GLOBAL | AP™
ADJUSTABLE PROSTHESIS

Restoring Anatomy

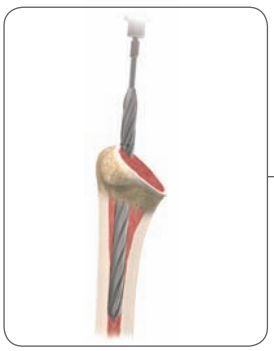
SURGICAL TECHNIQUE

never stop moving®

DePuy
companies of Johnson & Johnson

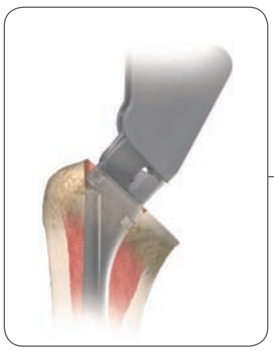
Global AP™ Adjustable Prosthesis Key Surgical Steps

Humeral Preparation and Head Selection

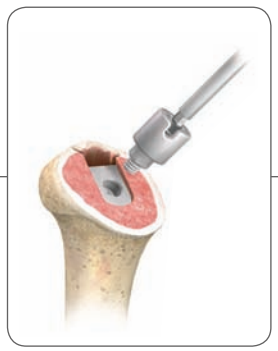


1. Humeral Canal Reaming

2. Proximal Humeral Preparation



3. Distal Humeral Broaching



4. Attaching the Calcar Alignment Guide

Fixed Angle Taper

Variable Angle Taper

Head Orientation Recording and Taper Impaction

1. Mount the trial stem ball cylinder assembly into the impaction block and tighten the front slide to secure in place.

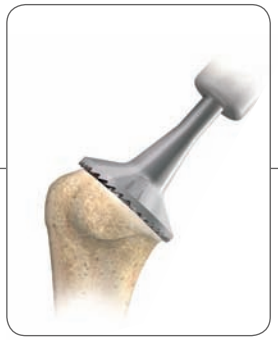
2. Withdraw the locking mechanism and mount the orientation device on top of the impaction stand.

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

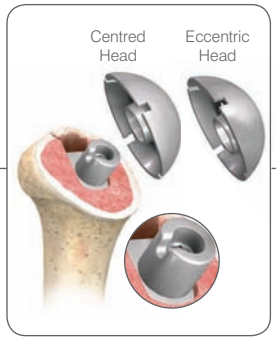
6. Reposition the orientation device with its recorded position. Re-insert the taper impactor and fully engage the tip of the impactor with the ball taper.

7. Strike the taper impactor with the slotted mallet 5-6 times with controlled hits.

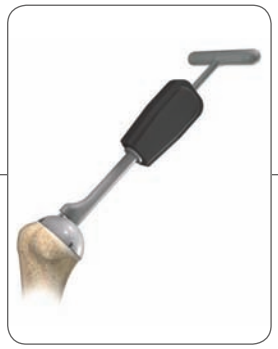
8. Remove the orientation device and place the selected head onto the impacted ball taper. If using an eccentric head, position the indicator on the underside of the head with the appropriate numeral on the face of the impaction stand.



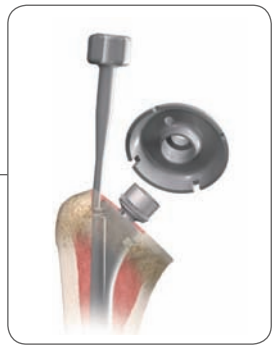
5. Confirm the Neck Resection and Ream



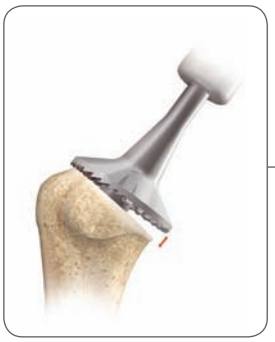
6. Trial Head Selection



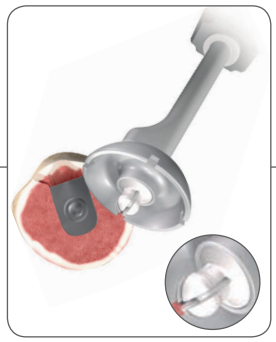
7. Locking the Trial Head Position



8. Trial Stem Removal



5. Confirm the Neck Resection



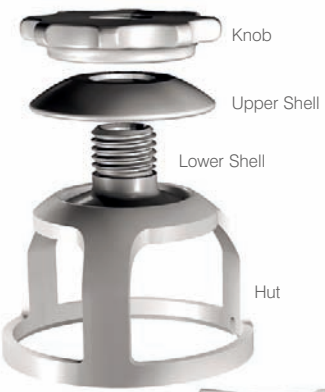
6. Variable Geometry Trial

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 orientation device assembly.

5. Remove the trial stem and insert the humeral stem implant into the impaction stand. Seat the stem sleeve and place the ball-taper loosely on top of the insert.

9. With the end of the plastic head impactor over the centre of the head, firmly impact the head 3 - 4 times using the slotted mallet.

Global AP™ Orientation Device



***'Power Tower'** Technology*

Global AP™ Impaction Block

GLOBAL | AP™
ADJUSTABLE PROSTHESIS

Welcome to the new Global AP™ (Adjustable Prosthesis) system. A system that has been developed by surgeons for surgeons by a world-leading design group including: Dr Ianotti (US), Dr Lafosse (France), Dr Rockwood (US), Dr Seebauer (Germany) and Dr Williams (US).

In a continued strive for excellence, the Global AP™ system has been evolved from 15 years clinical experience with the Global® and Global Advantage™ systems with a proven record of surgical success.[1] Global AP™ offers surgeons increased options, with a fixed 135˚ taper offering comparable outcomes to the existing Global Advantage™ system and a variable angle taper offering increased refinement to match the patient's anatomy. Both taper systems offer revisability of the head while retaining a well-integrated humeral stem.

This surgical technique outlines the design rationale and then follows a comprehensive overview of the soft tissue approach, bone resection and closure procedure. This system allows you to restore the joy of motion to your patients through accelerated recovery, improved function and enhanced survivorship.

The Global AP™ Adjustable Prosthesis System Surgeon Design Team


Dr Joseph Ianotti
USA


Dr Laurent Lafosse
France


Dr Ludwig
Seebauer
Germany


Dr Charles
Rockwood
USA


Dr Gerald Williams
USA

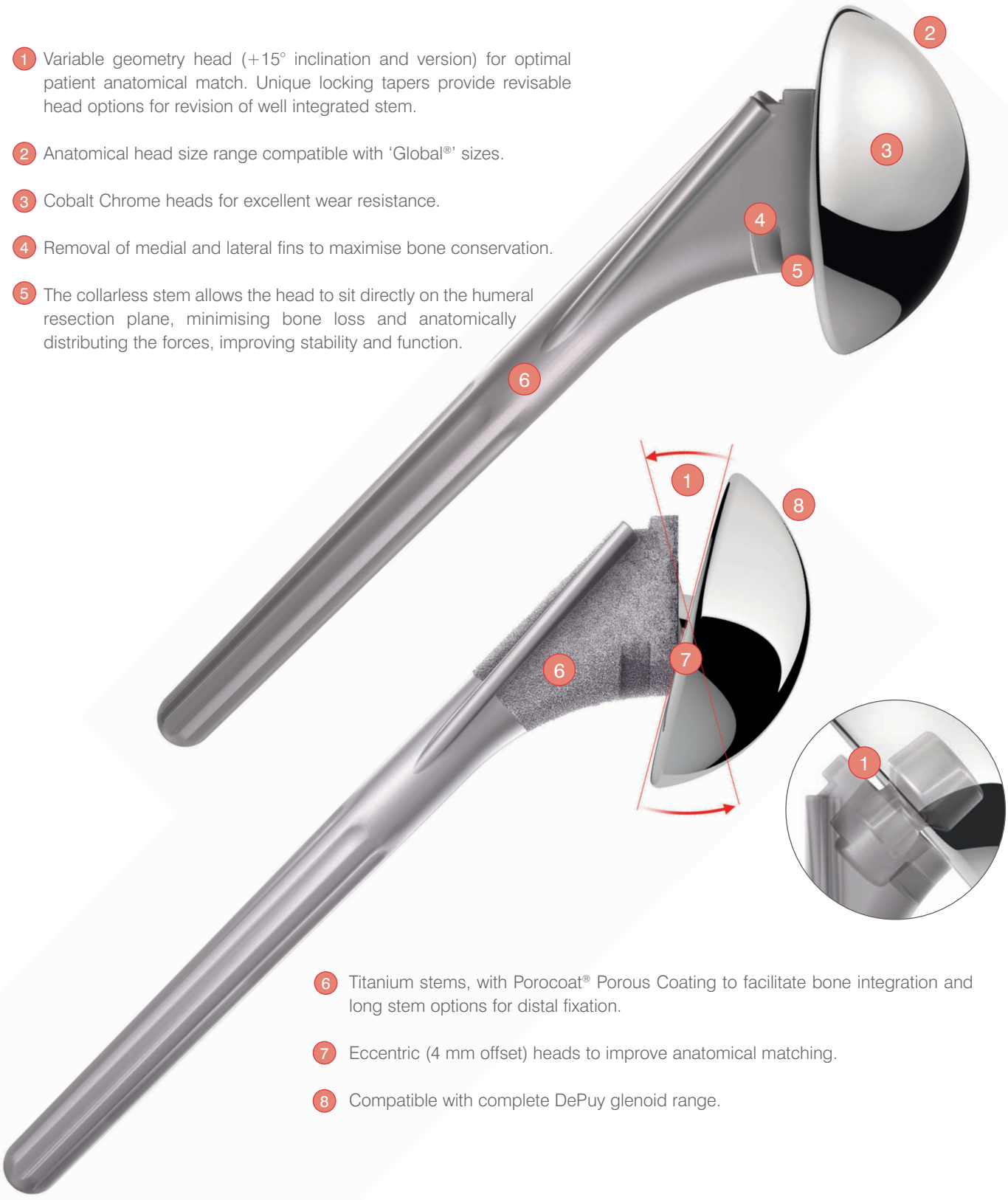
Contents

Design Rationale

GLOBAL | AP™
ADJUSTABLE PROSTHESIS

The Global AP™ press fit stem system is the outcome of 15 years clinical experience with the Global® shoulder prosthesis. Its fully anatomic design and intuitive surgical technique assist the surgeon to achieve appropriate joint biomechanics, implant stability and range of motion for the majority of patients.

1. Variable geometry head (+15° inclination and version) for optimal patient anatomical match. Unique locking tapers provide revisable head options for revision of well integrated stem.
2. Anatomical head size range compatible with 'Global®' sizes.
3. Cobalt Chrome heads for excellent wear resistance.
4. Removal of medial and lateral fins to maximise bone conservation.
5. The collarless stem allows the head to sit directly on the humeral resection plane, minimising bone loss and anatomically distributing the forces, improving stability and function.



6. Titanium stems, with Porocoat® Porous Coating to facilitate bone integration and long stem options for distal fixation.
7. Eccentric (4 mm offset) heads to improve anatomical matching.
8. Compatible with complete DePuy glenoid range.

GLOBAL® | A.P.G.
ANCHOR PEG GLENOID

6 SmartSet® GHV GENTAMICIN

1. Press fit central fluted peg supporting macro bony ingrowth and improved fixation.[2]
2. Peripheral minimally cemented pegs providing rotational stability.
3. Proven cross linked polyethylene technology (1020 XLK) reduces material wear, increasing implant longevity as compared with traditional UHMWPE.[3]
4. Sizing range and diametrical mismatch coupled with humeral head selection for best function and ease of use.
5. Anatomical sizing reduces the risk of overstuffing the joint.
6. SmartSet® GHV Gentamicin Bone Cement (SmartSet® GHV) with excellent fatigue strength,[4] has optimised handling characteristics[5] to help reduce possible incidence of cement debris.

Pre-operative Templating and Patient Positioning

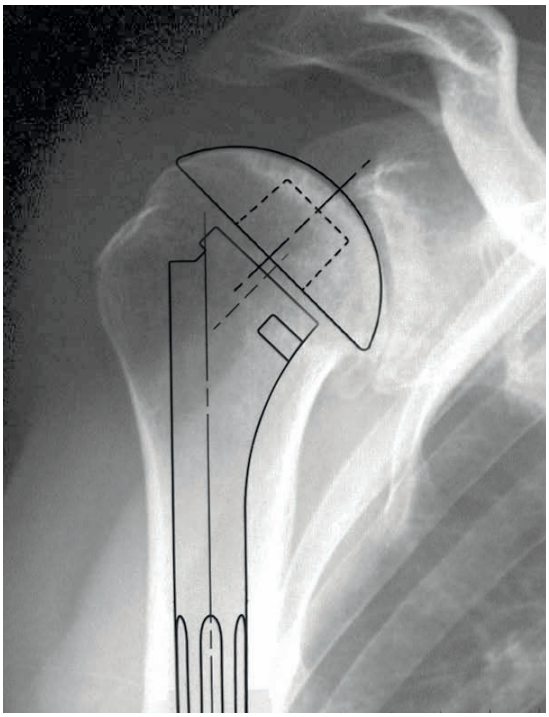


Figure 1

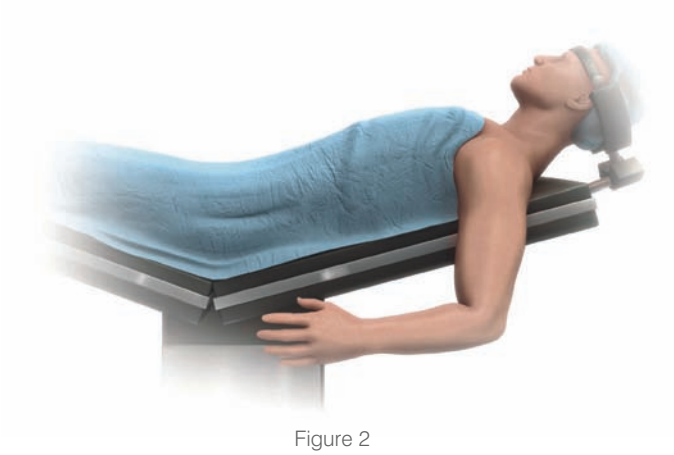


Figure 2

Figure 3

Pre-operative Templating

Pre-operative 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). Digital templating is also available (please consult your DePuy representative for further information).

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˚, the legs at around 20˚ and the knees in approximately 20˚ of flexion (Figure 2).

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 assistant's arm or mechanical 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

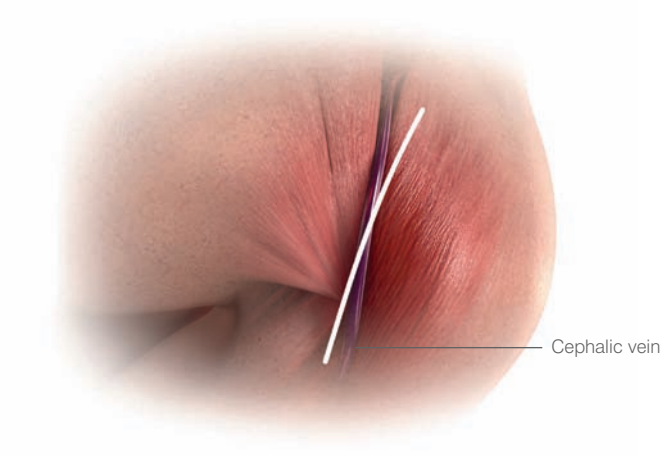


Figure 4

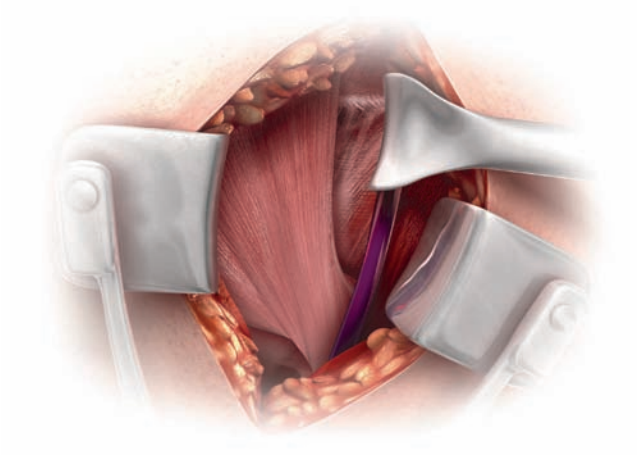


Figure 6

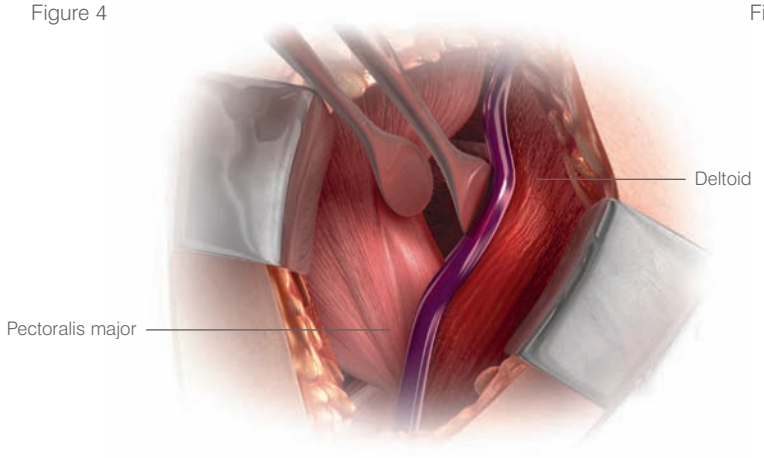


Figure 5

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 adjusted, depending on the exposure needed to provide adequate access and visualisation of the joint, and is determined by patient body anatomy.

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).

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

Exposure

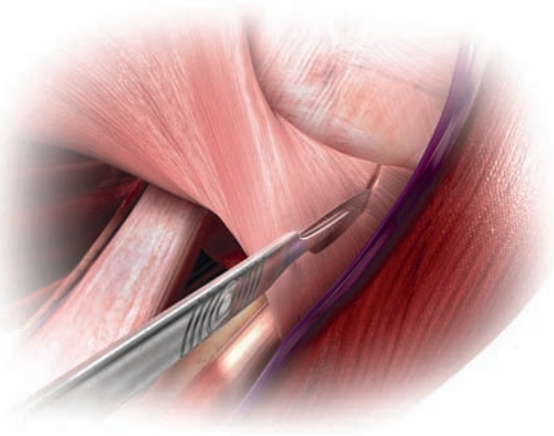


Figure 7

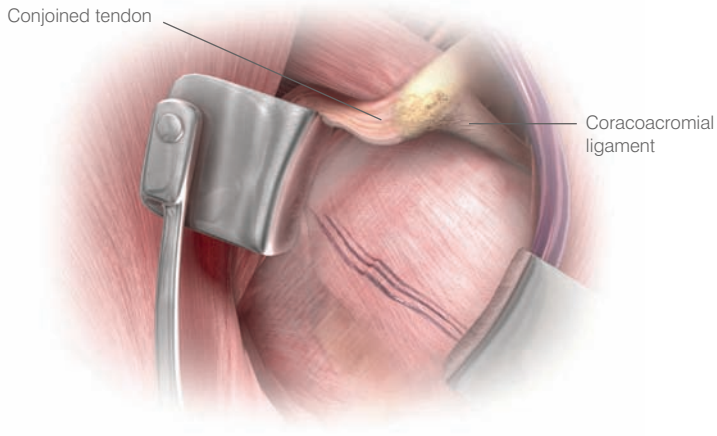


Figure 9

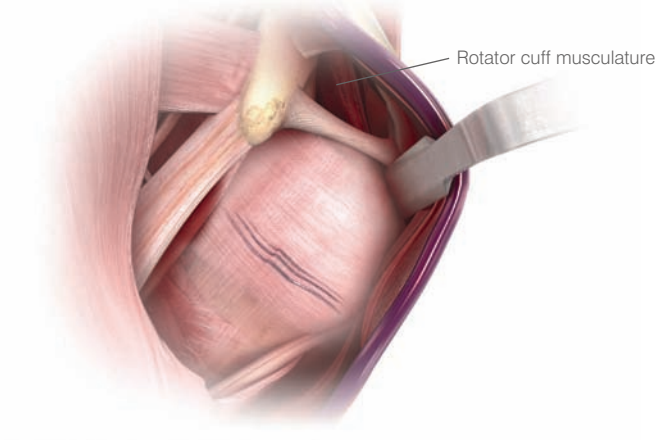


Figure 8

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 a scalpel (Figure 7). This will improve exposure of the inferior aspect of the joint and will not require repair during closure.

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 musculature is intact (Figure 8).

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

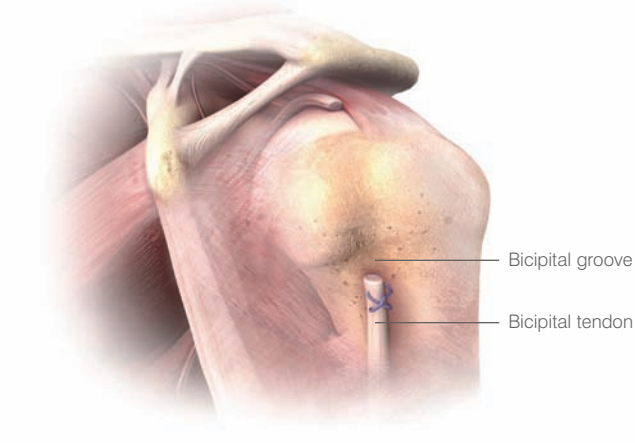


Figure 10

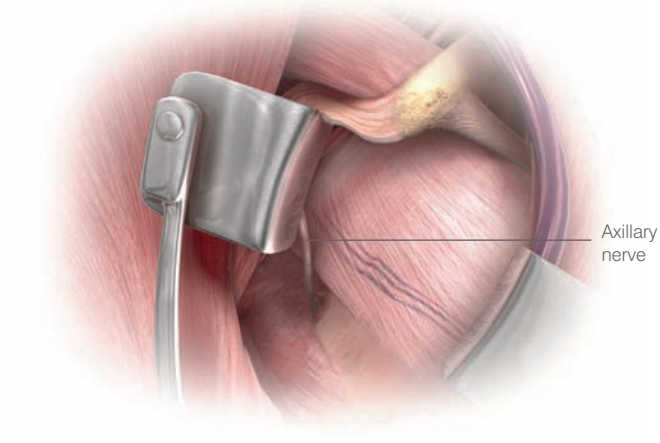


Figure 12

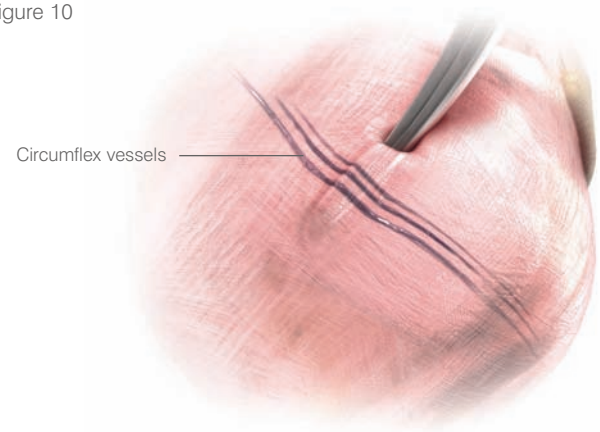


Figure 11

At this stage, the biceps tendon can be released from the bicepital groove, along the rotator interval at the base of the coracoid, down to the glenoid margin (Figure 10). Resect the long head of the biceps at the origin of the superior glenoid. Tenodese the biceps tendon to the bicepital groove.

Management of the Anterior Humeral Circumflex Vessels

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

Management of the Musculocutaneous and Axillary Nerves

It is important to be aware of the musculocutaneous nerve, which penetrates the coracobrachialis muscle 2.5 - 5 cm 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 latisimus dorsi tendon. This is especially important as it will protect the delicate axillary nerve and will define and expose the inferior capsule.

Subscapularis Tendon Release

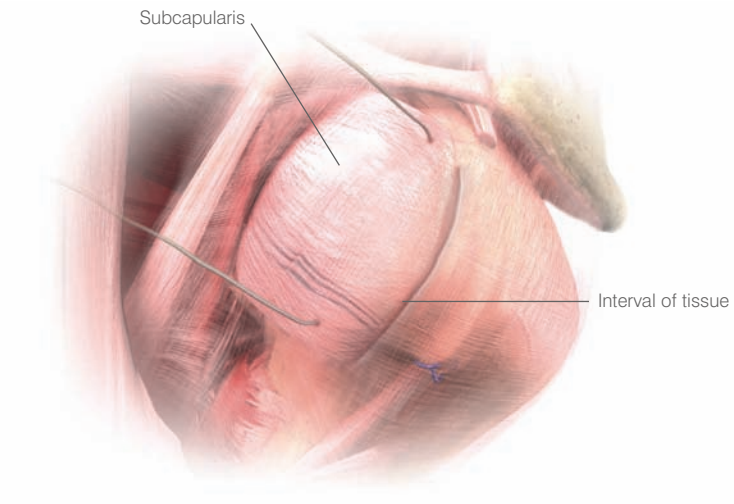


Figure 13

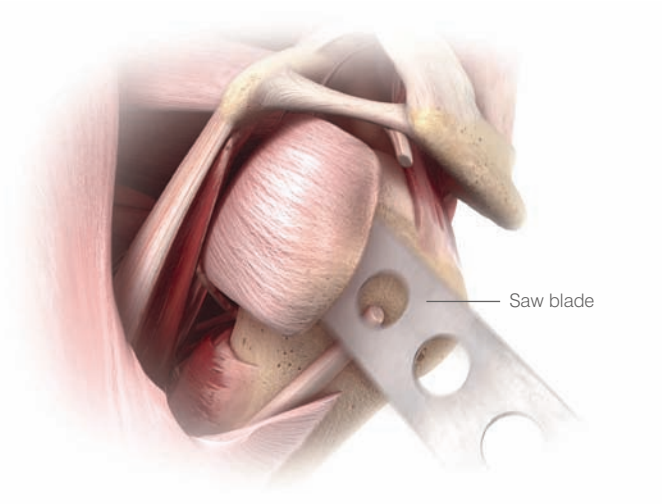


Figure 14

There are several methods to release the subscapularis. As a general guide, the following approaches will allow 40˚ or more of external rotation and correct internal rotation contraction:

- Intratendinous incision or lesser tuberosity osteotomy, performed when passive external rotation is 20˚ or more. On closure, the repair is made anatomically.
- Release from the lesser tuberosity, performed if external rotation is greater than -30˚, but less than 20˚. On closure, the tendon is advanced and repaired to the anatomic neck.
- Z-lengthening, performed if external rotation is less than -30˚. On closure the tendon is repaired in a z-lengthened state with the underlying anterior capsule.

This technique will only detail the first technique mentioned, a lesser tuberosity osteotomy.

First, create a complete interval of tissue between the lateral part of the subscapularis to define its attachment to the lesser tuberosity. This will define the subscapularis. Pass a suture through the tendenous portion of the subscapularis (Figure 13).

Move the arm into internal rotation to improve access to the lesser tuberosity. Introduce the saw blade at the interval created at the insertion side of the subscapularis and resect approximately 3 - 4 mm of the lesser tuberosity (Figure 14).

Capsule Release and Humeral Head Dislocation

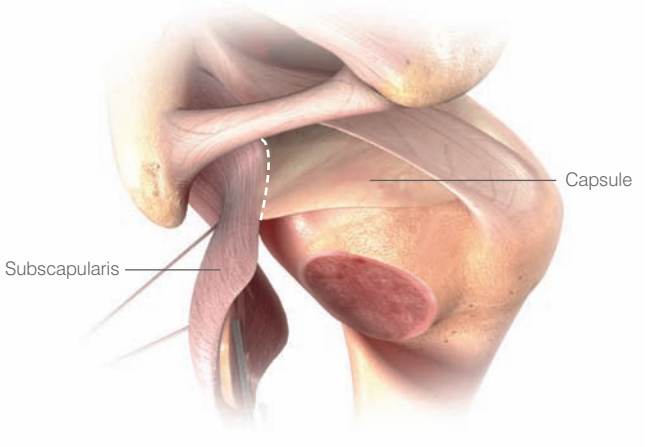
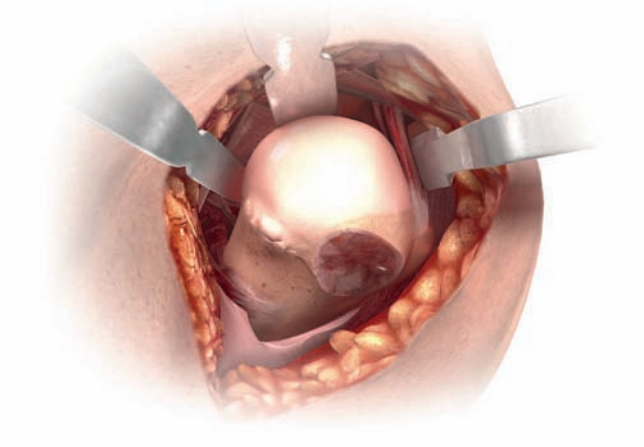


Figure 15



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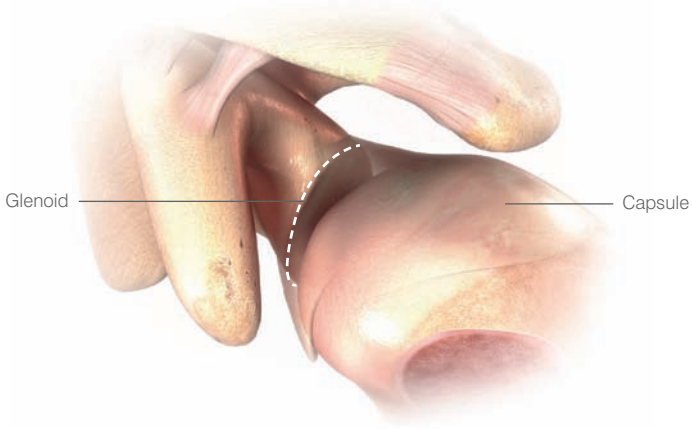


Figure 16

Separate the capsule from the subscapularis, inferiorly and medially, using a 15 mm blade and long handle. Release the rest of the anterior capsule from the subscapularis to the glenoid rim.

Release the coracohumeral ligament from the base of the coracoid. This will completely free the subscapularis from the inferior capsule. (Figure 15).

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

Note: Failure to sufficiently release the capsule will make it very difficult to bring the head up and out of the glenoid fossa.

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 visualise 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.

Guided Humeral Head Preparation and Resection

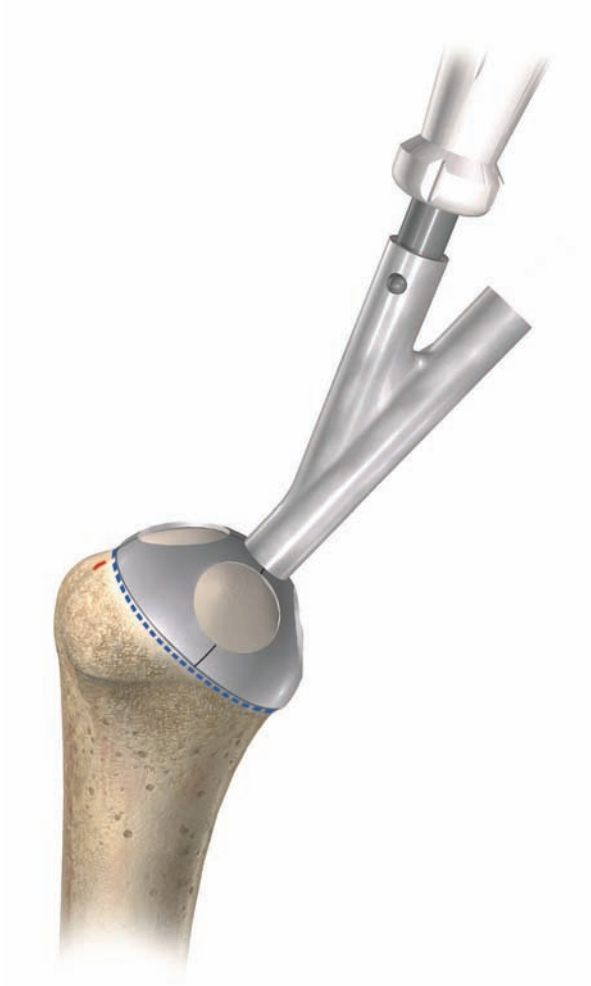


Figure 18

Figure 19

Assessing the Head Size

With a curved Crego or reverse Hohmann retractor placed along the anatomic neck superiorly to protect and retract the posterior-superior rotator cuff, mark the most superior point of the articular margin or anatomic neck with electrocautery or a marking pen.

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

Assemble the humeral head sizer (of the diameter determined during preoperative templating) to the sizer/drill guide handle. Place the sizer assembly over the humeral articular surface and align its superior mark with the mark on the humeral head. The rim of the head sizer should be parallel with the anatomic plane of the humerus (Figure 18). If the inferior articular margin is 3 mm below the rim of the sizer, the greater head height may be required. If the rim overlaps the articular margin, the lesser head height may be required.

Identifying the Centre 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 19). Remove the sizer and complete the axes.

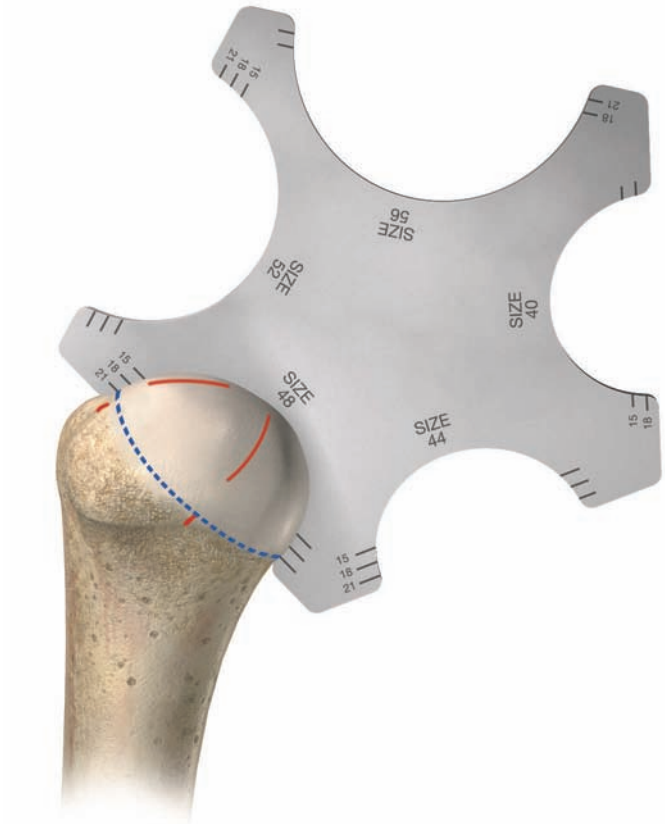


Figure 20

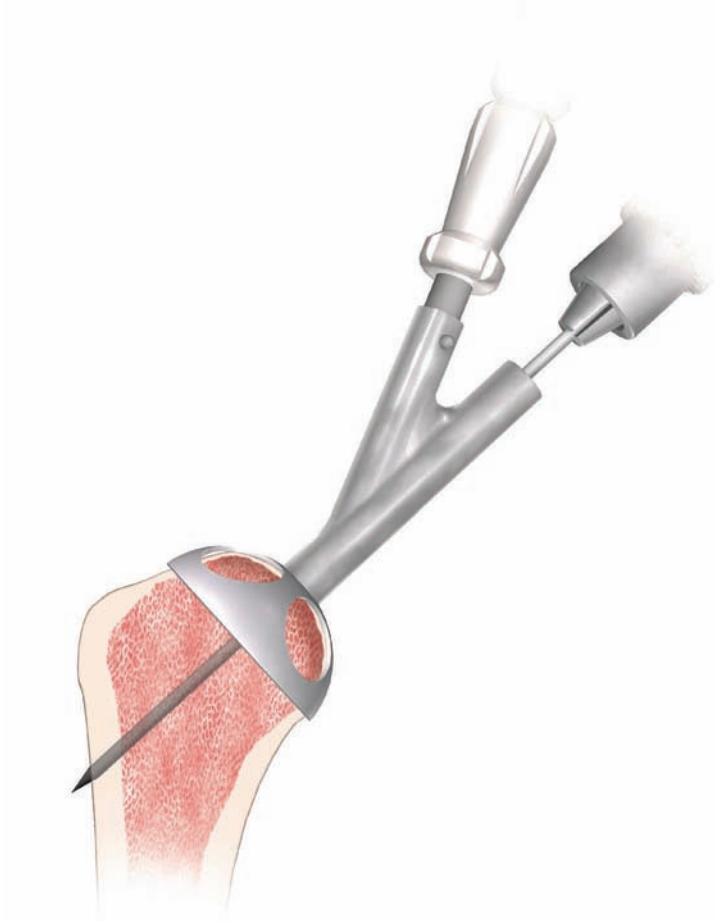


Figure 21

Visually assess the intersection to ensure the centre of the humeral head has been correctly identified. If not, repeat the previous steps. Use the head gauge to confirm the humeral head diameter and thickness (Figure 20).

Replace and centre the humeral sizer over the humeral head. Drill the threaded guide pin through the centre of the cannulated sizer and into the humeral head (Figure 21).

The tip of the guide pin should penetrate the lateral cortex of the humerus to prevent the guide pin from migrating in cancellous bone. Be careful not to penetrate the axillary nerve with the threaded guide pin once it exits the lateral cortex. Remove the humeral sizer leaving the guide pin in place.

Guided Humeral Head Preparation and Resection

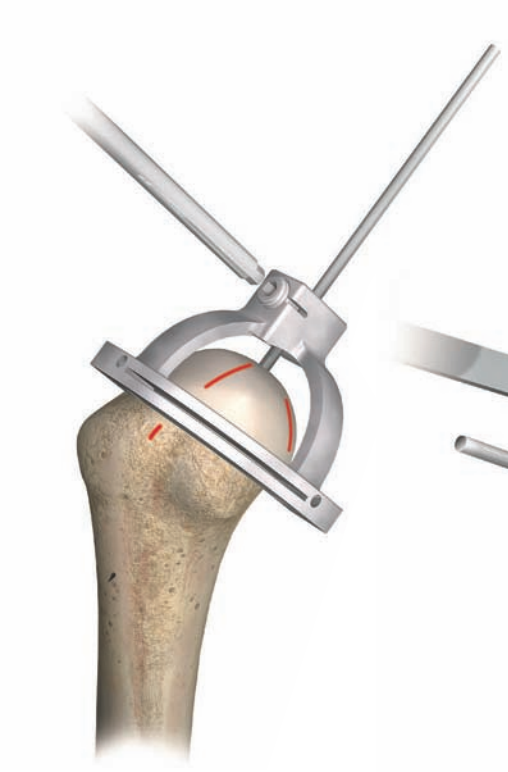


Figure 22

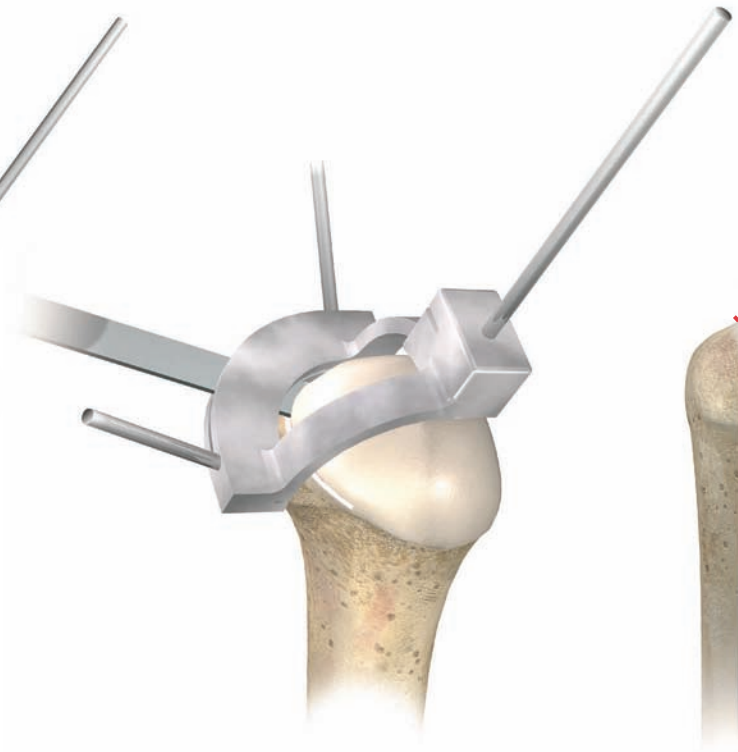


Figure 23

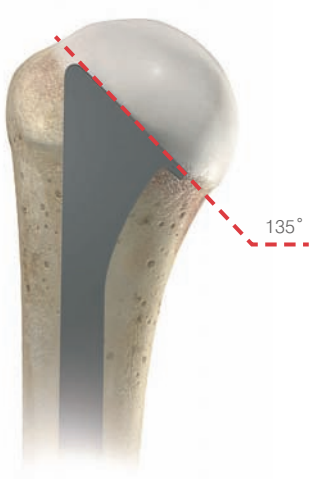


Figure 24

Humeral Head Resection

Pass the resection guide down the guide pin. Ensure that the saw capture slot is in alignment with the plane of the articular margin.

Engage the T-handle with the locking screw and secure the resection guide in position on the guide pin (Figure 22). Stabilise the guide by placing the two short 3 mm diameter 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 pins and complete the cut (Figure 23).

Use the sizer template to determine 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.

Alternative Free-hand Resection Technique

Alternatively, if the anatomical neck can be visualised clearly, it can be resected at the base of the neck at the anatomical angle and version defined by the patients anatomy using a freehand technique.

Use the humeral head cutting guide (which is fixed at 135˚) to help determine neck shaft angle and mark the resection. (Figure 24). 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 allowing the anatomic neck-shaft angle and humeral retroversion to be approximated. Once complete, the resection should be at the level of the supraspinatus insertion site.

Note: This cutting guide should be used as a reference as the resection cut should be made along the articular margin.

Note: As a general rule following resection, it is preferred that all of the cancellous bone from the head 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 trial stem on the driver extractor tool.

Humeral Canal Preparation

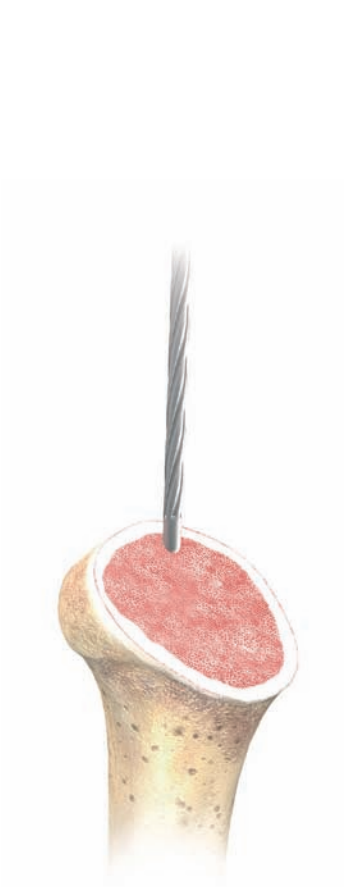


Figure 25

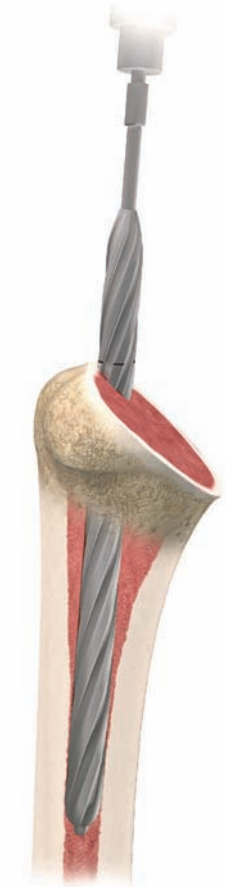


Figure 26

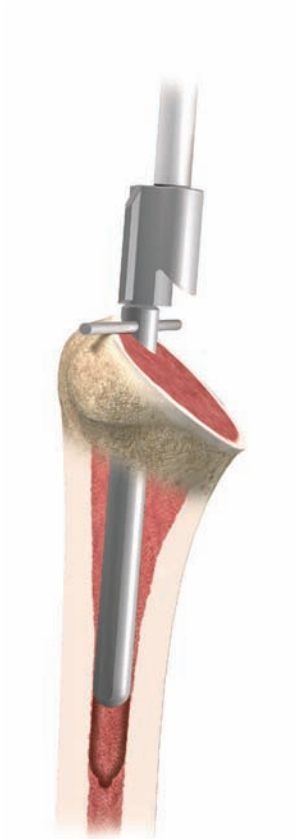


Figure 27

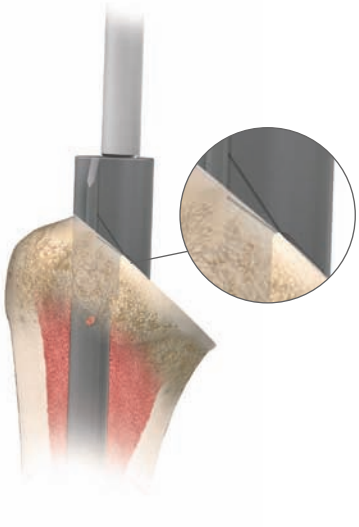


Figure 28

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 the intramedullary canal (Figure 25). 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 laser mark on the reamer is at the level of the resected bone (Figure 26). When using the long stem prosthesis, pass the entire length of the cutting flutes down the intramedullary canal. ***Note: Power reaming of the 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 trial stem and the final stem implant.***

Proximal Humeral Preparation

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 27).

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 ball taper (Figure 28).

Note: If it does not, the box osteotomy must be removed. The osteotomy must be readjusted to bring within the 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 proximal humerus that requires removal. This can be saved for bone graft at a later time.

Trial Stem Insertion

Figure 29

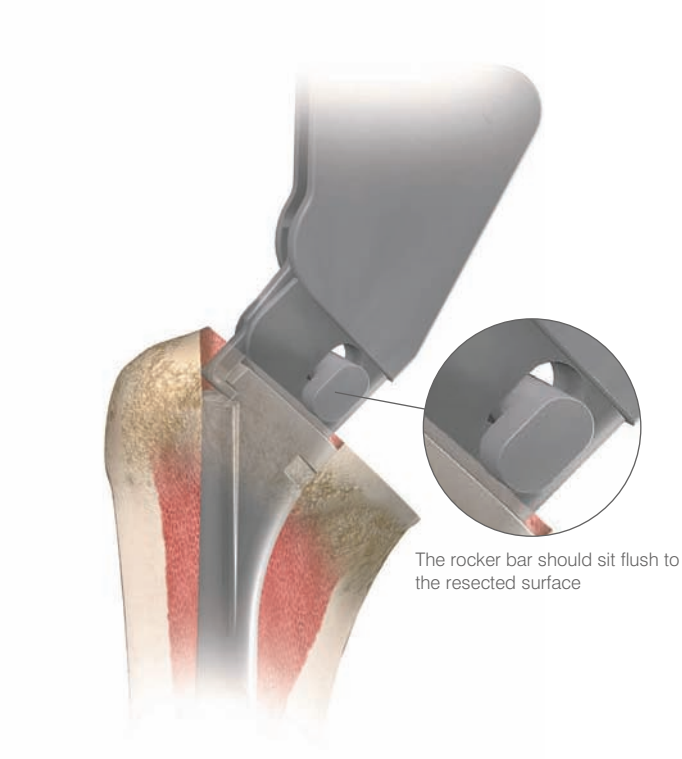


Figure 30

Select the trial stem that matches the diameter noted for the final reamer size. Attach the trial stem to the broach handle, making sure the trial stem face is flush with the locking surface. Lock the trial stem to the broach handle (Figure 29).

Carefully drive the trial stem into the proximal humerus so that the fins on the trial stem follow the tracks created by the box osteotome. (The trial stem is approximately 1 mm smaller than the corresponding humeral prosthesis, to obtain a proximal press-fit). Seat the trial stem until the rocker bar on the broach handle sits on the resected surface both front and back (Figure 30). Be cautious if cancellous bone is soft. Do not drive the rocker bar into soft bone, it should just touch or sit slightly above the osteotomy. At this point the trial stem 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 rocker bar does not just touch or sit slightly above cut surface, DO NOT try to aggressively drive it down. Instead, remove the trial stem and then pass the reamer deeper into the canal (further cutting with the osteotome may be needed). Then seat the trial stem again and remove any remaining osteophytes.

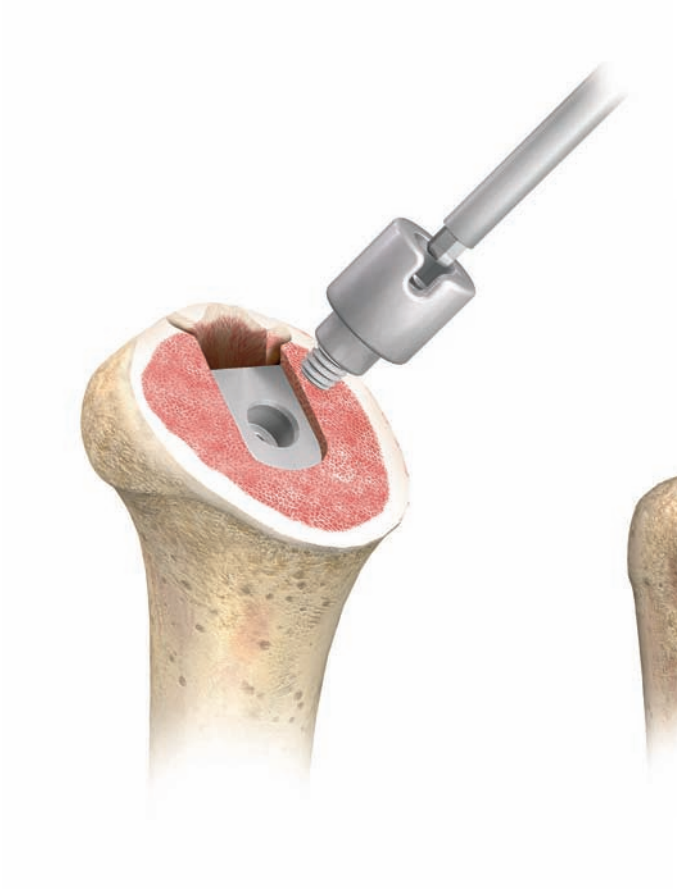


Figure 31

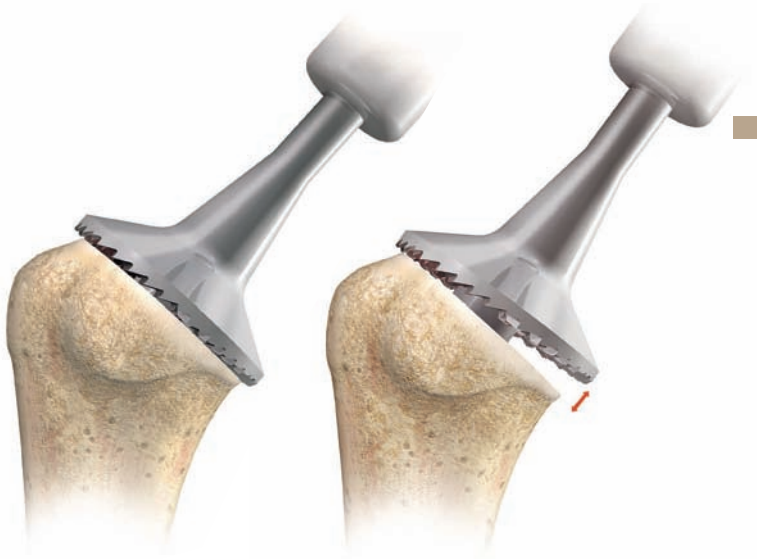


Figure 32

Figure 33

Attaching the Calcar Alignment Guide

Attach the Calcar Alignment Guide to the T-handle and locate and lock the guide into the recess on the humeral trial stem (Figure 31). Remove the T-handle. Sufficiently tighten the Calcar Alignment Guide, being cautious not to overtighten.

Confirming the Neck Resection

Select the appropriate size calcar reamer (see table opposite) and mount the reamer over the Calcar Alignment Guide. The angle of the calcar reamer when fixed onto the Calcar Alignment Guide will be perpendicular to the standard neck-shaft angle of 135˚. Assess its relationship to the resected plane. If the angle diverges by only a few degrees then the calcar reamer can be used to finalise the plane, providing an optimum resection for the fixed head configuration (Figure 32).

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

Note: The calcar reamer will be prevented from reaming further once it reaches the limitation of the Calcar Alignment Guide. This ensures a 135˚ osteotomy angle and a 2 mm countersink of the trial stem.

If the resection angle is not approximately parallel to the calcar reamer face, a variable angle ball cylinder trial is required (Figure 33).

Note: Refer to page 20 for hemi arthroplasty trial head selection.
Refer to page 21 for the variable angle procedure.
Refer to page 28 for the fixed head configuration.

Glenoid Preparation and Implantation

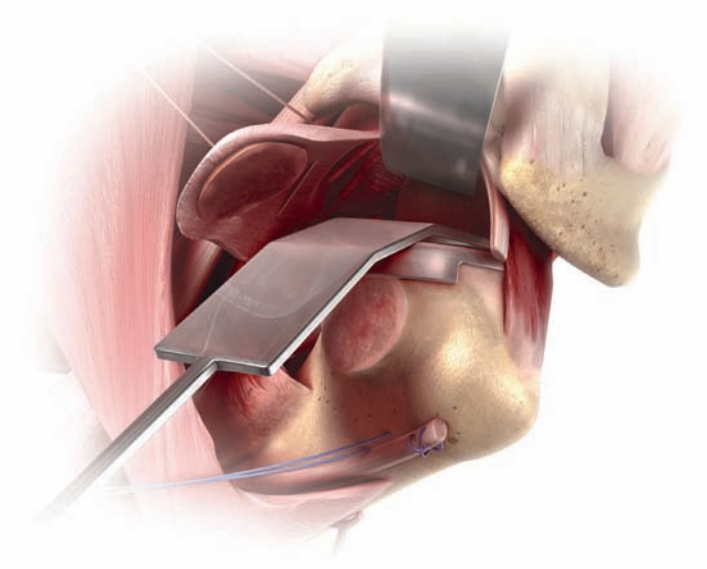


Figure 34

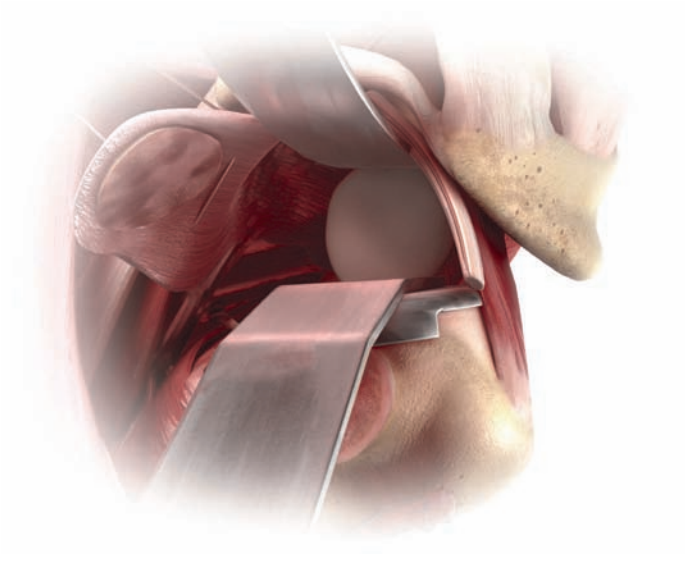


Figure 35

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 previous technique guides. 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 enhance 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.

Protecting the Humeral Osteotomy

Prior to initiating glenoid preparation, cover the humeral osteotomy surface with a small or large osteotomy protector. 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 (Figure 34).

Position the arm so that the surface of the osteotomy is parallel to the back of the glenoid. Push on the Bankart to expose the glenoid. Remove any remnants of soft tissue (biceps tendon, the superior and posterior labrum) to ensure the entire glenoid is visualised (Figure 35).

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

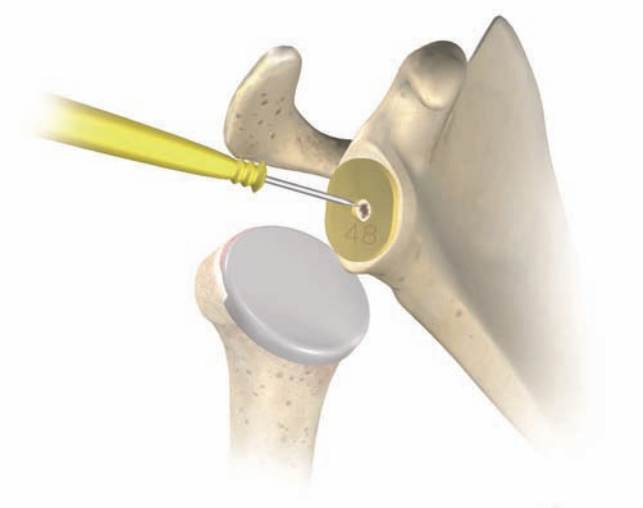


Figure 36

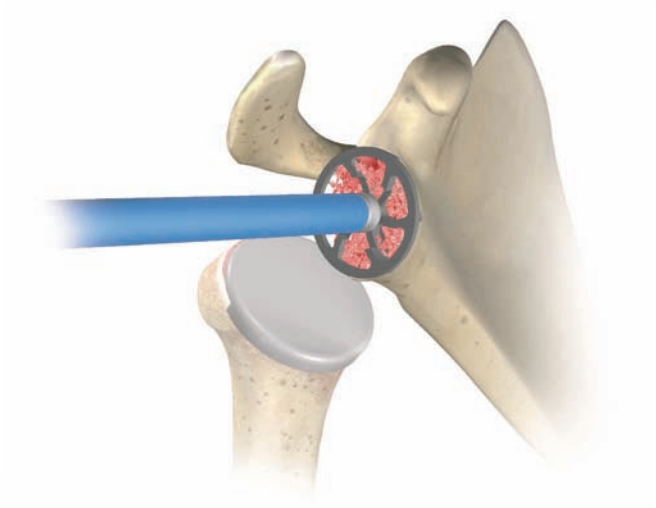


Figure 38

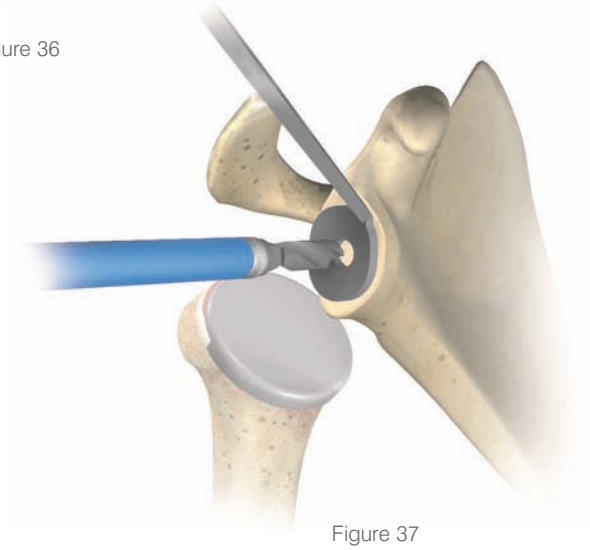


Figure 37

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 centre of the glenoid (Figure 36). Using the centre pilot hole drill bit (Figure 37) and the centre hole drill guide, align the drill guide hole with the centre mark just created. Drill the centre hole. If increased retroversion is noted on pre-operative radiographic studies, normalise 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 centre hole. Ream accordingly (Figure 38).

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

If increased retroversion is noted on the pre-operative CT scan or radiograph, place a finger along the anterior neck of the glenoid to provide a guide and adjust the angle of reaming to normalise the orientation of the glenoid.

If the surface has been correctly prepared, the component should be directly supported by precisely contoured bone. This will prevent the component from rocking, even when eccentric loads are applied to the implant.

Glenoid Preparation and Implantation

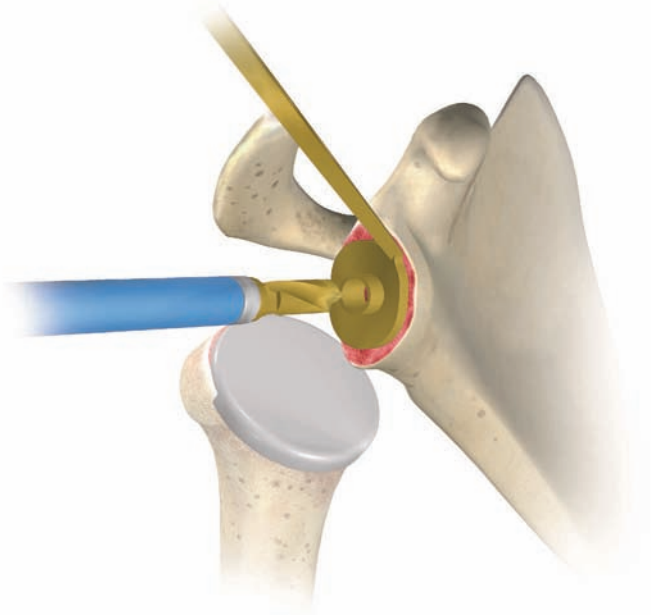


Figure 39

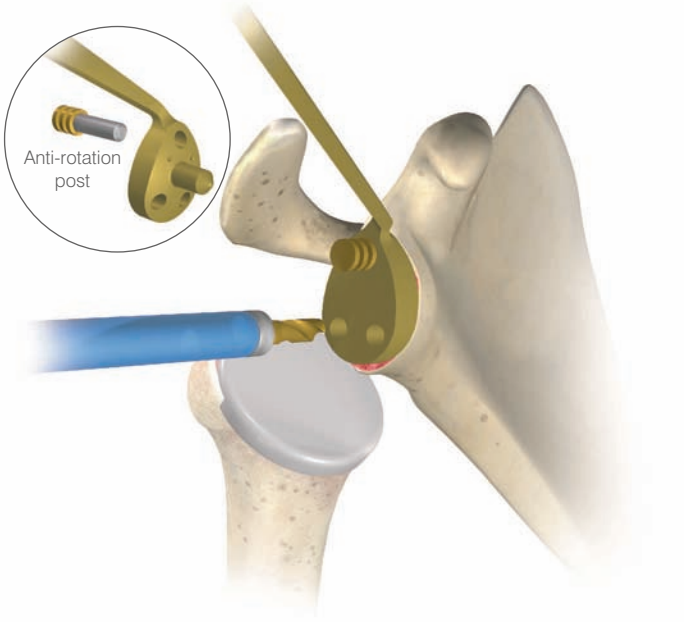


Figure 40

Place a Fukuda and a reverse Hohmann at the top of the glenoid, with an anterior retractor pulling the subscapularis anteriorly. Using the gold centre guide and the appropriate size anchor peg centre drill bit (see chart opposite), align the drill guide hole with the previously created centre drill hole that was used to ream the glenoid. Drill the centre anchor peg hole (Figure 39). 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.

After each peripheral hole is drilled, insert an anti-rotation post to maintain alignment of the guide while the subsequent holes are completed (Figure 40).

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

Anchor Peg Glenoid (mm)	Centre Drill Bit (mm)
40, 44	40, 44
48, 52, 56	48, 52, 56

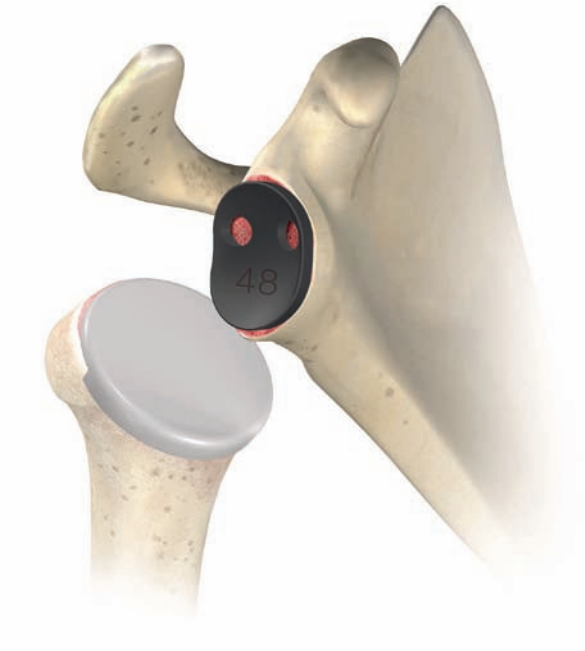


Figure 41

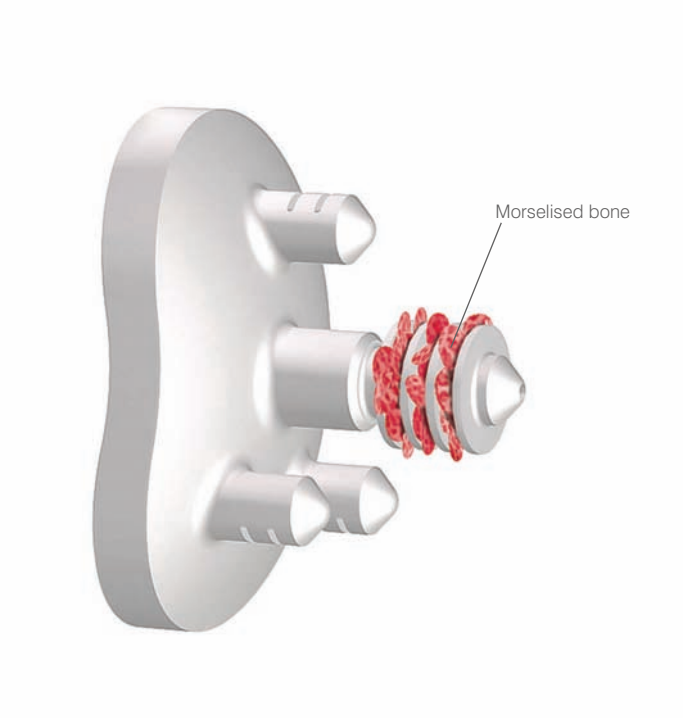


Figure 42

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 has good contact with the prepared glenoid surface (Figure 41). Remove the trial and irrigate the glenoid using pulsative lavage to remove blood and tissue debris from the four drill holes.

Note: If the scapula is penetrated by the peripheral drill, the cement should not be pressurised.

Open the appropriate size Anchor Peg Glenoid component. You can opt to use a paste of morselised bone gathered during glenoid reaming or drilling and interpose this between the flanges of the central peg (Figure 42).

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

Glenoid Preparation and Implantation

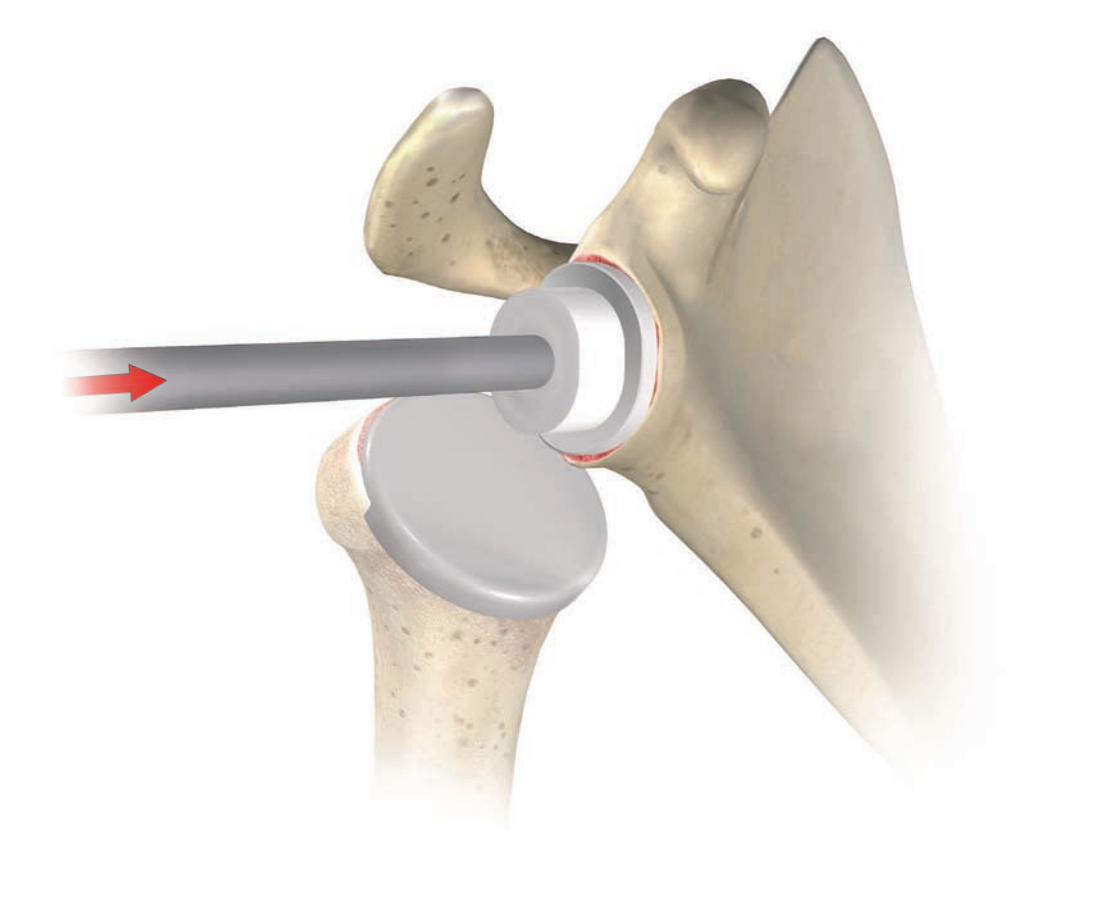


Figure 43

Whilst SmartSet® GHV bone cement is being vacuum mixed, obtain homeostasis by packing each of the peripheral holes with Thrombin and surgical gauze. When the cement is doughy and no longer sticky to touch, remove the gauze in preparation for the cement. Using syringe application or finger packing, apply a small amount of bone cement into each of the peripheral holes applying fingertip pressure to pressurise. Only a small amount of bone cement is required to form a 1 mm cement mantle around each peripheral hole.

Note: Excessive cement extruding from the holes and lying between the prosthesis and glenoid fossae 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 UHMWPE surface.

Introduce the Anchor Peg Glenoid implant. Use the Glenoid Impactor to seat the component. Impaction is complete when the rim is in complete contact with the perimeter of the glenoid (Figure 43). 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 centre anchor peg hole, which could preclude proper seating of the component.

This completes the glenoid aspect of the operation. You can now remove the osteotomy protector and return your countersink humeral trial stem.

Trial Head Selection: Fixed Angle

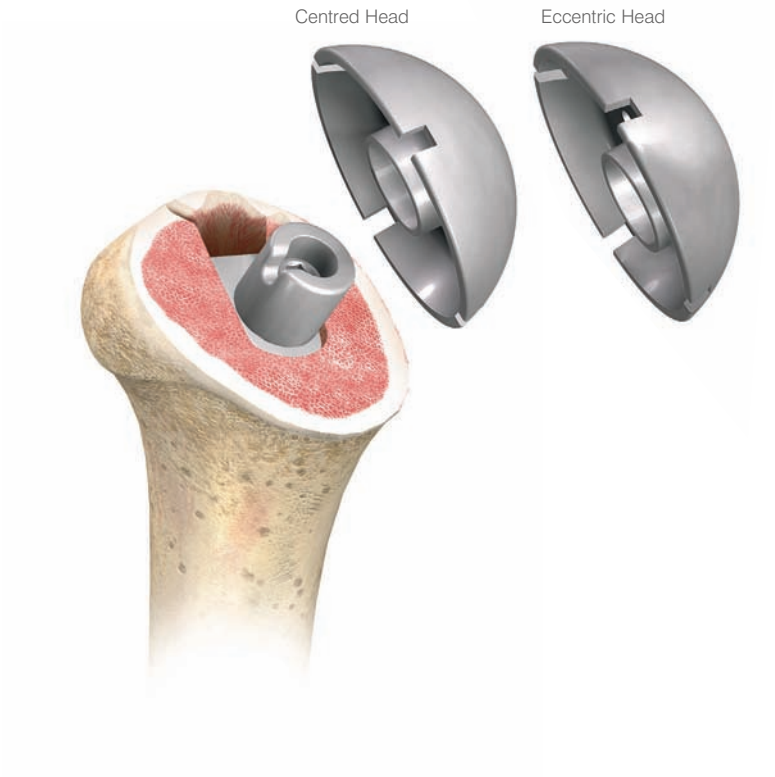


Figure 44

Figure 45

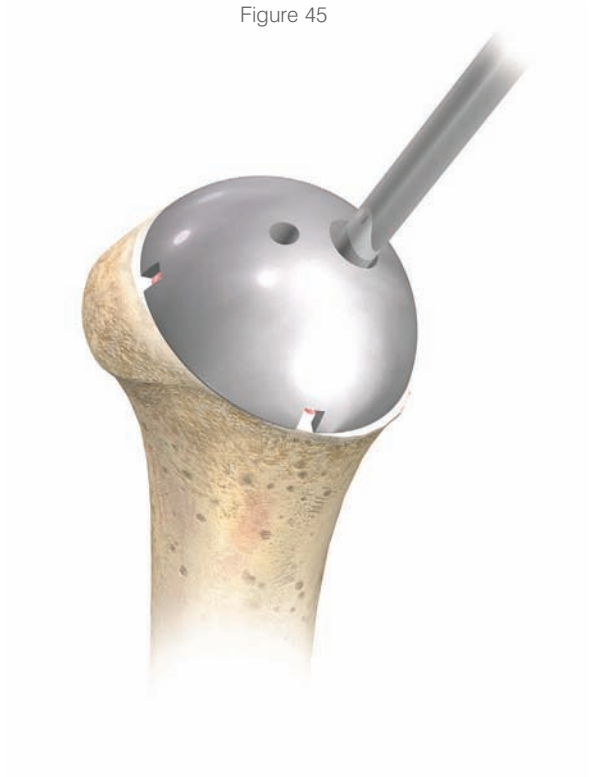


Figure 46

Re-attach the calcar alignment guide to the seated broach. Select the trial head that matches the diameter and depth of the measured humeral head (see table below). Engage the slot in the trial head sleeve onto the Calcar Alignment Guide (Figure 44).

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

Check that the trial head 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 height and reassess in place. Once confident that it is a good match, remove the trial head and compare it with the resected humeral head for confirmation of depth (Figure 45). 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 re-tightened. The entire humeral assembly is then removed with the broach removal tool (Figure 46).

Note: Refer to page 29 for head stem assembly.

Trial Head Selection: Variable Geometry

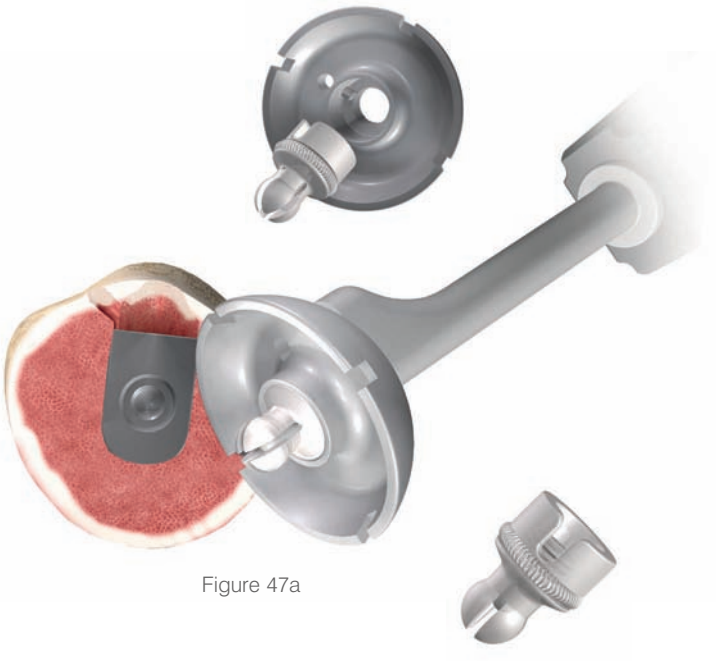


Figure 47a

Figure 47b

Figure 48 Figure 49

Figure 50

Ball Cylinder Trial / Head Assembly

Open the sterile, single use ball cylinder trial (2130-00-000). 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 47a).

Note: Loosen the screw so that approximately one thread can be seen through the cut out inside of the trial (Figure 47b).

Select the head trial that corresponds in diameter and height to the measured humeral head. Insert the ball cylinder trial into the trial head by aligning the internal positioning pin in the head barrel – with the keyway found on the ball cylinder trial. Use sufficient pressure to overcome the interference and "lock" the neck trial into the trial head. Engage the trial head/ball cylinder trial into the seated broach by hand so the assembly can easily be held together when mounting. These two items should mate (Figure 47). Proper engagement will be accompanied by a positive "snap" fix.

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.

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 48&49).

Locking The Trial Head Position

Once the trial head 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 trial head handle, stabilising the implant (Figure 49).*** Remove the handle and driver. 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 50).

Note: The position of the trial head can be adjusted by re-engaging the T-handle driver, and slightly loosening the peg screw. Once the new head orientation is obtained, re-tighten the screw.

Soft Tissue Balancing and Trial Stem Removal

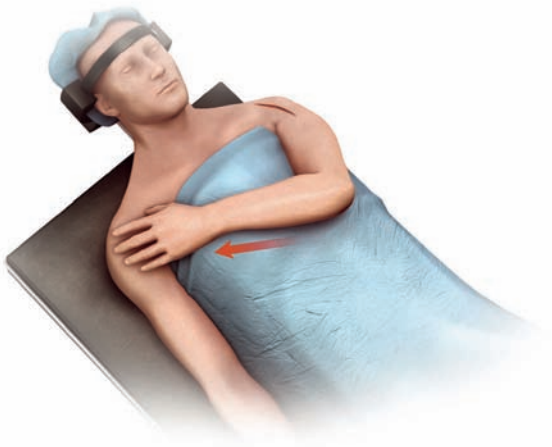


Figure 51

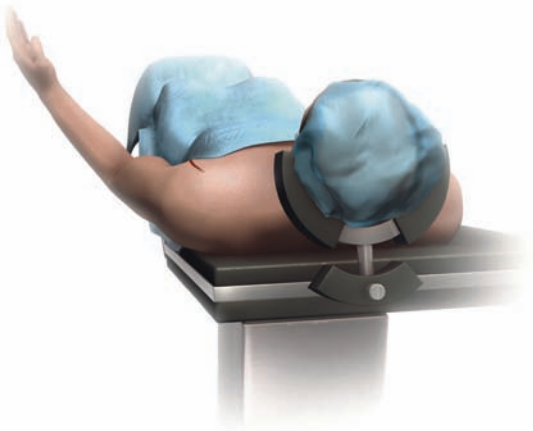


Figure 52

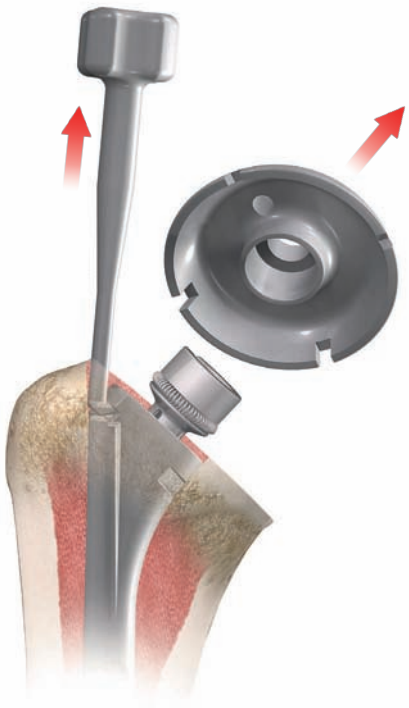


Figure 53

With the trial stem 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 51).

It should also be possible to externally rotate the arm 30 - 40˚ and still re-approximate 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 52).

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 trial head off the ball cylinder trial, without disturbing its “locked” orientation.

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 53). 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.

Note: All bone grafting should be completed before removing the trial stem as later insertion may influence the positioning of the final humeral stem.

Transferring the Head / Neck Orientation to the Definitive Implant: Variable Geometry

Figure 54

Figure 55

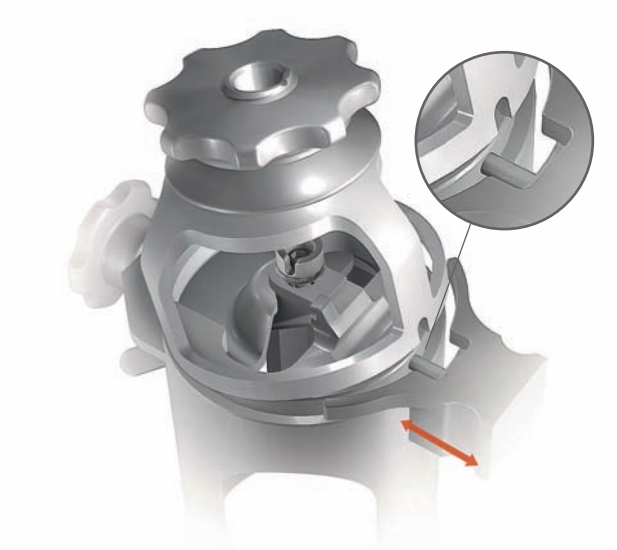


Figure 56

On a solid surface 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 (with sufficient stability to support impaction during implant assembly later in the procedure), mount the trial stem and trial ball taper assembly into the impaction block.

Note: Do not use the Mayo stand or other L-shaped table.

Align the back rim and the front groove of the trial stem with the mating features on the block. Secure the trial stem by firmly tightening the front block knob (Figure 54).

Verify that the trial stem 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 55).

Pull back the locking mechanism on the impaction block, align the key slot on the orientation dome with the locking mechanism pin and mount the orientation dome (Figure 56).

Figure 57

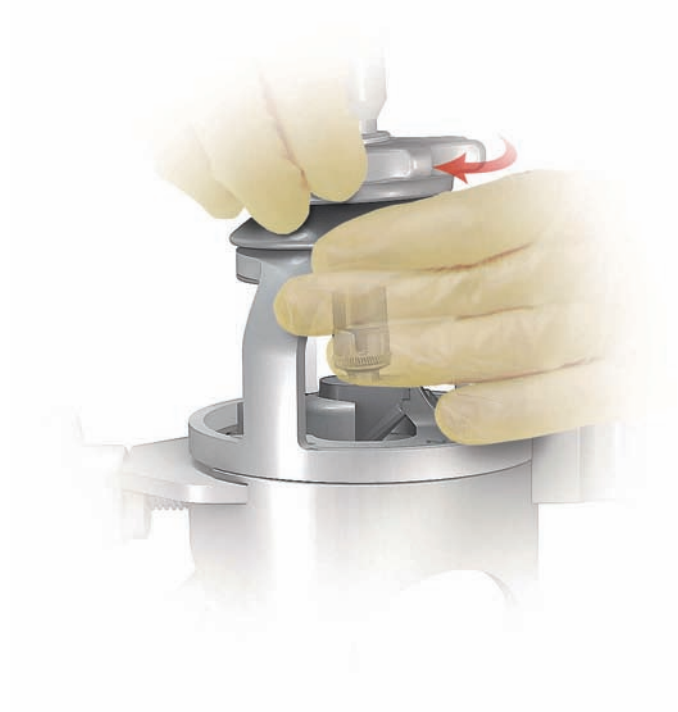


Figure 58

Loosen the locking ring-knob so that the shells articulate freely.

Slide the keyed impaction rod through the orientation dome, and engage into the ball cylinder trial (Figure 57). Let the tip slide into position WITHOUT significant force.

Note: This is best accomplished by viewing through the side of the orientation device.

Note: Excessive force could displace the "locked" position of the ball cylinder trial.

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 impaction base and apply a greater tightening force to the locking knob. Apply a second turn to fully lock the assembly (Figure 58).

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

Note: It is important to hold the impaction strike plate and resist any torque transferred to the knob while tightening the top locking knob on the orientation device.

Transferring the Head / Neck Orientation to the Definitive Implant: Variable Geometry

Figure 59

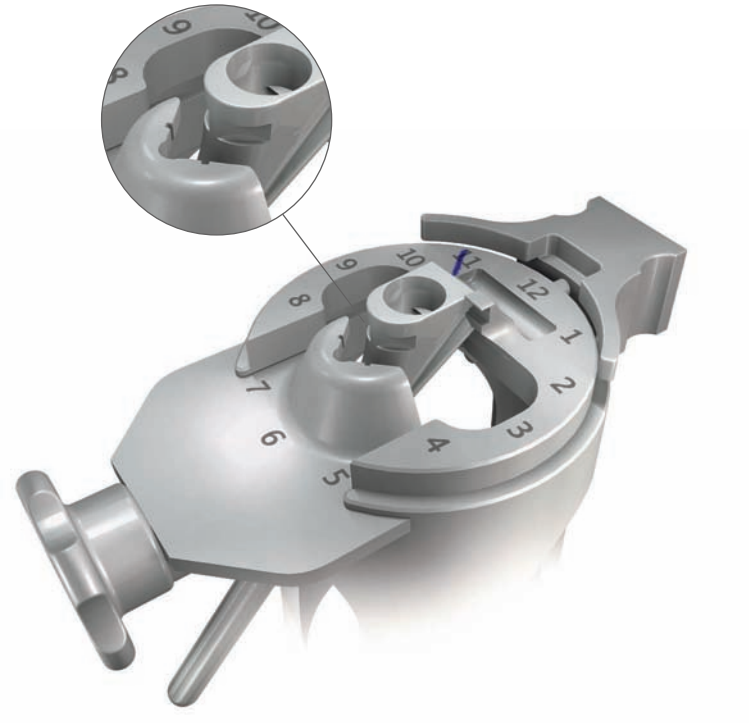


Figure 60

If an eccentric head has been selected, re-attach the trial head to the ball cylinder trial. The eccentric trial head is marked with an arrow, indicating maximum distance from the centre of the head. Use a sterile pen to mark the position of the arrow relative to the surface on the impaction tower. (Figure 59). Now remove the trial head.

Remove the trial stem from the impaction block and mount, in the same way, the corresponding sized definitive humeral stem implant (Figure 60).

Note: Do not change the implant size at this stage. 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. Maintain the sterile environment.

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.

Completing the Head / Stem Assembly: Variable Geometry

Figure 61

Figure 62

Figure 63

Insert the stem sleeve so that the flat surface engages into the slot in the top of the stem (Figure 61). Align the indicator mark on the top of the stem sleeve with the indicator mark on the top surface of the implant. The top surface of the stem sleeve should be flush with the top of the stem.

Note: The stem sleeve can be removed in the variable angle taper system. It allows for revision without removing a well implanted stem.

Loosely place the final ball taper into the stem sleeve, 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 fully (Figure 62). Ensure the rod is fully seated and flush with the top surface of the ball cylinder.

Position the tower so that the impaction rod is orientated towards the user. With the impaction tower and orientation dome held securely by an assistant, hit the impaction rod “squarely” to ensure that both tapers are simultaneously engaged (Figure 63). 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: Variable Geometry

Figure 64

Figure 65

Figure 66

Remove the impaction rod and orientation dome from the impaction block. Make a visual comparison between the trial stem and the final stem. Place the selected final humeral head component on the ball taper.

If an eccentric head has been selected, with a pen mark the arrow position (found on the non-articular surface) on top of the head, before placing it on the ball taper (Figure 64). Align the mark on the head with the mark made earlier on the impaction tower.

Centre the plastic perforated 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 65).

Note: It is very important to only use the plastic humeral head impactor, as this ensures correct head impaction without dislodgement of any portion of the ball taper.

Release the final assembly from the impaction tower. You can now make a visual comparison with the trial assembly to check for orientation of the eccentric head (Figure 66).

The construct is now ready for implantation.

Fixed Head Configuration

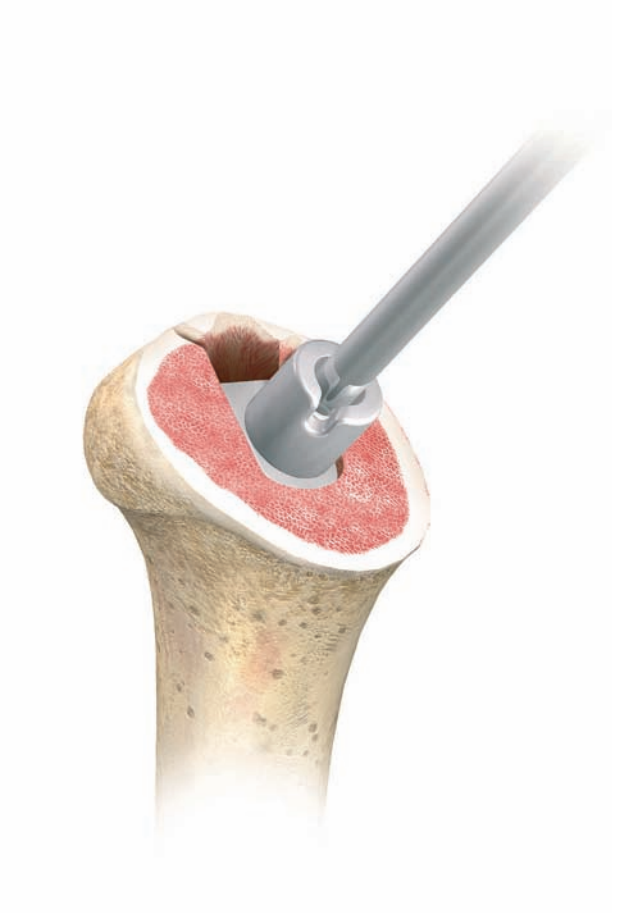


Figure 67

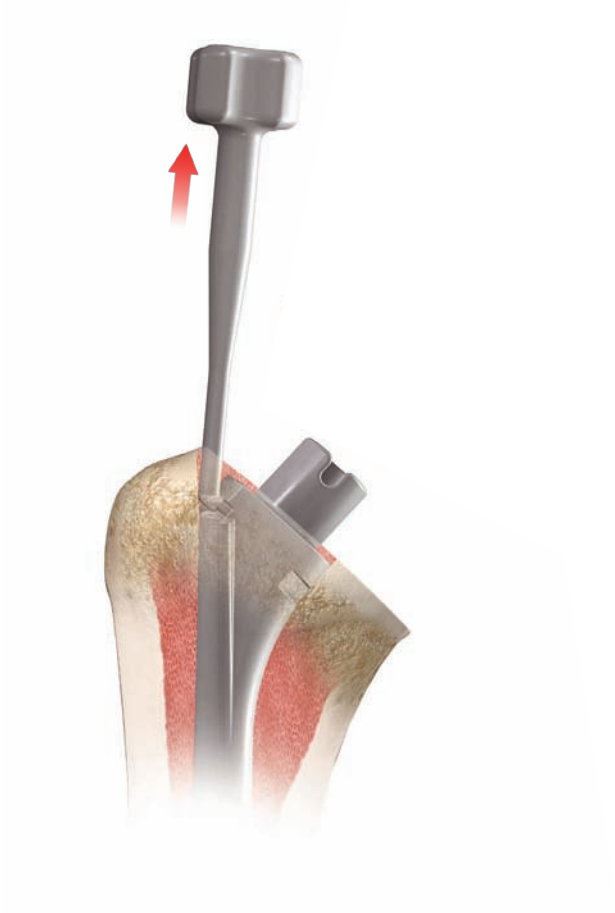


Figure 68

Assembling the Fixed Head to the Calcar Alignment Guide

If an eccentric head is selected, insert the calcar alignment guide into the seated trial stem, but do not tighten the calcar alignment guide screw using the T-handle (Figure 67). 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.

Note: Apply counter pressure to the trial head handle to resist tightening torque.

Remove the eccentric head and trial head handle.

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 68). 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 Angle Head / Stem Assembly

Figure 69

Figure 70

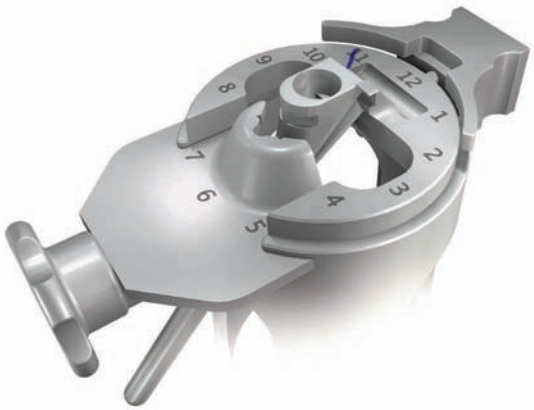


Figure 71

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 (with sufficient stability to support impaction during implant assembly later in the procedure), 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 block. Secure the trial stem by firmly tightening the front clamping knob (Figure 69).

Note: If a fixed neck and a centred head are used, it is not necessary to mount the trial stem in the impaction tower. If an eccentric head is used, then mounting in the impaction tower is only necessary to determine positioning of eccentricity.

Properly re-attach the trial head to the calcar alignment guide. The eccentric trial head is marked with an arrow, indicating maximum distance from the centre of the head. Use a sterile pen to mark the position of the arrow relative to the surface on the impaction tower (Figure 70). Now remove the trial head.

Remove the trial stem from the impaction block and mount, in the same way, the corresponding sized final humeral stem (Figure 71).

Note: Do not change the implant size at this stage. 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. Maintain the sterile environment.

Assembling the Fixed Head to the Fixed Angle Taper

Figure 72

Figure 74

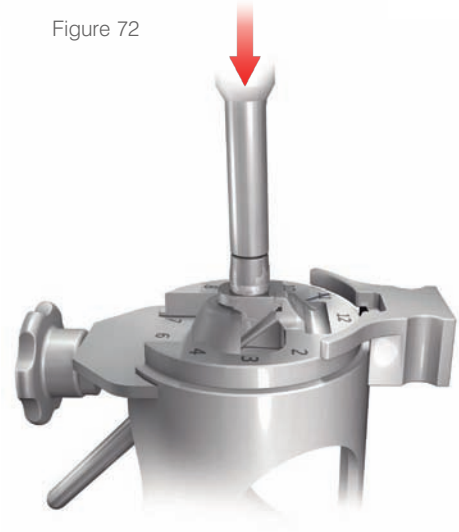


Figure 73

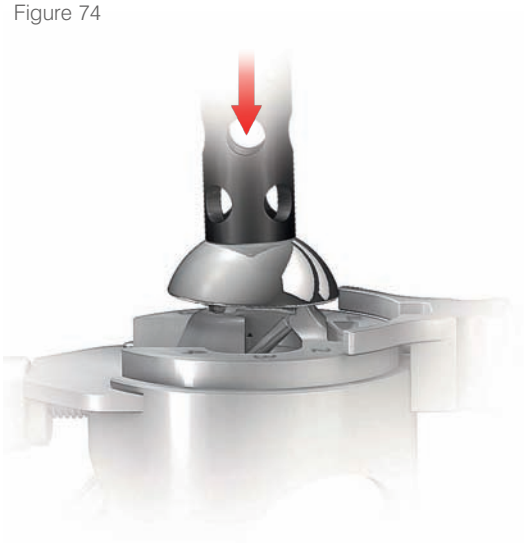


Figure 75

Make sure that the stem is inserted correctly into the impaction tower and that the laser lines on the stem are hidden by the mating features. Insert the fixed angle taper into the slot in the top of the stem, with the end etched "THIS SIDE UP" facing superiorly (Figure 72). Introduce the impaction 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 L-shaped table.

Impact the head of the rod sharply, three to four times, to ensure that both tapers are simultaneously engaged (Figure 73). Verify that the rod and fixed angle taper are still aligned, with the rims flush. Remove the impaction rod.

Place the selected final humeral head component on the fixed angle taper. If an eccentric head has been selected, with a pen, 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 impaction tower (Figure 74).

Centre the plastic perforated impactor on the humeral head, making sure that it is co-linear with ball taper and impact the head with three or four controlled impactions with the mallet (Figure 75).

Note: It is very important to only use the plastic impactor, as this ensures correct head impaction without dislodgement of any portion of the fixed angle taper.

The construct is now ready for implantation.

Insertion of the Final Humeral Head / Stem Assembly

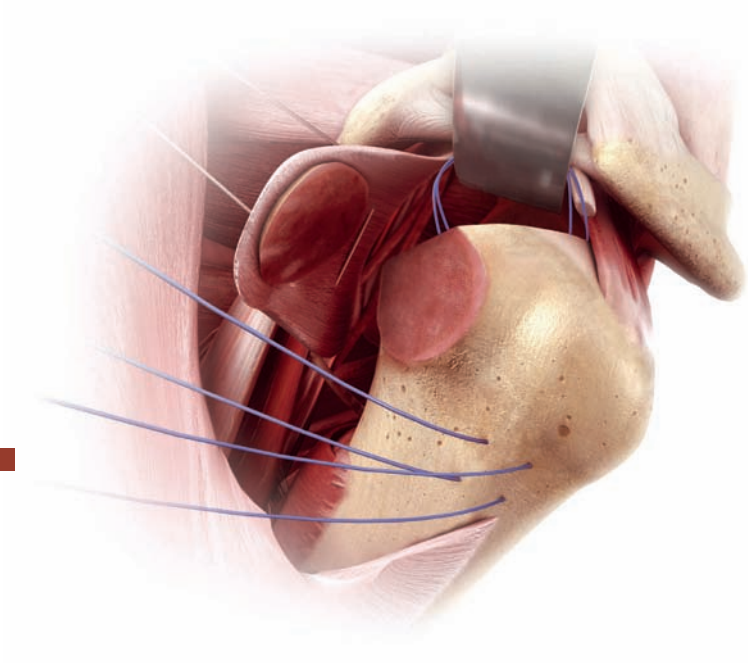


Figure 76

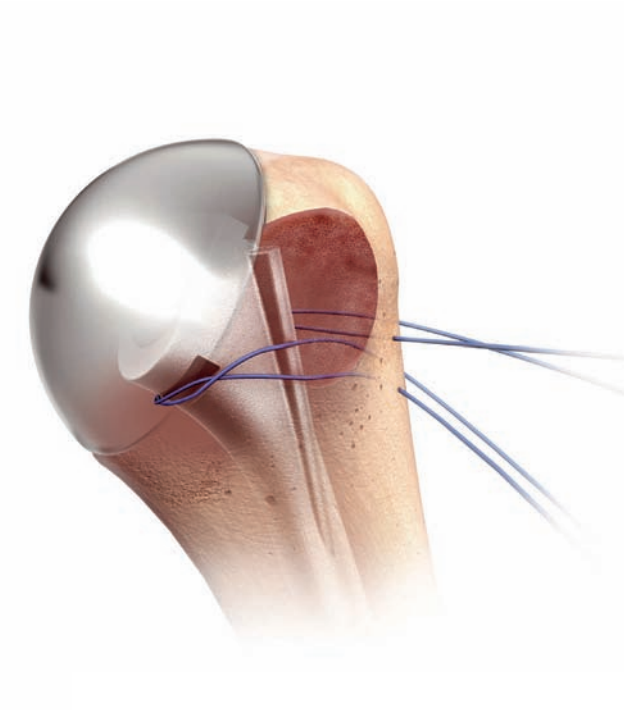


Figure 77

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

Before the final component assembly is inserted, plan the repair of the subscapularis tendon. If the tendon was taken directly off its insertion into the lesser tuberosity or as, in this approach, the tendon was removed with a small portion of the lesser tuberosity, drill four holes into the anterior neck within the bicepital groove to re-attach the tendon to bone (Figure 76).

When the tendon is sutured to the humeral neck, use a suture passer to pull loops of the sutures through the drill holes. 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.

When the subscapularis is removed with a small sliver of the lesser tuberosity, pass two permanent sutures through these holes for later tension band suturing of the lesser tuberosity fragment to its native bed. In this circumstance we recommend to place the sutures around the stem of the implant and pulling the slack out of sutures just before the implant is placed into its final seated position within the humeral canal (Figure 77).

Press-Fit, Impaction Bone Grafting or Cement

The final prosthesis is 1 mm larger across the anterior/posterior dimension than the trial stem so that in the majority of cases, a firm press-fit without cement can be obtained. If the trial stem 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 implant.

Figure 78

Do not advance the implant beyond the level of resection. In the case of the patient with a 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. If the cement is placed distal to the stem of the implant 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 implant and cement pressurisation is attainable.

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 plastic impactor to insert the assembly to the final seating position (Figure 78).

Note: The osteotomy surface should be perfectly covered from front to back and the version anatomic for the patient.

Remove any further osteophytes with a burr. The top of the humeral head is perpendicular to the shaft of the bone, and the humeral head is about 5 mm above the top of the greater tuberosity. There is a lip where the humeral head overhangings the bone. This is where the osteotomy is going to fit for the lesser tuberosity. 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

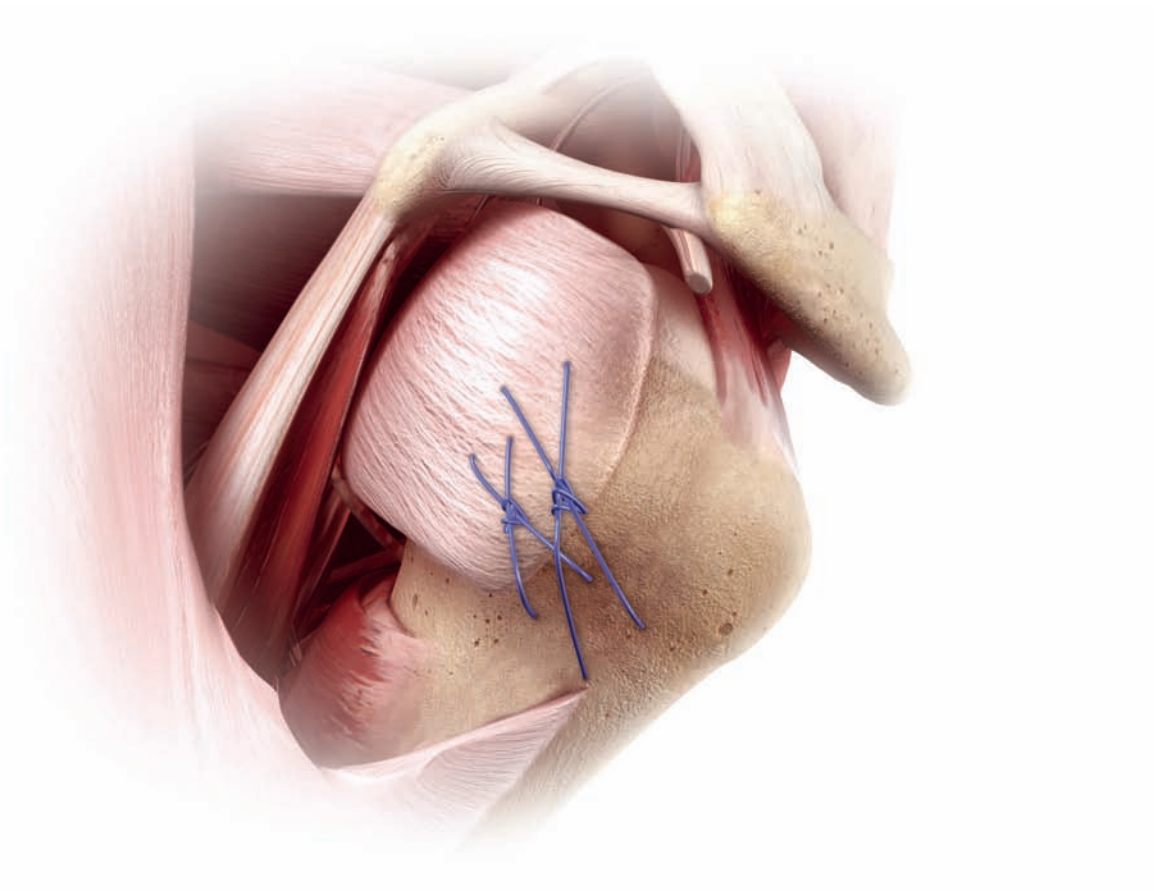


Figure 79

Using a 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 the lesser tuberosity then pass the previously placed #2 or larger non-absorbable suture (Mitek Orthocord™ is recommended) in the subscapularis tendon into the loop of sutures in the proximal humerus.

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. If the tendon was previously divided or was lengthened with a coronal Z-plasty technique, repair and secure it with the non-absorbable sutures.

When the subscapularis is removed with a small sliver of lesser tuberosity the non-absorbable sutures previously placed are then passed through the tendon to bone interface in a figure eight configuration (Figure 79). 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.

Wound Closure

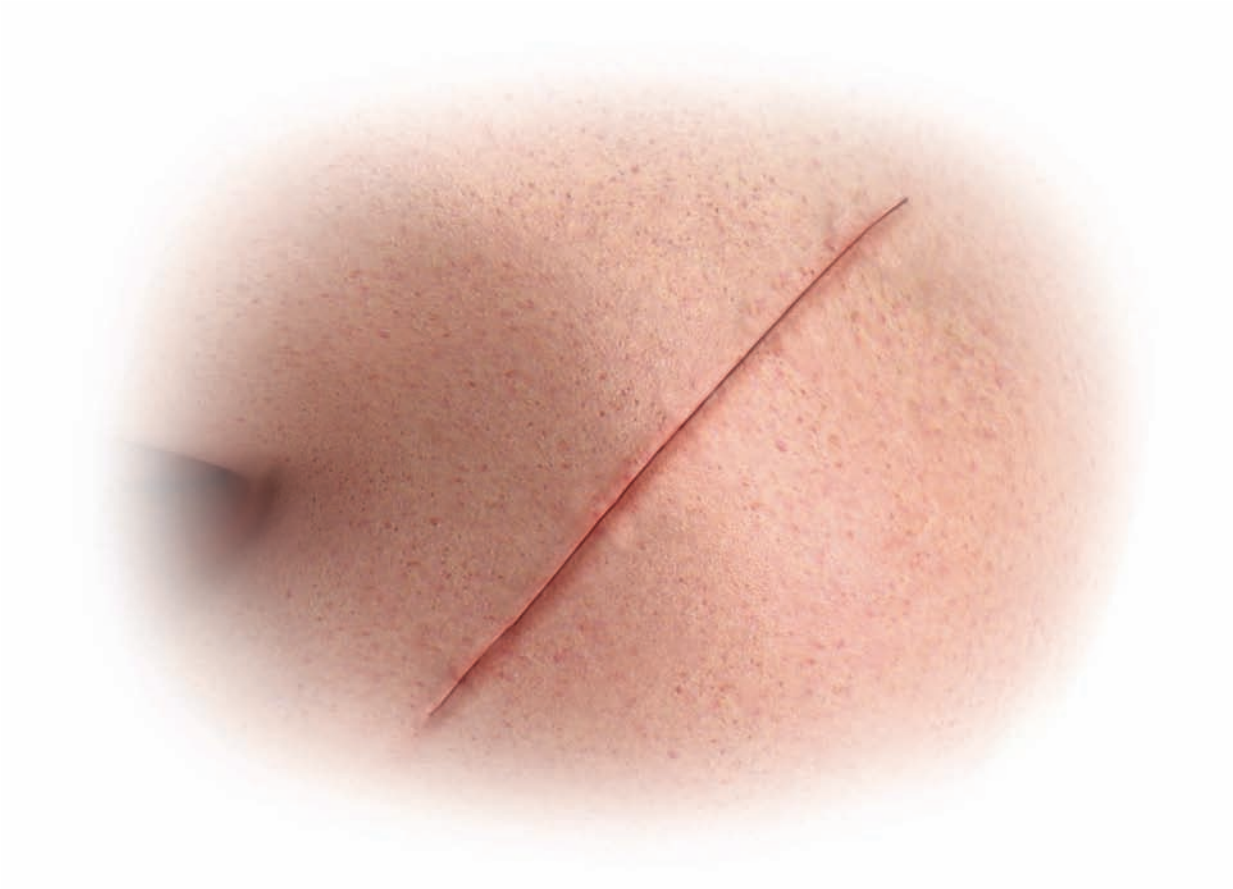


Figure 80

Thoroughly irrigate the wound with antibiotic solution and infiltrate the soft tissue with a local anesthetic that will last six to eight hours.

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 80).

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

Revision Procedure

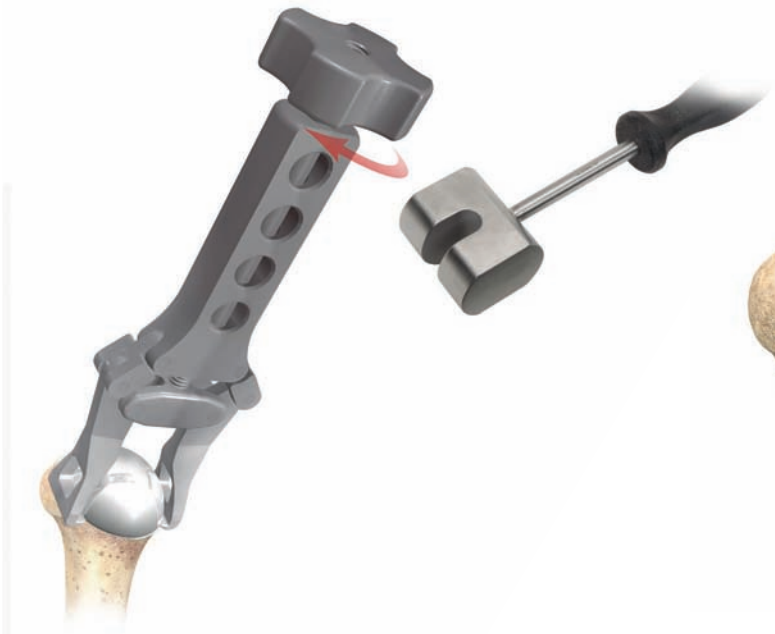


Figure 81

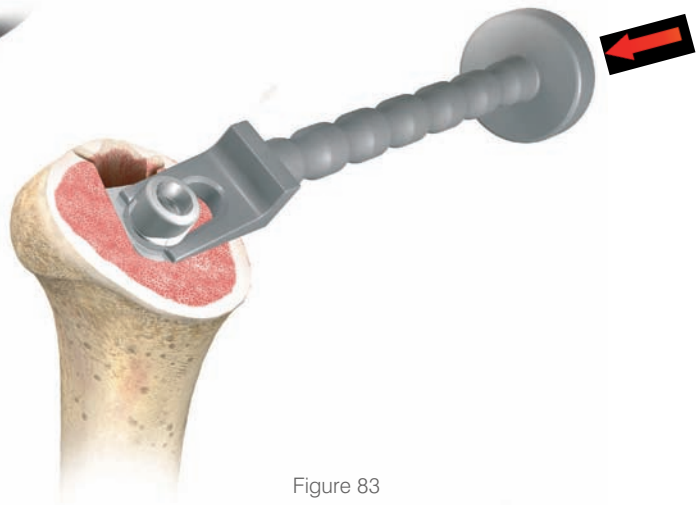


Figure 83

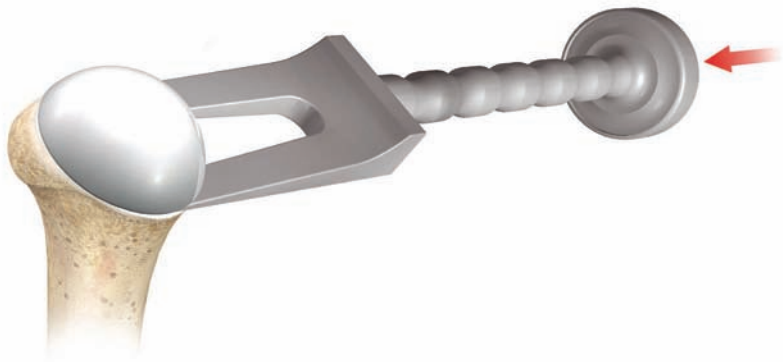


Figure 82

Figure 84

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 (2130-01-080). 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 underside of the wheel (Figure 81).

Alternatively, the humeral head can be removed using the humeral head distractor (2130-01-120). Place the two prongs of the distractor underneath the humeral head, either side of the taper between the humeral head and the osteotomy surface. Lift the head off the ball taper by impacting the end of the distractor (Figure 82).

Removing the Ball Taper

Place the two prongs of the ball taper distractor (2130-01-110) either side of the taper and impact the end of the tool to lift the taper away from the stem. ***The stem is designed so that the collar and the ball taper can be removed as a single unit.*** (Figure 83). However, if the stem sleeve remains in place within the stem, it is easily removed using the extractor tool (Figure 84).

Revision Procedure: Fixed Angle

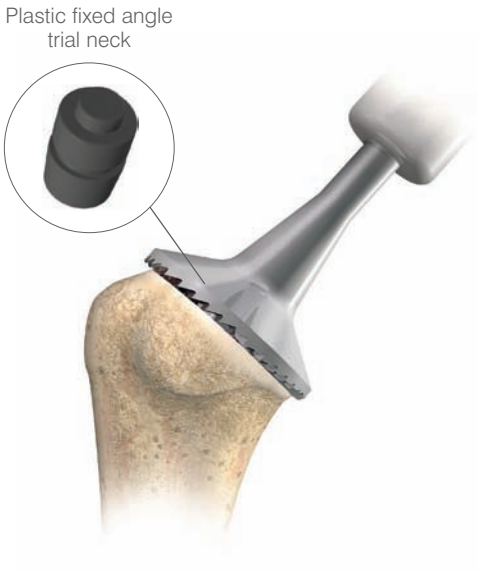


Figure 85

Figure 86

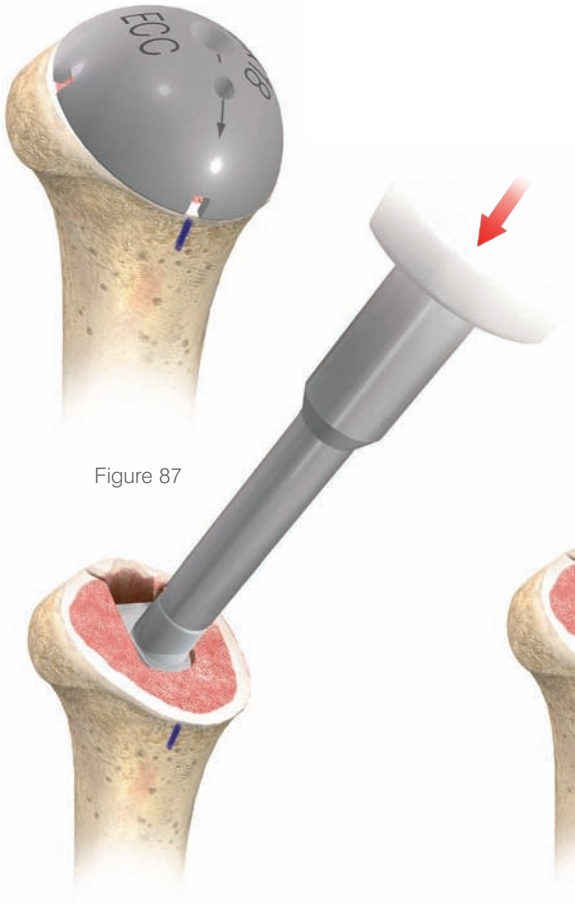


Figure 87

Figure 88

Figure 89

Revision Trial Humeral Head and Neck 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° angle of the fixed neck device (Figure 85).

If the neck angle is correct, place the trial head onto the fixed angle trial neck. Choose either the centred or eccentric trial head checking that it achieves appropriate coverage of cortical bone, with 5 - 8 mm height above the greater tuberosity (Figure 86). If necessary increase or decrease the selected head diameter and height and reassess in place.

If an eccentric head is used, the position of the arrow (indicating maximum distance from the centre of the head) needs to be marked on the bone with a sterile pen (Figure 87). 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 88). Verify that the rod and ball taper are still aligned, with the rims flush. Remove the impaction rod.

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 89). Impact the head using the plastic Humeral Head Impactor.

Note: Verify that the implant head taper engages before the bottom surface of the implant head touches the osteotomy surface. If this happens, then a small amount of bone must be removed.

Revision Procedure: Variable Geometry

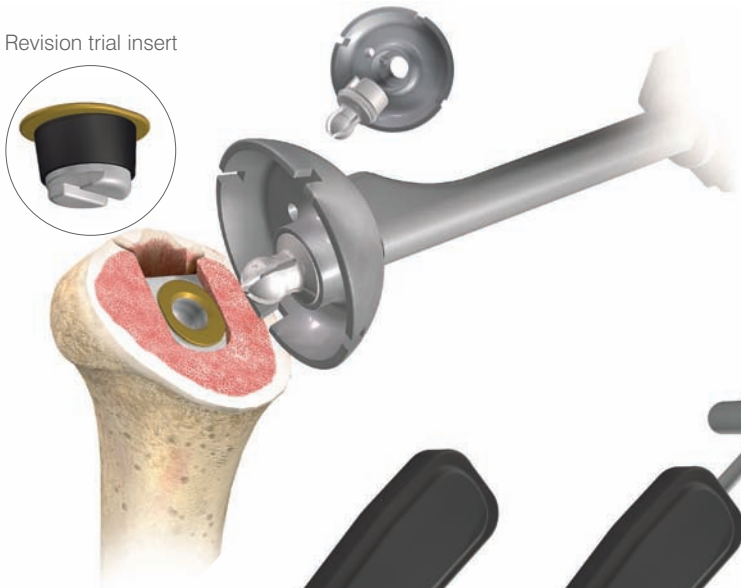


Figure 90

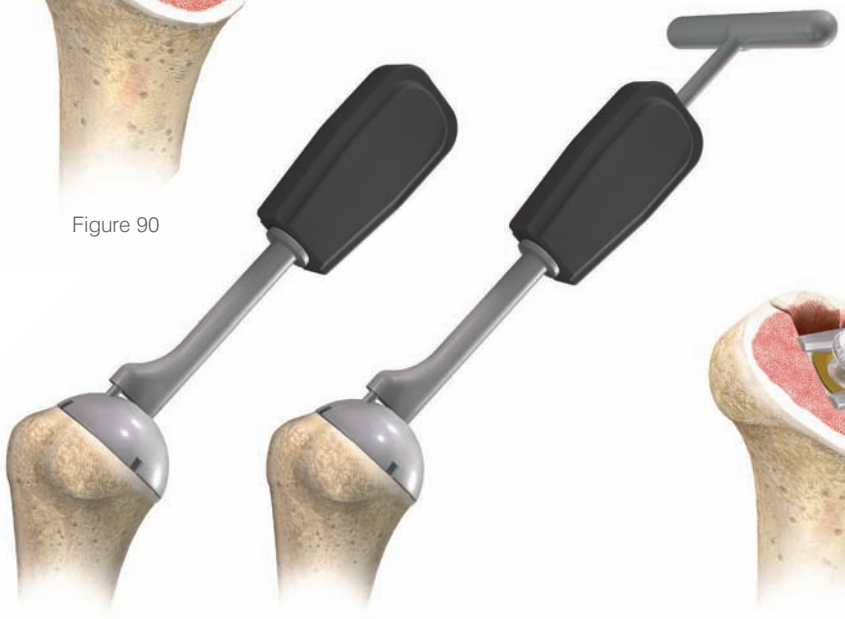


Figure 91

Figure 92

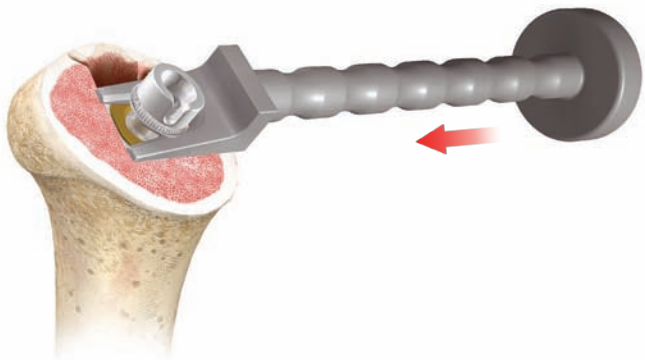


Figure 93

Revision Ball Cylinder Trial / Head Assembly

If the angle is not exact, select the revision trial insert and lightly tap into the stem 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 counter-clockwise. Take the trial head handle and insert the two prongs into the head (Figure 90).

Use the trial head handle to rotate and angle the assembly to achieve optimal version and coverage of the osteotomy (Figure 91).

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

Locking The Trial Head Position

Once the trial head 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, stabilising the implant (Figure 92).

If an eccentric head is used, the position of the arrow (indicating maximum distance from the centre 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 93).

Figure 94

Figure 95

Figure 96

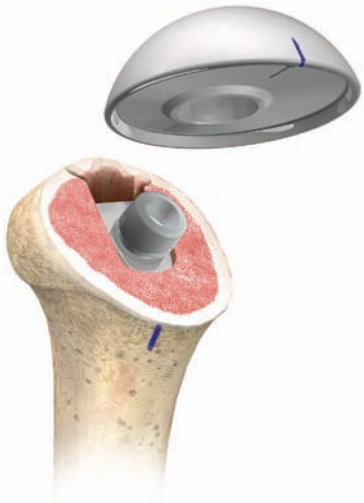


Figure 97

Revision Transfer Block

Once the trial is successfully completed 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) which simulates the taper of the intact stem, inside the impaction block and secure it into the mating features (Figure 94).

Note: The revision transfer block has two ends. The gold end is used for recording the angle on the trial, the silver end 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 - 58 on pages 23 - 24).

Remove the revision transfer block and place it silver end up, back in the impaction block (Figure 95). Repeat steps from the primary section, (Figures 62 - 63 on page 26).

The definitive assembly is removed from the revision transfer block and tapped into the implanted stem, using the impaction rod (Figure 96). Place the head onto the assembly and use the plastic Humeral Head Impactor to impact into its final position.

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 97). Impact, using the plastic Humeral Head Impactor.

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

Postoperative Protocol

1. The First Postoperative Day:

a. Remove the shoulder immobiliser on the day of surgery or at the latest by the next morning. With the shoulder sling immobiliser 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˚ 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˚ 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˚ 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 one 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 - 120˚ of passive flexion and external rotation of 10 - 15˚ 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˚), institute more stretching exercises, such as wall exercises, 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 - 140˚ of flexion and 20 - 40˚ of external rotation, institute strengthening exercises of the deltoid and rotator cuff muscles with Therabands. Gradually increase the resistance by using the different colours and strengths of Therabands. Strengthen the scapular stabiliser 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.

Ordering Information
Implants

PRIMARY IMPLANT CODES

Taper Implant Components

Cat No.	Description
1130-00-000	Ball Taper Adjustable Neck Assembly
1130-02-000	Fixed 135˚ 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

Porocoat® Humeral Stem Components

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

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

REVISION IMPLANT CODES

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

DISPOSABLES

2130-00-000	Ball Cylinder Trial Assembly (SINGLE-USE)
2130-02-000	Revision Insert (SINGLE-USE)

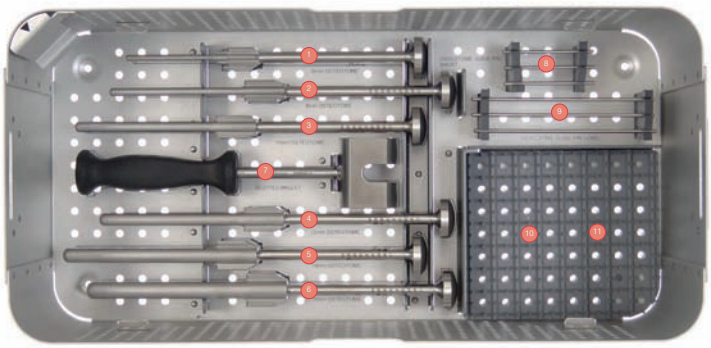
Ordering Information
Instruments

PRIMARY INSTRUMENT TRAYS - HUMERAL

Cat No.	Description
2130-24-000	Humeral Case 1 Case & Inserts
2130-24-020	Humeral Case 1 Lid
2130-24-010	Humeral Case 1 Base
2130-24-030	Humeral Case 1 Top Insert
2130-24-040	Humeral Case 1 Middle Insert

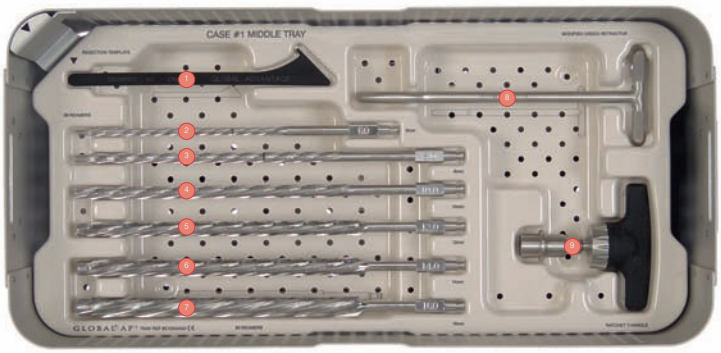
Humeral Case 1 Base

1	2130-01-006	Osteotome 6 mm
2	2130-01-008	Osteotome 8 mm
3	2130-01-010	Osteotome 10 mm
4	2130-01-012	Osteotome 12 mm
5	2130-01-014	Osteotome 14 mm
6	2130-01-016	Osteotome 16 mm
7	2810-01-003	Slotted Mallet
8	2130-18-000	3.2 mm Osteotome Guide Pin - Short
9	2130-20-000	3.2 mm Osteotome Guide Pin - Long
10	2130-01-017	Large Osteotomy Cover
11	2130-01-018	Small Osteotomy Cover



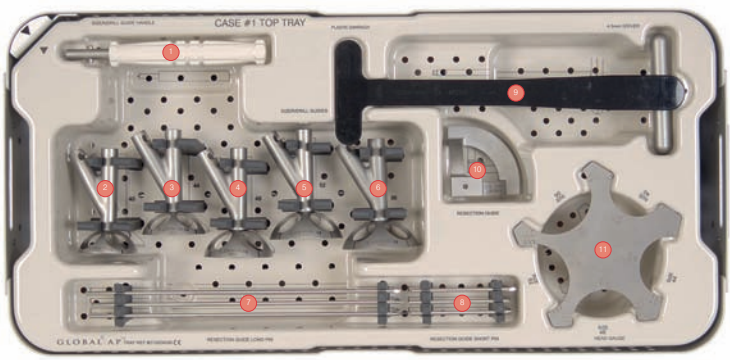
Humeral Case 1 Middle Insert

1	2128-61-071	Humeral Head Cutting Guide
2	2128-01-006	Humeral Reamer 6 mm
3	2128-01-008	Humeral Reamer 8 mm
4	2128-01-010	Humeral Reamer 10 mm
5	2128-01-012	Humeral Reamer 12 mm
6	2128-01-014	Humeral Reamer 14 mm
7	2128-01-016	Humeral Reamer 16 mm
8	2236-26-000	Modified Crego Retractor
9	2128-61-070	Ratchet T-handle



Humeral Case 1 Top Insert

1	2230-80-060	Humeral Head Sizer / Drill Guide Handle
2	2230-80-010	Humeral Head Sizer / Drill Guide 40 mm
3	2230-80-020	Humeral Head Sizer / Drill Guide 44 mm
4	2230-80-030	Humeral Head Sizer / Drill Guide 48 mm
5	2230-80-040	Humeral Head Sizer / Drill Guide 52 mm
6	2230-80-050	Humeral Head Sizer / Drill Guide 56 mm
7	140129	Resection Guide Pins - Long (3.2 mm x 9 inch Short Threaded Guide Pin)
8	2490-95-000	Resection Guide Pins - Short (AMK Fixation Pins 1/8 DIA x 3)
9	2130-01-100	4.5 mm Trial Driver
10	2130-01-020	Resection Guide
11	2130-01-019	Head Measurement Gauge

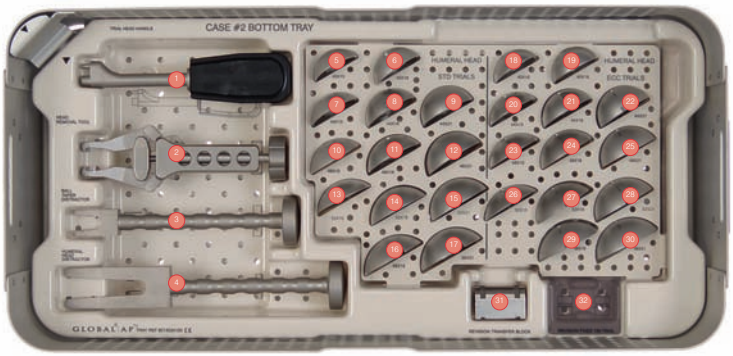


Ordering Information
Instruments

PRIMARY INSTRUMENT TRAYS - HUMERAL

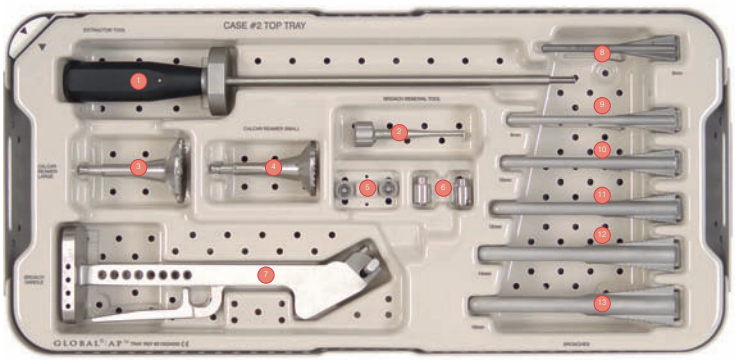
Cat No.	Description
2130-24-060	Humeral Case 2 Case & Inserts
2130-24-080	Humeral Case 2 Case Lid
2130-24-070	Humeral Case 2 Base
2130-24-090	Humeral Case 2 Top Insert
2130-24-100	Humeral Case 2 Lower Insert

Humeral Case 2 Base and Lower Insert



1	2130-01-105	Trial Head Handle
2	2130-01-080	Head Removal Tool
3	2130-01-110	Ball Taper Distractor
4	2130-01-120	Humeral Head Distractor
5	2130-40-500	Humeral Head 40 x 15 Standard Trial
6	2130-40-510	Humeral Head 40 x 18 Standard Trial
7	2130-44-500	Humeral Head 44 x 15 Standard Trial
8	2130-44-510	Humeral Head 44 x 18 Standard Trial
9	2130-44-520	Humeral Head 44 x 21 Standard Trial
10	2130-48-500	Humeral Head 48 x 15 Standard Trial
11	2130-48-510	Humeral Head 48 x 18 Standard Trial
12	2130-48-520	Humeral Head 48 x 21 Standard Trial
13	2130-52-500	Humeral Head 52 x 15 Standard Trial
14	2130-52-510	Humeral Head 52 x 18 Standard Trial
15	2130-52-520	Humeral Head 52 x 21 Standard Trial
16	2130-56-510	Humeral Head 56 x 18 Standard Trial
17	2130-56-520	Humeral Head 56 x 21 Standard Trial
18	2130-40-600	Humeral Head 40 x 15 Eccentric Trial
19	2130-40-610	Humeral Head 40 x 18 Eccentric Trial
20	2130-44-600	Humeral Head 44 x 15 Eccentric Trial
21	2130-44-610	Humeral Head 44 x 18 Eccentric Trial
22	2130-44-620	Humeral Head 44 x 21 Eccentric Trial
23	2130-48-600	Humeral Head 48 x 15 Eccentric Trial
24	2130-48-610	Humeral Head 48 x 18 Eccentric Trial
25	2130-48-620	Humeral Head 48 x 21 Eccentric Trial
26	2130-52-600	Humeral Head 52 x 15 Eccentric Trial
27	2130-52-610	Humeral Head 52 x 18 Eccentric Trial
28	2130-52-620	Humeral Head 52 x 21 Eccentric Trial
29	2130-56-610	Humeral Head 56 x 18 Eccentric Trial
30	2130-56-620	Humeral Head 56 x 21 Eccentric Trial
31	2130-01-000	Revision Transfer Block
32	2130-00-135	Fixed 135˚ Neck Trial

Humeral Case 2 Top Insert



1	2130-01-075	Extraction Handle
2	2130-01-085	Broach Removal Tool
3	2130-01-065	Large Calcar Reamer 48 / 52 / 56 mm
4	2130-01-060	Small Calcar Reamer 40 / 44 mm
5	2130-01-029	Broach Handle Adaptor
6	2130-01-070	Calcar Alignment Guide Assembly
7	2130-01-030	Broach Handle
8	2130-06-000	Humeral Stem 6 mm Broach / Trial
9	2130-08-000	Humeral Stem 8 mm Broach / Trial
10	2130-10-000	Humeral Stem 10 mm Broach / Trial
11	2130-12-000	Humeral Stem 12 mm Broach / Trial
12	2130-14-000	Humeral Stem 14 mm Broach / Trial
13	2130-16-000	Humeral Stem 16 mm Broach / Trial

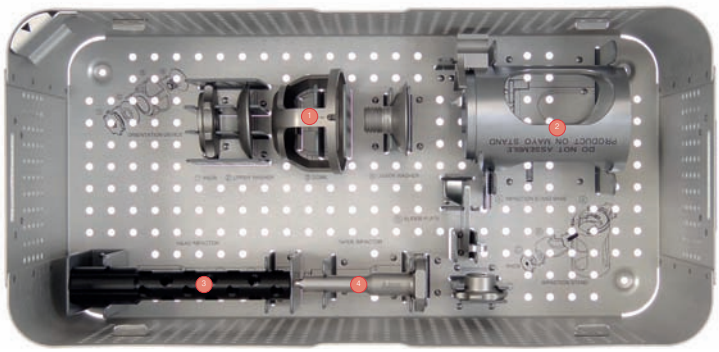
Ordering Information
Instruments

PRIMARY INSTRUMENT TRAYS - GLENOID

Cat No.	Description
2130-24-110	General Case & Inserts
2130-24-120	General Case Base
2130-24-130	General Case Lid
2130-24-140	General Case Top Insert
2130-24-150	General Case Middle Insert

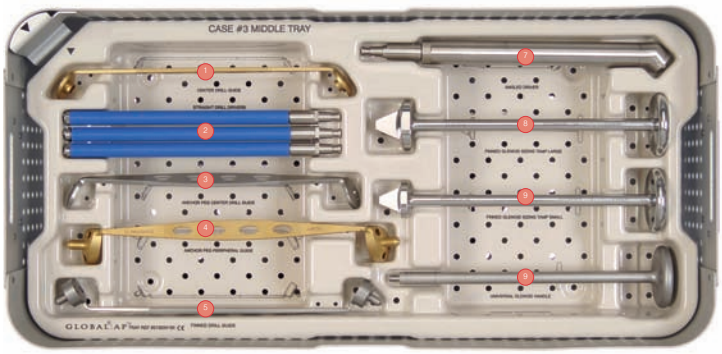
General Case Base

1. 2130-01-050 Orientation Device Assembly
2. 2130-01-040 Impaction Block Assembly
3. 2130-04-000 Head Impactor
4. 2130-01-055 Taper Impactor

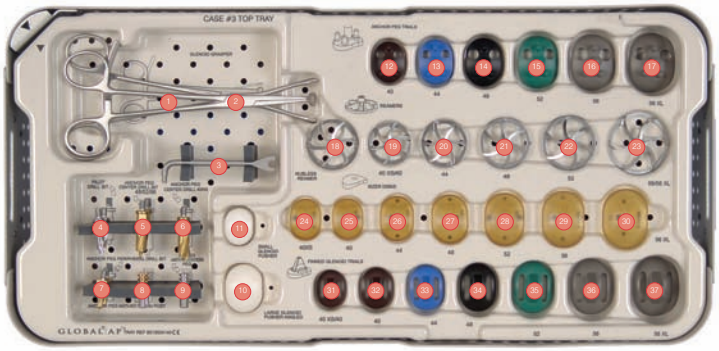


General Case Middle Insert

1. 2128-61-006 Centre Drill Guide
2. 2128-61-012 Straight Drill Driver
3. 2236-80-060 Anchor Peg Centre Drill Guide
4. 2236-80-080 Anchor Peg Peripheral Drill Guide
5. 2128-61-014 Keeled Glenoid Drill Guide
6. 2235-75-000 Angled Driver
7. 2128-61-016 Keeled Glenoid Tamp - Large
8. 2128-61-015 Keeled Glenoid Tamp - Small
9. 2236-03-000 Universal Glenoid Handle



General Case Top Insert



1. 2128-61-017 Glenoid Grasper
2. 2128-61-011 Anti-rotation Peg Grasper
3. 2235-72-000 45˚ Drill Wrench
4. 2128-61-007 Pilot Dill Bit
5. 2236-80-070 Anchor Peg Centre Drill Bit 48 / 52 / 56 mm
6. 2236-80-075 Anchor Peg Centre Drill Bit 40 / 44 mm
7. 2236-80-090 Anchor Peg Peripheral Drill Bit
8. 2236-80-091 Anchor Peg Anti-rotation Peg
9. 2128-61-010 Keeled Glenoid Anti-rotation Peg
10. 2236-22-000 Large Glenoid Pusher - Angled
11. 2236-21-000 Small Glenoid Pusher
12. 2236-80-000 Anchor Peg Glenoid Trial 40 mm
13. 2236-80-010 Anchor Peg Glenoid Trial 44 mm
14. 2236-80-020 Anchor Peg Glenoid Trial 48 mm
15. 2236-80-030 Anchor Peg Glenoid Trial 52 mm
16. 2236-80-040 Anchor Peg Glenoid Trial 56 mm
17. 2236-80-050 Anchor Peg Glenoid Trial 56 XL
18. 2128-61-005 Nubless Glenoid Reamer
19. 2128-61-000 Glenoid Reamer 40 XS / 40
20. 2128-61-001 Glenoid Reamer 44 mm
21. 2128-61-002 Glenoid Reamer 48 mm
22. 2128-61-003 Glenoid Reamer 52 mm
23. 2128-61-004 Glenoid Reamer 56 / 56 XL
24. 2234-88-000 Clear Glenoid Sizer Disk 40 XS
25. 2234-89-000 Clear Glenoid Sizer Disk 40 mm
26. 2234-90-000 Clear Glenoid Sizer Disk 44 mm
27. 2234-91-000 Clear Glenoid Sizer Disk 48 mm
28. 2234-92-000 Clear Glenoid Sizer Disk 52 mm
29. 2234-93-000 Clear Glenoid Sizer Disk 56 mm
30. 2234-95-000 Clear Glenoid Sizer Disk 56 XL
31. 2128-61-024 Keeled Glenoid Trial 40 XS
32. 2128-61-025 Keeled Glenoid Trial 40 mm
33. 2128-61-026 Keeled Glenoid Trial 44 mm
34. 2128-61-027 Keeled Glenoid Trial 48 mm
35. 2128-61-028 Keeled Glenoid Trial 52 mm
36. 2128-61-029 Keeled Glenoid Trial 56 mm
37. 2128-61-030 Keeled Glenoid Trial 56 XL

Ordering Information
Miscellaneous

DNIs

Cat No.	Description
2130-99-010	Humeral DNI Size 8
2130-99-020	Humeral Porocoat® Porous Coating DNI Size 8
2130-99-030	Standard Head DNI 48 x 18
2130-99-040	Eccentric Head DNI 48 x 18
2130-99-050	Neck Assembly DNI Components
2130-22-000	X-Ray Templates

Bone Cements

3095020	SmartSet® GHV Gentamicin 20g
3095040	SmartSet® GHV Gentamicin 40g
3092020	SmartSet® HV 20g
3092040	SmartSet® HV 40g

CEMVAC® Syringes

831215	Single Syringe Set (Box 20 x 1 Single pack)
831220	Single Syringe Set (Box 10 x 2 double pack)

CEMVAC® Instrumentation - Hardware

831202	CEMVAC® Syringe holder
831205	CEMVAC® one piece gun
831401	DePuy multi-pressure vacuum pump
3210016	Nozzle cutter
3210031	Airline with two fittings (international only)*
3210033	Airline with two fittings (Germany only)*

* manufactured by Penlon Ltd.

CEMVAC® Nozzle Tips

831231	Revision Nozzle (diameter symbol) 6.5 (x5)

Global AP™ Adjustable Prosthesis System

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

Intended Use / Indications
Total shoulder or hemi-shoulder replacement is indicated for:
- A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
- 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;
- 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:
- Un-united humeral head fractures;
- Avascular necrosis of the humeral head;
- Rotator cuff tear arthropathy.

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.

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

Press-fit or Cemented Components
Humeral stem prostheses without porous coating and labelled "for press fit or cemented use only" are indicated for press-fit un-cemented use or for use with bone cement.

Contraindications
The following conditions are contraindications for total shoulder and hemi-shoulder arthroplasty.
- Active local or systemic infection.
- Inadequate bone stock in the proximal humerus or glenoid fossa for supporting the components.
- 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.
- 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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