





RECOVERY FUNCTION SURVIVORSHIP

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



Described by Charles Neer in 1983¹, the shoulder pathology known as Cuff Tear Arthropathy (CTA) has historically been seen as a significant surgical challenge.

Non-constrained total or hemi shoulder arthroplasties have limited clinical outcomes in such indications, and most of the constrained and semi-constrained prostheses developed in the 1970's-1980's for CTA (in particular, all reversed ball and socket designs) remained purely experimental due to poor motion capability, instability and a high rate of glenoid loosening.^{2,6,16}

In 1985, Paul Grammont (Dijon University Hospital – France) designed the first semi-constrained reverse concept that met the challenges inherent in cuff tear arthropathy cases³. Known today as the DePuy Delta CTA™, this shoulder prosthesis is now accepted as the treatment of choice for shoulder cuff tear arthropathy⁴, with more than twenty years of clinical success and 20,000 cases performed all over the world.

Based on the experience of the Delta CTA™ System, the next generation of reverse shoulder arthroplasty, the DePuy Delta Xtend prosthesis has been designed using the latest scientific, engineering, and clinical knowledge in CTA cases in order to extend the clinical success associated with 20 year history of the Delta CTA.

Keeping the three design features that differentiated the Delta CTA™ from previous reverse designs and made it successful:

- Joint center of rotation positioned on the glenoid bone surface to avoid pull-out torques on the glenoid component⁵
- Non-anatomic neck-shaft angle (155°) for joint stability^{3,6}
- Optimal deltoid tensioning to maximize its action without over-stretching the tissues⁵

Reducing the risk of scapular neck erosion and maximizing the shoulder range of motion:^{7,8}

- Inferior overlap of the glenoid component allowed by a new eccentric glenosphere design and a new metaglene fixation system

Preserving bone to permit intervention and faster recovery with:

- Curved-back metaglene design⁹
- Reduced proximal geometry monobloc humeral stem for cemented application

Design based on the success of the Delta CTA™ Reverse Shoulder means that the Delta Xtend™ System is the next step forward for appropriate management of patients with Cuff Tear Arthropathy. The Delta Xtend™ System allows you to treat more patients, effectively.

The Delta Xtend™ Surgeon Design Team



Dr. Didier Capon
France



Dr. David Collins
USA



Prof. Anders
Ekelund
Sweden



Dr. Laurent
Lafosse
France



Prof. Lieven
De Wilde
Belgium



Dr. Cécile Nérot
France



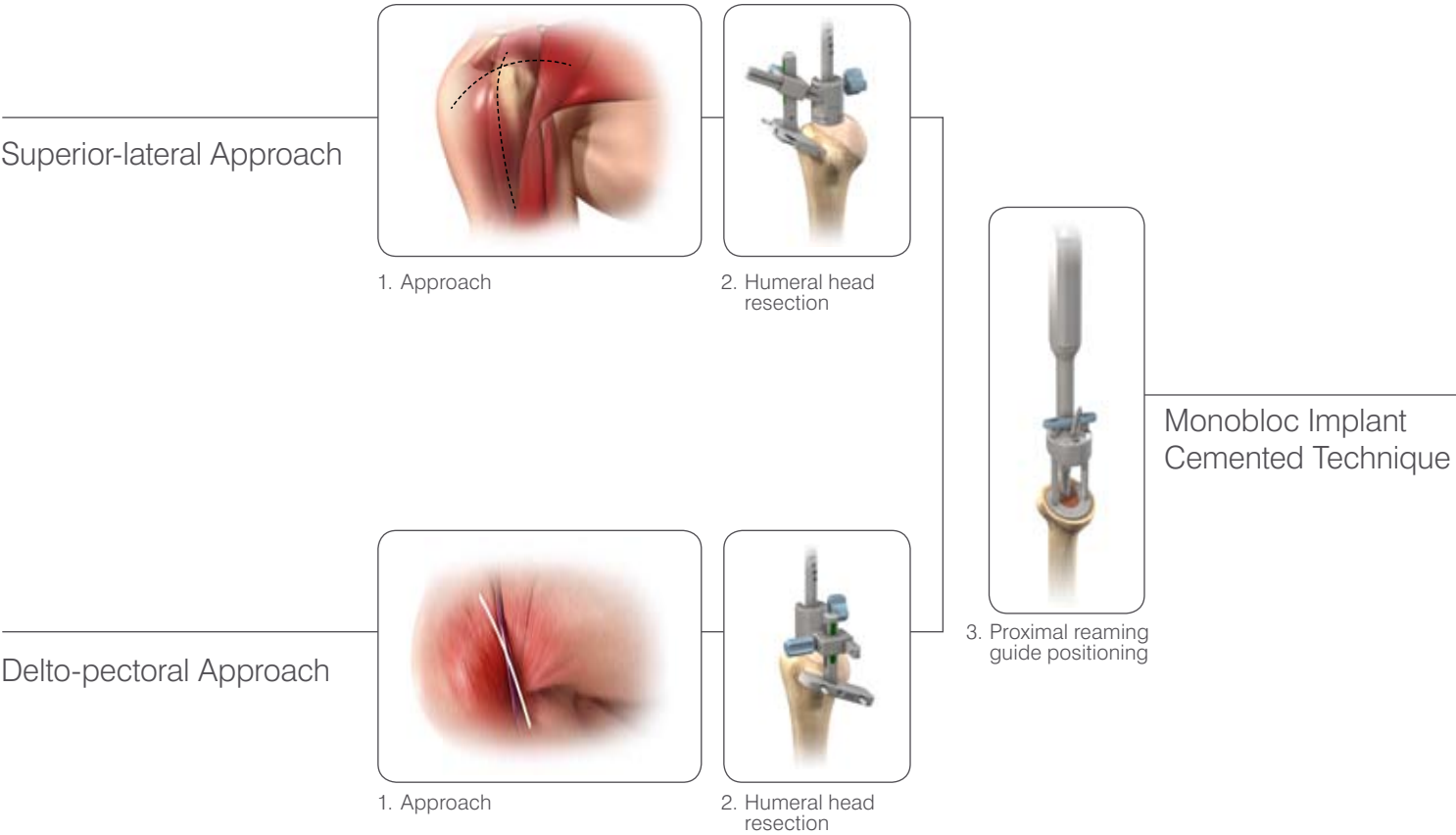
Dr. Ludwig
Seebauer
Germany



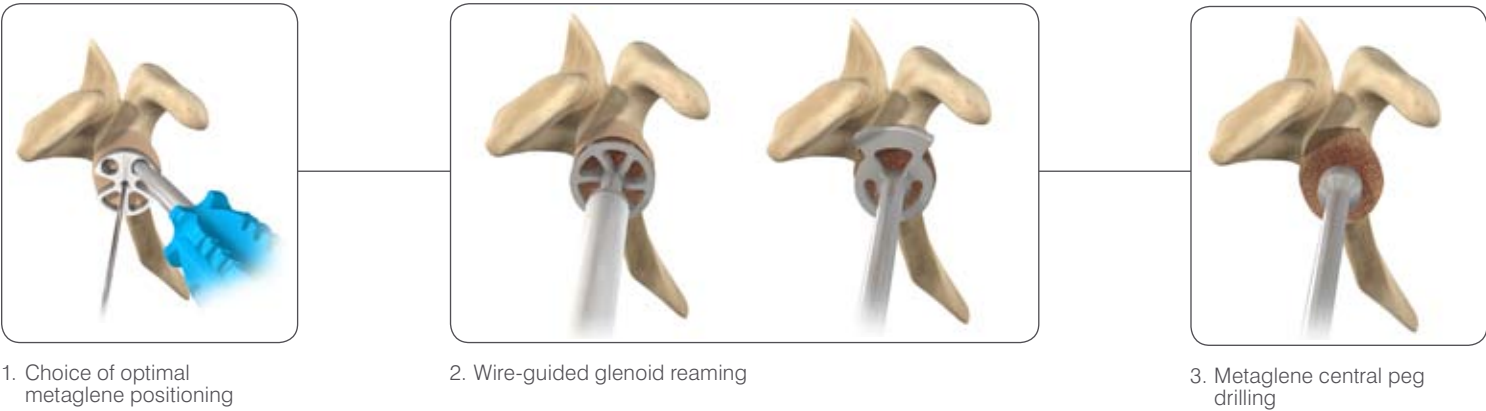
Dr. Michael
Wirth
USA

Delta Xtend™ Key Surgical Steps

Humeral Surgical Steps



Glenoid Surgical Steps





4. Determination of the epiphysis size



5. Proximal humeral reaming



6. Final implant insertion



7. Cup impaction

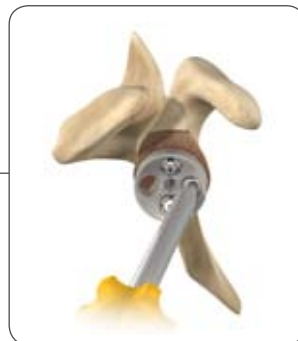
Glenoid Surgical Steps



4. Metaglene impaction



5. Inferior and superior locking screw fixation



6. Anterior and posterior spherical head screw fixation



7. Glenosphere implantation

Contents

Design Rationale

Surgical Technique

Pre-operative Templating and Patient Positioning	10
Surgical Approach	11-13
Intramedullary Canal Preparation	14
Humeral Head Resection.....	15-17
Exposing the Glenoid	18, 19
Positioning the Metaglene Central Peg	20-22
Reaming the Glenoid Bone	23,24
Metaglene Implantation	25
Inferior and Superior Metaglene Screw Placement.....	26-28
Anterior and Posterior Metaglene Screw Placement.....	29, 30
Placement of the Proximal Humeral Reaming Guide.....	31
Proximal Humeral Reaming	
Cemented Monobloc Humeral Implants	32
Humeral Trial Implant Insertion	
Cemented Monobloc Humeral Implants	33
Glenosphere Trial Placement.....	34
Cup Trials and Trial Reduction.....	35
Joint Tensioning and Stability Assessment	36
Definitive Glenosphere Fixation	37-39
Definitive Humeral Implant Insertion	
Cemented Monobloc Humeral Implants	40-41
Cases of Proximal Humeral Bone Loss.....	42, 43
Revision to Hemi-Arthroplasty	44
Post-Operative Management.....	45

Ordering Information

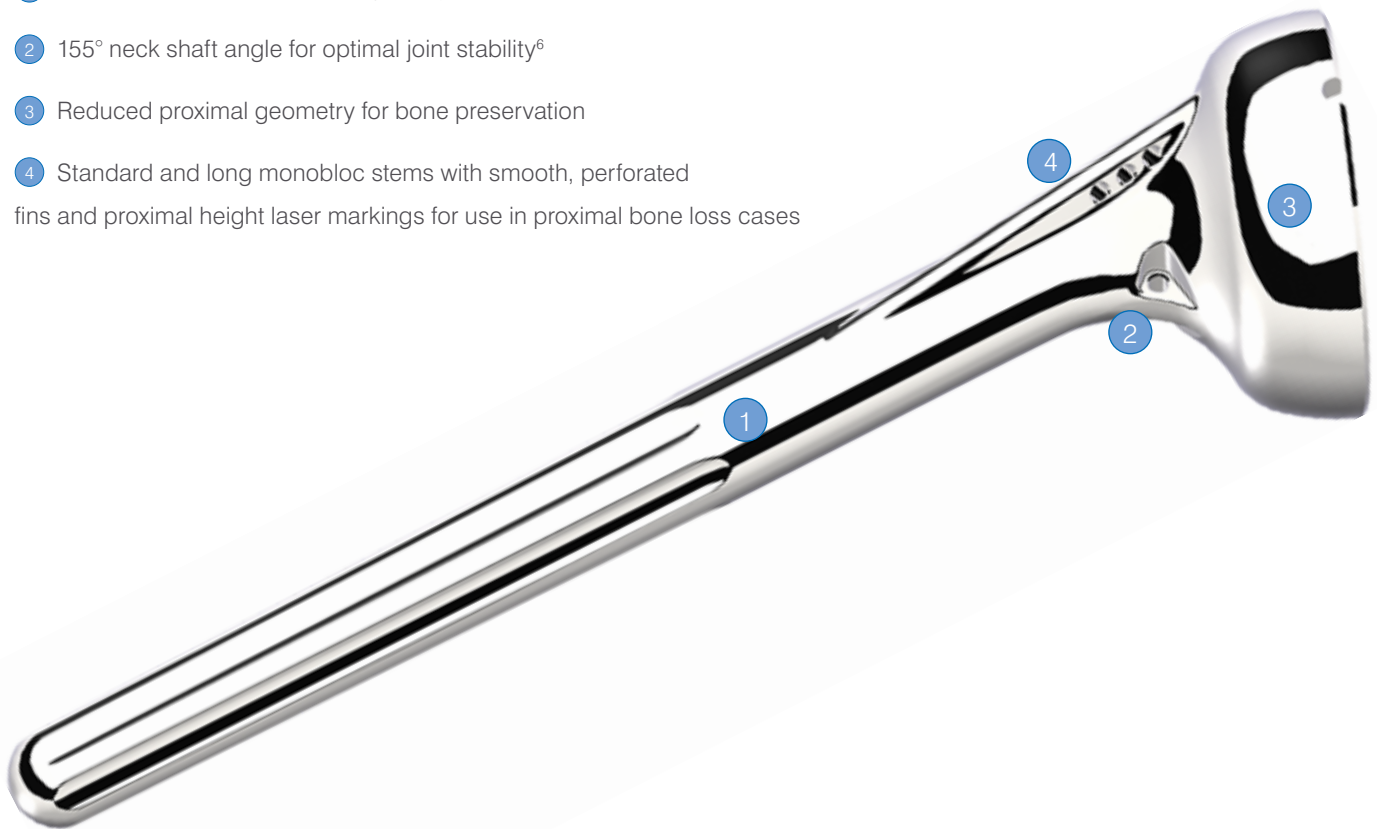
Implants.....	46
Instrumentation	47-49

Delta Xtend™ Design Rationale

The Delta Xtend™ System is a total, semi-constrained shoulder arthroplasty that reverses the normal relationship between the scapular and humeral components, moving the scapulo-humeral joint center of rotation medially and inferiorly, increasing the deltoid lever arm as well as the deltoid tension and therefore allowing the muscles of the deltoid group to compensate for rotator cuff deficiency⁵. The Delta Xtend™ humeral stem is designed for cemented fixation. The glenoid component is cementless with four screws as primary fixation and HA coating for secondary fixation. Each design feature has been defined to help achieve the clinical goals for CTA cases with the Delta Xtend Reverse Shoulder System: recovery, function, and survivorship.

Cemented Monobloc Humeral Implant

- ① Polished cobalt chromium alloy for optimized cemented fixation¹²
- ② 155° neck shaft angle for optimal joint stability⁶
- ③ Reduced proximal geometry for bone preservation
- ④ Standard and long monobloc stems with smooth, perforated fins and proximal height laser markings for use in proximal bone loss cases





Polyethylene Humeral Cups

5 +3, +6 and +9 mm cup sizes are available to adjust joint tension for optimal deltoid function based on clinical heritage^{4,5}



Glenoid Component

6 Increased glenosphere diameter (38 and 42 mm) and eccentric option for improved stability, maximized range of motion and reduced risk of scapular erosion⁸

7 Center of rotation on glenoid bone surface for high resistance to loosening shear forces^{5,8,13}

8 Two locking variable angle screws (compress and lock) and two compression screws with +/- 10 degrees adjustable angulation for metaglene primary fixation, to maximize resistance to loosening shear forces¹³

9 Curved back and smaller metaglene, for bone preservation and low positioning on the glenoid to reduce risk of scapular bone erosion^{8,13}



Delta Xtend™ CTA Heads

- Hemi-heads available in two diameters and two head heights for easy revision from reverse to hemi-arthroplasty
- Extended articular surface for improved potential range of motion



Pre-Operative Templating and Patient Positioning



Figure 1

Pre-operative Templating

An initial assessment of the glenoid bone should be carried out using radiographic and CT imaging to determine whether the patient is suitable for treatment. The size of the glenoid vault should be assessed inferiorly in particular to ensure that all four metaglene screws can be placed within glenoid bone.

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



Figure 2

Patient Positioning

The patient should be in the beach chair position, with the affected arm completely free and on a support (Figure 2).

Surgical Approach

The Delta Xtend™ prosthesis can be implanted using a superior-lateral deltoid split approach or a delto-pectoral approach.

The superior-lateral approach enables clear visualization of the glenoid and therefore facilitates the implantation of the glenoid components.

The delto-pectoral approach has the advantage of offering a good view of the inferior part of the glenoid. Therefore, the choice mainly depends on the surgeon's preference and clinical parameters.

Revision surgery, for instance, is usually performed using a delto-pectoral approach since the patient has already had that incision and since it allows for a longer humeral incision when faced with difficult removal of the humeral stem. However, for cases of retroverted glenoid, the implant placement can be more difficult via the delto-pectoral approach and can lead to damage of the deltoid muscle. Moreover, as the rotator cuff lesion is mainly located at the supero-posterior aspect of the cuff, the (partial) insertion of the remaining subscapularis (that is often needed through this approach) could weaken the remaining muscular structure. The superior-lateral approach may be preferred in these cases.

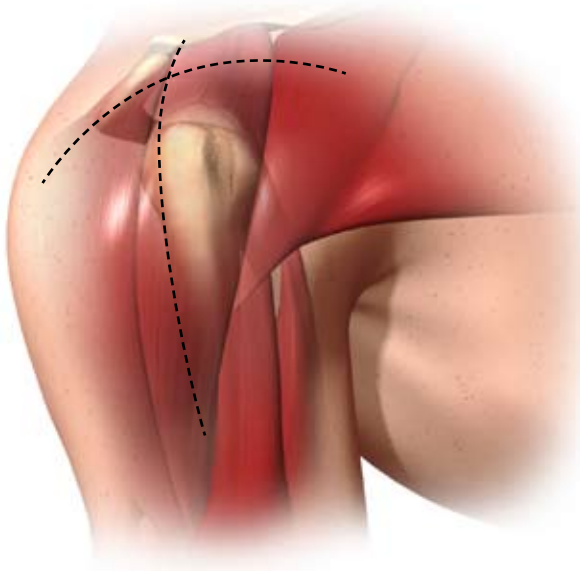


Figure 3



Figure 4

Superior-lateral Approach

The skin incision is 10-12 cm long and can be antero-posterior along the lateral edge of the acromion or made in a lateral direction (Figure 3). Following subcutaneous dissection, separate the anterior and middle deltoid muscle bundles opposite the lateral margin of the acromion using blunt dissection (Figure 4). The dissection starts at the level of the AC joint, 5-7 mm posterior to the tip of the acromion, and extends straight laterally down into the deltoid muscle. It should not extend more than 4 cm from the external aspect of the acromion in order to preserve the axillary nerve which is located at the turning fold of the subacromial bursa.

When the subacromial bursa is visible, gentle longitudinal traction in line with the limb allows a retractor to be placed in the subacromial space. The anterior deltoid is then released subperiosteally from its acromial insertion up to the AC joint. The deltoid release from the anterior acromion can include a small piece of bone to facilitate repair and to protect the deltoid muscle.

Once the subacromial bursa has been removed, the humeral head is visible at the anterior edge of the acromion. Exposure may be improved, if necessary, by dividing the AC ligament and performing acromioplasty.

The limb is then externally rotated and the head is dislocated antero-superiorly to facilitate positioning of the cutting guide. If the bicep tendon is still present, a tenotomy or tenodesis should be performed. The subscapularis, teres minor and infraspinatus are retained when present. A partial detachment of the subscapularis may be performed when the superior dislocation of the humerus is difficult to obtain.

Delto-pectoral Approach

The skin incision follows the line from the midpoint of the clavicle to the midpoint of the arm (Figure 5). Subcutaneous flaps are elevated to expose the fatty strip that marks the delto-pectoral interval. Dissect medial to the cephalic vein and retract it laterally with the deltoid muscle (Figure 6). Incise the clavipectoral fascia from the inferior border of the coracoacromial ligament distally to the superior border of the tendon of the sternal head of the pectoralis major (Figure 7). Sharply and bluntly dissect the humeroscapular motion interface (subacromial, subdeltoid and subcoracoid). Palpate the axillary nerve at the anterior-inferior border of the subscapularis muscle. Electrocoagulate or ligate the anterior humeral circumflex vessels near the humerus at the inferior border of the subscapularis (Figure 8).

If the bicep's long head tendon is intact, open its sheath and tenodesis the tendon in the groove or to the pectoralis major tendon with non-absorbable sutures. Excise the proximal biceps tendon and hypertrophic sheath. A biceps tenotomy can also be performed in elderly patients.

Place a tag suture in the tendon of the subscapularis, 2 cm medial to its point of insertion, in the lesser tuberosity. Release the tendon, along with the underlying capsule, from the lesser tuberosity and the proximal humerus (Figure 9). Strip the remaining inferior and posterior-inferior capsule from the humerus. Dislocate the humeral head (Figure 10).



Figure 5



Figure 6



Figure 7



Figure 8



Figure 9



Figure 10

Intramedullary Canal Preparation

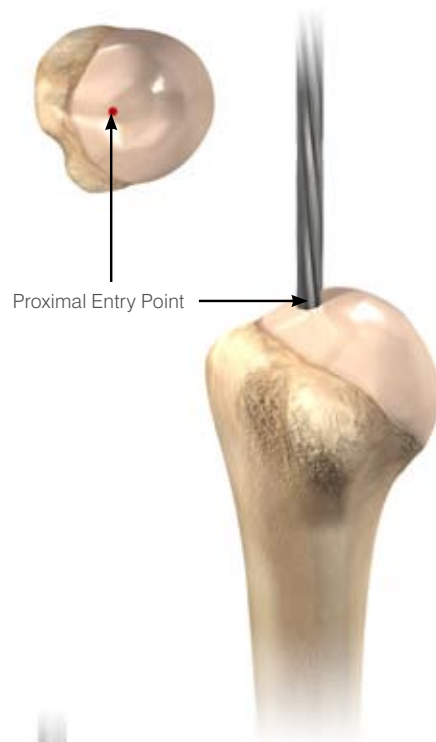


Figure 11



Figure 12

Using the 6 mm medullary canal reamer, make a pilot hole in the cortical surface of the bone eccentrically and as superior as possible so that the reamer passes directly down the intramedullary canal (Figure 11). Ream the medullary canal using the T-Handle on the reamer. Do not use a power tool as this could remove more bone than necessary.

When using the standard length prosthesis, pass the reamer down the intramedullary canal until the projecting circular mark on the reamer is level with the pilot hole. When using the long stem prosthesis, pass the entire length of the cutting flutes down the intramedullary canal.

Continue to ream sequentially until the reamer begins to bite on the cortical bone of the intramedullary canal of the humerus (Figure 12).

The final reamer size will determine the size of the cutting guide handle, the epiphyseal reaming guide, the broach, trial stem and final implant. For example, if the 12 mm reamer begins to gain purchase in the intramedullary cortical bone, use a 12 mm humeral trial stem and final component.

Humeral Head Resection

Select the handle for the cutting guide of the appropriate size. Taking the previous example, if reaming stopped at 12 mm, select the 12 mm handle. Select the cutting guide and cutting plate according to the surgical approach used (superior-lateral or delto-pectoral).

Assemble the plate on the cutting guide first (1) and then fix the cutting guide on the cutting handle (2) (Figure 13).

The cutting guide should be fully seated on the cutting handle.

Drive the cutting assembly down the intramedullary canal until it is fully in contact with the top of the humeral head. The orientation pin is then passed through the hole in the cutting handle in the desired retroversion. The retroversion is calculated with reference to the forearm axis. This should preferably be close to 0-10° since excessive retroversion can restrict joint rotation, especially internal rotation. The cutting handle should then be turned to align the orientation pin and the forearm (Figure 14).

Slide the cutting plate to adjust the resection level. The cutting plate color code shows if the resection level is appropriate. If the cutting level indicator is green, the guide is at the correct height. If it is red, the cutting plate needs to be adjusted (Figure 15).

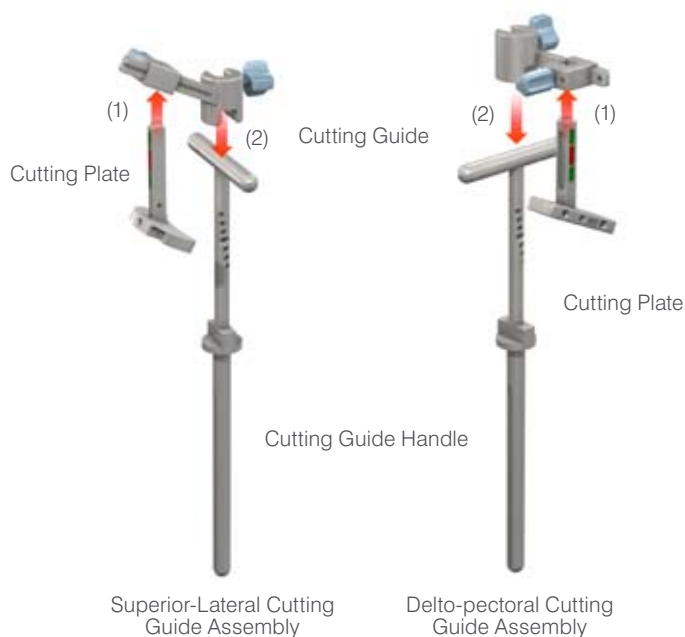


Figure 13



Figure 14

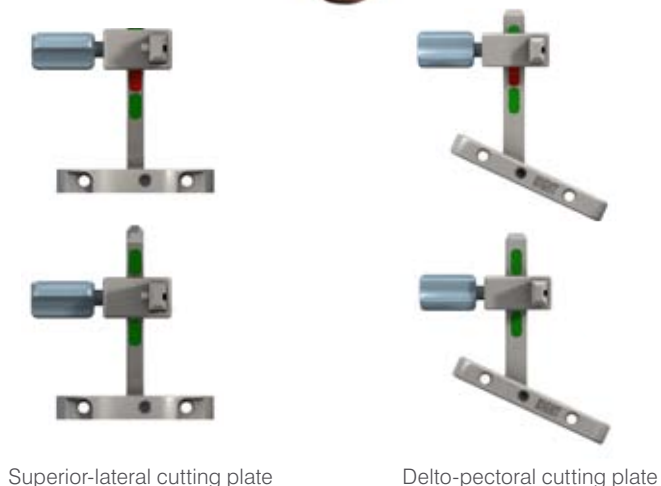


Figure 15



Superior-lateral approach



Delto-pectoral approach

Visually verify that the resection is 1 to 2 mm below the proximal area of the greater tuberosity (at the level of the supraspinatus insertion in an intact shoulder).

Note that the angle of the cut is 155° and therefore different from the anatomical neck/shaft angle (135°). This angle gives optimal joint stability to the reverse prosthesis.⁶

Pre-drill the cortical bone through the cutting plate using a 3.2 mm drill bit, and insert the two fixation pins to fix the cutting plate to the humerus (Figure 16).

Figure 16

Remove the cutting guide and add a third fixation pin through the cutting plate to secure the assembly and resect the humeral head, aligning the saw blade with the superior aspect of the cutting plate (Figure 17, Option 1).

Note: The two external pins are parallel. The cutting plate can therefore be turned upside down before securing it with the third pin to obtain a flat surface (Figure 17, Option 2).

Place a protecting plate on the humeral resection surface to protect the bone from damage during the following surgical steps (Figure 18).

Pass a forked retractor under the scapula to lower the humerus. If this provides a clear view of the glenoid surface, the resection level is correct. If not, a further humeral head resection may be performed.

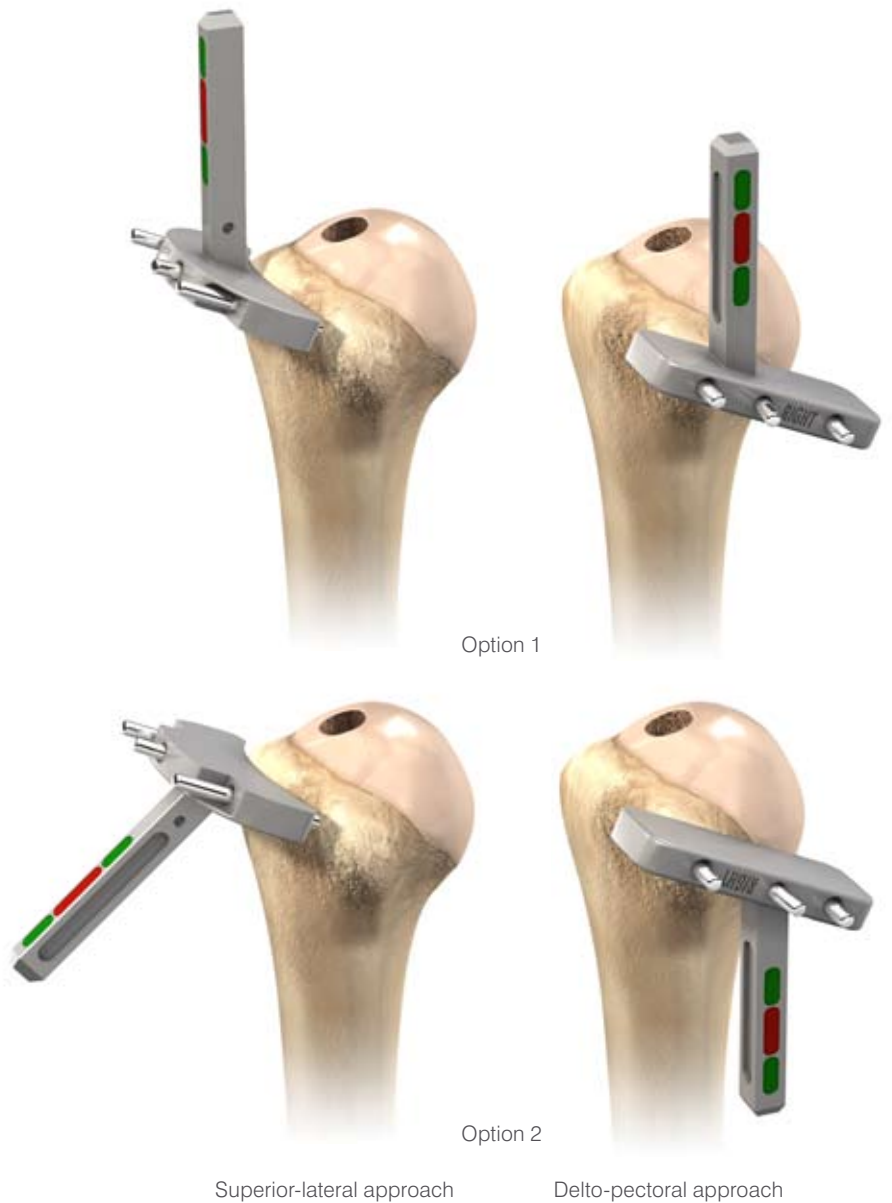


Figure 17



Figure 18

Exposing The Glenoid

Position a forked retractor in the axillary margin of the scapula under the inferior glenoid labrum to move the humerus down or backward, depending on the approach taken (Figure 19).

When exposing the glenoid, it is critical to note the presence of the axillary nerve and protect it at all times. Excise the biceps remnant and entire labrum. Release the entire capsule from around the glenoid. In certain cases, the capsule may have to be excised depending on the extent of any contractures and the adequacy of exposure. In some cases, the origin of the triceps long head may be incised from the infraglenoid tubercle.

Bluntly (finger or elevator) dissect in a circumferential manner from the base of the coracoid process to well beyond the most inferior aspect of the glenoid. It is essential to palpate the following osseous scapular orientation points: the base of the coracoid process, the inferior part of the glenoid neck and, when possible, infra glenoid tubercle and lateral border of the scapula. Retractors should be placed so that the entire glenoid face is in clear view to aid accurate placement of the guide pin.



Figure 19

Subscapularis Mobilization in the Delto-pectoral Approach

Both sharp and blunt methods are used to mobilize the subscapularis. Completely release the rotator interval to the base of the coracoid process and release the superior border of the subscapularis from the base of the coracoid process. Then completely release the motion interface between the coracoid muscles (conjoined tendon) and the anterior subscapularis. Lastly, completely release the posterior border of the subscapularis tendon and distal muscle belly from the anterior and anterior-inferior glenoid rim, glenoid neck and the most lateral part of the scapular body.

Glenoid Preparation

Remove any remnants of labrum from the glenoid. Then remove all articular cartilage (large straight curette) from the glenoid face. In addition, any osteophytes present may also have to be removed to determine the bony anatomy.

Positioning the Metaglene Central Peg

Positioning of the metaglene is important to achieve an optimal glenoid fixation, to limit potential bone impingement and to achieve a final good, stable range of motion. Therefore, particular attention should be given to that surgical step.

The position chosen should maximize contact with the glenoid bone surface and to allow secure fixation of the screws in bone.

The metaglene should ideally be positioned on the lower circular area of the glenoid bone. The metaglene central peg is positioned in the center of the inferior circle of the glenoid (This point is often posterior and inferior to the intersection of the glenoid axis) (Figure 20).

These anatomical reference points help to position the metaglene as inferior as possible on the glenoid bone in order to limit potential bone impingement, while keeping a secure glenoid implant fixation. However, radiographic, CT images combined with X-ray templates and per-operative view can lead to a choice of position a little bit more superior to obtain fixation in good bone stock and complete seating of the metaglene on the bone.

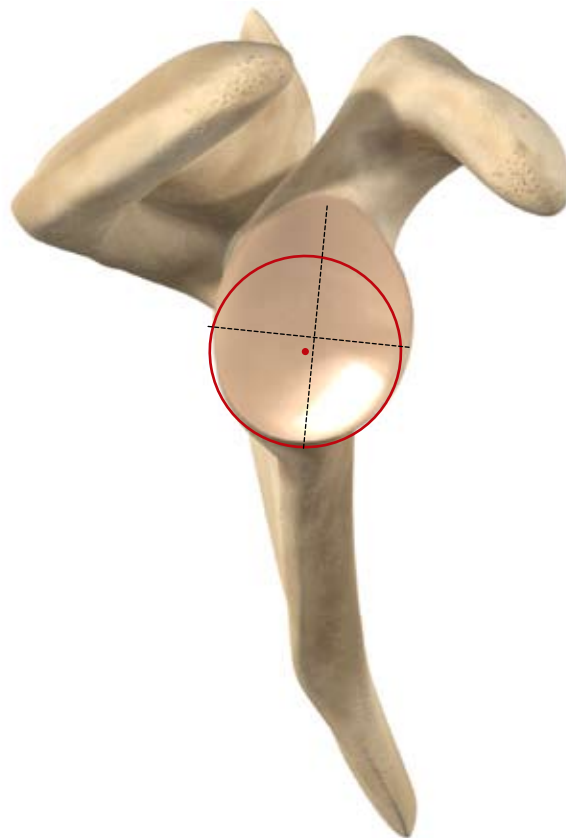


Figure 20



Figure 21



Figure 22

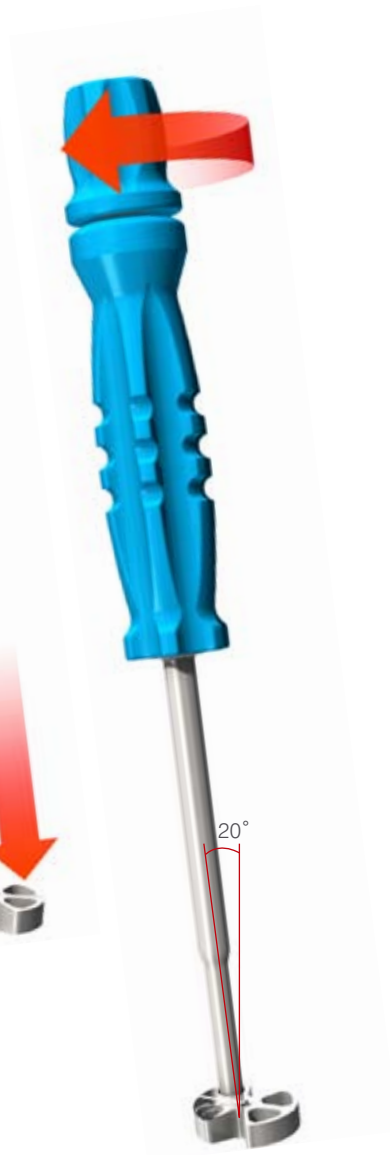


Figure 23

The metaglene positioner is used to obtain the optimal metaglene position. The positioner plate is the same diameter as the metaglene.

Assemble the positioner by inserting and threading the internal rod into the positioner handle (Figure 21).

Insert the hex head tip of the handle in the corresponding plate hole (right or left depending on the shoulder being operated upon) and lock the assembly by tightening the internal rod (Figure 22).

Note: The handle is set at an angle of 20° to the plate to ensure optimal visibility (Figure 23).

Position the plate as low as possible so that its border follows the inferior edge of the glenoid. Note that inferior osteophytes may result in mal-positioning. X-rays should therefore be checked to avoid this problem.

Providing that the morphology of the glenoid hasn't been altered by the disease, the guide plate is perpendicular to the plane of the glenoid face. Make sure that the proximal handle of the instrument is not tilted superiorly. The guide pin should be inserted either perpendicularly to the glenoid face or with the distal tip of the guide pin in a slightly superior direction. This ensures that the glenosphere will either be perpendicular to the plane of the glenoid face or have a slight inferior tilt which may reduce the risk of scapular notching.

Place the 2.5 mm metaglene central guide pin in the plate's central hole and drill it through the far cortex using a power tool (Figure 24).

Remove the metaglene positioner, leaving the guide pin in place (Figure 25).

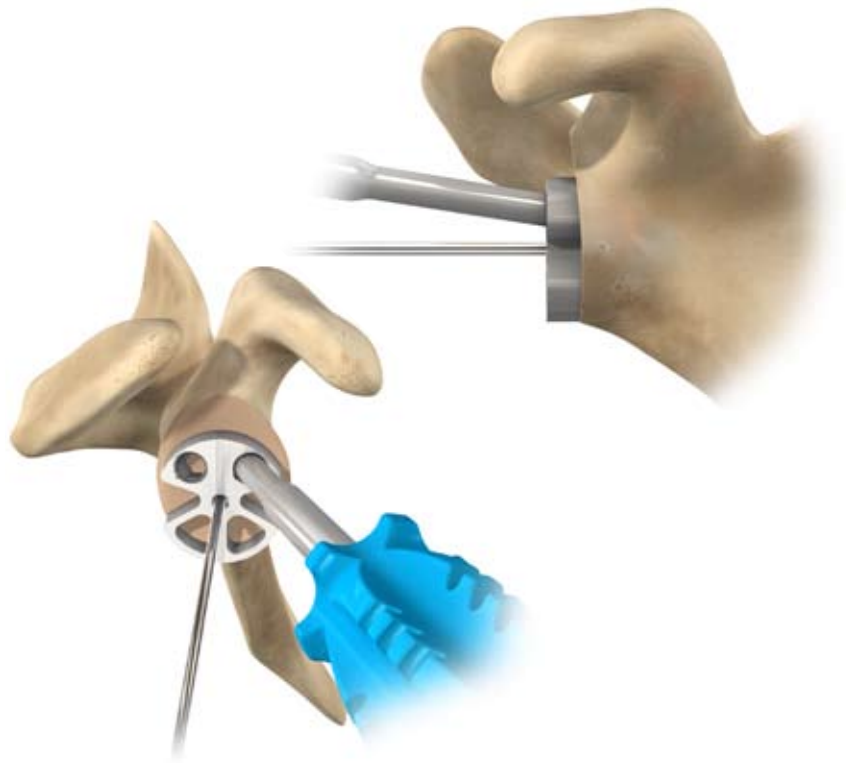


Figure 24

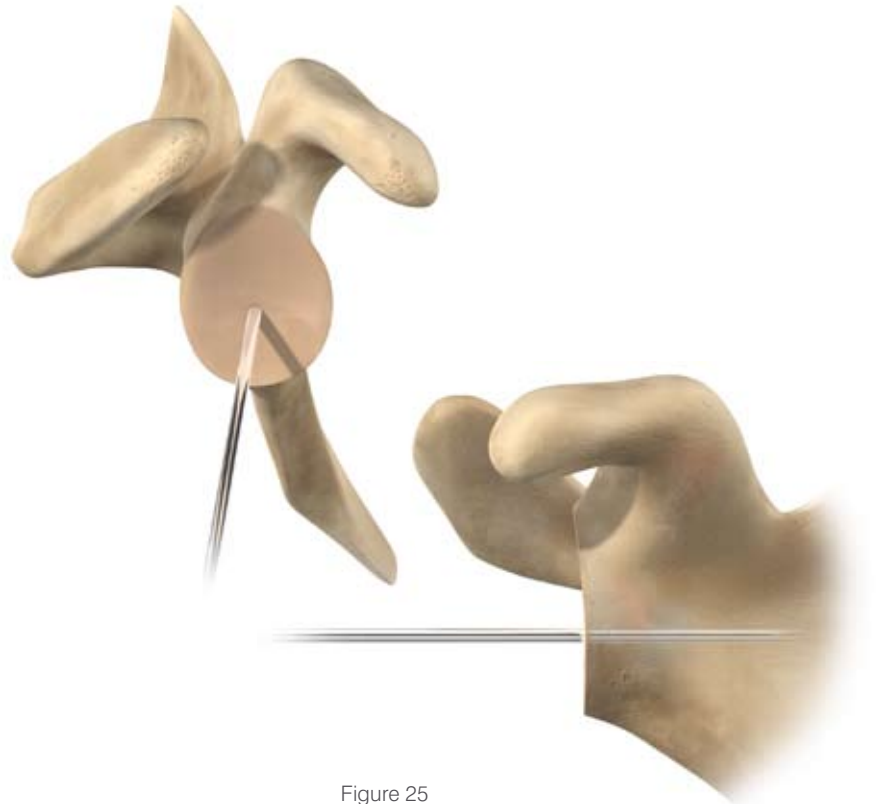


Figure 25

Reaming the Glenoid Bone



Figure 26



Figure 27



Figure 28

Slide the 27 mm glenoid resurfacing reamer onto the central guide pin and ream either manually or using a power tool. This reamer prepares a smooth curved surface with the same diameter as the metaglene (Figure 26). Use the metaglene reamer carefully to avoid any inadvertent fracturing of the glenoid, especially if the glenoid is sclerotic. Make sure the axillary nerve is protected. Initiate and proceed with the reaming, turning at low speed prior to engaging the glenoid. It is useful to collect the osseous products of reaming and irrigate often to maximize visualization and thereby ensure optimal reaming. Be careful not to over ream and to preserve the subchondral bone.

Ream the superior glenoid bone by hand, using the manual 42 mm glenoid reamer (Figure 27). This step is necessary to avoid any potential conflict between the glenosphere and the superior area of the glenoid bone (Figure 28).

Manual reaming should be carried out until the central part of the manual reamer is in full contact with the curved central glenoid surface.

Use the manual glenoid reamer to ream the glenoid anteriorly, posteriorly and inferiorly if necessary. A smooth surface without any remaining cartilage should be obtained.

Check the adequacy of the reaming by applying the glenoid reaming level checker on the glenoid surface. No space (except if due to bone erosion) should be seen between the instrument and the glenoid surface (Figure 29).

Remove the resurfacing reamer, leaving the metaglene central guide pin in place (Figure 30).

Connect the cannulated stop drill to the power source and drill the central hole over the guide pin until full contact between the drill and bone is obtained (Figure 31).

Remove the stop drill and the central guide pin.



Figure 29

Figure 30



Figure 31

Metaglene Implantation



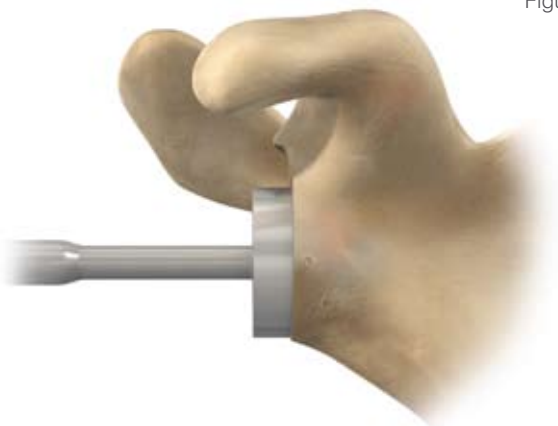
Figure 32



Figure 33

Assemble the internal rod of the metaglene holder in the metaglene holder main body. Insert the metaglene holder hex tip in the final metaglene implant central hole and tighten the assembly. (Figure 32).

Place the metaglene on the glenoid bone and ensure that the metaglene is fully seated. Apply bone graft if necessary to help fill surface irregularities between the metaglene and the glenoid bone. Rotate the metaglene so that the inferior screw can be aimed toward the scapular neck. The vertical metaglene marking should be aligned with the scapular neck inferiorly and with the base of the coracoid process superiorly (long axis of the glenoid bone) (Figure 33). The metaglene peg is 0.6 mm larger in diameter than the drill to enable a press fit. Gently impact with a mallet in the proper orientation for inferior screw placement and then remove the metaglene holder.



Inferior and Superior Metaglene Screw Placement

Locking metaglene screws allow an angulation of ± 10 degrees around the optimal 17 degrees screw positioning recommended by Professor Grammont (Figure 34).

Place the 2.5 mm drill guide in the metaglene inferior hole. The drill guide can be angled to ± 10 degrees but should always be seated fully in the metaglene hole. Palpate the scapular neck and aim into good bone. Using the 2.5 mm drill bit, start drilling through the subchondral bone to approximately 10 to 12 mm deep (Figure 35). Then stop drilling and push gently on the drill bit to make sure that the drill is contained in the bone. Redirect and re-drill if uncontained. When a satisfactory drilling direction has been obtained, drill and push until the cortex is perforated.

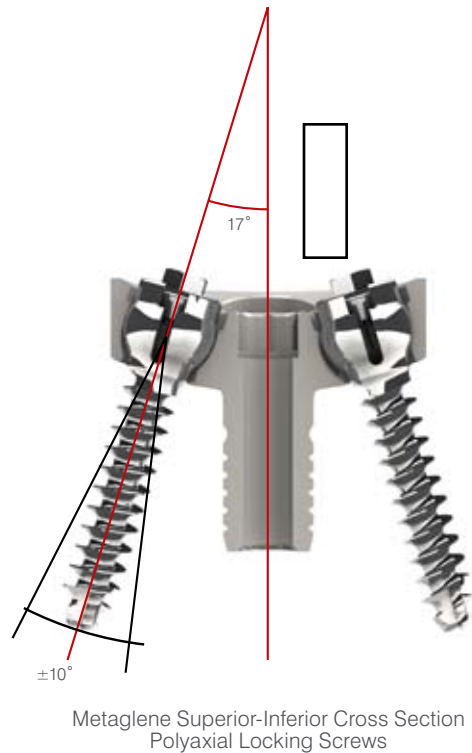


Figure 34

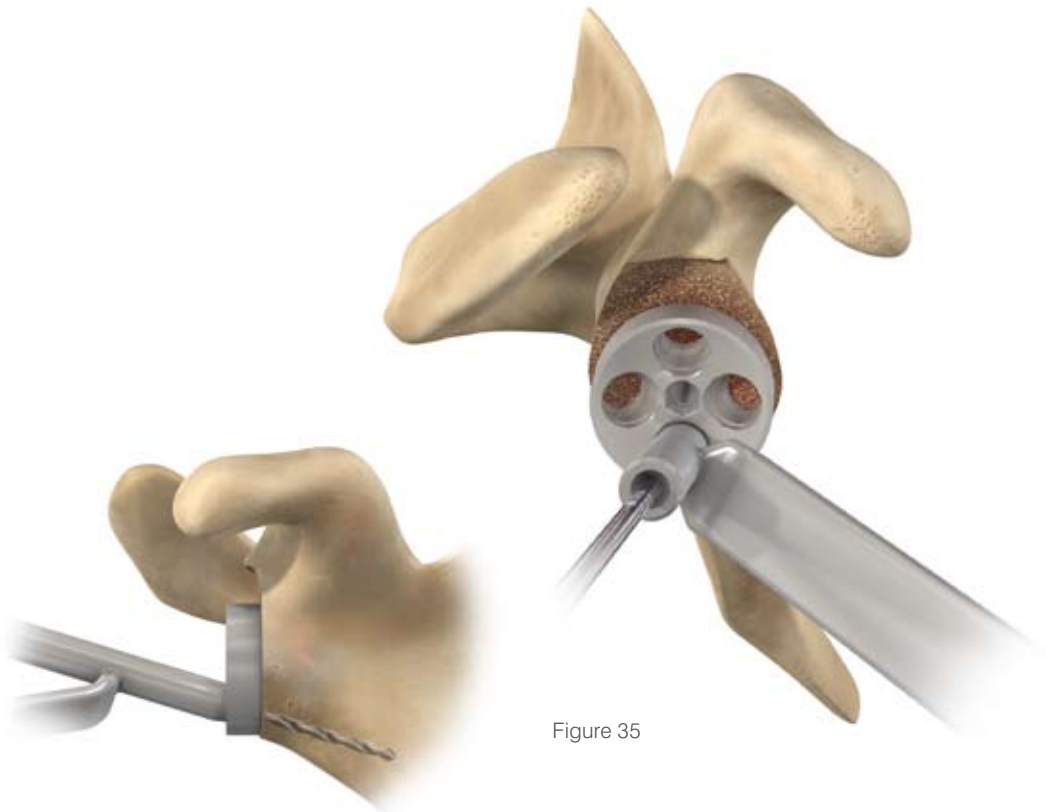


Figure 35



Figure 36

The goal is to have a sufficiently long screw inferiorly, usually 36 mm or more. The length of the screw is indicated on the drill bit by laser markings (Figure 36). The screw depth gauge can also be used to assess optimal screw length.

Insert the 1.2 mm guide pin through the drill guide and then remove the drill guide (Figure 37).

Slide the locking screw of the appropriate length onto the guide pin. Check that the internal tightening screw is unlocked (It should rotate freely) (Figure 38).



Figure 37



Figure 38



Slide the locking screwdriver body on the guide pin and insert the tip into the 4 slots on the screw (Figure 39). Do not use the internal screwdriver rod at this stage.

Slide down the screwdriver sleeve completely to protect the screw head.

Tighten the screw to compress the plate (Figure 40).

Remove the screw guide pin with the pin extractor before final tightening to avoid stripping, making sure that the internal locking screw stays in place.

Repeat the same steps for the superior locking screw.

Drill the hole for the superior locking screw anticipating exit through the far cortex (Figure 41). The superior screw should be directed at the base of the coracoid process and should have an anterior orientation to avoid the suprascapular nerve.

To obtain optimal compression of the metaglene plate on bone, alternate tightening of the superior and inferior locking screws (Figure 42).



Figure 39

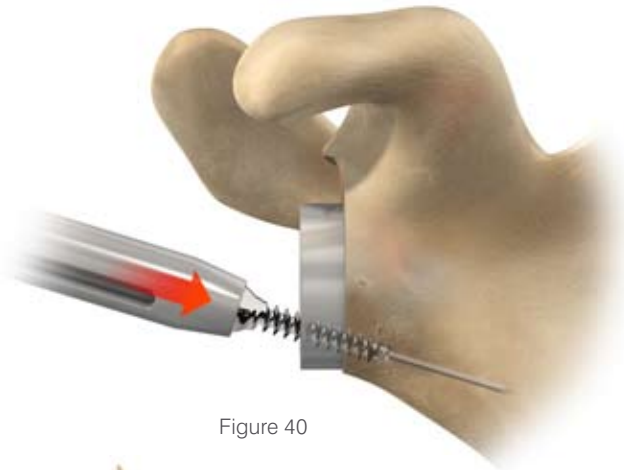


Figure 40

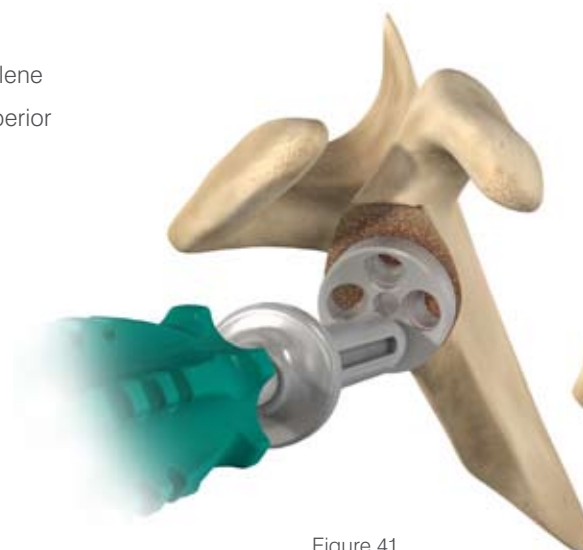
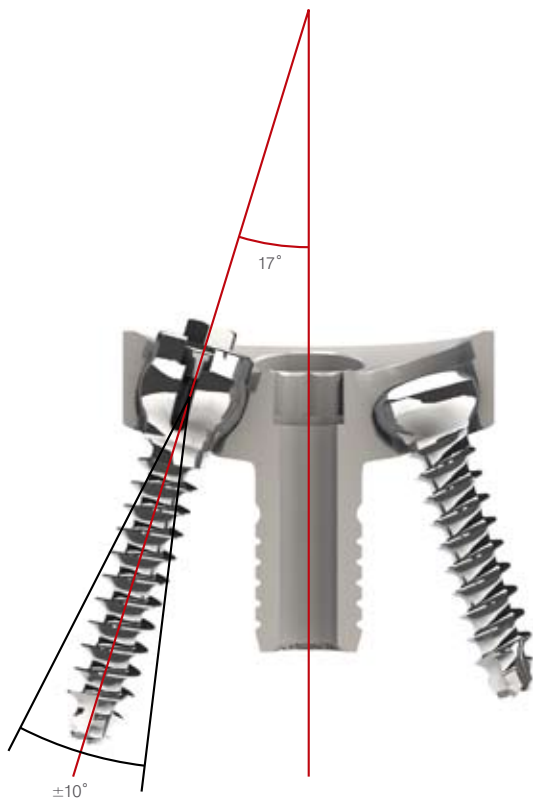


Figure 41



Figure 42

Anterior and Posterior Metaglene Screw Placement



Metaglene Anterior-Posterior Cross Section
Polyaxial Locking or Non-locking Screws

Figure 43

The surgeon may use locking or non-locking screws in the anterior or posterior holes. Both types of screws will allow an angulation of up to ± 10 degrees, but not in a direction convergent to the central peg axis to avoid conflict with the central peg (Figure 43).

Use the 2.5 mm drill bit with the drill guide to set the most appropriate angle for ensuring that each screw is located in reliable bone stock (Figure 44).

The preferred position is usually chosen by palpating the anterior and posterior aspects of the scapula as well as examining the X-rays and CT scans. Drill in the direction of the central glenoid vault in an attempt to maximize the anterior and posterior compression screw lengths, in a direction parallel to or divergent from the central peg.



Figure 44

Screw length is determined from the laser marks on the drill bits or by using the depth gauge.

Slide the corresponding screws onto the guide pin and tighten using the 3.5 mm cannulated hex screwdriver for non-locking screws or the locking screwdriver for locking screws (Figure 45).

Follow the same procedure for the posterior screw, then alternately tighten both screws until they are fully tightened.

Proceed with locking all variable angle screws used. Place the locking screwdriver main body in the head of the inferior screw. Make sure that the screwdriver sleeve is in its upper position and not in contact with the screw head.

Slide the locking screwdriver internal rod into the main body. The tip of the internal rod will make contact with the screw head. Tighten it fully, locking the screw in place by expanding its head (Figure 46).

Repeat the same steps to secure the superior locking screw and anterior or posterior screws if variable angle screws have been used.

The metaglene is left in place (Figure 47) and the humeral preparation is then carried out.



Figure 45



Figure 46



Figure 47

Placement of the Proximal Humeral Reaming Guide

Cemented Monobloc Humeral Implants

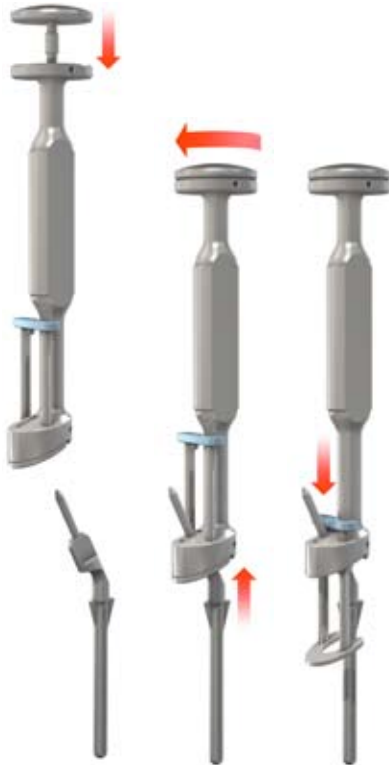


Figure 48

Figure 49

Figure 50

Select the appropriate proximal reaming guide size (Figure 48). For example, if a 12 mm intramedullary reamer and a 12 mm cutting handle were previously used, select the 12 mm proximal reaming guide.

Slide and screw the internal rod of the reaming guide holder into the holder main body. Then slide the reaming guide into the reamer holder and fasten the two parts together by firmly tightening the upper round handle (Figure 49).

Push the holder horseshoe plate fully down (Figure 50).

Slide the proximal reaming guide down into the intramedullary canal, rotating it if necessary to ensure that the horseshoe plate sits flat on the bone resection surface (Figure 51).

Drive the proximal reaming guide down until complete contact between the metal block and the resected bone surface is achieved (Figure 52).

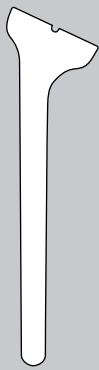
Unscrew the upper round handle of the holder and remove the holder, leaving the proximal reamer guide in place (Figure 53).



Figure 51

Figure 52

Figure 53



Proximal Humeral Reaming Cemented Monobloc Humeral Implants



Disk Size 1

Figure 54



Figure 55

The monobloc implant size should be chosen to match the initial distal reaming diameter.

Choose the most appropriate epiphysis size by placing a monobloc implant sizer disk in size 1 or 2 on the proximal reaming guide. The most appropriate size will be the sizer disk that provides the best possible coverage of the bone resection surface (Figure 54).

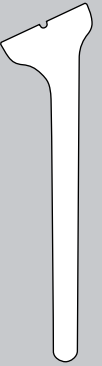
The size chosen, epiphysis size 1 or 2, will determine proximal reamer and final implant sizes.

Remove the sizer disk.

Select the appropriate proximal reamer for the monobloc implant, size 1 or 2, from the results of the previous trials. Ream the metaphysis using a power reamer (Figure 55).

Complete reaming is achieved when the external reamer flange is in full and complete contact with the bone resection surface.

When the proximal reaming has been completed, remove the reaming guide using the reaming guide holder.



Humeral Trial Implant Insertion

Cemented Monobloc Humeral Implants

Select the appropriate trial humeral implant. For example, if the initial distal reaming was carried out using the 12 mm reamer and proximal reaming was carried out using the size 1 proximal reamer, select monobloc humeral trial epiphysis number 1 with diameter 12 mm.

Mount the trial implant on the humeral implant driver and drive it down the intramedullary canal.

The implant orientation should be checked using the orientation pin placed in the implant driver handle. The pin should be placed in the same retroversion position used to position the cutting guide, i.e. close to 0 to 10 degrees retroversion. The orientation pin should then be aligned with the forearm axis and the trial implants driven down (Figure 56).

Impact the trial implant by gently tapping the implant driver handle and remove the driver, leaving the trial implant in place (Figure 57). The driver is detached by pushing on the blue button.

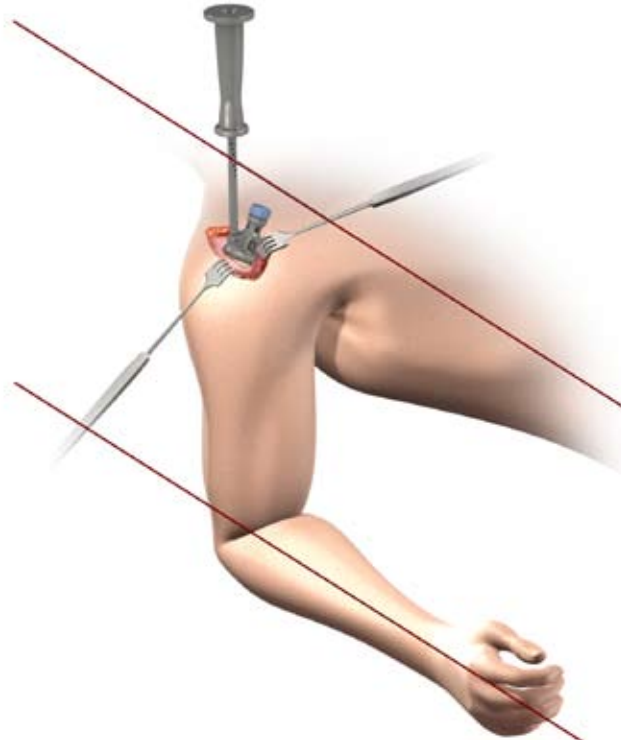


Figure 56



Figure 57

Glenosphere Trial Placement



Figure 58

The glenosphere implants are available in two diameters, 38 mm and 42 mm, and are either standard or eccentric spheres.

An overlap of 3 to 5 mm is recommended to avoid conflict with the scapular neck (figure 58). Depending on the shape of the scapular neck, this overlap can be achieved by using a standard metaglene just by lowering the metaglene. The largest 42mm glenosphere is recommended if the size of the joint (allows to increase both the overlap and the range of motion). The eccentric glenospheres are recommended for more transverse scapular necks.

Cup Trials and Trial Reduction

Fit the appropriate trial glenosphere (38 mm or 42mm, centered or eccentric) to the the metaglene using the metaglene holder (Figure 59).

For eccentric glenospheres, the vertical laser mark on the trial glenosphere should be aligned with the base of the coracoid superiorly and the scapular neck inferiorly (Figures 59 and 60).

The arrow indicates the position of the eccentricity and should be positioned inferiorly, aligned with the scapular neck (Figures 60).

Place the humeral trial cup (38 or 42 mm depending on the glenosphere size), with +3 mm of lateral offset, in the trial epiphysis (Figure 61). The shoulder should then be reduced with longitudinal traction and assessed for a full range of motion.



Figure 59

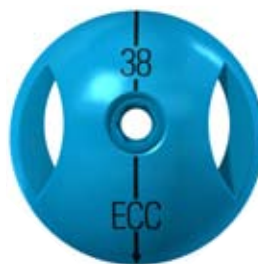


Figure 60



Figure 61

Joint Tensioning and Stability Assessment



Figure 62

Joint tensioning and stability assessment should be performed with particular care, using the following guidelines:

- Tension within the conjoined tendon should be noticeably increased and detectable by palpation.
- With the arm in a neutral position, apply a longitudinal traction force to the arm while observing the movement of the shoulder with respect to the entire shoulder girdle as well as the trial prosthetic joint. Tension is appropriate if, in response to the longitudinal traction, the entire shoulder moves before detectable separation of the trial prosthetic surfaces.
- External rotation may appropriately demonstrate slight gapping between the glenosphere and articular surface (2 to 3 mm maximum).
- Positioning a hand or fist near the axilla to serve as a fulcrum, further adduct the arm and look for undesirable tendencies to sublux or dislocate laterally (a small opening of 2 to 3 mm is acceptable). Estimate the maximum forward elevation.
- Assess stability at 90 degrees, abduction with the humerus in neutral, maximum internal and maximum external rotation. Estimate the maximum forward elevation¹⁵.

If instability can be demonstrated, it is critical to identify the cause and develop a solution to the problem. Make sure that the implants have been positioned correctly with respect to the bone and to each other. Overcome any conflicts between the proximal humeral component and soft tissues or osseous structures that surround the glenosphere (e.g. non-union of the greater tuberosity) by excision of the conflicting elements. Inadequate tensioning may be overcome using:

- a thicker cup (+6 mm or +9 mm)
- a 42 mm glenosphere.
- a modular humeral lengthener or retentive cups in more extreme cases.

If unable to reduce the joint, the options include additional soft tissue releases and lowering the level of humeral resection. When the trials are satisfactory, the trial glenosphere should be removed using the extraction T-Handle so that final implant fixation can be performed.

Definitive Glenosphere Fixation

Standard Glenosphere

Insert the 1.5 mm guide pin through the central hole of the metaglene.

Engage the 3.5 mm cannulated hex screwdriver in the final glenosphere. Slide the glenosphere on the 1.5 mm guide pin until it is in contact with the metaglene (Figure 63). Proper alignment between the glenosphere and metaglene is absolutely essential to avoid cross threading between the components.

If the glenosphere seems difficult to thread onto the metaglene, do not force engagement but re-align the components. If necessary, remove the inferior retractor or improve the capsular release. It is also important to check that there is no soft tissue between the metaglene and glenosphere.

When accurate thread engagement is obtained and after a few turns, remove the guide pin to avoid stripping in the screwdriver.

Standard glenosphere

Tighten until the scapula begins to rotate slightly in a clockwise direction, meaning that the glenoid bearing is closing on the taper of the metaglene.

Gently tap on the glenosphere with the glenosphere impactor a minimum of three times (Figure 64). Tighten the glenosphere central screw again. Care should be taken to ensure that the glenoid bearing is fully locked onto the metaglene. The gentle hammering procedure and screw tightening can be repeated, if necessary, until the screw is fully tightened .



Figure 63



Figure 64

Definitive Glenosphere Fixation

Eccentric Glenosphere



Figure 65



Figure 66



Figure 67

Eccentric glenosphere

Slide the glenosphere orientation guide onto the screwdriver core and position it in the eccentric glenosphere central slot (Figure 65).

The arrow marked on the orientation guide should be aligned with the base of the coracoid process to position the eccentricity correctly. Maintain the orientation guide in the required position and screw the glenosphere into place using the screwdriver until the glenoid bearing closes on the taper of the metaglene (Figure 66).

Obtain further impaction of the junction by gently hammering the glenosphere with the glenosphere impactor a minimum of three times (Figure 67). Then tighten the glenosphere central screw again. Care should be taken to ensure that the glenoid bearing is fully locked onto the metaglene.

Repeat if necessary until screw is fully tightened.

Definitive Glenosphere Fixation Glenosphere Removal

If it is necessary to remove the glenosphere (revision or intra-operative size modification), the glenosphere/metaglene junction can be disassembled by unscrewing the glenosphere central screw using the 3.5 hex head screwdriver (Figure 68). This operation should be done smoothly to avoid central screw damage.

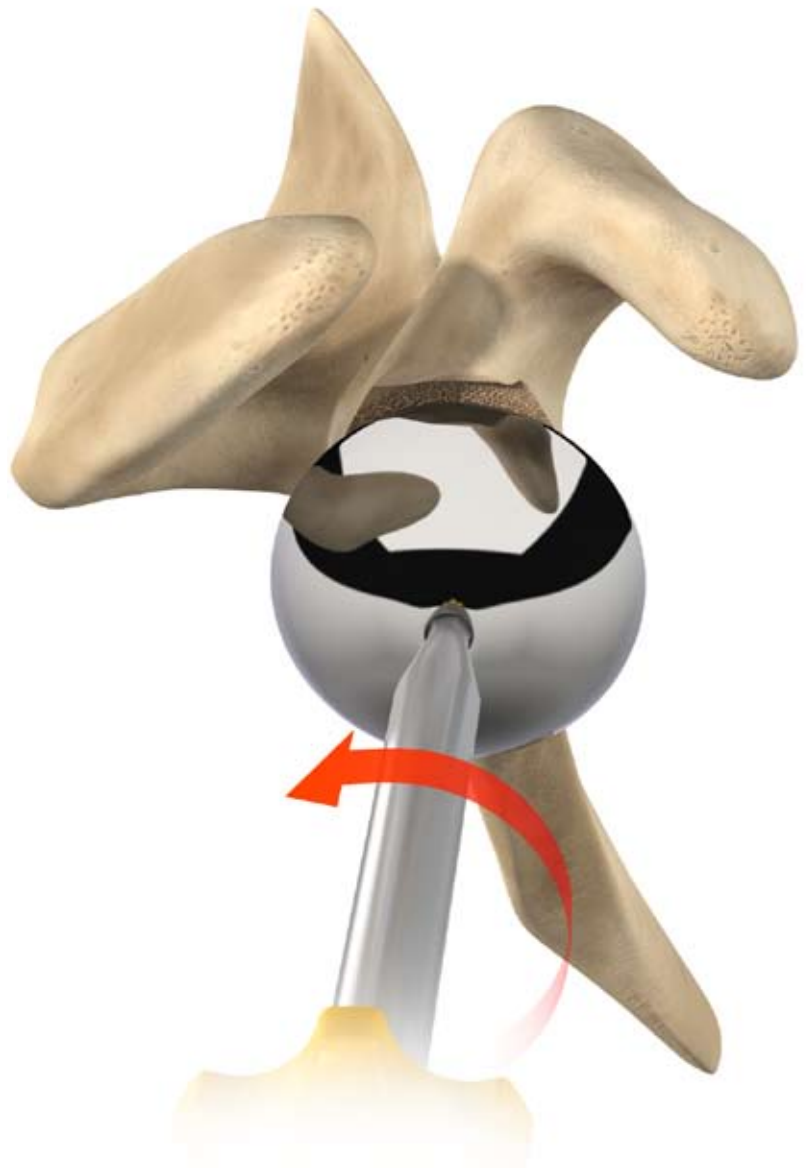
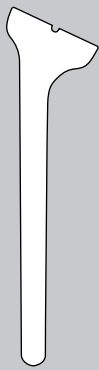


Figure 68



Definitive Humeral Implant Insertion Cemented Monobloc Humeral Implants

Remove the trial cups and trial implants using the humeral implant driver. Select the appropriate final monobloc humeral implant corresponding to the trial implant.

Inserting cement restrictor

Determine the trial size of the cement restrictor and gauge the implantation depth (Figure 69). Check that the trial restrictor is firmly seated in the canal, then remove trial.

Use pulsatile lavage and a nylon brush to clear the humeral canal of debris and to open the interstices of the bone ready for the cement. Place the definitive cement restrictor at the appropriate depth and check that it is firmly seated in the canal.

Pass non-absorbable sutures such as DePuy Mitek Orthocord® Suture, through the proximal humerus near the lesser tuberosity to enable secure re-attachment of the subscapularis (if possible). Avoid re-attachment if unable to externally rotate the humerus to zero degrees.

Irrigate the canal, during a secondary cleaning, using pulsatile lavage to remove loose bone remnants and marrow. Some surgeons may wish to insert a one-inch gauze pre-soaked in an epinephrine (1:1,000,000 solution) or hydrogen peroxide solution to aid haemostasis and the drying of the humeral canal (Figure 70).

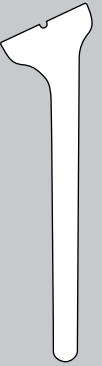
Cement in the humeral implant as directed.



Figure 69



Figure 70



Definitive Humeral Implant Insertion

Cemented Monobloc Humeral Implants

Implant insertion

Introduce the final implant in the chosen version in line with the long axis of the humerus, using the humeral implant driver (0 degrees to 10 degrees of retroversion) (Figure 71).

Excess cement will extrude from the canal and should be removed before curing is complete. Inspect the exposed portion of the humeral component for cement and remove as necessary. Maintain pressure on the driver until the cement is fully polymerized to avoid micromotion that could cause crack propagation. Remove the lap sponge dam and irrigate the wound thoroughly. Place the trial articular surface and reduce the joint. Confirm stability and dislocate the humerus.

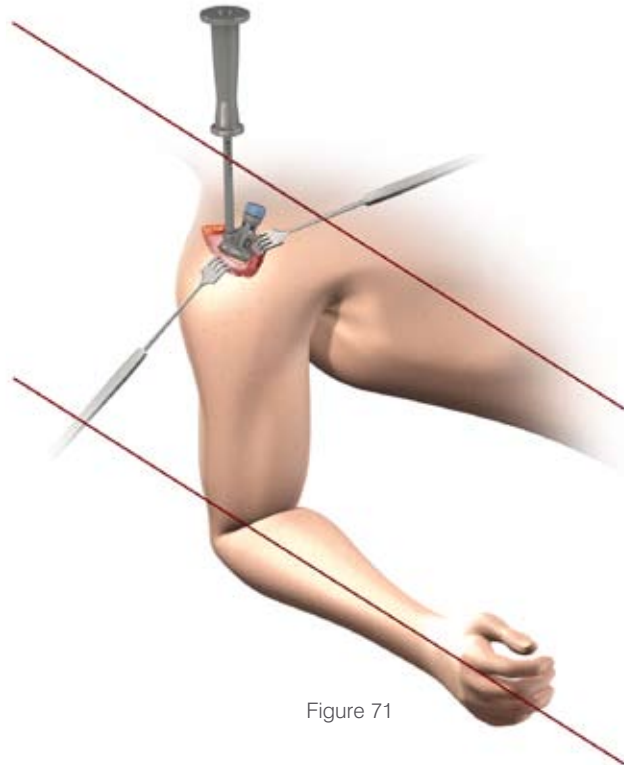


Figure 71

Final cup fixation

Impact the final humeral cup using the cup impactor (Figure 72). When a humeral spacer is needed, impact it first on the epiphysis and then impact the final cup on it.

Note: All junction surfaces between the implant components should be clean and free of any tissue before impaction.

Reduce the joint and carry out a final assessment of joint stability and range of motion.



Figure 72

Cases of Proximal Humeral Bone Loss



Figure 73

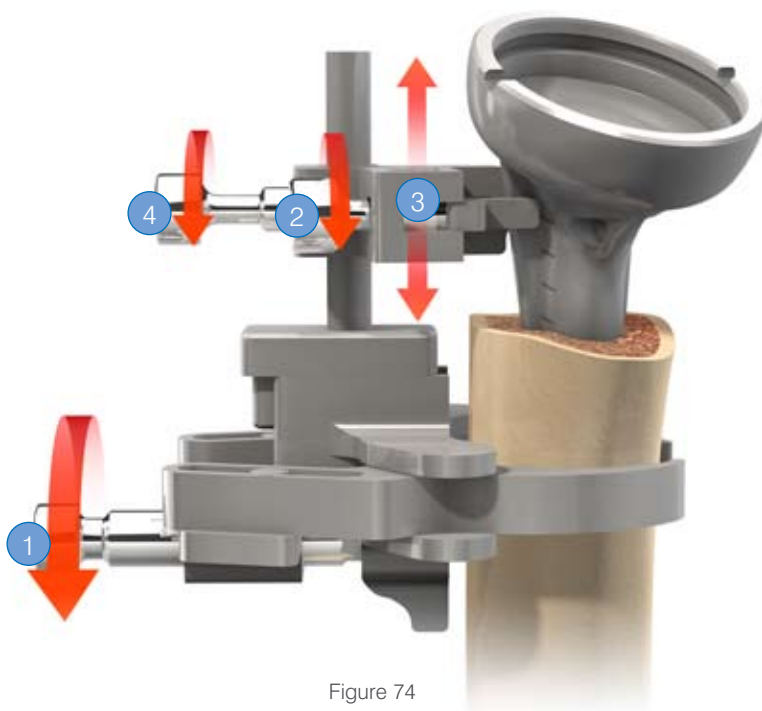


Figure 74

Cases of proximal bone loss will be treated using cemented monobloc humeral implants to avoid any risk of component dissociation. Long monobloc stems may be required in some cases.

The preparation of the humeral canal for long stems uses the same technique described for standard stems, with the exception of the procedure for reaming the humeral canal, which differs in this respect: the entire length of the cutting flutes should be passed down the intramedullary canal instead of being stopped at the mark (Figure 73).

A positioning jig is available to hold both the trial long stem and the final implant in place at the correct height and in retroversion.

Tighten the fin clamp on the humeral shaft first using the 3.5 mm screwdriver (1) (Figure 74).

Place the fin clamp over the vertical height gauge of the humeral shaft clamp and secure the fin clamp to the central hole in the anterior fin of the prosthesis (2). Place the prosthesis at the appropriate height (3) and tighten the fin clamp to secure it to the vertical height gauge (4).

The jig can be left in place while testing motion, and used to place the final stem at the height determined during the trials.

Cases of Proximal Humeral Bone Loss

Note that aligning the retroversion guide pin with the forearm places the implant in 30 degree retroversion. Readjust the retroversion of the jig to match 0 to 10 degrees retroversion as used for the reverse shoulder prosthesis (Figure 75).

Height lines are also present on the trial long stems to enable better marking of the appropriate prosthesis height. Determine an appropriate mark, then place the trial stem beside the final implant and mark the corresponding height (Figure 76). Use that mark to cement the stems at the proper height.

Sutures through the stem fin holes (smooth edges) can be used to reconstruct the proximal humerus.

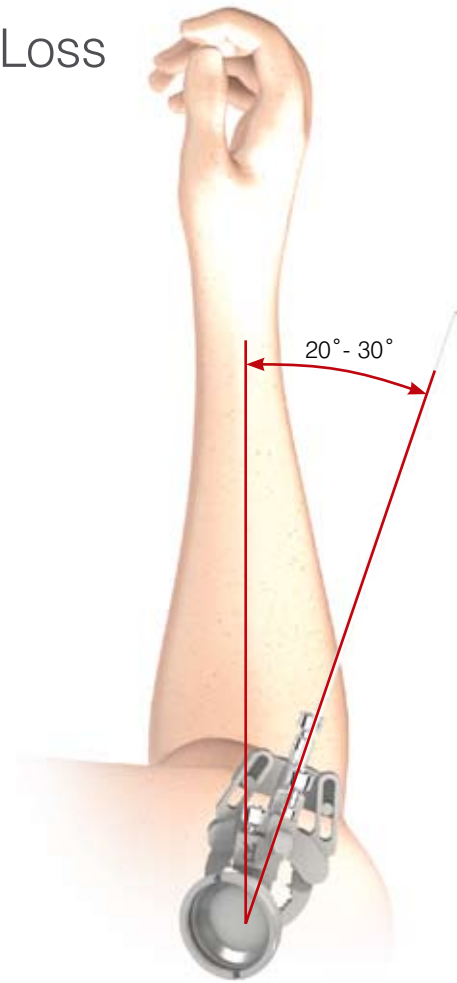


Figure 75



Figure 76

Revision to Hemi-Arthroplasty



Figure 77



Figure 78

When revision of a reverse shoulder is required due to glenoid loosening, or when glenoid bone stock is insufficient to fix a metaglene securely, the reverse shoulder can be converted to an hemi-prosthesis as a salvage procedure. Specific hemi-heads with lateral head coverage, Delta Xtend™ CTA heads, are available.

Remove the glenosphere using the 3.5 hex head screwdriver. Remove the metaglene locking screws using the locking screwdriver and the non-locking screw using the 3.5 mm hex head screwdriver. Remove the metaglene using the extraction T-Handle and remove the humeral cup using the cup extraction clamp (Figure 77).

Place the Delta Xtend™ CTA head reamer guide in the epiphysis (Figure 78). Align the anterior and posterior slot of the reaming guide with the slots of the epiphysis and impact the reaming guide gently with a mallet.

Assemble the Delta Xtend™ CTA head reamer with the T-Handle. Ream the area around the epiphysis manually (Figure 79). If the Delta Xtend™ CTA trial head does not obtain perfect seating on the epiphysis, finish the preparation using a rongeur.

Choose the appropriate size of Delta Xtend™ CTA head using the trial heads.

Gently impact the appropriate final head using the humeral head impactor (Figure 80). Make sure that the junction surfaces between the components are clean and free of any soft tissue before impaction. The retroversion of the Delta Xtend™ CTA head should be chosen to match the patient's anatomy. This requires that the head is placed in the proper orientation before impacting.



Figure 79



Figure 80

Post-Operative Management

Post-operative physiotherapy is an important factor in the outcome of this procedure, since stability and mobility now depend on the deltoid alone. The physiotherapy program, which should be planned to suit each individual patient, consists of two phases:

1. Early phase (0 to 6 weeks)

Two days after the operation, the patient may be mobile. This early phase is dedicated to gentle and gradual recovery of the passive range of shoulder motion: abduction of the scapula, anterior elevation and medial and lateral rotation. An abduction cushion may be used to relieve pressure on the deltoid. Physiotherapy is mainly performed with the patient supine, passive and with both hands holding a bar that is manipulated by the contralateral hand, as described by Neer. The patient is encouraged to use the affected arm post-operatively to eat and write, but should not use it to push behind the back or to raise themselves from the sitting position to the standing position. In conjunction with these exercises for scapulohumeral recovery, it is important to strengthen muscle connection with the scapula in order to facilitate muscle and implant function. Passive exercise in a swimming pool is recommended as soon as scars begin to form. More caution is required to protect the deltoid muscle from excessive demand if a superior approach has been used for surgery.

2. Late phase (after 6 weeks)

After the sixth week, active strengthening movements may gradually be added to the programme. These exercises, which closely follow everyday activities, are to be performed in a sitting or standing position using conventional methods, with isometric exercises and resistance movements becoming increasingly important. A series of exercises for rhythmic stabilization of the upper arm as well as eccentric work on lowering the arms complete the strengthening of the muscles. Physiotherapy may be performed over a period of at least six months.

Ordering Information

Implants

STANDARD IMPLANT CODES

Cemented Monobloc Humeral Implants

1307-08-100	Monobloc Humeral Cemented Epiphysis Size 1 Diameter 8 mm Std
1307-10-100	Monobloc Humeral Cemented Epiphysis Size 1 Diameter 10 mm Std
1307-12-100	Monobloc Humeral Cemented Epiphysis Size 1 Diameter 12 mm Std
1307-14-100	Monobloc Humeral Cemented Epiphysis Size 1 Diameter 14 mm Std
1307-10-200	Monobloc Humeral Cemented Epiphysis Size 2 Diameter 10 mm Std
1307-12-200	Monobloc Humeral Cemented Epiphysis Size 2 Diameter 12 mm Std
1307-14-200	Monobloc Humeral Cemented Epiphysis Size 2 Diameter 14 mm Std



Polyethylene Cup and Humeral Spacer

1307-38-203	Standard Humeral PE Cup Diameter 38 mm +3 mm
1307-38-206	Standard Humeral PE Cup Diameter 38 mm +6 mm
1307-38-209	Standard Humeral PE Cup Diameter 38 mm +9 mm
1307-42-203	Standard Humeral PE Cup Diameter 42 mm +3 mm
1307-42-206	Standard Humeral PE Cup Diameter 42 mm +6 mm
1307-42-209	Standard Humeral PE Cup Diameter 42 mm +9 mm
1307-38-106	Retentive Humeral PE Cup Diameter 38 mm +6 mm
1307-42-106	Retentive Humeral PE Cup Diameter 42 mm +6 mm
1307-30-009	Humeral Spacer +9 mm



Glenoid Implants

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



1307-60-000 Metaglène

1307-70-018	Non Locking Metaglène Screw Diameter 4.5 mm Length 18 mm
1307-70-024	Non Locking Metaglène Screw Diameter 4.5 mm Length 24 mm
1307-70-030	Non Locking Metaglène Screw Diameter 4.5 mm Length 30 mm
1307-70-036	Non Locking Metaglène Screw Diameter 4.5 mm Length 36 mm
1307-70-042	Non Locking Metaglène Screw Diameter 4.5 mm Length 42 mm



1307-90-024	Locking Metaglène Screw Diameter 4.5 mm Length 24 mm
1307-90-030	Locking Metaglène Screw Diameter 4.5 mm Length 30 mm
1307-90-036	Locking Metaglène Screw Diameter 4.5 mm Length 36 mm
1307-90-042	Locking Metaglène Screw Diameter 4.5 mm Length 42 mm
1307-90-048	Locking Metaglène Screw Diameter 4.5 mm Length 48 mm

REVISION IMPLANT CODES

Cemented Monobloc Long Stems

1307-08-110	Monobloc Humeral Cemented Epiphysis Size 1 Diameter 8 mm Long
1307-10-110	Monobloc Humeral Cemented Epiphysis Size 1 Diameter 10 mm Long
1307-12-110	Monobloc Humeral Cemented Epiphysis Size 1 Diameter 12 mm Long
1307-14-110	Monobloc Humeral Cemented Epiphysis Size 1 Diameter 14 mm Long
1307-10-210	Monobloc Humeral Cemented Epiphysis Size 2 Diameter 10 mm Long
1307-12-210	Monobloc Humeral Cemented Epiphysis Size 2 Diameter 12 mm Long
1307-14-210	Monobloc Humeral Cemented Epiphysis Size 2 Diameter 14 mm Long



CTA heads

1307-48-021	Delta Xtend™ CTA Head Diameter 48 x 21 mm
1307-48-026	Delta Xtend™ CTA Head Diameter 48 x 26 mm
1307-52-021	Delta Xtend™ CTA Head Diameter 52 x 21 mm
1307-52-026	Delta Xtend™ CTA Head Diameter 52 x 26 mm



Ordering Information

Instruments

STANDARD INSTRUMENT CODES - HUMERAL

Humeral Bone Resection

2128-01-006	Medullary Canal Reamer Diameter 6 mm
2128-01-008	Medullary Canal Reamer Diameter 8 mm
2128-01-010	Medullary Canal Reamer Diameter 10 mm
2128-01-012	Medullary Canal Reamer Diameter 12 mm
2128-01-014	Medullary Canal Reamer Diameter 14 mm
2128-01-016	Medullary Canal Reamer Diameter 16 mm

2128-61-070	Standard Hudson T-Handle
1524-00-000	Hudson to AO converter

2307-70-008	Handle for Cutting Guide Diameter 8 mm
2307-70-010	Handle for Cutting Guide Diameter 10 mm
2307-70-012	Handle for Cutting Guide Diameter 12 mm
2307-70-014	Handle for Cutting Guide Diameter 14 mm
2307-70-016	Handle for Cutting Guide Diameter 16 mm

2307-71-000	Orientation Pin
-------------	-----------------

2307-72-003	Delto-pectoral Cutting Guide
2307-72-004	Delto-pectoral Cutting Plate

2307-73-003	Superior Lateral Cutting Guide
2307-73-004	Superior Lateral Cutting Plate

2490-95-000	Fixation Pin for Cutting Guide Diameter 3.2 mm (pack of 5, single use)
-------------	------------------------------------------------------------------------

2307-99-004	Pin Extractor
2307-85-000	Humeral Resection Protecting Plate
9399-99-315	Drill Bit Diameter 3.2 mm (single use)

Epiphyseal Reaming

2307-74-001	Holder for Proximal Reaming Guides
2307-74-002	Internal Rod for Reaming Guide Holder

2307-74-008	Proximal Reaming Guide Diameter 8 mm
2307-74-010	Proximal Reaming Guide Diameter 10 mm
2307-74-012	Proximal Reaming Guide Diameter 12 mm
2307-74-014	Proximal Reaming Guide Diameter 14 mm
2307-74-016	Proximal Reaming Guide Diameter 16 mm

2307-76-000	Centered Proximal Reaming adaptor
2307-76-001	Eccentric Proximal Reaming adaptor Size 1
2307-76-002	Eccentric Proximal Reaming adaptor Size 2

2307-78-003	Proximal Reamer for Modular Implant Size 1
2307-78-004	Proximal Reamer for Modular Implant Size 2

2307-77-003	Epiphyseal Disk for Modular Implant Size 1
2307-77-004	Epiphyseal Disk for Modular Implant Size 2

2307-81-003	Proximal Reamer for Monobloc Implant Size 1
2307-81-004	Proximal Reamer for Monobloc Implant Size 2

2307-80-003	Epiphyseal Disk for Monobloc Implant Size 1
2307-80-004	Epiphyseal Disk for Monobloc Implant Size 2



Ordering Information

Instruments

Rasps and Impactors

2307-01-030 Broach Handle

2307-79-010 Humeral Broach Diameter 10 mm

2307-79-012 Humeral Broach Diameter 12 mm

2307-79-014 Humeral Broach Diameter 14 mm

2307-79-016 Humeral Broach Diameter 16 mm

2307-01-031 Goniometer

2307-84-001 Locking Wrench for Modular Implant Diameter 10-12 mm

2307-84-002 Locking Wrench for Modular Implant Diameter 14-16 mm

2307-01-032 Broach Handle Plate

2001-65-000 Humeral Head Impactor

2307-68-000 Spacer Impactor Tip

2307-67-000 Cup Impactor Tip

2307-83-000 Humeral Implant Driver

Humeral Trials

2307-08-100 Monobloc Humeral Trial Epiphysis Size 1 Diameter 8 mm Std

2307-10-100 Monobloc Humeral Trial Epiphysis Size 1 Diameter 10 mm Std

2307-12-100 Monobloc Humeral Trial Epiphysis Size 1 Diameter 12 mm Std

2307-14-100 Monobloc Humeral Trial Epiphysis Size 1 Diameter 14 mm Std

2307-10-200 Monobloc Humeral Trial Epiphysis Size 2 Diameter 10 mm Std

2307-12-200 Monobloc Humeral Trial Epiphysis Size 2 Diameter 12 mm Std

2307-14-200 Monobloc Humeral Trial Epiphysis Size 2 Diameter 14 mm Std

2307-38-403 Standard Humeral Cup Trial Diameter 38 mm +3 mm

2307-38-406 Standard Humeral Cup Trial Diameter 38 mm +6 mm

2307-38-409 Standard Humeral Cup Trial Diameter 38 mm +9 mm

2307-42-403 Standard Humeral Cup Trial Diameter 42 mm +3 mm

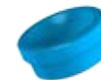
2307-42-406 Standard Humeral Cup Trial Diameter 42 mm +6 mm

2307-42-409 Standard Humeral Cup Trial Diameter 42 mm +9 mm

2307-38-506 Retentive Humeral Cup Trial Diameter 38 mm +6 mm

2307-42-506 Retentive Humeral Cup Trial Diameter 42 mm +6 mm

2307-30-009 Humeral Spacer Trial +9 mm



STANDARD INSTRUMENT CODES - GLENOID

Glenoid Reaming

2307-87-003 Metaglene Positioner Plate

2307-87-005 Metaglene Holder

2307-87-002 Metaglene Holder Internal Rod

2307-87-004 Metaglene central Guide Pin Diameter 2.5 mm (Single-use)

2307-89-000 Glenoid cannulated Stop Drill Diameter 7.5 mm

2307-88-027 Glenoid Resurfacing Reamer Diameter 27 mm

2307-88-142 Glenoid Manual Reamer Diameter 42 mm

2307-88-300 Glenoid Reaming Level Checker

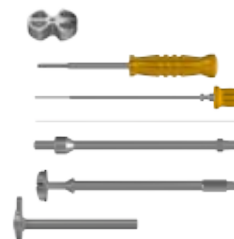
Metaglene Fixation

2307-90-003 Glenoid drill Guide Diameter 1.2 & 2.5 mm

2307-90-004 Screw Guide Pin Diameter 1.2 mm Length 120 mm (1 Pack of 5, Single-use)

2307-90-005 Drill Bit Diameter 2.5 mm Length 120 mm (Single-use)

2307-93-000 3.5 mm Cannulated Hex Screwdriver



Ordering Information

Instruments

2307-92-003 Locking Screwdriver Main Body
2307-92-004 Locking Screwdriver Internal Rod

A5307 Screw depth Gauge

Glenosphere Positioning

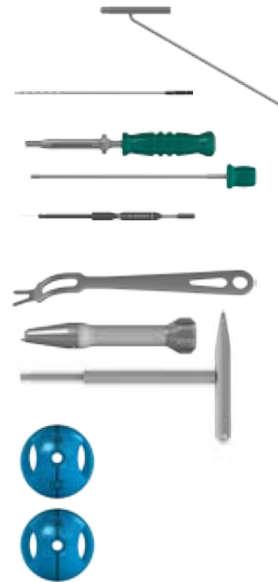
2307-86-002 V shape Glenoid retractor
2307-95-000 Glenosphere Orientation Guide
2307-96-000 Glenosphere Guide Pin Diameter 1.5 mm Length 300 mm (1 Pack of 2, Single-use)
2307-99-002 Extraction T-Handle

Glenoid Trials

2307-60-038 Eccentric Glenosphere Trial Diameter 38 mm
2307-60-042 Eccentric Glenosphere Trial Diameter 42 mm
2307-60-138 Standard Glenosphere Trial Diameter 38 mm
2307-60-142 Standard Glenosphere Trial Diameter 42 mm

Glenoid Trays

2307-99-913 Delta Xtend™ Glenoid Base
2307-99-934 Delta Xtend™ Glenoid Lid
2307-99-935 Delta Xtend™ Glenoid Bottom Tray
2307-99-936 Delta Xtend™ Glenoid Top Tray



REVISION INSTRUMENTS CODES

Reamers

2307-82-001 Delta CTA Head Reaming Guide
2307-82-003 Delta CTA Head Reamer

Trial Implants

2307-08-110 Monobloc Humeral Trial Epiphysis Size 1 Diameter 8 mm Long
2307-10-110 Monobloc Humeral Trial Epiphysis Size 1 Diameter 10 mm Long
2307-12-110 Monobloc Humeral Trial Epiphysis Size 1 Diameter 12 mm Long
2307-14-110 Monobloc Humeral Trial Epiphysis Size 1 Diameter 14 mm Long
2307-10-210 Monobloc Humeral Trial Epiphysis Size 2 Diameter 10 mm Long
2307-12-210 Monobloc Humeral Trial Epiphysis Size 2 Diameter 12 mm Long
2307-14-210 Monobloc Humeral Trial Epiphysis Size 2 Diameter 14 mm Long

2307-48-121 Delta Xtend™ CTA Head Trial Diameter 48 mm x 21 mm
2307-48-126 Delta Xtend™ CTA Head Trial Diameter 48 mm x 26 mm
2307-52-121 Delta Xtend™ CTA Head Trial Diameter 52 mm x 21 mm
2307-52-126 Delta Xtend™ CTA Head Trial Diameter 52 mm x 26 mm



Extraction Devices

ITH003 Delta Stem Impactor/Extractor
ETH001 Standard Humeral Prosthesis Extractor
MDE001 Extraction Rod
MAI001 Slap Hammer
2307-99-001 Cup Extraction clamp
2128-01-035 Global™ FX Positioning Jig

Templates

2307-99-099 Delta Xtend™ Templates

Cases and Trays

2307-99-005 Delta Xtend™ Humeral 1 Case Complete
2307-99-006 Delta Xtend™ Humeral 2 Case Complete
2307-99-007 Delta Xtend™ Glenoid Case Complete
2307-99-008 Delta Xtend™ Revision 1 Case Complete

References

1. Neer, CS 2nd, et al. "Cuff-Tear Arthropathy." *Journal of Bone Joint Surgery* 1983; 65-A 1232-1244
2. Broström, LA, et al. "The Kessel Prosthesis in Total Shoulder Arthroplasty. A five Year Experience"; *Clin Orthop* 1992; 277:155-60
3. Grammont, PM., et al. "Delta Shoulder Prosthesis For Rotator Cuff Rupture." *Orthopaedics* 1993; 16: 65-8
4. Sirveaux, F., et al. "Grammont Inverted Total Shoulder Arthroplasty in the Treatment of Glenohumeral Osteoarthritis With Massive Rupture of the Cuff. Results of a Multicenter Study of 80 Shoulders." *Journal of Bone Joint Surgery Br* 2004;86B:388-395.
5. De Wilde, LF., et al. "Shoulder Prosthesis Treating Cuff Tear Arthropathy: A Comparative Biomechanical Study." *Journal of Orthopedic Research* 2004; 22:1222-1230.
6. Boileau, P., et al. "Grammont Reverse Prosthesis: Design Rationale and Biomechanics." *Journal Shoulder Elbow Surgery* 2005; 14: 147-161.
7. Nyfeller, RW., et al. "Biomechanical Relevance of Glenoid Component Positioning in the Reverse Delta III Prosthesis." *Journal Shoulder Elbow Surgery* 2005 Sept-Oct; 14(5): 524-528.
8. Middernacht, BO., et al. "Anatomy of the Glenoid : Consequences For Implantation of the Reverse Prosthesis", under submission.
9. Wirth, MA., et al. "Compaction Bone-Grafting in Prosthetic Shoulder Athroplasty." *Journal of Bone Joint Surgery* 2007; 89-A 50-57.
10. Head, WC., et al. "Titanium Alloy as a Material of Choice for Cementless Femoral Components in Total Hip Arthroplasty," *Clin Orthop Relat Res.* 1995 Feb;(311):85-90.
11. Karelse, A., MD, et al. "Prosthetic Component Relationship of the Reversed Delta III Total Shoulder Prosthesis in the Transverse Plane of the Body." Under submission.
12. Collis, D., et al. 'Comparison of Clinical Outcomes in Total Hip Arthroplasty Using Rough and Polished Cemented Stems with Essentially the Same Geometry.' *Journal of Bone and Joint Surgery. ORG*, 2002; vol 84-A: 4.
13. Data on file, DePuy France DHF, 2006.
14. De Wilde, F., et al. "Functional Recovery After a Reverse Prosthesis For Reconstruction of the Proximal Humerus in Tumor Surgery." *Clin Orthop Relat Res.* 2005 Jan;(430):156-62.
15. Van Seymortier, P., et al. "The Reverse Shoulder prosthesis (Delta III) In Acute Shoulder Fractures: Technical Considerations with Respect to Stability." *Acta Orthop Belg.* 2006 Aug;72(4):474-7.
16. Fenlin, JM., Jr. "Total Glenohumeral Joint Replacement." *Orthop Clin North Am* 1975; 6:565-83.

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

INDICATIONS

Delta Xtend™ Reverse Shoulder prosthesis is indicated for use in a grossly rotator cuff deficient joint with severe arthropathy or a previous failed joint replacement with a grossly rotator cuff deficient joint.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

In cases of bone defects in the proximal humerus, the monobloc implant should be used and then only in cases where the residual bone permits firm fixation of this implant. Delta Xtend™ hemi-shoulder replacement is also indicated for hemi-arthroplasty if the glenoid is fractured intraoperatively.

The metaglene component is HA coated and is intended for cementless use with the addition of screws for fixation. All other components are for cemented use only.

CONTRAINDICATIONS

The following are contraindications for shoulder arthroplasty:

1. Active local or systemic infection;
2. Poor bone quality and/or inadequate bone stock to appropriately support the prosthesis;
3. Severe deformity;
4. Muscle, nerve or vascular disease;
5. Obesity, drug abuse, over activity or mental incapacity.

WARNINGS AND PRECAUTIONS

The following conditions tend to adversely affect the fixation of the shoulder replacement implants:

1. Marked osteoporosis or poor bone stock,
2. Metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone support for the implant (e.g., diabetes mellitus, steroid therapies, immunosuppressive therapies, etc.),
3. History of general or local infections,
4. Severe deformities leading to impaired fixation or improper positioning of the implant;
5. Tumors of the supporting bone structures;
6. Allergic reactions to implant materials (e.g. bone cement, metal, polyethylene);
7. Tissue reactions to implant corrosion or implant wear debris;
8. Disabilities of other joints.

ADVERSE EVENTS

The following are the most frequent adverse events encountered after total or hemi-shoulder arthroplasty:

1. Change in position of the prosthesis, often related to factors listed in WARNINGS AND PRECAUTIONS.
2. Early or late infection;
3. Early or late loosening of the prosthetic component(s), often related to factors listed in WARNING AND PRECAUTIONS;
4. Temporary inferior subluxation. Condition generally disappears as muscle tone is regained;
5. Cardiovascular disorders including venous thrombosis, pulmonary embolism and myocardial infarction;
6. Hematoma and/or delayed wound healing;
7. Pneumonia and/or atelectasis;
8. Subluxation or dislocation of the replaced joint.



DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988
USA
Tel: +1 (800) 366 8143
Fax: +1 (574) 371 4865

DePuy International Ltd
St Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (113) 387 7800
Fax: +44 (113) 387 7890