoid, resting on the osteotomy cover, and an anterior Bankart retractor in the front of the shoulder.

Position the arm so that the osteotomized surface is parallel to the back wall of the glenoid. Remove any remnants of soft tissue such as the biceps tendon and the superior and posterior labrum to ensure the entire glenoid is visualized (Figure 32).

*Note: It may, on occasion, be necessary to remove more of the labrum and capsule to provide the necessary glenoid exposure.*

# Anchor Peg Glenoid Procedure

## Glenoid Preparation

When exposure is deemed adequate for use of the Anchor Peg Glenoid instrumentation, use the appropriate glenoid sizing disc to help mark the center of the glenoid (Figure 33). Using the center pilot hole drill bit (Figure 34) and the central hole drill guide, align the drill guide hole with the center mark just created. Drill the central hole. If increased retroversion is noted on preoperative imaging studies, then orient the drill to correct this retroversion by placing the drill guide in a plane that is anteverted from the native glenoid plane. Normalize the orientation of the glenoid face using a spherical reamer, which corresponds with the previously selected glenoid sizing disk. Insert the nub of the face of the reamer into the central hole. Ream accordingly (Figure 35). It is important to remember that over-reaming will both decrease the surface area of the glenoid face and reduce the depth of the glenoid vault. Excessive glenoid reaming should be avoided.

*Note: Take care to preserve subcondral bone and avoid over reaming the glenoid since this will reduce the area of the glenoid face and the depth of the glenoid vault.*

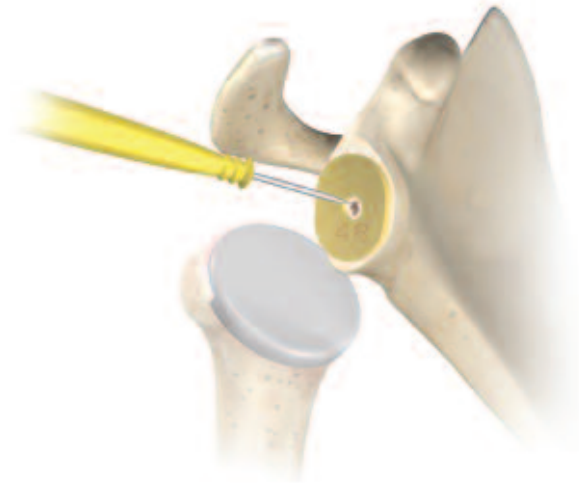


Figure 33

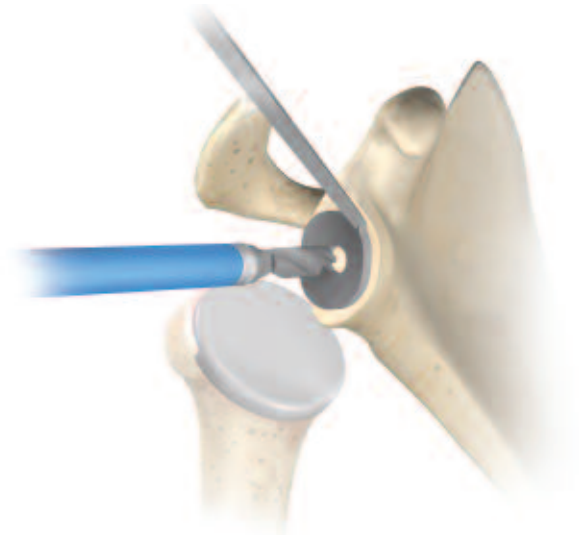


Figure 34

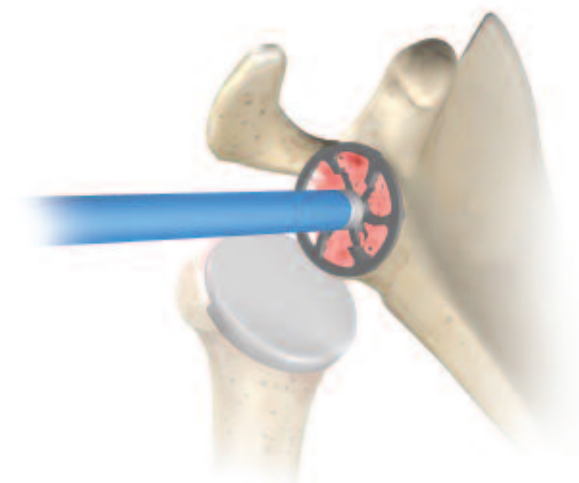


Figure 35

# Anchor Peg Glenoid Procedure

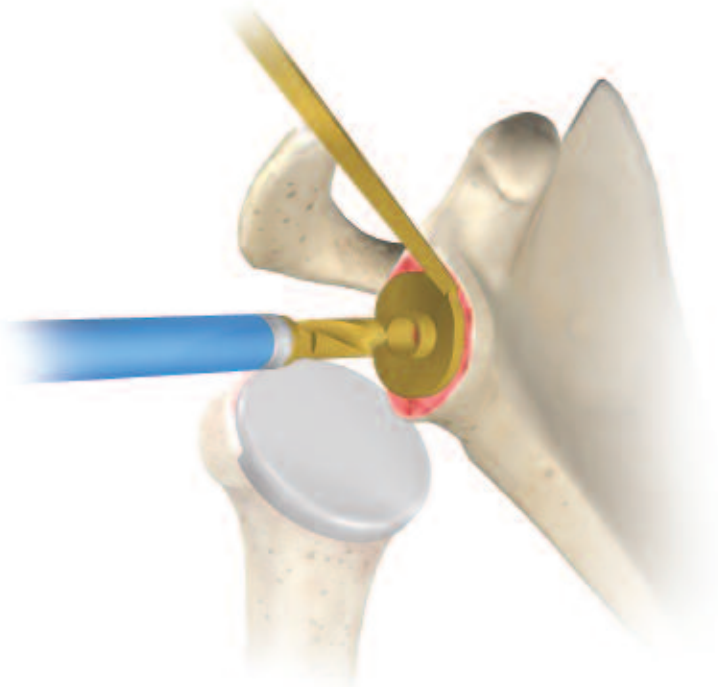


Figure 36

Using the gold central guide and the appropriate size anchor peg center drill bit, align the drill guide hole with the previously created central drill hole that was used to ream the glenoid. Drill the central anchor peg hole (Figure 36). Insert the tip of the peripheral drill guide into the anchor peg hole. Use the smaller peripheral drill bit to create the peripheral drill holes.

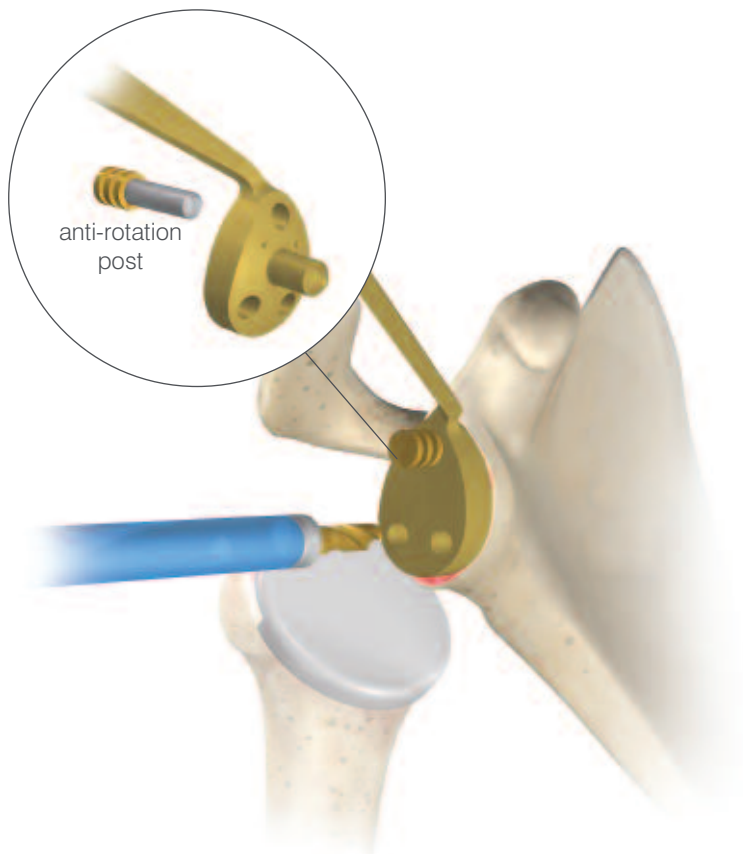


Figure 37

After each peripheral hole is drilled, insert an anti-rotation post to maintain alignment of the guide while the subsequent holes are completed (Figure 37). The preferred scenario is drilling so as to not penetrate the scapula which will allow you to pressurize the cement. Check the quality of the glenoid bone preparation by determining if the component is directly supported by precisely contoured bone, which should prevent the component from rocking, even when an eccentric load is applied to the rim of the implant.

*Note: If a size 40 mm or 44 mm Anchor Peg Glenoid is to be used, use the smaller center drill bit. If a 48 mm, 52 mm or 56 mm Anchor Peg Glenoid is to be used, use the larger center drill bit.*

*Note: Glenoid component loosening or excessive wear may occur if the glenoid component lacks sufficient bone support.*

### Implantation of the Anchor Peg Glenoid Trial

Select the appropriate Anchor Peg Glenoid trial and impact the trial onto the glenoid. Check that the component sits flush with the prepared glenoid surface (Figure 38). Remove the trial and irrigate the glenoid using pulsative lavage to remove blood and tissue debris from the four drill holes.

Check each peripheral hole to determine whether it penetrates the scapula at its base. You will cement the penetrating holes but the cement will not be pressurized.

*Note: If the scapula is penetrated by the glenoid peripheral hole drill, the cement should not be pressurized.*



Figure 38

Open the appropriate size Anchor Peg Glenoid component. Use a paste of morselized bone gathered during glenoid reaming or drilling and interpose this between the flanges of the central peg (Figure 39).

*Note: Typically bone from the glenoid hole drill is often too granular to fit between the fins of the anchor peg glenoid. The bone paste from reaming the glenoid or bone from the cancellous region of the humeral head osteotomy works best.*

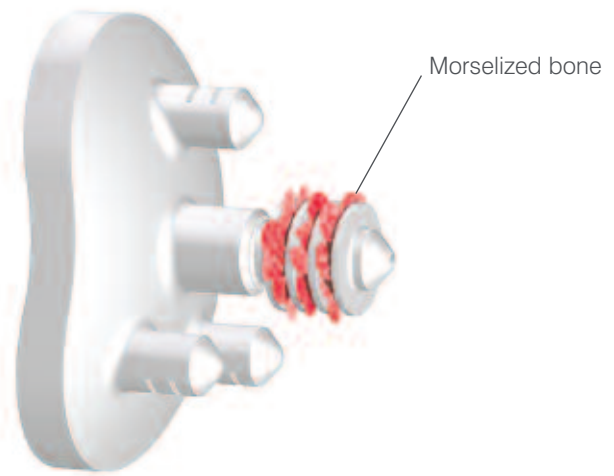


Figure 39



# Anchor Peg Glenoid Procedure

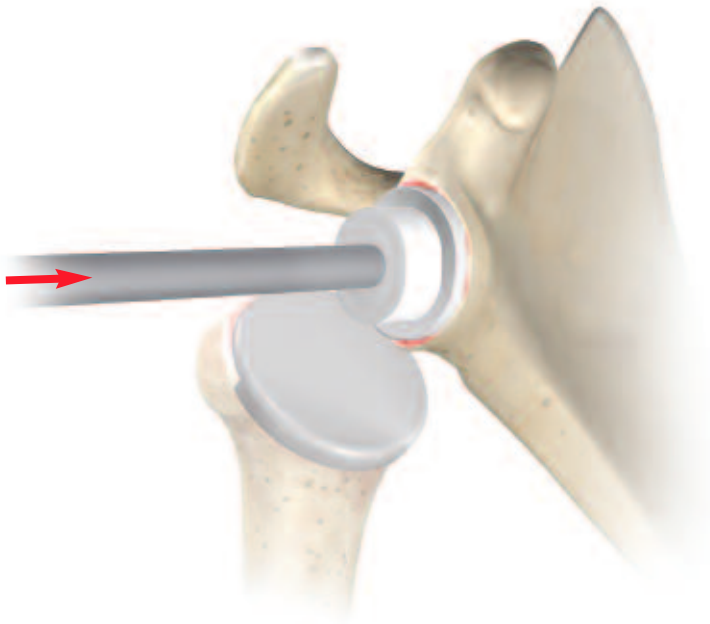


Figure 40

While cement is being prepared, obtain hemostasis by packing each of the three peripheral holes with thrombin and Surgicel® gauze (Ethicon). Mix cement using SmartSet® GHV by manual or syringe application. The cement is placed into a 20 cc syringe with a luer lock tip. The cap of the syringe is left in place and its end cut with scissors. The tip is inserted and the cement pressurized into each of the peripheral holes. Suction the central hole to remove any cement that may have entered this hole while pressurizing the peripheral holes.

*Note: Excessive cement extruding from the drilled holes and lying between the prosthesis and glenoid fossa is undesirable. It may create an uneven mantle for the glenoid prosthesis, and the cement may fragment with repetitive loading and become loose in the joint, causing damage to the high-density polyethylene surface.*

Insert the Anchor Peg Glenoid prosthesis and use the glenoid impactor to seat the component until there is complete contact with the perimeter of the glenoid (Figure 40). Maintain pressure directly on the glenoid component until the cement has hardened.

*Note: Cement injected under high pressure by a syringe technique may result in cement extruding from the cancellous walls of the peripheral holes into the central anchor peg hole, which could preclude proper seating of the component. Ensure the central hole is clear prior to implant insertion.*

# Osteotomy Evaluation

## Attaching The Calcar Alignment Guide

Attach the calcar alignment guide to the T-handle and lock the guide into the recess on the humeral broach (Figure 41). Sufficiently tighten the calcar alignment guide, being cautious not to overtighten. Remove the T-handle.



Figure 41

## Confirming the Neck Resection

Select the appropriate size calcar reamer (see table below) and mount the reamer over the calcar alignment guide. The angle of the calcar reamer when fixed onto the trial will be perpendicular to the standard neckshaft angle of 135 degrees. Assess its relationship to the resected plane. If the angle diverges by only a few degrees then the calcar reamer can be used to finalize the plane, providing an optimum resection for the fixed head configuration (Figure 42). Remove the calcar alignment guide when completed.



Figure 42

**Note: Be sure to ream until the calcar reamer bottoms out on the alignment guide. DO NOT USE POWER. This ensures a 135 degree osteotomy angle and that there is a 2 mm countersink of the broach.**

If the resection angle is not approximately parallel to the calcar reamer face, a variable angle neck is required (Figure 43). Refer to page 25 for the procedure.



Figure 43

Humeral Head Size	Calcar Reamer
40, 44, 48	Small
52, 56	Large

# Fixed Neck Trial

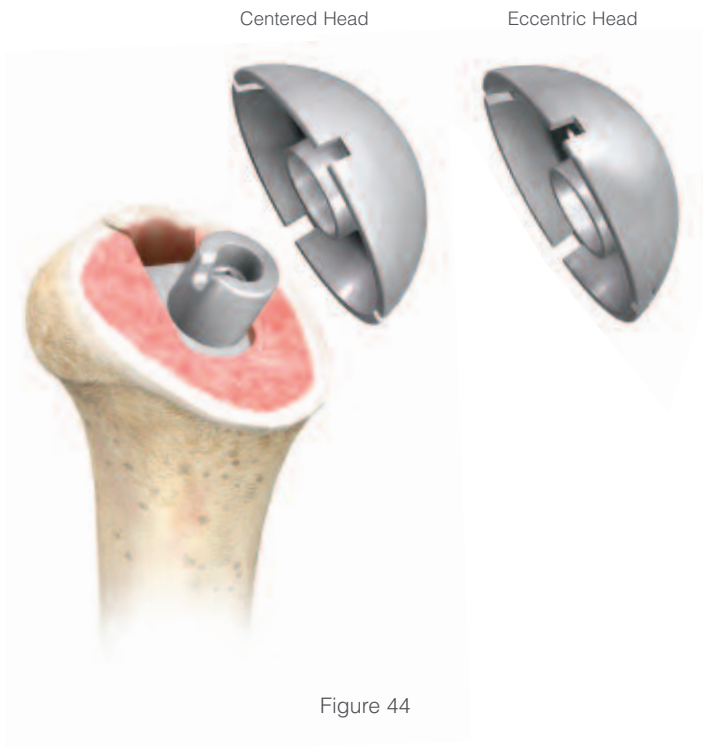


Figure 44

Reattach the calcar alignment guide to the seated broach. Select the head trial that matches the diameter and depth of the measured humeral head (see table below). Engage the key in the head trial sleeve into the slot in the calcar alignment guide (Figure 44).

Head Size (mm)	Head Heights (mm)
40	15, 18
44	15, 18, 21
48	15, 18, 21
52	15, 18, 21
56	18, 21



Figure 45

Check that the head trial achieves appropriate coverage of cortical bone, with 5-8 mm height above the greater tuberosity. Proper head thickness can be determined during trial reduction. If necessary increase or decrease the selected head size and type and reassess in place. A final decision will be made during trial reduction, with the glenoid component in place. Remove the trial head and use the T-handle driver to remove the fixed angle trial.

*Note: If an eccentric head achieves better coverage than a standard head, the alignment guide must be loosened to adjust eccentricity, then retightened. The entire humeral assembly is then removed with the broach removal tool (Figure 45).*

# Variable Neck Trial

## Ball Cylinder Trial/Head Trial

Open the sterile, single use ball cylinder trial. Check that the peg screw is appropriately positioned and that the expandable sphere is not expanded. If necessary, adjust by using the T-handle to turn the screw counterclockwise (Figure 46). **Note: For the variable neck trial, loosen the screw so that approximately one thread can be seen through the cut out inside of the trial (Figure 46a).**

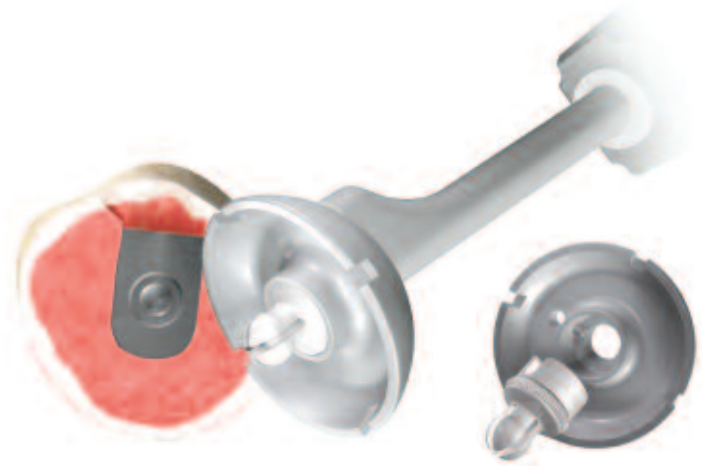


Figure 46

Select the head trial that corresponds in diameter and height to the measured humeral head. Insert the ball cylinder neck trial into the trial head by aligning the slot on the neck trial with the knob inside the central based of the trial head. Use sufficient pressure to overcome the interference and “lock” the neck trial into the trial head.



Figure 46a

Engage the trial head/ball cylinder trial into the seated broach by hand so the assembly can easily be held together when mounting. Proper engagement will be accompanied by a positive “snap.” **Note: Verify that the trial head is resting on the osteotomy. If it is not, the head and/or ball cylinder is not properly seated.**



Figure 47

Figure 48

Take the trial head handle and insert the two prongs into the head. Use the trial head handle to rotate and angle the assembly to achieve optimal version and coverage of the osteotomy (Figure 47).

## Locking The Trial Head Position

Once the head trial position is set, feed the T-handle driver through the trial head handle and lock the assembly in place with a clockwise turn of the peg screw. **Note: When tightening the variable neck trial locking screw with the T-handle driver, take care to apply counter pressure to the handle, stabilizing the implant (Figure 48).**

Remove the driver and handle. Check the fit against the osteotomy surface visually and run an index finger around the perimeter of the trial head to feel and verify that no significant gap exists (Figure 49). **Note: The position of the trial head can be adjusted by re-engaging the trial head handle and T-handle driver and slightly loosening the locking screw. Once the new head orientation is obtained, retighten the screw.**



Figure 49

# Soft Tissue Balancing and Trial Stem Removal



Figure 50

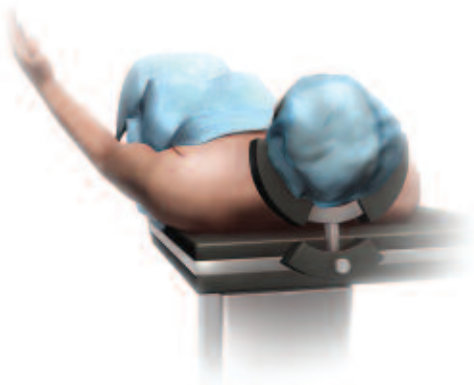


Figure 51



Figure 52

With the broach and selected humeral head in place, use a burr or a rongeur to remove any residual osteophytes extending beyond the periphery of the humeral head.

It is important to balance soft tissue tension with the appropriate trial humeral head in place. It should be possible to fully internally rotate the arm across the chest so that the hand of the involved shoulder easily rests on top of the opposite shoulder, without elevating the involved shoulder off the table (Figure 50).

It should also be possible to externally rotate the arm 30-40 degrees and still reapproximate the subscapularis tendons to the cut surface of the neck of the humerus. The humeral head should posteriorly sublux 50 percent or more but should spontaneously reduce when the posterior force is released (Figure 51).

If the fit of the humeral head is so tight that the functional internal or external rotation or posterior subluxation cannot be obtained, then further soft tissue release posteriorly is required. When the final combination of sized trial body and head has been determined, slide the head trial off the ball cylinder, without disturbing its "locked" orientation.

Extract the stem from the humeral canal using the extractor tool attached to the broach removal tool and a mallet with moderate impaction force (Figure 52). Make sure the extractor tool is held in vertical alignment with the stem axis. Assistance may be required to hold the extractor tool in place. Clear away any bone or soft tissue captured in the front or back grooves of the stem.



# Transferring the Head/Neck Orientation to the Definitive Implant

On a solid surface away from the operating table (with sufficient stability to support impaction during implant assembly later in the procedure), mount the stem and ball cylinder assembly into the impaction block.

*Note: Do not use the Mayo stand or other non-rigid surface.*

Align the back rim and the front groove of the trial stem with the mating features on the block. Secure the broach by firmly tightening the front block knob (Figure 53).

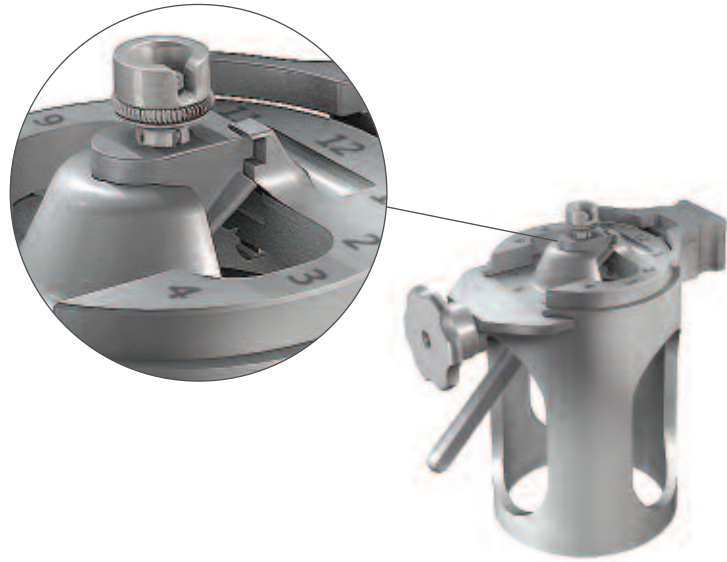


Figure 53

Verify that the trial broach is inserted correctly into the impaction tower with indicator marks on the sliding clamp hidden by the mating features on the implant.

Now assemble the four components of the orientation dome (Figure 54).



Figure 54

Pull back the locking mechanism on the impaction block, align the key slot on the bottom of the orientation dome with the locking mechanism pin and mount the orientation dome (Figure 55).

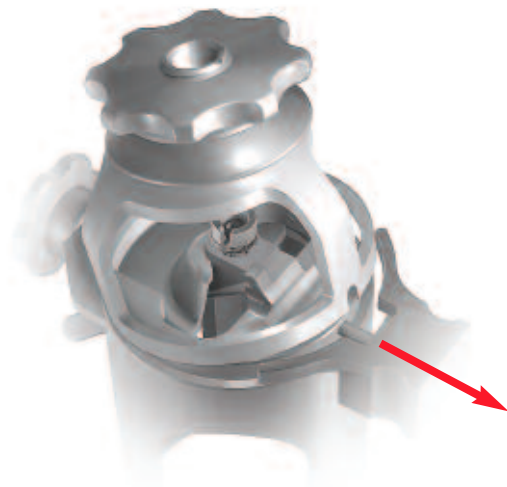


Figure 55

# Transferring the Head/Neck Orientation to the Definitive Implant



Figure 56

Loosen the locking knob so that the shells articulate freely.

Slide the keyed impactor rod through the orientation dome, taking care to ensure it is engaged into the ball cylinder trial (Figure 56).

*Note: This is best accomplished by viewing through the side window.*

*Note: Let the tip slide into position without significant force. Align the tip of the impactor rod into the locked neck trial. Jamming the impactor rod could disorient the “locked” position.*



Figure 57

Once the rod is fully engaged, hold the strike plate of the impactor rod while pressing down with light hand pressure and then firmly tighten the top locking knob of the orientation dome. Firmly grasp the impactation base and apply a greater tightening force to the locking knob (Figure 57).

Carefully remove the impactor rod. The orientation of the humeral trial construct is now recorded. Remove the orientation dome from the impaction block.

# Transferring the Head/Neck Orientation to the Definitive Implant

If an eccentric head has been selected, reattach the trial head to the ball cylinder trial. The eccentric trial head is marked with an arrow, indicating maximum distance from the center of the head. The head must be remounted first. Use a sterile pen to mark the position of the arrow relative to the surface on the impaction tower (Figure 58). Now remove the trial head.



Figure 58

Remove the trial stem from the impaction block and mount, in the same way, the corresponding sized final humeral stem (Figure 59).

*Note: Do not change the size of the humeral implant component once the neck position has been recorded by the positioning dome. This will cause the final head/neck position to be inaccurate.*

*Note: If a long revision stem is used, it will be necessary to move the impaction stand to the edge of the table so that the stem of the prosthesis can hang off the table.*

Verify that the stem is inserted correctly into the impaction tower with indicator marks on the sliding clamp hidden by the mating features on the implant.

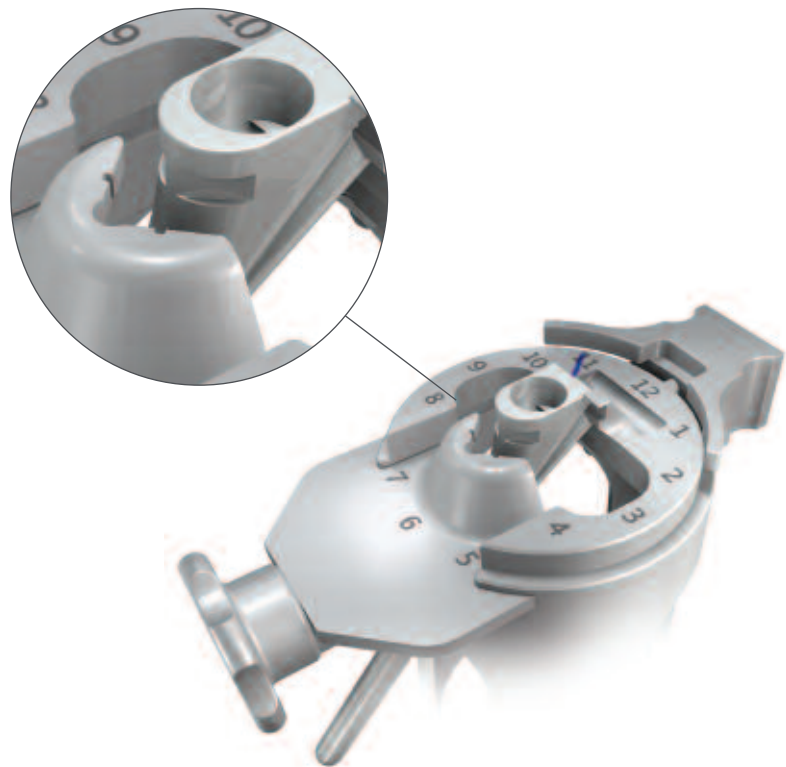


Figure 59

# Completing the Head/Stem Assembly



Figure 60

Insert the stem insert so that the flat surface engages into the slot in the top of the stem (Figure 60). Align the indicator mark on the top of the stem insert with the indicator mark on the top surface of the implant. The top surface of the stem insert should be approximately flush with the top of the stem.



Figure 61

Loosely place the final ball taper into the stem insert, generally angled toward the final orientation. Remount and secure the orientation dome on top of the impaction block. Carefully slide the impaction rod through the orientation dome assembly. Adjust the ball taper so that the tip of the rod engages with it (Figure 61). Ensure the rod is fully seated and flush with the top surface of the ball taper.

**Note:** Position the impaction tower so that the impaction rod is orientated toward the user.



Figure 62

With the impaction tower and orientation dome held securely by an assistant, hit the impactor “squarely” to ensure that both tapers are simultaneously engaged (Figure 62). Five to six controlled impactions is optimal. Verify that the rod and ball taper are still aligned, with the rims flush.

**Note:** Tapping the impactor rod lightly a few times will lock the tapers in position prior to full impaction.

# Completing the Head/Stem Assembly

Remove the impaction rod and orientation dome from the impaction block. Place the selected final humeral head component on the ball taper.

If an eccentric head has been selected, use a sterile pen to mark arrow position (found on the non-articular surface) on top of the head, before placing it on the ball taper (Figure 63). Align the mark on the head with the mark made earlier on the impaction tower.



Figure 63

Center the black perforated Celcon humeral head impactor on the humeral head, making sure that it is co-linear with the ball taper and impact the head with three or four firm taps with the mallet (Figure 64).

*Note: When impacting the final head it is very important to only use the Celcon humeral head impactor, as this ensures correct head impaction without dislodgement of any portion of the ball taper.*



Figure 64

Remove the final assembly from the impaction tower. Make a visual comparison with the trial assembly to check for orientation of the eccentric head (Figure 65).

The construct is now ready for implantation.



Figure 65



# Fixed Head Configuration

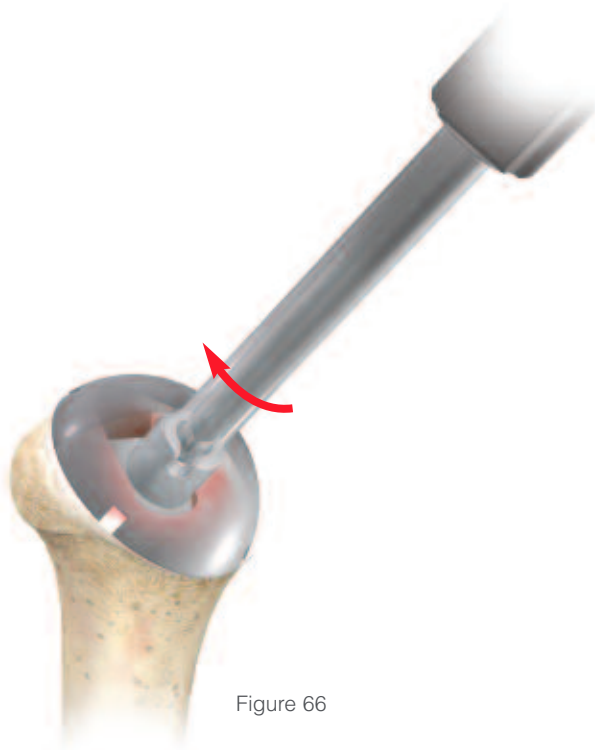


Figure 66

## Assembling the Fixed Head to the Fixed Angle Taper

If an eccentric head is selected, insert the calcar alignment guide into the seated broach. Start, but do not tighten the calcar alignment guide screw using the T-handle (Figure 66). Attach the eccentric head and rotate it until optimal coverage is achieved.

Use the trial head handle to properly position the trial head. Then use the T-handle to lock the calcar alignment guide in place. Remove the eccentric head, T-handle and trial head handle.



Figure 67

Extract the trial stem from the humeral canal using the extractor tool attached to the stem removal tool and a mallet with moderate impaction force (Figure 67). Make sure the extractor tool is held in vertical alignment with the stem axis. Assistance may be required to hold the extractor tool in place. Clear away any bone or soft tissue captured in the front or back grooves of the trial stem.

# Fixed Head Configuration

*Note: If a fixed neck and a standard (non eccentric) head are used, directly place the final humeral component into the impaction tower. It is not necessary to mount the trial broach in the impaction tower. If an eccentric head is used, then mounting of the broach in the impaction tower is necessary to determine positioning of eccentricity.*

Assemble the impaction stand and orientation device per the guide etched on the bottom of the instrument case. On a clear surface away from the operating table, mount the trial stem into the impaction tower. Align the back rim and the front groove of the trial stem with the mating features on the impaction block. Secure the broach by firmly tightening the front clamping knob (Figure 68).



Figure 68

Properly reattach the trial head to the calcar alignment guide. The eccentric trial head is marked with an arrow, indicating maximum distance from the center of the head. Use a sterile pen to mark the position of the arrow relative to the surface on the impaction tower (Figure 69). Now remove the trial head.



Figure 69

Remove the trial stem from the impaction block and mount, in the same way, the corresponding sized final humeral stem (Figure 70).

*Note: Do not change the size of the humeral implant component once the neck position has been recorded by the positioning dome. This will cause the final head/neck position to be inaccurate.*



Figure 70

# Assembling the Fixed Head to the Fixed Angle Taper



Figure 71

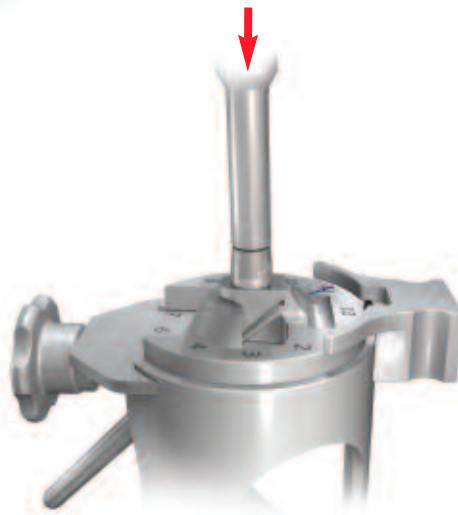


Figure 72



Figure 73



Figure 74

Insert the stem correctly into the impactation tower with the indicator marks on the sliding clamp hidden by the mating features on the implant. Insert the fixed angle taper into the slot in the top of the stem, with the end etched "THIS SIDE UP" facing superiorly (Figure 71). Introduce the impactation rod to the top of the fixed angle taper. Ensure the rod is fully seated and flush with the fixed angle taper.

**Note: Do not use the Mayo stand or other non-rigid surface.**

Impact the head of the rod sharply, three to four times, to ensure that the fixed angle taper is completely engaged (Figure 72).

Place the selected humeral head component on the fixed angle taper. If an eccentric head has been selected, use a sterile pen to mark the arrow position (found on the non-articular surface) on top of the head before placing on the fixed angle taper. Align the mark on the head with the mark made on the impactation tower (Figure 73).

Center the black perforated Celcon impactor on the humeral head, making sure that it is co-linear with the fixed angle neck taper and impact the head with three or four controlled impactions with the mallet (Figure 74).

The construct is now ready for implantation.

# Preparation for Repair of Subscapularis Tendon

**1a:** If the tendon was taken directly off its insertion into the lesser tuberosity then the tendon is sutured to the humeral neck using suture loops passed through drill holes made within the biceps groove (Figure 75).

These suture loops will be used after the humeral prosthetic is inserted to pass the permanent sutures that are placed in the end of the subscapularis tendon. These suture loops will be used later to pull the heavy non-absorbable sutures placed in the subscapularis out through the neck of the humerus.

**1b:** Another method is to cut the tendon mid substance and then suture tendon to tendon (Figure 76).

For alternative methods, please see page 36.

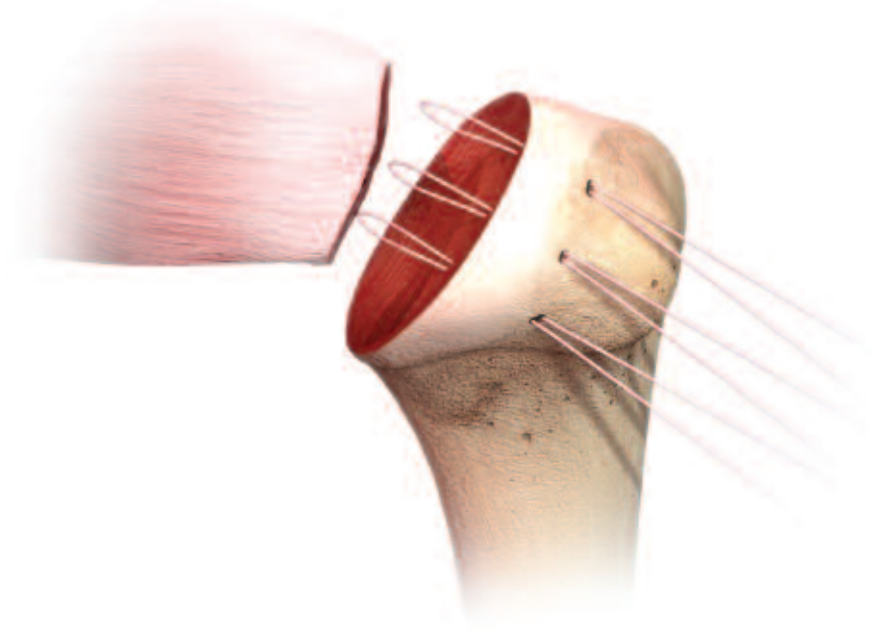


Figure 75

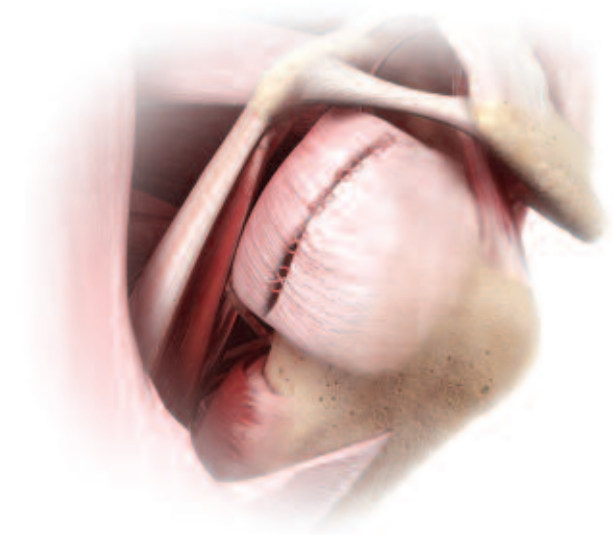


Figure 76

# Insertion of the Final Humeral Head/Stem Assembly

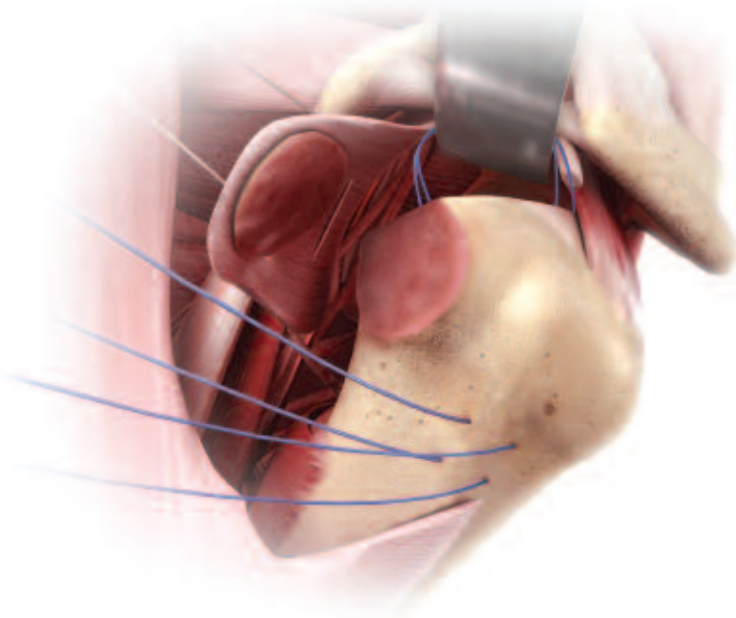


Figure 77



Figure 78

**1c:** If the subscapularis tendon was removed with a small portion of lesser tuberosity, two permanent sutures are passed through two sets of holes for later tension band suturing of the lesser tuberosity fragment to its native bed (Figure 77).

In this circumstance we recommend placing the sutures around the stem of the prosthesis and pulling the slack out of the sutures just before the prosthesis is placed into its final seated position within the humeral canal (Figure 78).

**Press-Fit, Impaction Bone Grafting or Cement**  
Before the final component assembly is inserted, plan the repair of the subscapularis tendon.

The final prosthesis is 1 mm larger across the anterior/posterior dimension than the trial broach so that, in the majority of cases, a firm press-fit without cement can be obtained. If the trial broach was slightly loose after humeral canal preparation, use either autogenous bone graft from the resected head of the humerus or cement for fixation of the final prosthesis. As a general rule following the resection of the head, it is preferred that all of the cancellous bone be removed and saved. If bone graft is used, place the cancellous bone down in the medullary canal, particularly into the inter-tuberosity region, and repeatedly impact it in place using the broach/trial on the driver extractor tool.

*Note: If impaction grafting is performed it should be done at the time of the use of the trial broach and before final recording of the trial ball taper or fixed angle taper. Use of impaction grafting will in many cases change the orientation of the stem in the canal and result in a change in the orientation of the head to the osteotomy surface.*



# Insertion of the Final Humeral Head/Stem Assembly

Only advance the broach until the broach handle rocker bar is just touching or slightly above the level of resection. In the case of the patient with severe osteoporotic humerus, use small pieces of the resected head as bone graft, which can produce a firm press-fit of the final prosthesis. The decision to use cement or a press-fit technique is up to the individual surgeon. In some instances, such as previous surgical procedures, fractures, osteoporosis or a degenerative cyst in the humerus, it may be necessary to use cement. The cement technique will vary from case to case. Since the stem of the prosthesis fills the reamed out medullary canal, it is rarely necessary to place the cement deep down the canal of the proximal humerus. If the cement is placed distal to the stem of the prosthesis then the use of a cement restrictor is suggested so that the cement does not extend more than 2 cm distal to the stem of the prosthesis and cement pressurization is attainable.



Figure 79

If defects exist in the proximal humerus and the fins of the prosthesis are not in contact with the bone, fill that area with cement. Regardless of the method used, place the final humeral head/stem assembly down the intramedullary canal by hand. Use the Celcon impactor to insert the assembly to the final seated position (Figure 79).

***Note: To assess final positioning of the humeral component the osteotomy surface should be perfectly covered from front to back by the head, and the version should be anatomic for the patient.***

Remove any further osteophytes with a burr. The humeral head should be about 5 mm above the top of the greater tuberosity. If a lesser tuberosity osteotomy was performed there is often a portion of the anterior part of the humeral prosthesis that overhangs the bone. This is where the lesser tuberosity is going to fit. Now perform the final checks for range of motion, correct version and stability.

***Note: Long stem humeral components are available for revisions or fractures of the humeral shaft.***

# Joint Reduction and Repair of the Subscapularis Tendon

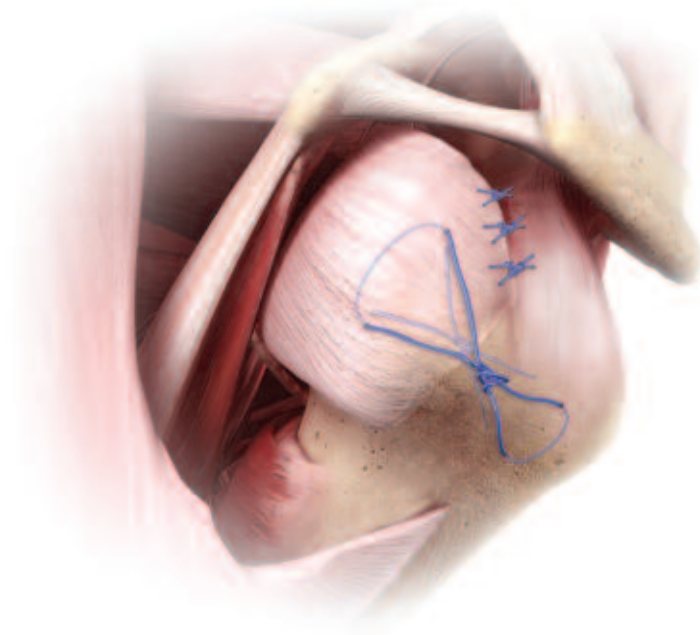


Figure 80

Using the plastic Darrach retractor as a skid, with gentle traction, internal rotation and finger pressure on the humeral prosthesis, reduce the head into the glenoid fossa. If the subscapularis was taken off of the lesser tuberosity then pass the previously placed #2 or larger non-absorbable suture (Mitek Orthocord is recommended) in the subscapularis tendon (Figure 80).

When the subscapularis is removed with a small sliver of lesser tuberosity the non-absorbable sutures previously placed are then passed through the tendon at its interaction into the bone in a figure of eight configuration (Figure 80). Also secure the repair of the subscapularis with sutures placed at the rotator interval. Use of the heavy sutures allows immediate passive movement beginning the day of surgery without fear of detaching the subscapularis tendon. Before wound closure, palpate the axillary nerve a final time to assure that it is in its normal position and is intact.

# Joint Reduction and Repair of the Subscapularis Tendon

If the subscapularis was taken off of the lesser tuberosity then place three #2 Orthocord sutures into the subscapularis tendon in a Mason Allen suture configuration (Figure 81) using the previously placed suture loops (Figure 75). Pull the loops of sutures with the subscapularis sutures out through the bone and use the sutures to secure the tendon back to the bone (Figures 82 and 83). Alternate the limbs of each paired suture through the suture loops so that the permanent sutures are tied over a bone bridge within the bicipital groove.



Figure 81

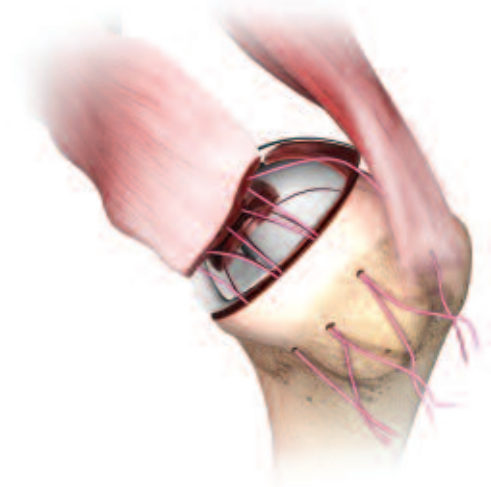


Figure 82

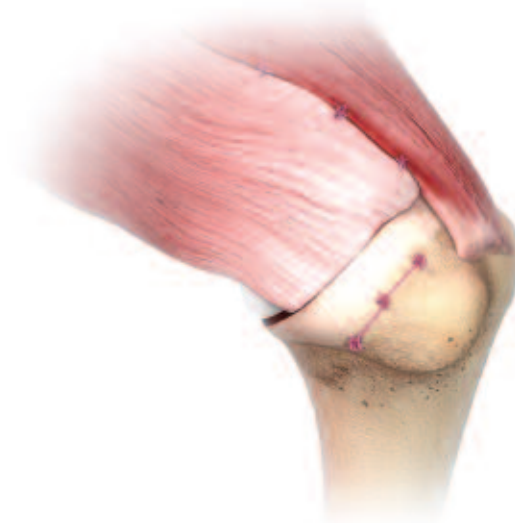


Figure 83

# Wound Closure



Figure 84

Thoroughly irrigate the wound with antibiotic solution. If a regional anesthetic is not used then infiltrate the soft tissue with a local anesthetic that will last six to eight hours. The Hemo-Drain® LC closed wound drainage system (Cat. No. 5421-04-000 for 1/8 in.) is recommended to prevent formations of post-operative hematoma.

The wound may be closed according to surgeon preference. Our preference is to close the deep layer of fat with a 2-0 Vicryl® suture (Ethicon); the subcuticular fat as a separate layer and finally the skin with a running subcuticular nylon structure. Careful attention to wound closure will result in a cosmetically acceptable incision (Figure 84).

After the dressing and shoulder immobilizer are in place, the use of a cold wrap is recommended. This prefrozen wrap can be placed on the shoulder in the operating room and replaced with another unit every three hours. The combination of regional anesthetic or local anesthetic and the immediate cooling seems to decrease the amount of postoperative pain.

# Revision Procedure

Removal of the humeral head during revision surgery can be achieved without disturbing a well-fixed stem.

## Removing the Humeral Head

The humeral head can be removed using the humeral head removal tool attached to the extractor tool. Place the jaws of the removal tool around the humeral head so that the teeth are inserted into the gap between the humeral head and the osteotomy surface. Tighten the jaws by turning the wheel at the top of the tool. Then use a mallet to remove the head by tapping the extractor tool (Figure 85).

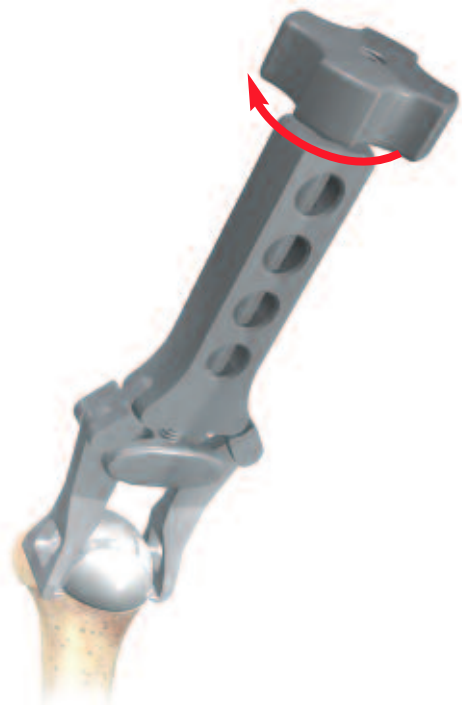


Figure 85

Alternatively, the humeral head can be removed using the humeral head distractor. Place the two prongs of the distractor between the humeral head and the osteotomy surface so that the prongs will advance in each side of the linking component. Lift the head off the ball taper by impacting the end of the distractor (Figure 86).



Figure 86

## Removing the Ball Cylinder

Place the two prongs of the ball taper trial distractor around the taper and impact the end of the tool to lift the taper away from the stem. The stem is designed so that the stem insert and the ball taper can be removed as a single unit (Figure 87). However, if the stem insert remains in place within the stem, it is easily removed using the extractor tool (Figure 88).



Figure 87

Figure 88



# Revision Procedure



Figure 89



Figure 90

## Revision Fixed Angle Neck Trial Assembly

Place the plastic, fixed angle trial neck into the tapered recess in the implanted stem and lightly tap in place. Place the calcar reamer over the plastic trial to determine how close the neck resection angle is to the 135 degree angle of the fixed neck device (Figure 89).

If the neck angle is correct, place the head trial onto the fixed angle trial neck. Choose either the centered or eccentric head trial, verifying that it achieves appropriate coverage of cortical bone, with 5-8 mm height above the greater tuberosity (Figure 90). If necessary increase or decrease the selected head diameter and height and reassess in place.



Figure 91



Figure 92

If an eccentric head is used, the position of the arrow (indicating maximum distance from the center of the head) needs to be marked on the bone with a sterile pen (Figure 91). Remove the head and fixed angle trial neck.

Insert the fixed angle taper into the slot in the top of the stem. Using the impaction rod, impact sharply, three to four times to ensure that the fixed angle taper is completely engaged (Figure 92). Remove the impaction rod.



Figure 93

Place the definitive head onto the fixed angle taper. If an eccentric head has been selected, mark the arrow position (found on the non-articular surface) using a sterile marker on top of the head. Align with the mark previously made on the bone surface (Figure 93). Impact the head using the Celcon humeral head impactor.

**Note:** Verify the head taper engages the neck before the bottom surface of the head hits the osteotomy surface. If the head contacts bone before the taper engages then a small amount of bone must be removed.

# Revision Procedure

## Revision Ball Cylinder Trial/Head Trial Assembly

If the angle is not 135°, select the revision trial insert and lightly tap into position using the impaction rod. Open the sterile ball cylinder trial. Check that the peg screw is appropriately positioned and that the expandable sphere is not expanded. If necessary, adjust by using the T-handle to turn the screw counterclockwise.

Insert the ball cylinder neck trial into the trial head by aligning the slot on the neck trial with the nub inside the central barrel of the trial head. Use sufficient pressure to overcome the interference spring and “lack” the trial neck into the trial head. Insert the trial head/neck assembly into the revision trial insert.

**Note:** Engage the trial head/ball cylinder trial into the seated revision trial insert by hand. Proper engagement will be accompanied by a positive “snap”. Verify that the trial head is resting on the osteotomy. If it is not, the head and/or ball cylinder trial is not properly seated.

Take the trial head handle and insert the two prongs into the head (Figure 94).

Use the trial head handle to rotate and angle the assembly to achieve optimal version and coverage of the osteotomy (Figure 95).

### Locking The Trial Head Position

Once the head trial position is set, feed the T-handle driver through the trial head handle and lock the assembly in place with a clockwise turn of the peg screw. When tightening the T-handle driver, take care to apply counter pressure to the handle, stabilizing the implant (Figure 96).

If an eccentric head is used, the position of the arrow (indicating maximum distance from the center of the head) needs to be marked on the bone with a sterile pen. The head can now be removed. The revision trial insert and the ball cylinder trial can now be removed by gently prying up with the ball taper distractor (Figure 97).

**Note:** When removing the adjustable neck trial/revision trial insert assembly be careful to avoid changing the orientation of the recorded angle of the ball trial cylinder.

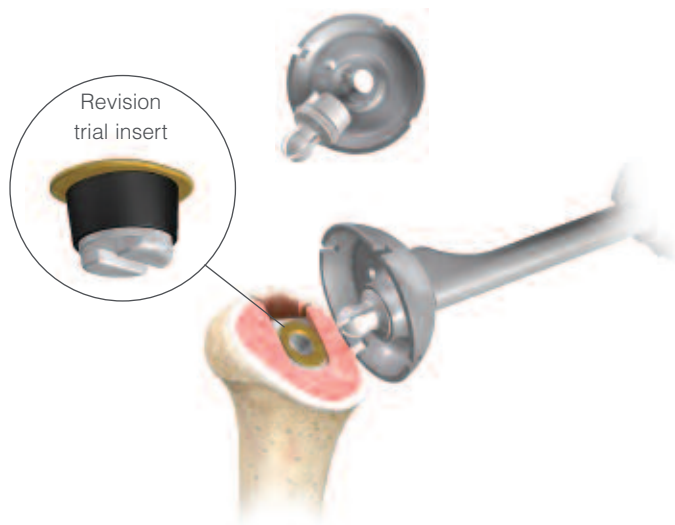


Figure 94

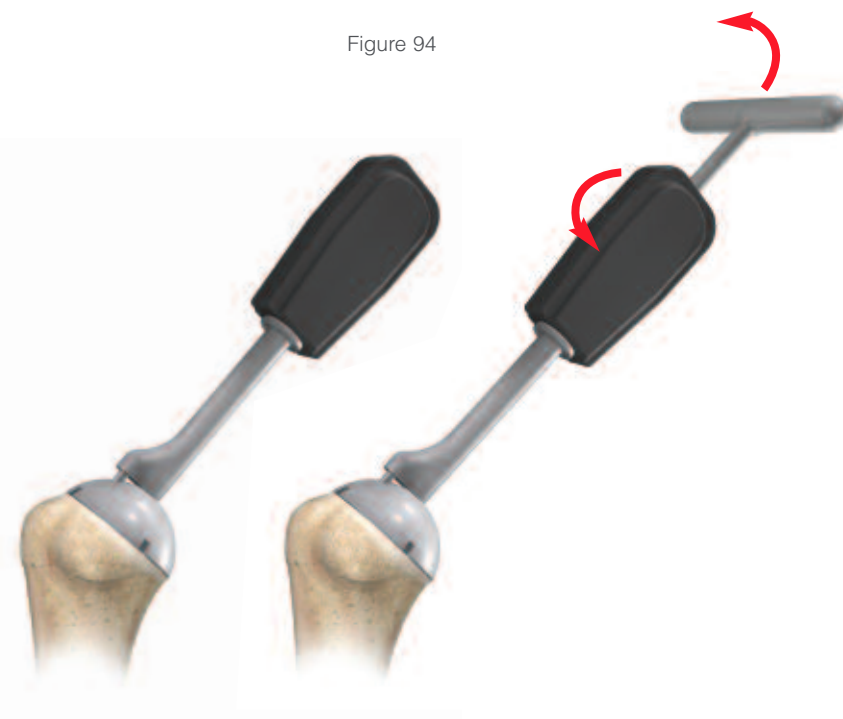


Figure 95

Figure 96



Figure 97

# Revision Procedure



Figure 98



Figure 99



Figure 100



Figure 101

## Revision Transfer Block

Once the trial is successfully complete the only change from the primary technique (for transferring neck angle) is the use of the revision transfer block. Place the revision transfer block (gold end up) inside the impaction block and secure it into the mating features (Figure 98).

*Note: The revision transfer block has two ends. The gold end is used for recording the angle on the trial, the silver is used to transfer the angle to the definitive assembly.*

Firmly tighten the knob on the front of the block and continue with the procedure outlined on the primary section of this guide, using the revision transfer block (Figures 54 - 57 on pages 27 - 28).

Remove the revision transfer block and place it silver end up, back in the impaction block (Figure 99). Repeat steps from the primary section, (Figures 61 - 62 on page 30).

The definitive linking component assembly is removed from the revision transfer block and tapped into the implanted stem with 3-4 controlled impactions, using the impactation rod (Figure 100). Place the head onto the assembly and use the Celcon humeral head impactor to impact into its final position.

*Note: Verify the head taper engages before the bottom surface of the head hits the osteotomy surface. If the head contacts bone before the taper engages then a small amount of bone must be removed.*

If an eccentric head has been selected, mark the arrow position (found on the non-articular surface) using a sterile marker on top of the head. Align with the mark previously made on the bone surface (Figure 101). Impact, using the Celcon humeral head impactor.

# Key Tips Summary

## Humeral Preparation

*Failure to sufficiently release the capsule from the humeral neck to the posterior-inferior area will make it very difficult to bring the head up and out of the glenoid fossa.*

*Using a rongeur or other instrument, remove any unwanted osteophytes to return proximal humerus to near native anatomy.*

*There is only one plane that is exactly in alignment with the anatomic neck. It is therefore critical that the periphery of the hooded template be parallel to the anatomic neck and then the pin is drilled into the center of the head.*

*Power reaming of the humeral canal should be avoided as it may remove more bone than necessary.*

## Broaching

*Be cautious if cancellous bone is soft. Do not drive the broach handle rocker bar into soft bone, the rocker bar should just touch or sit slightly above the osteotomy.*

*If the broach handle rocker bar does not just touch or sit slightly above the cut osteotomy surface, do not try to aggressively drive it down. Rather, remove the broach and then pass the reamer deeper into the canal (further cutting with the osteotome may be needed). Then seat the broach again and remove any osteophytes.*

*If utilizing the impaction bone grafting technique, it is important that it is done at the time the trial/broach is inserted into the humerus. This will ensure proper positioning of the stem and head trials and will translate correctly to the final implant. Impaction bone grafting at the point of final implant insertion can force the implant into an incorrect position.*

## Glenoid Preparation

*Protecting the humeral osteotomy prior to initiating glenoid preparation, cover the humeral osteotomy surface with an osteotomy cover. This will help avoid damaging the proximal humerus.*

*It may, on occasion, be necessary to remove more of the labrum and capsule to provide the necessary glenoid exposure.*

*Take care to preserve subcondral bone and avoid over reaming the glenoid since this will reduce the area of the glenoid face and the depth of the glenoid vault.*

*Glenoid component loosening or excessive wear may occur if the glenoid component lacks sufficient bone support.*

*If the scapula is penetrated by the glenoid peripheral hole drill, the cement should not be pressurized.*

*Typically bone from the glenoid drill is often too granular to fit between the fins of the anchor peg glenoid. The bone paste from reaming the glenoid or bone from the cancellous region of the humeral head osteotomy works best.*

*Excessive cement extruding from the drilled holes and lying between the prosthesis and glenoid fossa is undesirable. It may create an uneven mantle for the glenoid prosthesis, and the cement may fragment with repetitive loading and become loose in the joint, causing damage to the high-density polyethylene surface.*

*Cement injected under high pressure by a syringe technique may result in cement extruding from the cancellous walls of the peripheral holes into the central anchor peg hole, which could preclude proper seating of the component. Ensure central hole is clear prior to implant insertion.*

# Key Tips Summary

## Humeral Trialing

*Be sure to ream until the calcar reamer bottoms out on the alignment guide. DO NOT USE POWER. This ensures a 135 degree osteotomy angle and that there is a 2 mm countersink of the broach.*

*If an eccentric head achieves better coverage than a standard head, the alignment guide must be loosened to adjust eccentricity, then retightened. The entire humeral assembly is then removed with the broach removal tool.*

*For the variable neck trial, loosen the screw so that approximately one thread can be seen through the cut out inside of the trial.*

*Verify that the trial head is resting on the osteotomy. If it is not, the head and/or ball cylinder is not properly seated.*

*When tightening the variable neck trial locking screw with the T-handle driver, take care to apply counter pressure to the handle, stabilizing the implant.*

*The position of the trial head can be adjusted by re-engaging the trial head handle and T-handle driver and slightly loosening the locking screw. Once the new head orientation is obtained, retighten the screw.*

## Component Impaction

*Do not use the Mayo stand or other non-rigid surface.*

*Let the tip slide into position without significant force. Align the tip of the impactor rod into the locked neck trial. Jamming the impactor rod could disorient the "locked" neck position.*

*Do not change the size of the humeral implant component once the neck position has been recorded by the positioning dome. This will cause the final head/neck position to be inaccurate.*

*If a long revision stem is used, it will be necessary to move the impaction stand to the edge of the table so that the stem of the prosthesis can hang off the table.*

*Position the impaction tower so that the impaction rod is orientated toward the user.*

*Tapping the impactor rod lightly a few times will lock the tapers in position prior to full impaction.*

*When impacting the final head it is important to only use the Celcon humeral head impactor, as this ensures correct head impaction without dislodgement of any portion of the ball taper.*

*If a fixed neck and a standard (non eccentric) head are used, directly place the humeral implant component into the impaction tower. It is not necessary to mount the trial broach in the impaction tower. If an eccentric head is used, then mounting of the trial broach in the impaction tower is necessary to determine positioning of eccentricity.*



# Key Tips Summary

## Implant Insertion

*If impaction grafting is performed it should be done at the time of the use of the trial broach and before final recording of the trial ball taper or fixed angle taper. Use of impaction grafting will in many cases change the orientation of the stem in the canal and result in a change in the orientation of the head to the osteotomy surface.*

*To assess final positioning of the humeral component the osteotomy surface should be perfectly covered from front to back by the head, and the version should be anatomic for the patient.*

## Revision

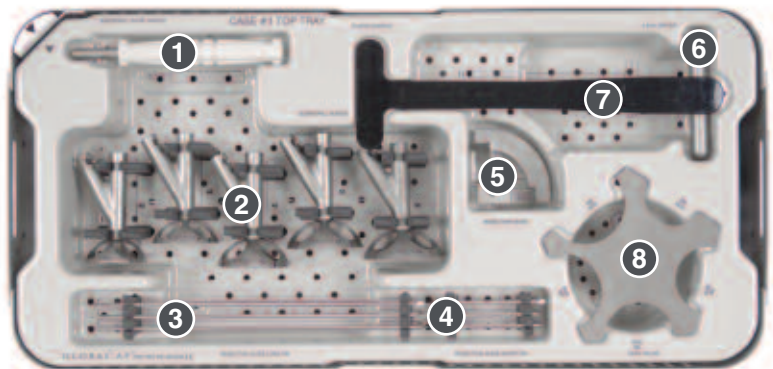
*Verify that the head taper engages the neck before the bottom surface of the head hits the osteotomy surface. If the head contacts bone before the taper engages then a small amount of bone must be removed.*

*Engage the trial head/ball cylinder trial into the seated revision trial insert by hand. Proper engagement will be accompanied by a positive “snap”. Verify that the trial head is resting on the osteotomy. If it is not, the head and/or ball cylinder trial is not properly seated.*

*When removing the adjustable neck trial/revision trial insert assembly be careful to avoid changing the orientation of the recorded neck angle.*

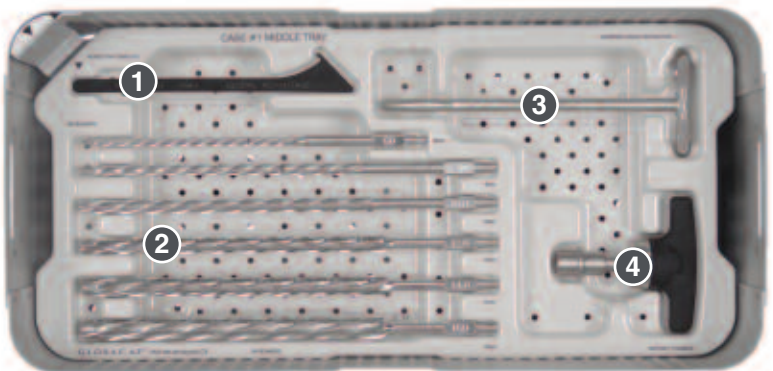
# Instrument Case #1

- 1 Head Sizers/Drill Guide Handle
- 2 Head Sizer/Drill Guide Sizes 40 - 56 mm
- 3 Resection Guide Long Pins
- 4 Resection Guide Short Pins
- 5 Resection Guide
- 6 4.5 mm Trial Driver
- 7 Plastic Darrach
- 8 Head Gauge



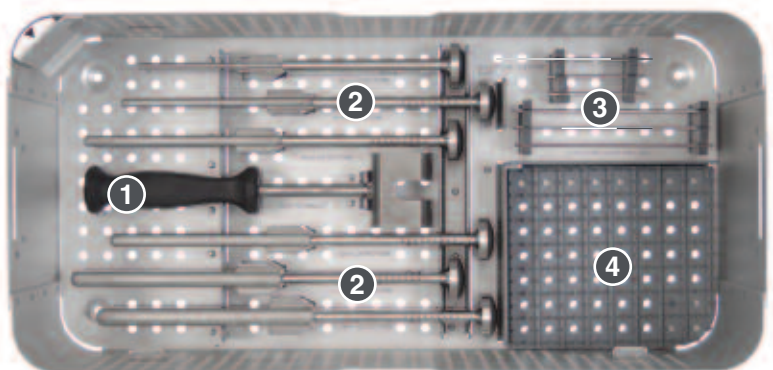
TOP TRAY

- 1 Humeral Head Cutting Guide
- 2 Reamers Sizes 6 - 16 mm
- 3 Modified Crego Retractor
- 4 Ratchet T-Handle



MID TRAY

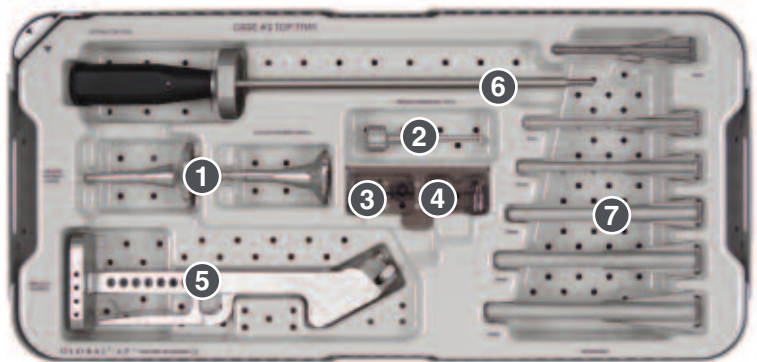
- 1 Slotted Mallet
- 2 Osteotomes Sizes 6 - 16 mm
- 3 Osteotome Guide Pins Short/Long
- 4 Osteotomy Covers Small/Large



BASE

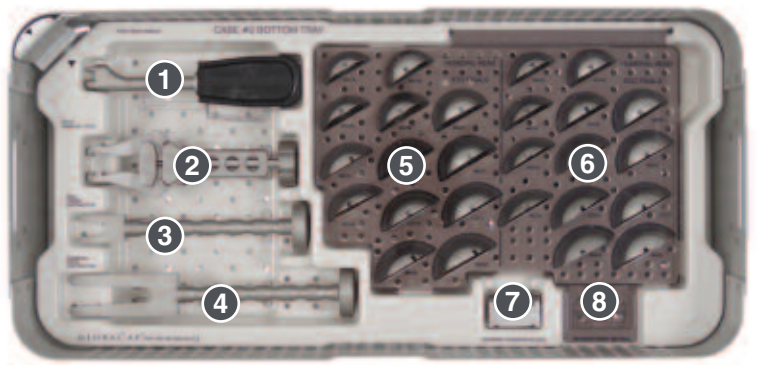
# Instrument Case #2

- 1 Calcar Reamers  
Small/Large
- 2 Broach Removal Tool
- 3 Broach Handle  
Adapter
- 4 Calcar Alignment  
Guide
- 5 Broach Handle
- 6 Extractor Tool
- 7 Humeral Stem Broach  
Trials Sizes 6 - 16 mm



TOP TRAY

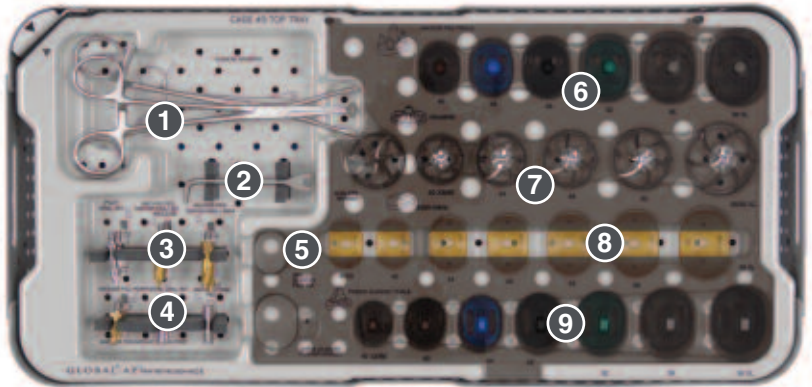
- 1 Trial Head Handle
- 2 Head Removal Tool
- 3 Ball Taper Distractor
- 4 Humeral Head  
Distractor
- 5 Humeral Head Trials
- 6 Humeral Head  
Eccentric Trials
- 7 Revision Transfer Block
- 8 Revision Fixed 135° Trial



BASE

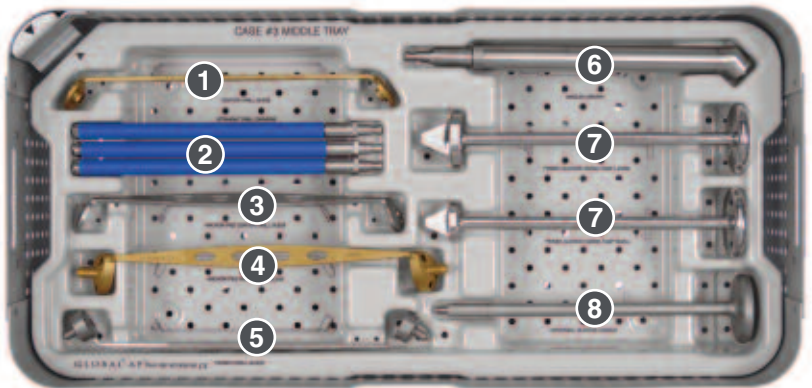
# Instrument Case #3

- 1 Glenoid Grasper/Anti-Rotation Peg Grasper
- 2 Drill/Reamer Wrench
- 3 Pilot Hole Drill Bits/Anchor Peg Center Hole Drill Bits
- 4 Anchor Peg Peripheral Hole Drill Bits/Anti-Rotation Posts
- 5 Glenoid Pushers Small/Large
- 6 Anchor Peg Trial Glenoids Sizes 40 - 56 mm
- 7 Reamers Sizes 40 - 56 mm
- 8 Glenoid Sizers Sizes 40 - 56 mm
- 9 Finned Trial Glenoids Sizes 40 - 56 mm



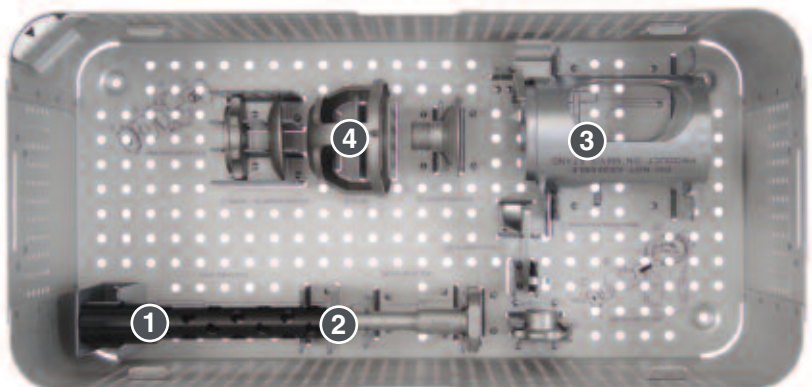
TOP TRAY

- 1 Anchor Peg Center Drill Guide
- 2 Straight Drill Drivers
- 3 Keeled Glenoid Center Drill Guide
- 4 Anchor Peg / Peripheral Drill Guide
- 5 Keeled Glenoid Peripheral Drill Guide
- 6 Angled Driver
- 7 Finned Glenoid Sizing Tamps Small/Large
- 8 Universal Glenoid Handle



MID TRAY

- 1 Head Impactor
- 2 Taper Impactor
- 3 Impaction Stand Base
- 4 Orientation Device



BASE



# Ordering Information

## Instruments

140129	3.2 mm x 9 inch Short Threaded Guide Pin	2234-89-000	Clear Glenoid Sizer Disk 40 mm
2128-01-006	Humeral Reamer 6 mm	2234-90-000	Clear Glenoid Sizer Disk 44 mm
2128-01-008	Humeral Reamer 8 mm	2234-91-000	Clear Glenoid Sizer Disk 48 mm
2128-01-010	Humeral Reamer 10 mm	2234-92-000	Clear Glenoid Sizer Disk 52 mm
2128-01-012	Humeral Reamer 12 mm	2234-93-000	Clear Glenoid Sizer Disk 56 mm
2128-01-014	Humeral Reamer 14 mm	2234-95-000	Clear Glenoid Sizer Disk 56 XL
2128-01-016	Humeral Reamer 16 mm	2235-72-000	Drill Wrench
2128-61-000	Glenoid Reamer 40 XS/40	2235-75-000	Angled Driver
2128-61-001	Glenoid Reamer 44 mm	2236-03-000	Universal Glenoid Handle
2128-61-002	Glenoid Reamer 48 mm	2236-21-000	Small Glenoid Pusher
2128-61-003	Glenoid Reamer 52 mm	2236-22-000	Large Glenoid Pusher - Angled
2128-61-004	Glenoid Reamer 56/56 XL	2236-26-000	Modified Crego Retractor
2128-61-005	Nubless Glenoid Reamer	2236-31-000	Celcon Darrach Retractor
2128-61-006	Center Drill Guide	2236-80-000	Anchor Peg Glenoid Trial 40 mm
2128-61-007	Pilot Hole/Peripheral Keeled Glenoid Drill Bit	2236-80-010	Anchor Peg Glenoid Trial 44 mm
2128-61-010	Keeled Glenoid Antirotation Peg	2236-80-020	Anchor Peg Glenoid Trial 48 mm
2128-61-011	Anti-rotation Peg Grasper	2236-80-030	Anchor Peg Glenoid Trial 52 mm
2128-61-012	Straight Drill Driver	2236-80-040	Anchor Peg Glenoid Trial 56 mm
2128-61-014	Keeled Glenoid Drill Guide	2236-80-050	Anchor Peg Glenoid Trial 56 XL
2128-61-015	Keeled Glenoid Tamp - Small	2236-80-060	Anchor Peg Center Drill Guide
2128-61-016	Keeled Glenoid Tamp - Large	2236-80-070	Anchor Peg Center Drill Bit 48/52/56 mm
2128-61-017	Glenoid Grasper	2236-80-075	Anchor Peg Center Drill Bit 40/44 mm
2128-61-024	Keeled Glenoid Trial 40 XS	2236-80-080	Anchor Peg Peripheral Drill Guide
2128-61-025	Keeled Glenoid Trial 40 mm	2236-80-090	Anchor Peg Peripheral Drill Bit
2128-61-026	Keeled Glenoid Trial 44 mm	2236-80-091	Anchor Peg Antirotation Peg
2128-61-027	Keeled Glenoid Trial 48 mm	2490-95-000	Fixation Pins 1/8 DIA X 3
2128-61-028	Keeled Glenoid Trial 52 mm	2810-01-003	Slotted Mallet
2128-61-029	Keeled Glenoid Trial 56 mm	2130-00-000	Ball Cylinder Trial Assembly
2128-61-030	Keeled Glenoid Trial 56 XL	2130-00-135	Fixed 135 Degree Neck Trial
2128-61-070	Ratchet T-Handle	2130-01-000	Revision Transfer Block
2128-61-071	Celcon Humeral Head Cutting Guide	2130-01-006	Osteotome 6 mm
2230-80-010	Humeral Head Sizer/Drill Guide 40 mm	2130-01-008	Osteotome 8 mm
2230-80-020	Humeral Head Sizer/Drill Guide 44 mm	2130-01-010	Osteotome 10 mm
2230-80-030	Humeral Head Sizer/Drill Guide 48 mm	2130-01-012	Osteotome 12 mm
2230-80-040	Humeral Head Sizer/Drill Guide 52 mm	2130-01-014	Osteotome 14 mm
2230-80-050	Humeral Head Sizer/Drill Guide 56 mm	2130-01-016	Osteotome 16 mm
2230-80-060	Humeral Head Sizer/Drill Guide Handle	2130-01-017	Large Osteotomy Cover
2234-88-000	Clear Glenoid Sizer Disk 40 XS	2130-01-018	Small Osteotomy Cover



# Ordering Information

2130-01-019	Head Measurement Gauge	2130-24-110	General Case & Inserts
2130-01-020	Resection Guide Assembly	2130-24-120	General Base
2130-01-029	Broach Handle Adapter	2130-24-130	General Case Lid
2130-01-030	Broach Handle	2130-24-140	General Top Insert
2130-01-040	Impaction Block Assembly	2130-24-150	General Middle Insert
2130-01-050	Orientation Device Assembly	2130-40-500	Humeral Head 40 x 15 Trial
2130-01-055	Taper Impactor	2130-40-510	Humeral Head 40 x 18 Trial
2130-01-060	Small Calcar Reamer 40/44 mm	2130-40-600	Humeral Head 40 x 15 Eccentric Trial
2130-01-065	Large Calcar Reamer 48/52/56 mm	2130-40-610	Humeral Head 40 x 18 Eccentric Trial
2130-01-070	Calcar Alignment Guide Assembly	2130-44-500	Humeral Head 44 x 15 Trial
2130-01-075	Extraction Handle	2130-44-510	Humeral Head 44 x 18 Trial
2130-01-080	Head Removal Tool	2130-44-520	Humeral Head 44 x 21 Trial
2130-01-085	Broach Removal Tool	2130-44-600	Humeral Head 44 x 15 Eccentric Trial
2130-01-100	4.5 mm Trial Driver	2130-44-610	Humeral Head 44 x 18 Eccentric Trial
2130-01-105	Trial Head Handle	2130-44-620	Humeral Head 44 x 21 Eccentric Trial
2130-01-110	Ball Taper Distractor	2130-48-500	Humeral Head 48 x 15 Trial
2130-01-120	Humeral Head Distractor	2130-48-510	Humeral Head 48 x 18 Trial
2130-02-000	Revision Insert	2130-48-520	Humeral Head 48 x 21 Trial
2130-04-000	Head Impactor	2130-48-600	Humeral Head 48 x 15 Eccentric Trial
2130-06-000	Humeral Stem 6 mm Broach/Trial	2130-48-610	Humeral Head 48 x 18 Eccentric Trial
2130-08-000	Humeral Stem 8 mm Broach/Trial	2130-48-620	Humeral Head 48 x 21 Eccentric Trial
2130-10-000	Humeral Stem 10 mm Broach/Trial	2130-52-500	Humeral Head 52 x 15 Trial
2130-12-000	Humeral Stem 12 mm Broach/Trial	2130-52-510	Humeral Head 52 x 18 Trial
2130-14-000	Humeral Stem 14 mm Broach/Trial	2130-52-520	Humeral Head 52 x 21 Trial
2130-16-000	Humeral Stem 16 mm Broach/Trial	2130-52-600	Humeral Head 52 x 15 Eccentric Trial
2130-18-000	3.2 mm Osteotomy Guide Pin - Short	2130-52-610	Humeral Head 52 x 18 Eccentric Trial
2130-20-000	3.2 mm Osteotomy Guide Pin - Long	2130-52-620	Humeral Head 52 x 21 Eccentric Trial
2130-22-000	X-Ray Templates	2130-56-510	Humeral Head 56 x 18 Trial
2130-24-000	Humeral 1 Case & Inserts	2130-56-520	Humeral Head 56 x 21 Trial
2130-24-010	Humeral 1 Base	2130-56-610	Humeral Head 56 x 18 Eccentric Trial
2130-24-020	Humeral 1 Case Lid	2130-56-620	Humeral Head 56 x 21 Eccentric Trial
2130-24-030	Humeral 1 Upper Insert	2130-99-010	Humeral DNI Size 8
2130-24-040	Humeral 1 Middle Insert	2130-99-020	Humeral Porocoat® Porous Coating DNI Size 8
2130-24-060	Humeral 2 Case & Insert	2130-99-030	Standard Head DNI 48 x 18
2130-24-070	Humeral 2 Base	2130-99-040	Eccentric Head DNI 48 x 18
2130-24-080	Humeral 2 Case Lid	2130-99-050	Neck Assembly DNI Components
2130-24-090	Humeral 2 Top Insert		
2130-24-100	Humeral 2 Lower Insert		

# Ordering Information

## Implants

### Neck Implant Components

- 1130-00-000 Ball Taper Adjustable Neck Assembly
- 1130-02-000 Fixed 135 Degree Taper Assembly

### Humeral Stem Components

- 1130-06-000 Humeral Stem 6 mm
- 1130-08-000 Humeral Stem 8 mm
- 1130-10-000 Humeral Stem 10 mm
- 1130-12-000 Humeral Stem 12 mm
- 1130-14-000 Humeral Stem 14 mm
- 1130-16-000 Humeral Stem 16 mm

### PC Coated Humeral Stem Components

- 1130-06-200 Porocoat Coated Humeral Stem 6 mm
- 1130-08-200 Porocoat Coated Humeral Stem 8 mm
- 1130-10-200 Porocoat Coated Humeral Stem 10 mm
- 1130-12-200 Porocoat Coated Humeral Stem 12 mm
- 1130-14-200 Porocoat Coated Humeral Stem 14 mm
- 1130-16-200 Porocoat Coated Humeral Stem 16 mm

### Humeral Stem Revision Components

- 1130-08-010 Humeral Stem 8 mm Long
- 1130-10-010 Humeral Stem 10 mm Long
- 1130-12-010 Humeral Stem 12 mm Long
- 1130-14-010 Humeral Stem 14 mm Long

### Humeral Head Components

- 1130-40-500 Humeral Head 40 x 15
- 1130-40-510 Humeral Head 40 x 18
- 1130-44-500 Humeral Head 44 x 15
- 1130-44-510 Humeral Head 44 x 18
- 1130-44-520 Humeral Head 44 x 21
- 1130-48-500 Humeral Head 48 x 15
- 1130-48-510 Humeral Head 48 x 18
- 1130-48-520 Humeral Head 48 x 21
- 1130-52-500 Humeral Head 52 x 15
- 1130-52-510 Humeral Head 52 x 18
- 1130-52-520 Humeral Head 52 x 21
- 1130-56-510 Humeral Head 56 x 18
- 1130-56-520 Humeral Head 56 x 21
- 1130-40-600 Humeral Head 40 x 15 Eccentric
- 1130-40-610 Humeral Head 40 x 18 Eccentric
- 1130-44-600 Humeral Head 44 x 15 Eccentric
- 1130-44-610 Humeral Head 44 x 18 Eccentric
- 1130-44-620 Humeral Head 44 x 21 Eccentric
- 1130-48-600 Humeral Head 48 x 15 Eccentric
- 1130-48-610 Humeral Head 48 x 18 Eccentric
- 1130-48-620 Humeral Head 48 x 21 Eccentric
- 1130-52-600 Humeral Head 52 x 15 Eccentric
- 1130-52-610 Humeral Head 52 x 18 Eccentric
- 1130-52-620 Humeral Head 52 x 21 Eccentric
- 1130-56-610 Humeral Head 56 x 18 Eccentric
- 1130-56-620 Humeral Head 56 x 21 Eccentric

# Postoperative Protocol

## 1. The First Postoperative Day:

- a. Remove the shoulder immobilizer on the day of surgery or at the latest by the next morning. With the shoulder sling immobilizer removed, the patient may gently move the arm into comfortable positions.
- b. Perform passive flexion of the patient's arm up to 90 or 120 degrees or as far as is comfortable for the patient.
- c. An alternative technique uses CPM, which is instituted when the patient is transferred off the operating room table onto the recovery room bed. This allows continuous passive flexion of the arm up to 90 or 120 degrees or more.
- d. Instruct the supine patient on how to perform passive flexion of the arm using the other arm as a power source and/or through the use of a pulley and rope system attached to the overhead bed frame. At the extreme of flexion, hold the arm for a count of five. Each passive exercise should include five repetitions and be performed three to four times per day.
- e. Instruct the supine patient in how to develop passive external rotation stretching exercises with a three-foot stick. This is done to a level that is 10 degrees less than the degree of external rotation that was achieved in the OR after closure of the wound.
- f. Instruct the upright patient in performing the pendulum exercises three to four times per day.
- g. Encourage the patient to use the hand and arm for gentle everyday activities such as eating, brushing teeth, drinking liquids, etc.

## 2. On the Second and Third Postoperative Days:

- a. Continue the patient with passive flexion and external rotation exercises. If the surgeon prefers to use an overhead pulley, then instruct the patient to use an overhead pulley, in the upright position, to increase passive flexion and continue to use the arm for gentle living activities.
- b. Usually, dismiss the patient on the third day or when 90 to 120 degrees of passive flexion and external rotation of 10 to 15 degrees are achieved. Instruct the patient to continue exercises three to four times per day, seven days a week.
- c. Encourage the patient to continue using the arm for gentle daily living activities.

## 3. Remove the running subcutaneous sutures at two weeks.

## 4. Follow-up Visit (Four to Six Weeks):

- a. If the patient does not have sufficient passive motion (120 - 140 degrees), institute more stretching exercises, such as wall climbing, more overhead stretching with the pulley, the three-foot stick, etc.
- b. Encourage the patient to use the arm for progressive everyday activities.
- c. If the patient has weakness of the anterior deltoid, institute a specific exercise program which will strengthen the anterior deltoid in the supine position.

## 5. Subsequent Follow-up Visit (Six to Eight Weeks):

- a. Continue the stretching exercise of the shoulder three to four times per day.
- b. When the patient has sufficient passive range of motion, such as 120 to 140 degrees of flexion and 20 to 40 degrees of external rotation, institute strengthening exercises of the deltoid and rotator cuff muscles with Therabands. Gradually increase the resistance by using the different colors and strengths of Therabands. Strengthen the scapular stabilizer muscle, such as the trapezius muscle, by performing shoulder shrug exercises against weight. Strengthen the serratus anterior and rhomboid muscles by using wall push-ups and progressing to knee push-ups as indicated.

## 6. Carefully instruct the patient that keeping the shoulder loose and strong is a life-long ongoing rehabilitation program.







**Important:** This Essential Product Information sheet does not include all of the information necessary for selection and use of a 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. Rotator cuff tear arthropathy.

**Global C.A.P.™ is indicated for intact or repairable rotator cuff.**

4. Deformity and/or limited motion.

**Porocoat® Porous-Coated Components**

Porocoat porous-coated humeral stem prostheses are indicated for cemented or cementless use with fixation provided by biological tissue in-growth into the porous coating.

**Global C.A.P. is intended for cementless use only.**

**Cemented Components**

Humeral stem and Glenoid components labeled "For cemented use only" are indicated only for use with bone cement.

**Press-fit or Cemented Components**

Humeral stem prostheses without porous coating and labeled "for press fit or cemented use only" are indicated for press-fit uncemented use or for use with bone cement.

**Contraindications**

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

1. Active local or systemic infection.
2. Inadequate bone stock in the proximal humerus or glenoid fossa for supporting the components.
3. 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.

The following condition is a contraindication for total shoulder arthroplasty:

1. Absent, irreparable or nonfunctional rotator cuff or other essential muscles.

**Warnings and Precautions:**

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. The following conditions tend to adversely affect shoulder replacement implants: excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, disabilities of other joints.

**Adverse Events:**

The following are the most frequent adverse events after shoulder arthroplasty: change in position of the components, loosening of components, dislocation, infection, hematoma, pneumonia, and cardiovascular disorders.

Revised: 02/03/06



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