DELTA XTEND™

Reverse Shoulder System

Surgical Technique

DePuy Synthes

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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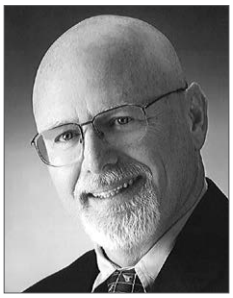

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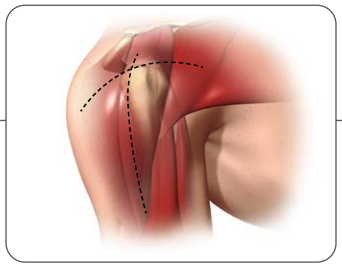
DELTA XTEND™ System Key Surgical Steps

Humeral Surgical Steps

Superior-lateral Approach



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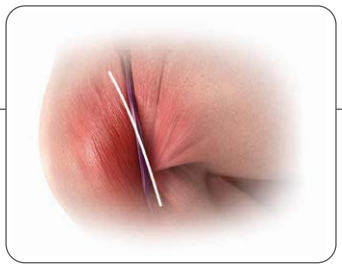

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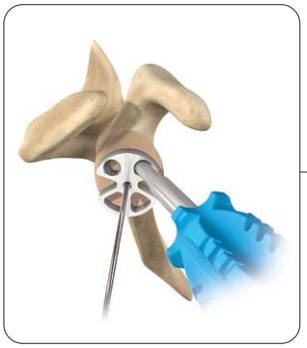

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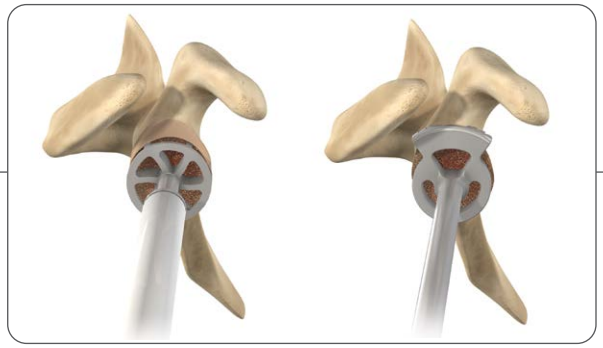

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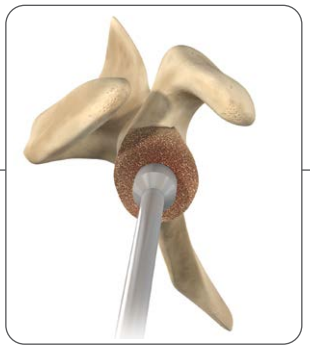

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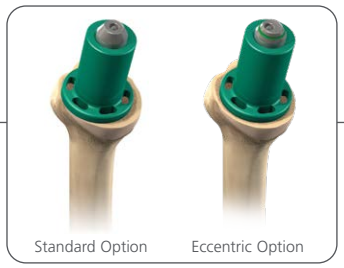

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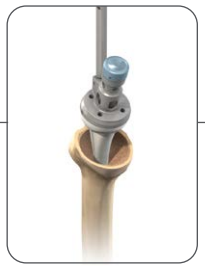

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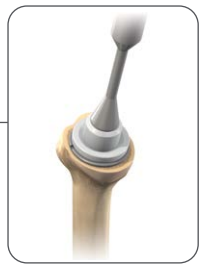

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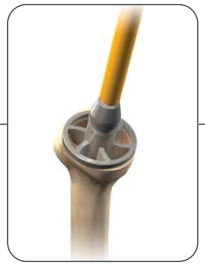
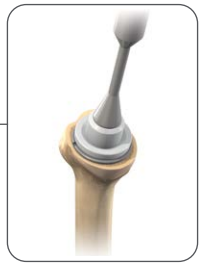
4. Determination of the Epiphysis Size



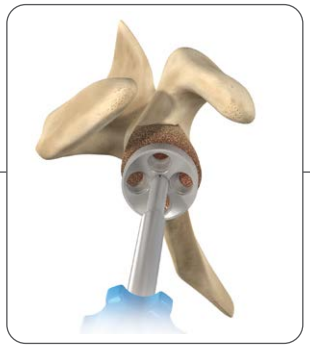
5. Proximal Humeral Reaming

6. Final Implant Insertion



7. Cup Impaction

Glenoid Surgical Steps



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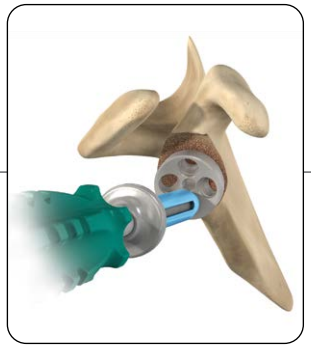

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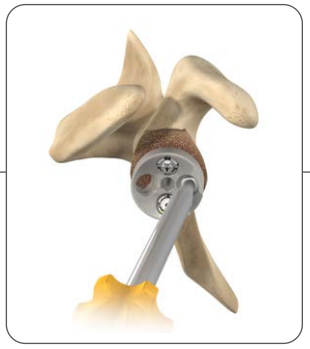

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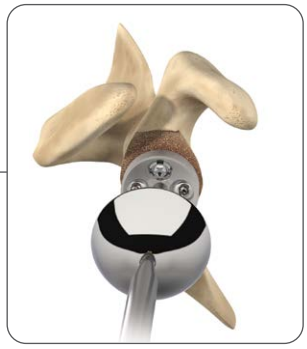

7. Glenosphere Implantation


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Pre-Operative Templating and Patient Positioning

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.

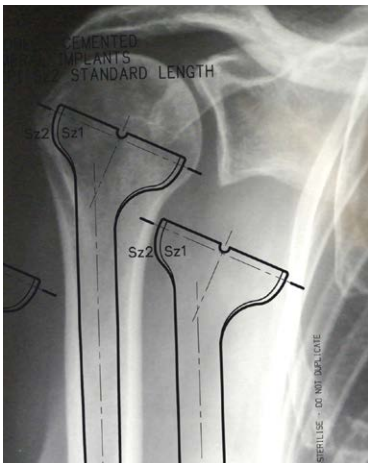


Figure 1

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 Shoulder 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.

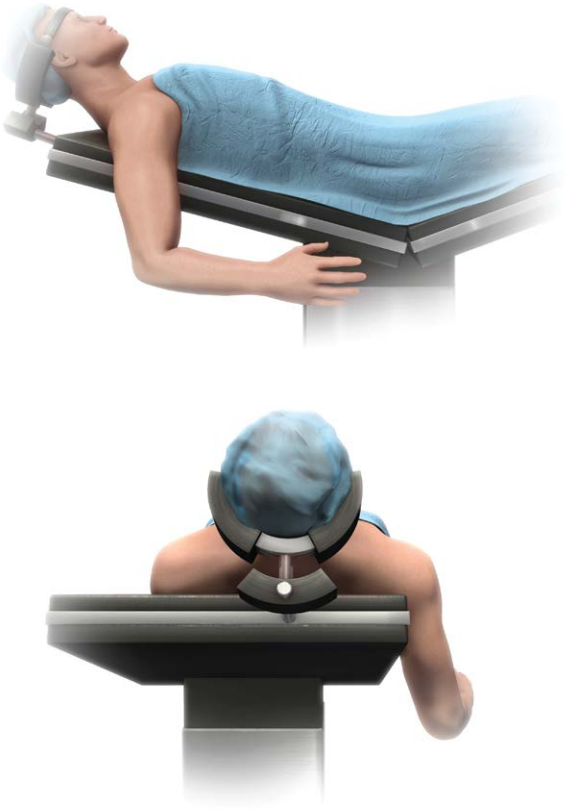


Figure 2

Superior-lateral Approach

The skin incision is 10-12cm 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, 5-7mm posterior to the tip of the acromion, and extends straight laterally down into the deltoid muscle. It should not extend more than 4cm 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.

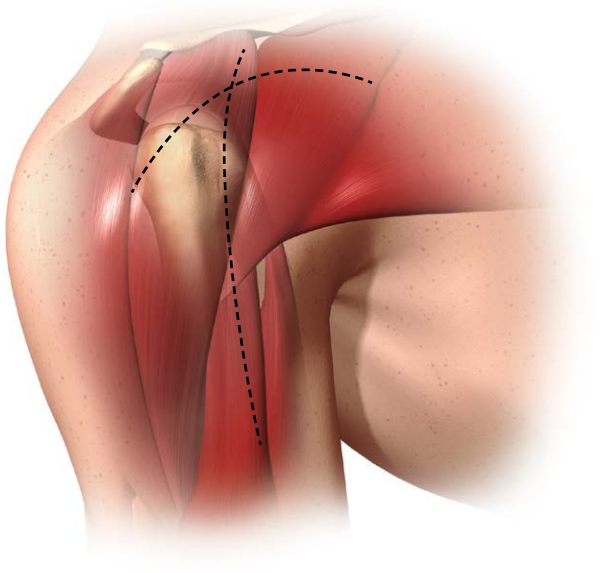


Figure 3

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.

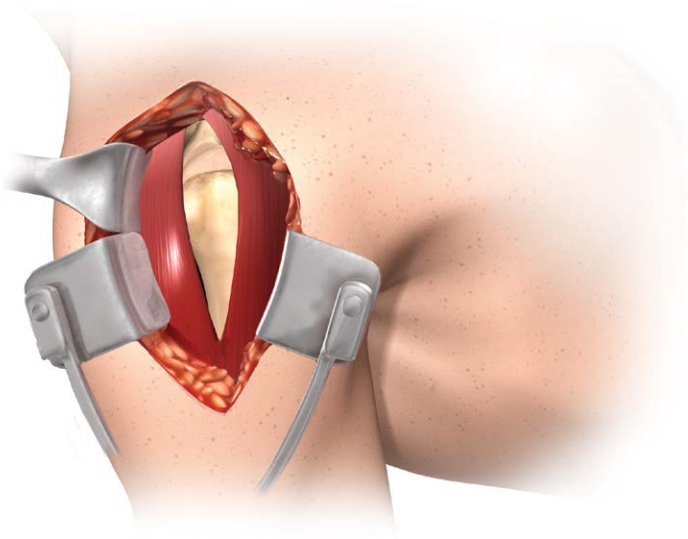


Figure 4

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 tenodese 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, 2cm 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

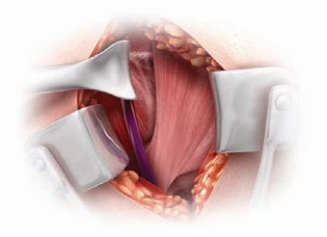


Figure 6

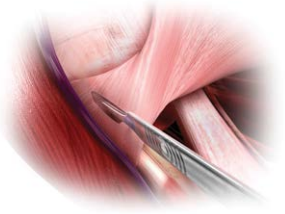


Figure 7

Figure 8

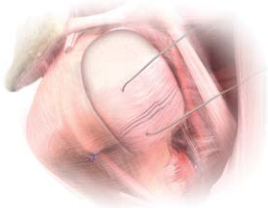


Figure 9

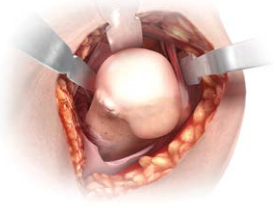


Figure 10

Intramedullary Canal Preparation

Using the 6mm 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 12mm reamer begins to gain purchase in the intramedullary cortical bone, use a 12mm humeral trial stem and final component.

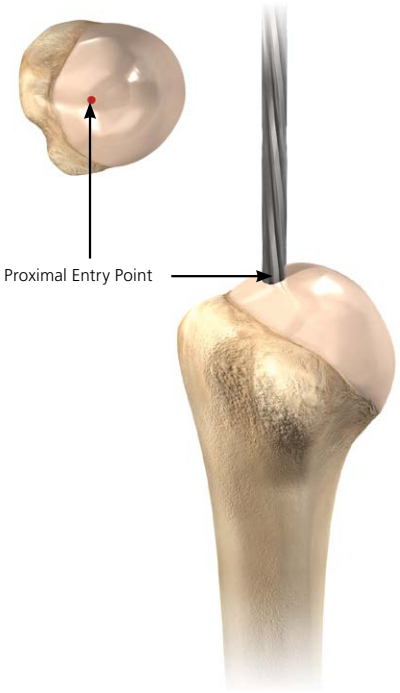


Figure 11

Figure 12

Humeral Head Resection

Resection Methods

Option 1 (Global Unite style cut guides):

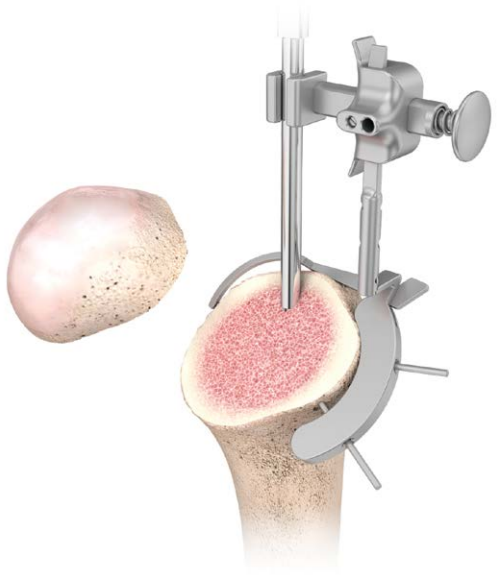
NOTE: Be sure to select the cut guide matching the angle desired for the humeral cut (145 or 155 degrees).

Assemble the appropriate right or left resection guide to the Quick Clamp and attach it to the reamer shaft.

Adjust the version by placing the Orientation Guide Pin in the desired version hole on the resection guide and align with the forearm.

Affix the resection guide to the humerus using three pins. When the 145 system is used, the superior pin should be inserted into the hole corresponding to the size of the bullet tip reamer.

Remove the reamer and Quick Clamp assembly and resect the humeral head utilizing an oscillating power saw.



Resection Methods

Option 2 (DELTA XTEND style cut guides):

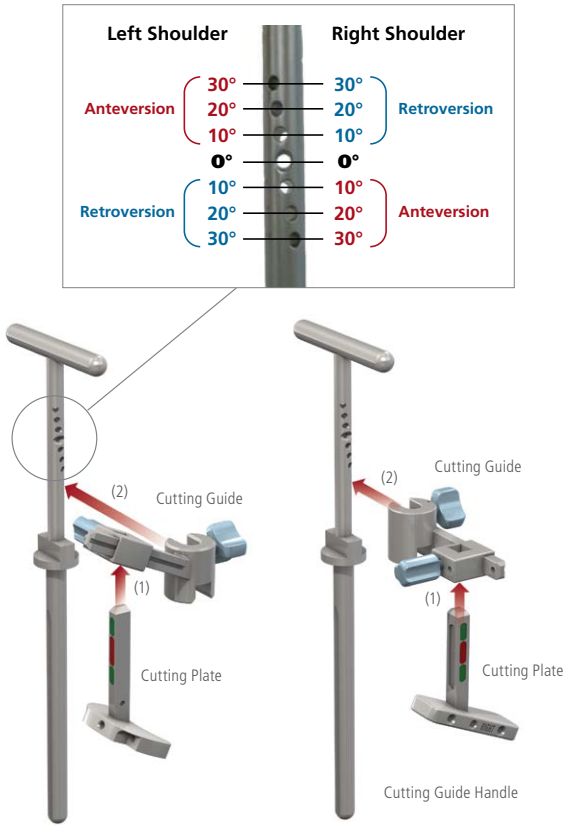
NOTE: Be sure to select the cut guide matching the angle desired for the humeral cut (145 or 155 degrees).

Select the handle for the cutting guide of the appropriate size. Taking the previous example, if reaming stopped at 12mm, select the 12mm 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 to 10 degrees 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).



Superior-lateral Cutting Guide Assembly

Delto-pectoral Cutting Guide Assembly

Figure 13

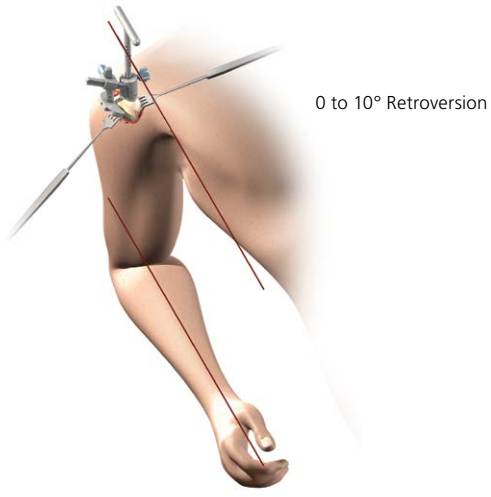


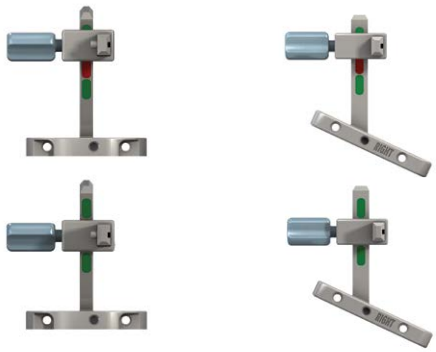
Figure 14

Slide the cutting plate to adjust the resection level. The cutting plate color code shows if the resection level is appropriate. The colored markings on the cutting plate are to be used as a guide only to aid in assessing resection height.

For 155° cut - visually verify that the resection is approximately 1 to 2mm below the proximal area of the greater tuberosity (at the level of the supraspinatus insertion in an intact shoulder).

For 145° cut - visually verify that the resection is approximately 2-3mm below the lateral border of the articular cartilage.

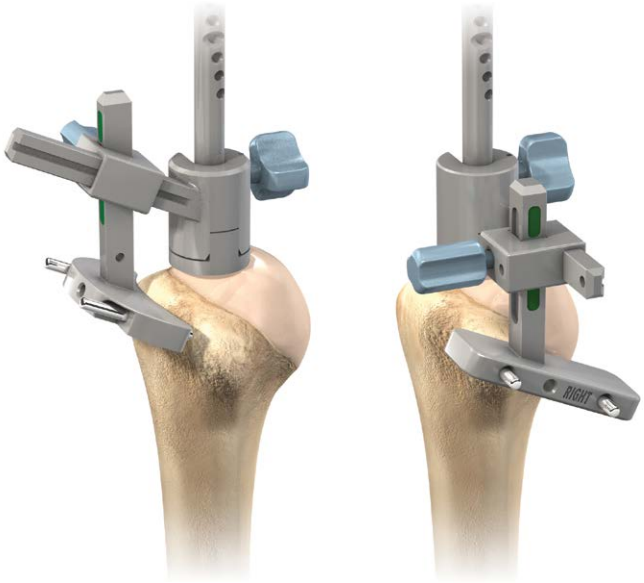
Pre-drill the cortical bone through the cutting plate using a 3.2mm drill bit, and insert the two fixation pins to fix the cutting plate to the humerus (Figure 16). When the 145 system is used, the superior pin should be inserted into the hole corresponding to the size of the T-handle.



Superior-lateral Cutting Plate

Delto-pectoral Cutting Plate
(155° cutting plates shown)

Figure 15



Superior-lateral Approach

Delto-pectoral Approach
(155° cutting plate shown)

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, Step 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, Step 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.

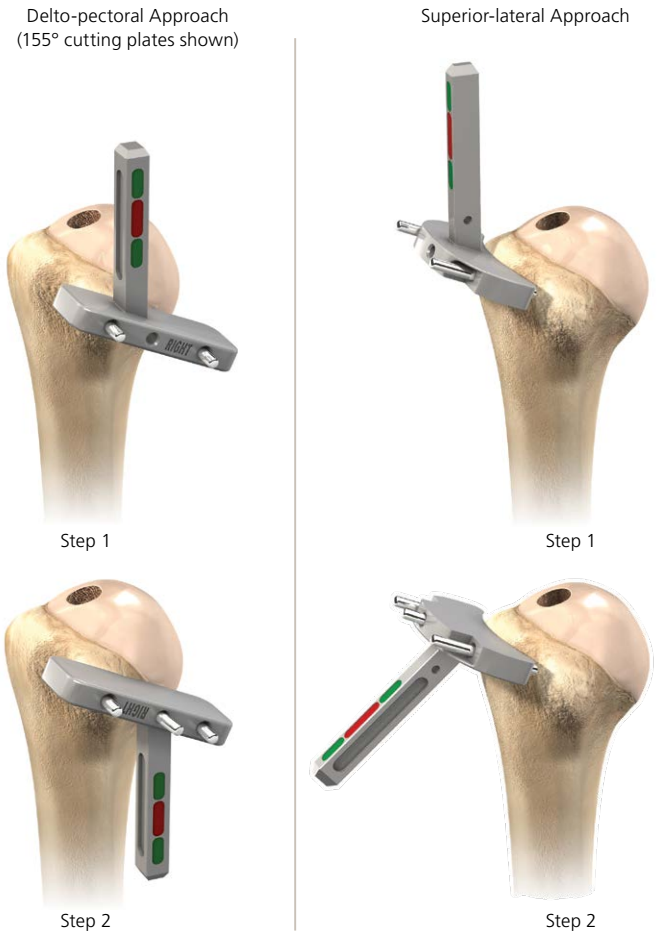


Figure 17

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 (Figure 20).

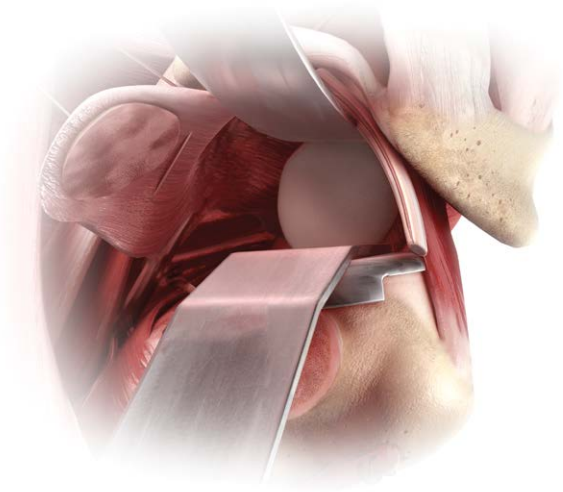


Figure 20

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 21).

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 pre-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.

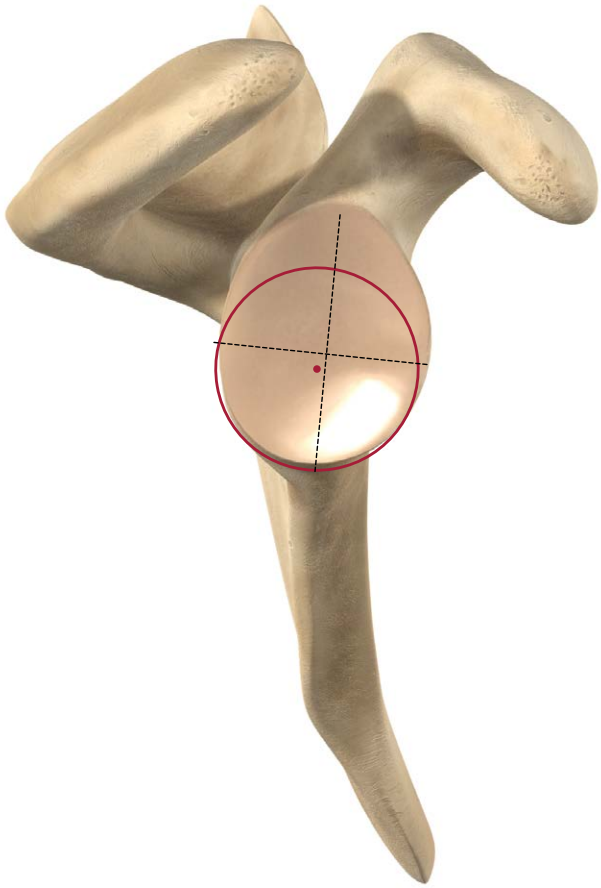


Figure 21

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 22).

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 23).

Note: The handle is set at an angle of 20 degrees to the plate to ensure optimal visibility (Figure 24).

Figure 22

Figure 23

Figure 24

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 malpositioning. 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 2.5mm metaglene central guide pin in the plate is central hole and drill it through the far cortex using a power tool (Figure 25).

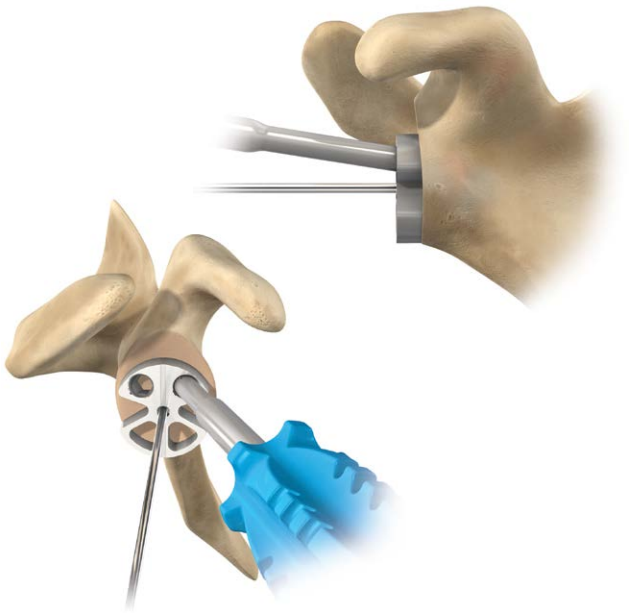


Figure 25

Remove the metaglene positioner, leaving the guide pin in place (Figure 26).

Note: The 2.5mm Breakaway Guide Pin (2230-00-019) may be used as a substitute for the Metaglene Central Guide Pin (2307-87-004).

The grooves on the 2.5mm Breakaway Guide Pin are exclusively used for the breakaway feature and are not intended to indicate the depth to which the pin should be inserted.

The pin is designed to break at the grooves. Be aware that it may break unintentionally if subjected to too much bending force.

After use of the guide pin is complete, confirm that all sections (totaling the full length of the original, unbroken pin) have been removed.

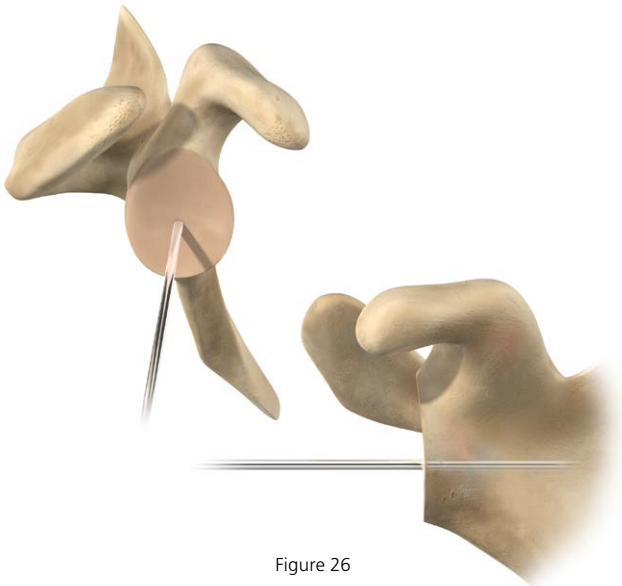


Figure 26

Reaming the Glenoid Bone

Slide the 27mm 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 27). 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 42mm glenoid reamer (Figure 28). This step is necessary to avoid any potential conflict between the glenosphere and the superior area of the glenoid bone (Figure 29).

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

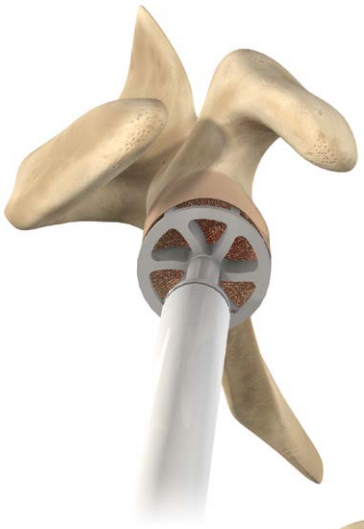


Figure 27

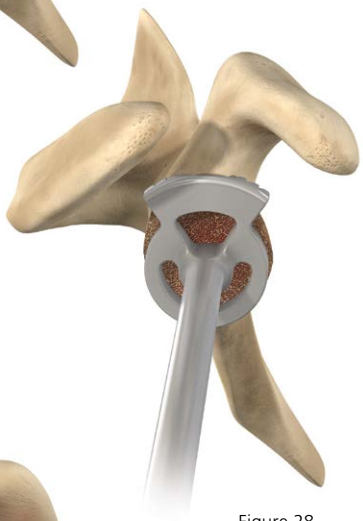


Figure 28

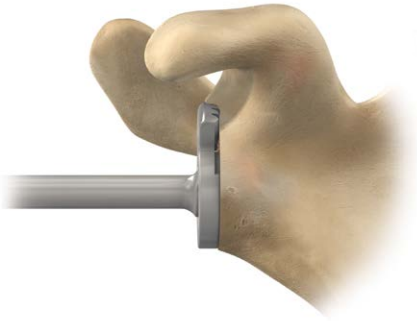


Figure 29

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 30).

Remove the resurfacing reamer, leaving the metaglene central guide pin in place (Figure 31).

Refering to the chart below, connect the appropriate size 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 32).

Remove the stop drill and the central guide pin.

Note: After use of the guide pin is complete, confirm that all sections (totaling the full length of the original, unbroken pin) have been removed.

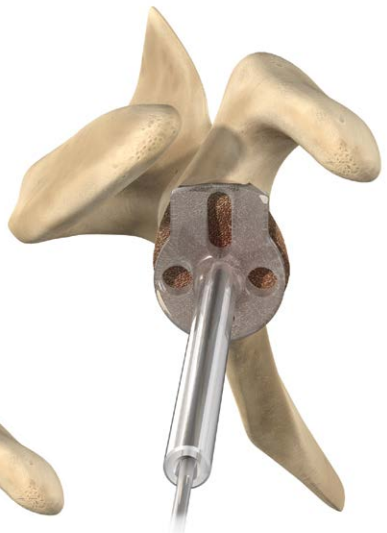


Figure 30

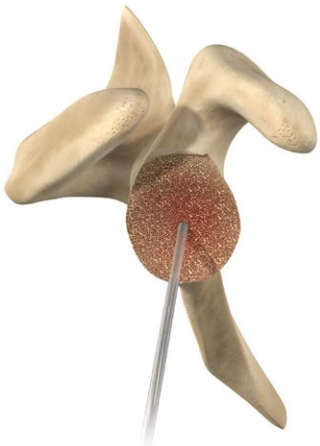


Figure 31

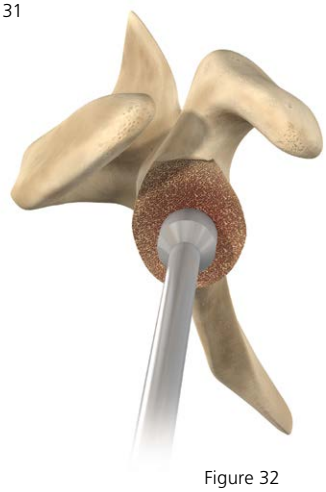
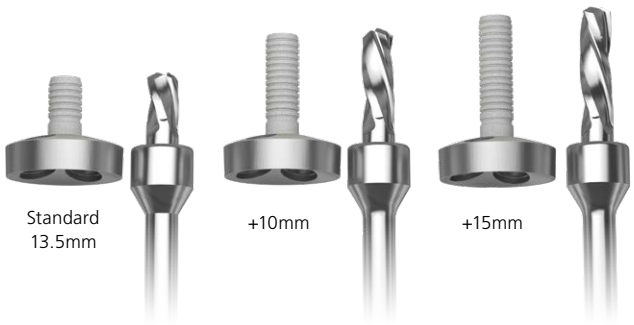


Figure 32

Size	Metaglene	Cannulated Drill
Standard (13.5mm)	1307-60-000	2307-89-000
+10mm	1407-60-020	2407-89-010
+15mm	1407-60-025	2407-89-015



Metaglene Implantation

Assemble the internal rod of the metaglene holder in the metaglene holder main body. Insert the metaglene holder hex tip in the desired final metaglene implant central hole and tighten the assembly. (Figure 33).

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 34). The metaglene peg is 0.6mm 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.

Figure 33

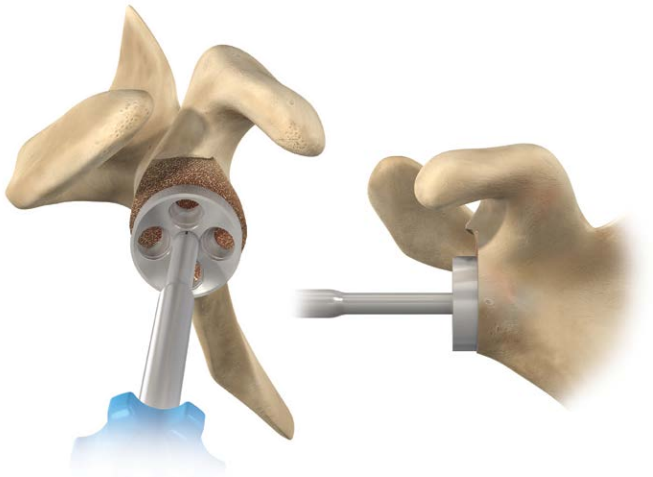
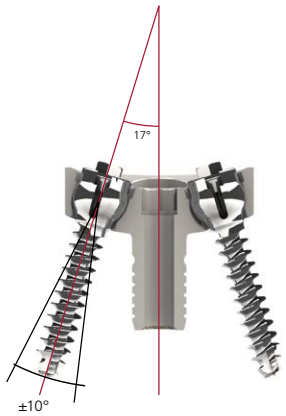


Figure 34

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 35).

Place the 2.5mm 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 2.5mm drill bit, start drilling through the subchondral bone to aproximately 10 to 12mm deep (Figure 36). Then stop drilling and push gently on the drill bit to make sure that the drill is contained in the bone. Redirect and redrill if uncontained. When a satisfactory drilling direction has been obtained, drill and push until the cortex is perforated.



Metaglene Superior-Inferior Cross Section
Polyaxial Locking Screws

Figure 35

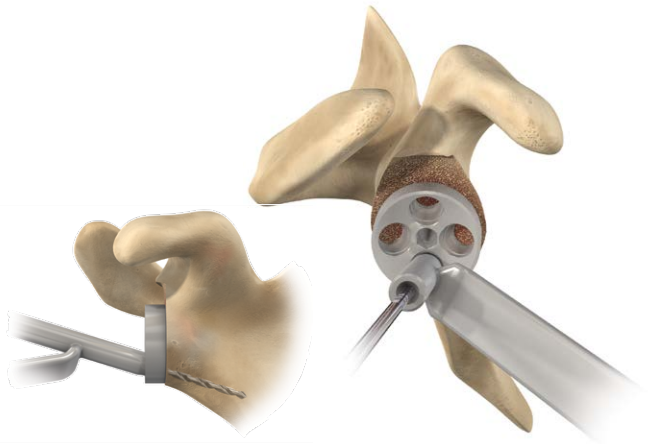


Figure 36

The goal is to have a sufficiently long screw inferiorly, usually 36mm or more. The length of the screw is indicated on the drill bit by laser markings (Figure 37). The screw depth gauge can also be used to assess optimal screw length.

Figure 37

Insert the 1.2mm guide pin through the drill guide and then remove the drill guide (Figure 38).

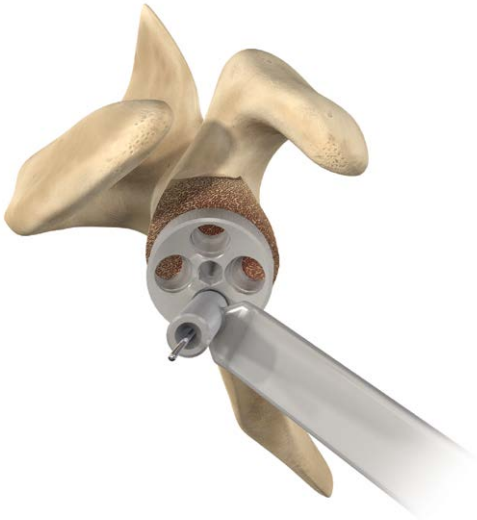


Figure 38

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 39).

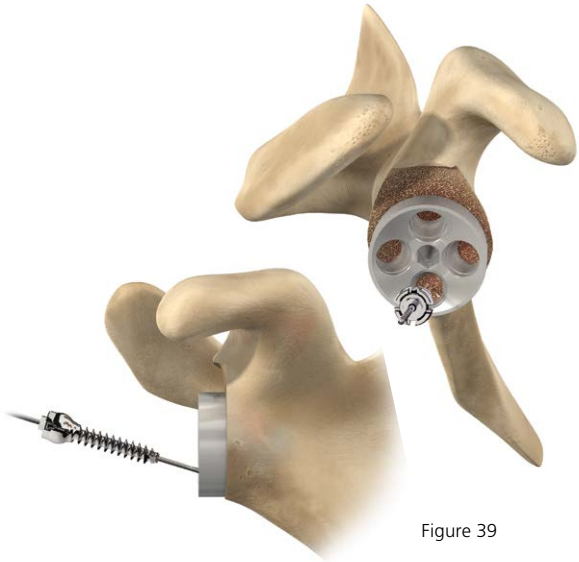


Figure 39

Slide the locking screwdriver body on the guide pin and insert the tip into the four slots on the screw (Figure 40). Do not use the internal screwdriver rod at this stage.

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

Tighten the screw to compress the plate (Figure 41a).

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.

Note: Use care to ensure that the driver remains in axial alignment with the screw so that the driver tip remains fully engaged (Figure 41b).

Note: The tip of the screwdriver can lose contact with the fins and does not torque evenly on all sides if the protecting sleeve is not used (Figure 41c).

Note: The protecting sleeve is not designed to lock onto the screw. It must be held in place with a finger during insertion.

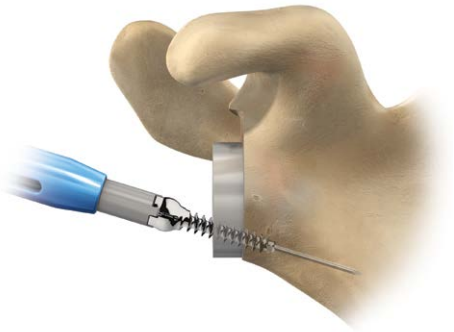


Figure 40

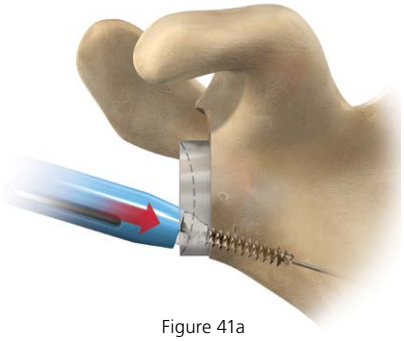


Figure 41a

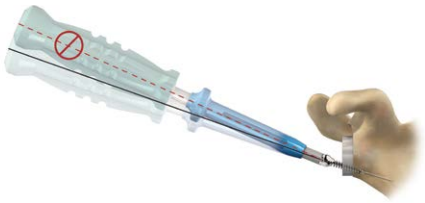


Figure 41b

Figure 41c

Drill the hole for the superior locking screw anticipating exit through the far cortex using the same methods as Figure 36 (inferior screw placement) (Figure 42). 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 43).

Note: Use care to ensure that the driver remains in axial alignment with the screw so that the driver tip remains fully engaged.

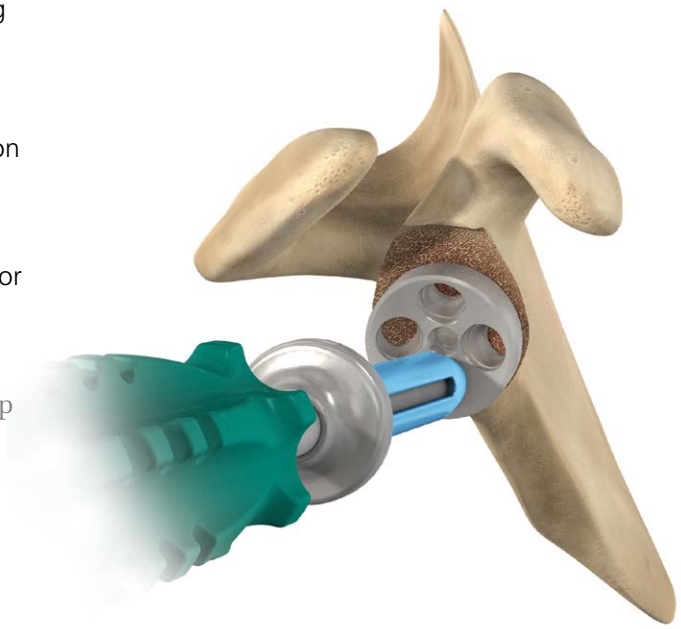


Figure 42

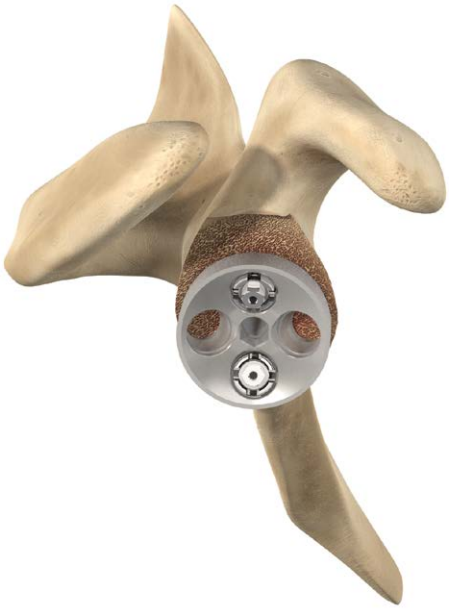


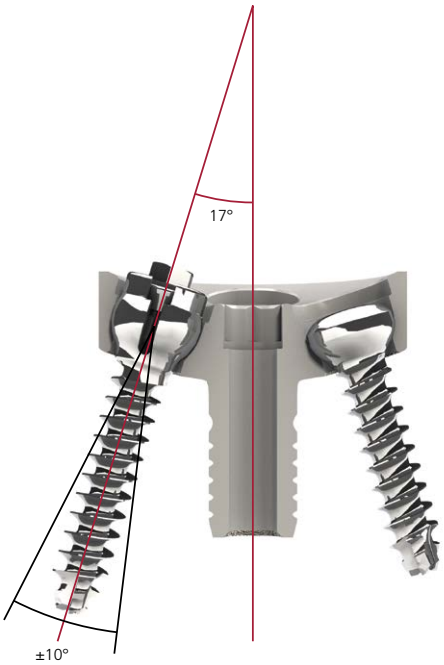
Figure 43

Anterior and Posterior Metaglene Screw Placement

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 44).

Use the 2.5mm drill bit with the drill guide to set the most appropriate angle for ensuring that each screw is located in reliable bone stock (Figure 45).

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.



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

Figure 44

Figure 45

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 3.5mm cannulated hex screwdriver for non-locking screws or the locking screwdriver for locking screws (Figure 46).

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 47).

Note: After inserting all four screws, tighten the locking screws with the internal rod for the locking screwdriver. Pull the sleeve up and off the screw head for this step.

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 48) and the humeral preparation is then carried out.

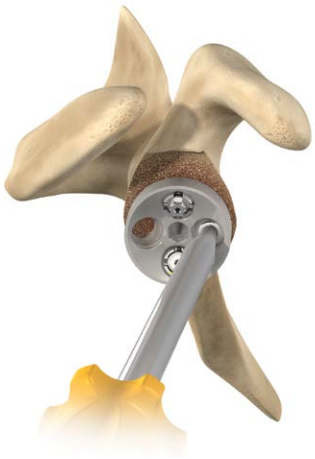


Figure 46

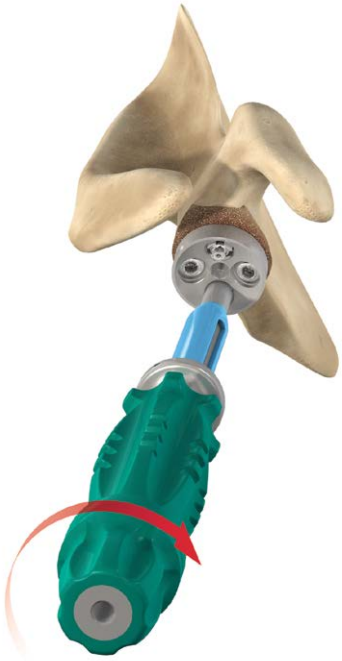


Figure 47

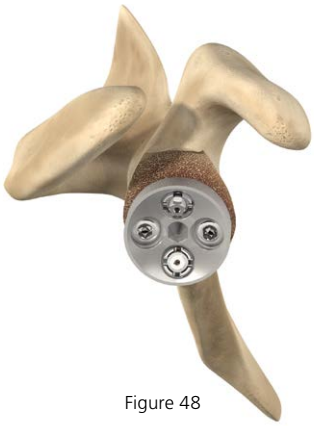


Figure 48

Placement of the Proximal Humeral Reaming Guide - 155°

Cemented Monobloc Humeral Implants and Cementless Modular Humeral Implants

The following surgical steps apply to the instrumentation and implantation for a 155° epiphysis.

Select the appropriate proximal reaming guide size (Figure 49). For example, if a 12mm intramedullary reamer and a 12mm cutting handle were previously used, select the 12mm 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 50).

Push the holder horseshoe plate fully down (Figure 51).

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 52).

Drive the proximal reaming guide down until complete contact between the metal block and the resectioned bone surface is achieved (Figure 53).

Unscrew the upper round handle of the holder and remove the holder, leaving the proximal reamer guide in place (Figure 54).

The subsequent surgical steps depend on whether the humeral implant is cementless or cemented. For cementless implants, see pages 34-36. For cemented implants, see pages 37-38.

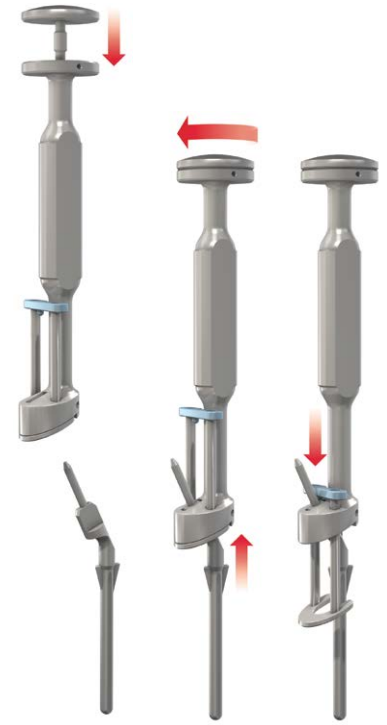


Figure 49 Figure 50 Figure 51

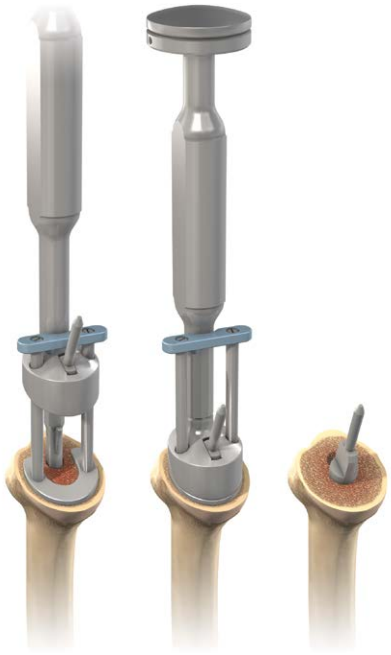


Figure 52 Figure 53 Figure 54

Placement of the Proximal Humeral Reaming Guide - 145°

The following surgical steps apply to the instrumentation and implantation for a 145° epiphysis.

Select the appropriate proximal reaming guide size (Figure 49). For example, if a 12mm intramedullary reamer and a 12mm cutting handle were previously used, select the 12mm proximal reaming guide.

Slide the reaming guide into the ream guide inserter and fasten the two parts together firmly by pulling the inserter lever towards the handle until locked in a vertical position (Figure 50).

Push the holder horseshoe plate fully down (Figure 51).

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 52).

Drive the proximal reaming guide down until complete contact between the metal block and the resectioned bone surface is achieved (Figure 53).

Open the lever on the ream guide inserter to release the proximal reamer guide, leaving the guide in place (Figure 54).

Figure 49

Figure 50

Figure 51

Figure 52

Figure 53

Figure 54

Proximal Humeral Reaming

Note: Make sure you are using the dedicated instruments for cementless modular implants

The cementless modular implant is designed to allow the surgeon to place the epiphysis in anatomic version and the stem in anatomic version for an optimal press-fit.

The size and type (centered or eccentric) of modular epiphysis should be chosen to ensure that the best possible coverage of the bone resection surface is achieved.

First select the centered proximal modular reamer adaptor, and place it on the reaming guide's angled pin.

Choose the most appropriate epiphysis size using the modular implant sizer disks, size 1 or 2. The sizer disk chosen should provide the best coverage of the bone resection surface without overhang (Figure 55).

If this does not provide a good fit with the bone resection surface, switch the centered proximal modular reamer adaptor for the eccentric adaptor in size 1. Be careful to position the eccentricity so that it is posterior and not anterior, double checking with the markings (anterior and posterior) on the adaptor.

Then check the epiphysis size again with sizer disk 1. If the bone coverage is not sufficient, use eccentric adaptor size 2 and sizer disk size 2 (Figure 56).

Remember the final decision made, with respect to the centered or eccentric epiphysis and size 1 or 2, will determine reamer and final implant sizes.

Figure 55

Figure 56

Note: Make sure you are using the dedicated instruments for cementless modular implants

Remove the sizer disk, leaving the proximal modular reamer adaptor in place (Figure 57).

Select the appropriate proximal modular reamer in size 1 or 2, according to the results of the previous trials. Ream using a power tool. Power reaming should always be carried out carefully.

Complete reaming is achieved when the external reamer flange is in full and complete contact with the bone resection surface (Figure 58).

When the proximal reaming has been completed, first remove the reaming adaptor. Then remove the reaming guide using the reaming guide holder. If any bone remains in the center of the epiphysis, remove it.

Figure 57

Figure 58

Distal Humeral Broaching

Note: Make sure you are using the dedicated instruments for cementless modular implants

The stem size will have been determined from the previous intramedullary reaming. If the 12mm intramedullary reamer has been used, select the 12mm broach and attach it to the broach handle. Make sure that the goniometer is in place on the broach handle and that the Broach Handle and goniometer selected match the neck shaft angle (145° versus 155°).

Drive the broach into place, carefully checking that its anterior fin is aligned with the anterior aspect of the bicipital groove. This will ensure good distal stem orientation (anatomic version) for an optimized press-fit (Figure 59).

Drive the broach down carefully, (to avoid any cortical bone damage) until the rocking bar of the broach handle is in full contact with bone, both at the anterior and posterior aspects of the resection surface (Figure 60).

If there is a cortical bone damage where the rocking bar should contact bone, place the broach handle plate on the resection.

Read the adjustment angle which is indicated on the instrument.

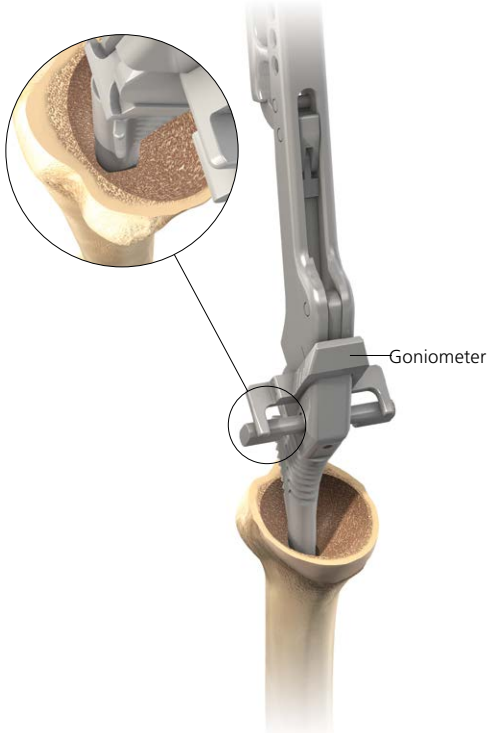


Figure 59

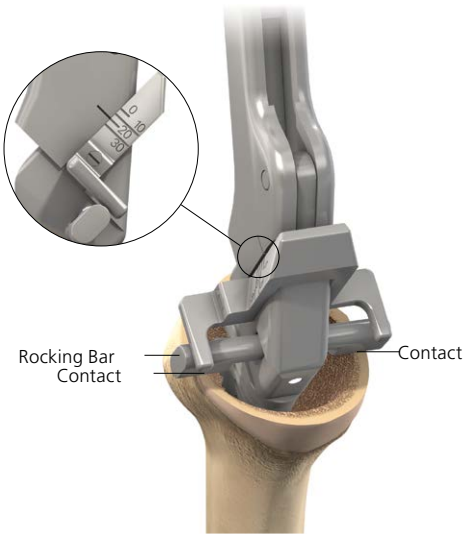


Figure 60

Humeral Trial Stem and Epiphysis Insertion - 155°

The following surgical steps apply to the instrumentation and implantation for a 155° epiphysis.

Note: Make sure you are using the dedicated instruments for cementless modular implants

The trial modular epiphysis (centered or eccentric, size 1 or 2, depending on the proximal reaming choices made) is placed on the trial modular stem (size chosen during distal reaming and broaching).

The epiphysis position corresponds to the adjustment position previously read on the broach handle goniometer. For example, if "20" right was read on the goniometer, the epiphysis hole marked "20" right should be positioned in line with the stem orientation peg (Figure 61).

Note: This position corresponds to the difference between the version of the stem (close to anatomical retroversion) and the epiphysis version for a reverse shoulder.

No calculation is required: the instrumentation has been designed to provide indication of this position on the goniometer.

The two components are then screwed together using the 3.5mm hex screwdriver and the special locking wrench for modular implants (Figure 62).

Both components are then mounted on the humeral implant driver by pushing and then releasing the blue button (Figure 63).

Figure 61

Figure 62

Figure 63

Note: Make sure you are using the dedicated instruments for cementless modular implants

The component is then driven down the intramedullary canal, aligning the anterior fin of the stem with the bicipital groove.

The implant orientation can also 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 degrees retroversion. The orientation pin should then be aligned with the forearm axis and the trial implants driven down (Figure 64).

Impact the trial implant by gently tapping in the implant driver handle and remove the driver, leaving the trial implant in place (Figure 65). The driver is detached by pushing the blue button.

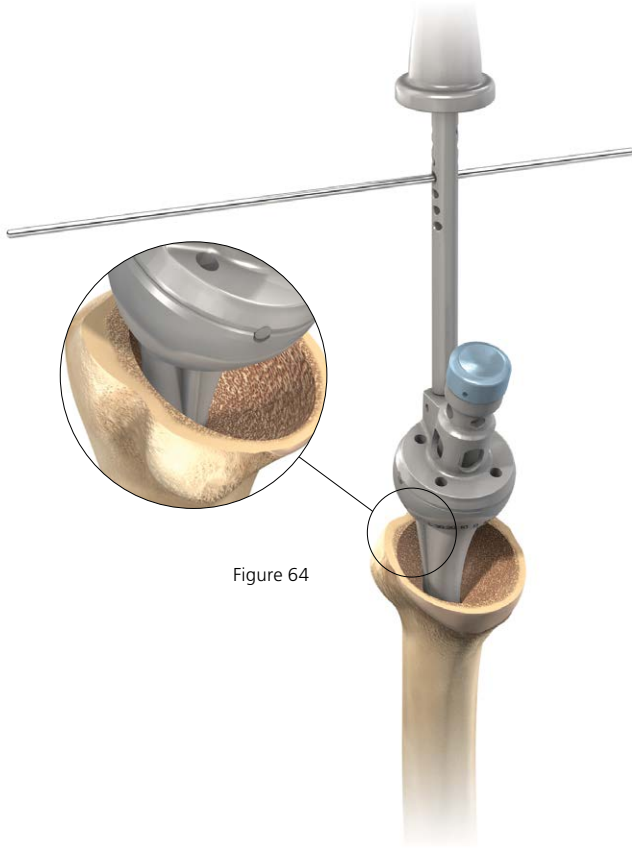


Figure 64

Figure 65

Humeral Trial Stem and Epiphysis Insertion - 145°

The following surgical steps apply to the instrumentation and implantation for a 145° epiphysis.

The trial modular epiphysis (centered or eccentric, size 1 or 2, depending on the proximal reaming choices made) is placed on the trial modular stem (size chosen during distal reaming and broaching).

The epiphysis position corresponds to the adjustment position previously read on the broach handle goniometer. For example, if "20" right was read on the goniometer, the epiphysis hole marked "20" right should be positioned in line with the stem orientation peg.

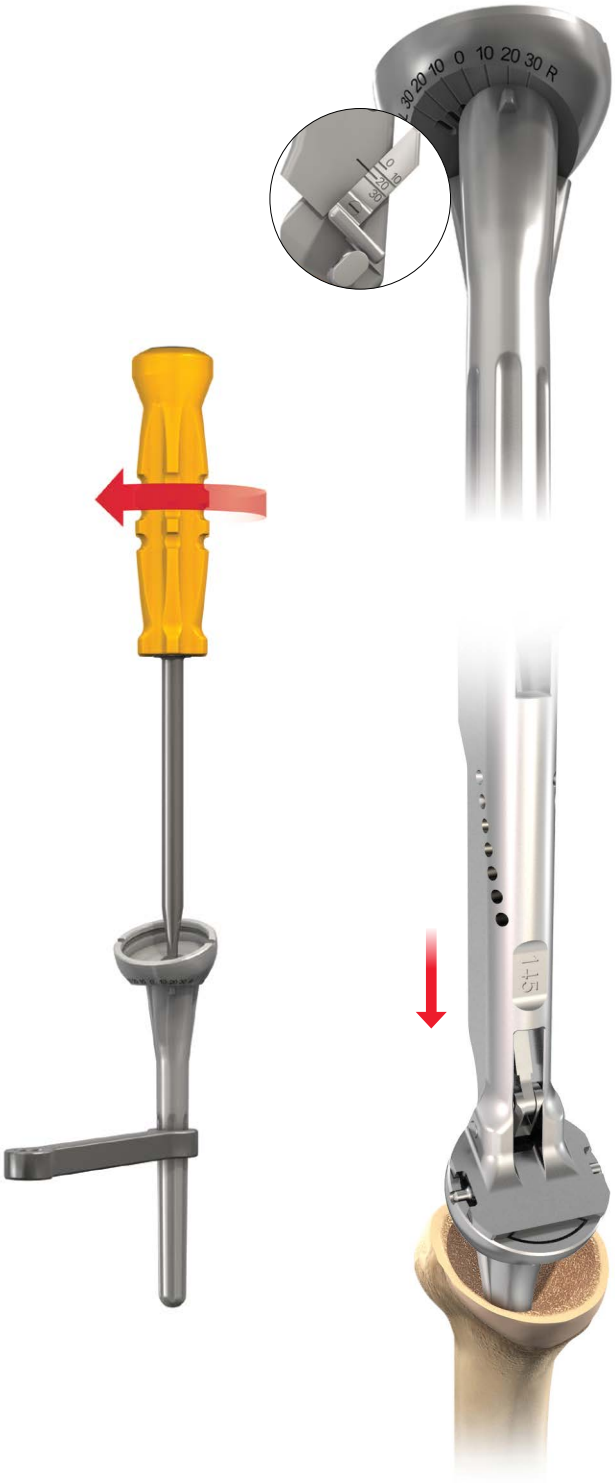
Note: This position corresponds to the difference between the version of the stem (close to anatomical retroversion) and the epiphysis version for a reverse shoulder.

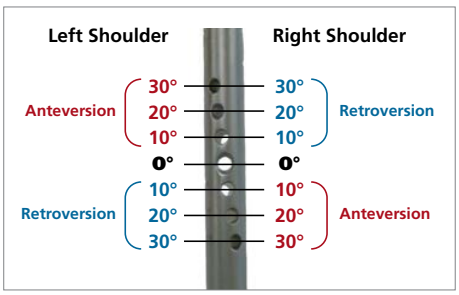
No calculation is required: the instrument has been designed to provide indication of this position on the goniometer.

The two components are then screwed together using the 3.5mm hex screwdriver and the special locking wrench for modular implants.

Both components are then mounted on the 145 humeral implant driver by pulling the driver lever closed until locked into a vertical position.

Impact the trial so that it is firmly fixed within the canal. An alignment rod may be attached to the inserter at the desired retroversion. The alignment rod is inserted into the desired version hole on the inserter and is then aligned to the forearm.





Proximal Humeral Reaming

Note: Make sure you are using the dedicated instruments for Cemented Monobloc Humeral Implants

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 66).

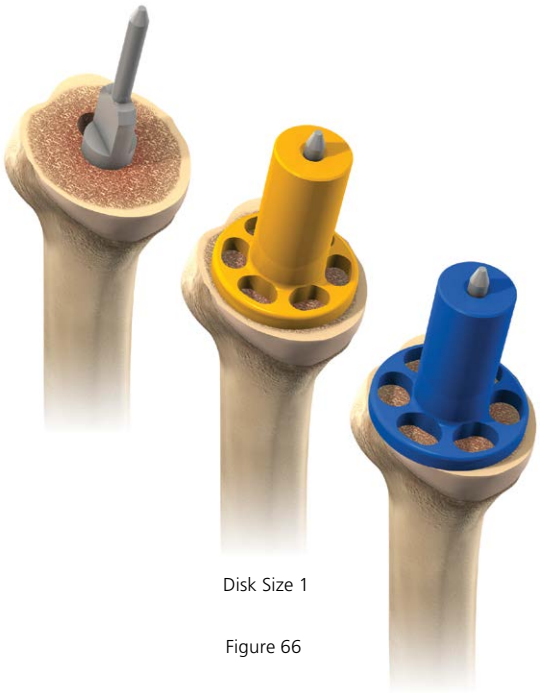
The size chosen, epiphysis size 1 or 2, will determine proximal reamer and final implant sizes.

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 67).

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.



Disk Size 1

Figure 66

Figure 67

Humeral Trial Implant Insertion

Note: Make sure you are using the dedicated instruments for Cemented Monobloc Humeral Implants

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

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 68).

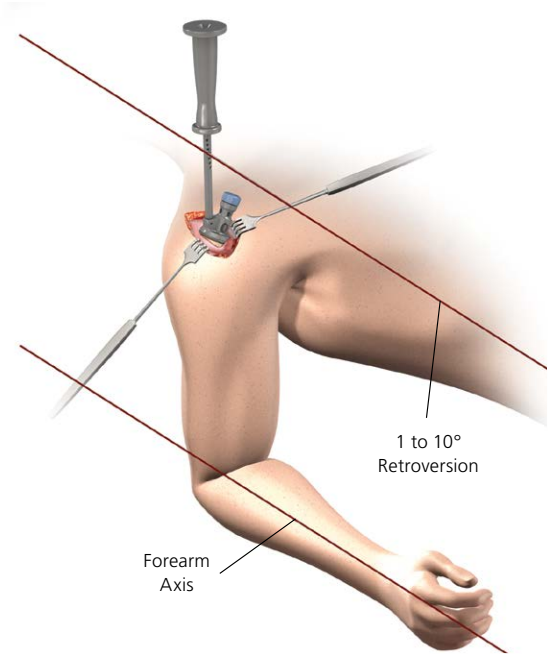


Figure 68

Impact the trial implant by gently tapping the implant driver handle and remove the driver, leaving the trial implant in place (Figure 69). The driver is detached by pushing on the blue button.

Figure 69

Glenosphere Trial Placement

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

An overlap of 3 to 5mm is recommended to avoid conflict with the scapular neck (Figure 70). Depending on the shape of the scapular neck, this overlap can be achieved by using a standard metaglene just by lowering the metaglene. The 42mm glenosphere is recommended if the size of the joint allows (increases both the overlap and the range of motion). The eccentric glenospheres are recommended for more transverse scapular necks.

Fit the appropriate trial glenosphere (38mm or 42mm, centered or eccentric, +0mm, +2mm, +4mm, +6mm, or +8mm of lateralization) to the the metaglene using the metaglene holder (Figure 71). The trial glenosphere utilizes an interference fit to make the connection with the metaglene.

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 71 and 72).

The arrow indicates the position of the eccentricity and should be positioned inferiorly, aligned with the scapular neck (Figure 72).

Note: If it is difficult to place the glenosphere trial, then check to ensure the superior portion of the glenoid has been reamed adequately and that there is no soft tissue in the way.

Figure 70

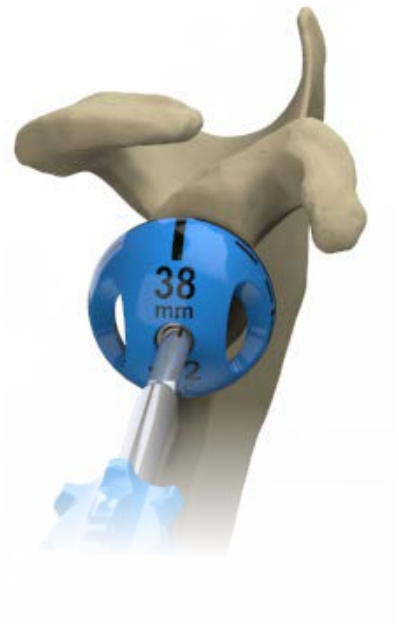


Figure 71

Figure 72

Cup Trials and Trial Reduction

Place the humeral trial cup (38 or 42mm depending on the glenosphere size), with +3mm of lateral offset, in the trial epiphysis (Figure 73). The shoulder should then be reduced with longitudinal traction and assessed for a full range of motion (Figure 74).

Figure 73

Figure 74

Joint Tensioning and Stability Assessment

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 3mm 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 3mm is acceptable). Estimate the maximum forward elevation.[1]
- Assess stability at 90 degrees, abduction with the humerus in neutral, maximum internal and maximum external rotation. Estimate the maximum forward elevation.[1]

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 (+6mm or +9mm)
- A lateralized glenosphere
- A 42mm 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 1.5mm guide pin through the central hole of the metaglene.

Engage the 3.5mm cannulated hex screwdriver in the final glenosphere. Slide the glenosphere on the 1.5mm guide pin until it is in contact with the metaglene (Figure 75). 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.

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 76). 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.

Note: Glenosphere will sit about 1mm proud on the metaglene with consistent uniformity

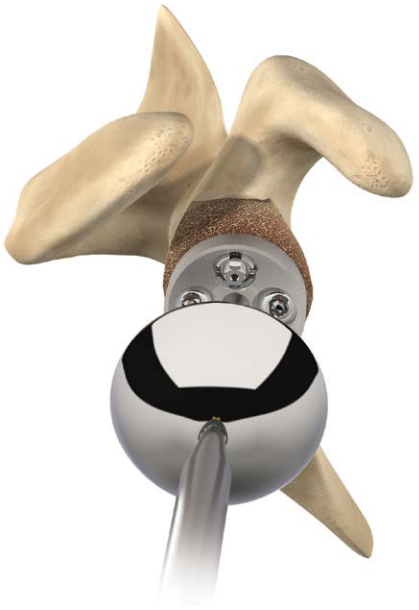


Figure 75

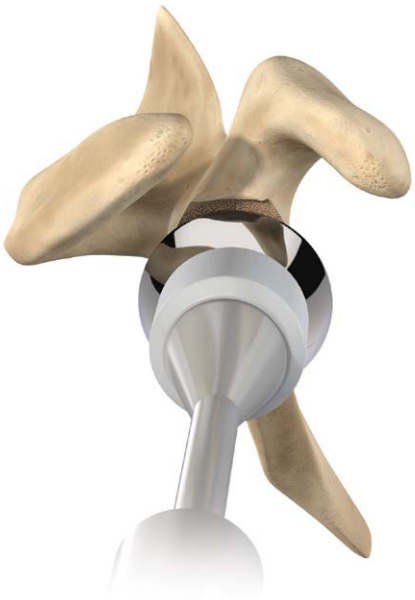


Figure 76

Eccentric Glenosphere

Slide the glenosphere orientation guide onto the screwdriver core and position it in the eccentric glenosphere central slot (Figure 77).

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 78).

Obtain further impaction of the junction by gently hammering the glenosphere with the glenosphere impactor a minimum of three times (Figure 79). 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.

Note: Glenosphere will sit about 1mm proud on the metaglene with consistent uniformity

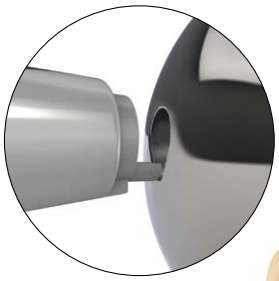


Figure 77

Figure 78

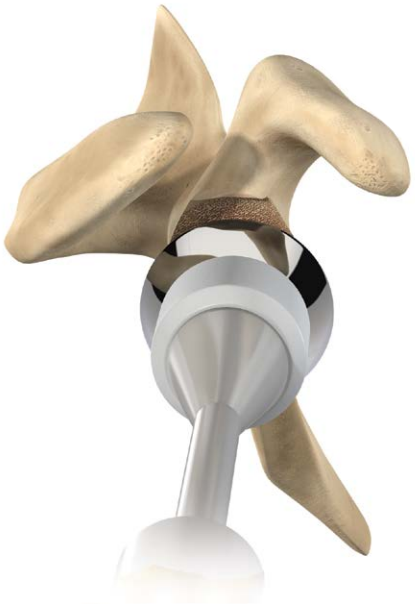


Figure 79

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 3.5mm hex head screwdriver (Figure 80). This operation should be done smoothly to avoid central screw damage.

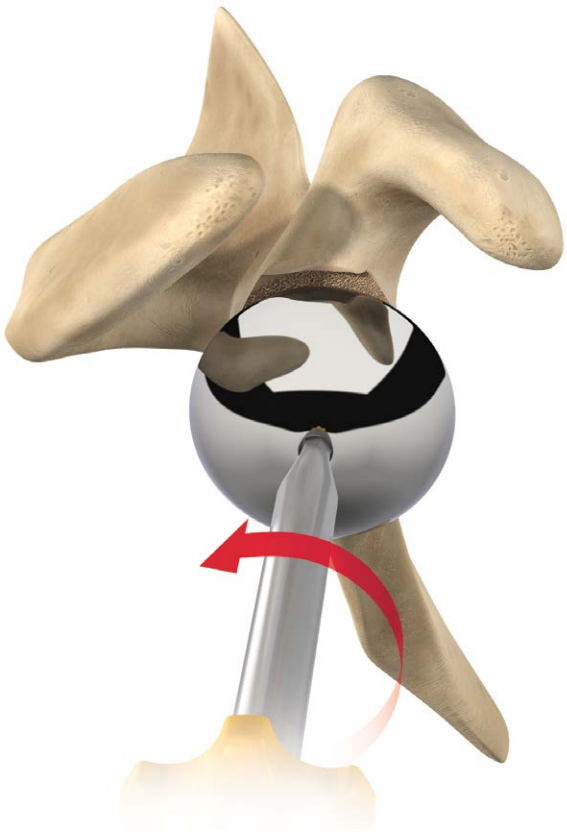


Figure 80

Definitive Humeral Implants Insertion

Cementless Modular Humeral Implants - 155°

The following surgical steps apply to the instrumentation and implantation for a 155° epiphysis.

Note: Make sure you are using the dedicated instruments for cementless modular implants.

Remove the trial cups and trial implants using the humeral implant driver.

Select the appropriate final modular humeral implants that correspond to the trial implants.

Place the final modular epiphysis on the final modular stem in the same rotational position used for the trial implants (Figure 81).

Screw the final modular epiphysis together with the final humeral stem, using the 3.5mm hex screwdriver and the special locking wrench for modular implants (Figure 82).

Both components should then be mounted on the humeral implant driver and driven down the intramedullary canal, aligning the anterior fin of the stem with the bicipital groove (Figure 83). The top of the HA or Porocoat® on the epiphysis should be aligned with the edge of the bone resection.

Note: 155° epiphysis implants are available in HA-coated or Porocoat® options.

Figure 81

Figure 82

Figure 83

Definitive Humeral Implants Insertion

Cementless Modular Humeral Implants- 145°

The following surgical steps apply to the instrumentation and implantation for a 145° epiphysis.

Remove the trial cups and trial implants using the 145° humeral implant driver.

Select the appropriate final modular humeral implants that correspond to the trial implants.

Place the final modular epiphysis on the final modular stem in the same rotational position used for the trial implants.

Screw the final modular epiphysis together with the final humeral stem, using the 3.5mm hex driver and the special locking wrench for modular implants.

Both humeral components should then be mounted on the humeral implant driver and driven down the intramedullary canal, aligning the anterior fin of the stem with the bicipital groove. The top of the Porocoat® on the epiphysis should be aligned with the edge of the bone resection.

Cemented Monobloc Humeral Implants

Note: Make sure you are using the dedicated instruments for 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 84). 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 or partially absorbable sutures, such as ORTHOCORD Suture, through the proximal humerus near the lesser tuberosity to enable secure re-attachment of the subscapularis (if possible).11 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 85).

Cement in the humeral implant as directed.

Figure 84

Figure 85

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 86).

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.

Note: Retroversion is calculated with reference to the forearm axis (0 to 10 degrees)

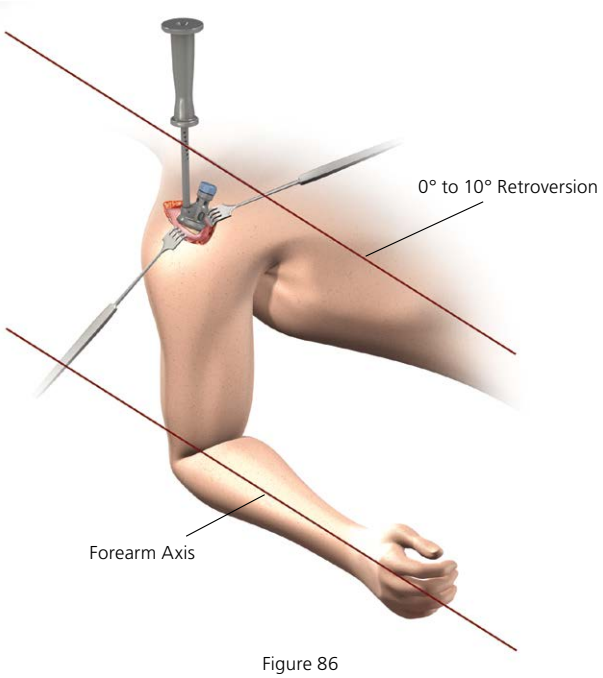


Figure 86

Final cup fixation

Impact the final humeral cup using the cup impactor (Figure 87).

Step 1

Insert the polyethylene humeral cup by hand. Turn it 180 degrees in the epiphysis to make sure that it is evenly seated and that there is no soft tissue, cement or fluid interfering with the cup to epiphysis connection (Figure 88).

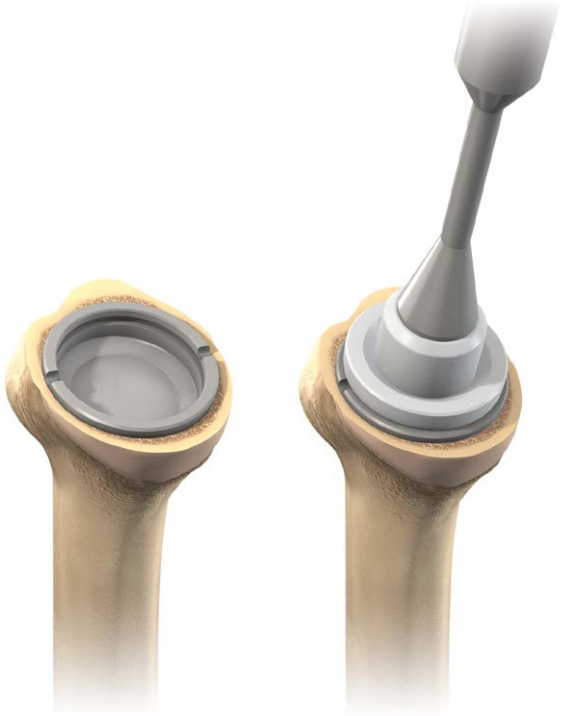


Figure 87

Figure 88

Step 2

Once you are confident that you have perfect aligment, impact the humeral cup at a 90 degree angle to the epiphysis (Figure 89). Make sure the arm is fully supported to ensure full impaction.

Step 3

Once fully seated there will be approximately a 1mm gap between the lip of the cup and the epiphysis. The 1mm gap will aid future revisions if necessary. The cup should not move or shift when touched. If this is the case, realign the implant and repeat the impaction steps (Figure 90).

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.

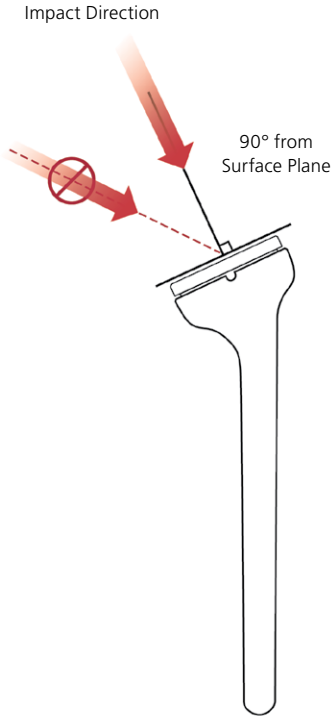


Figure 89

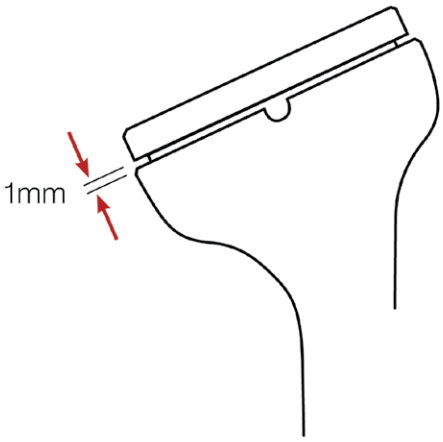


Figure 90

Cases of Proximal Humeral Bone Loss

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 91).

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.

1. Tighten the fin clamp on the humeral shaft first using the 3.5mm screwdriver (Figure 92).
2. 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.
3. Place the prosthesis at the appropriate height.
4. Tighten the fin clamp to secure it to the vertical height gauge.

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

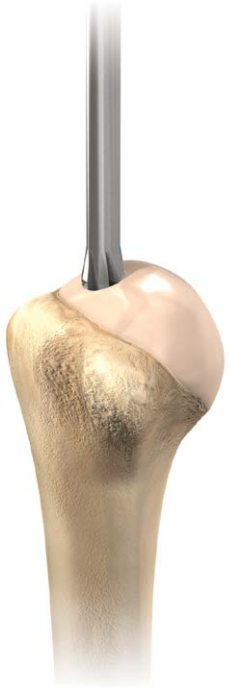


Figure 91

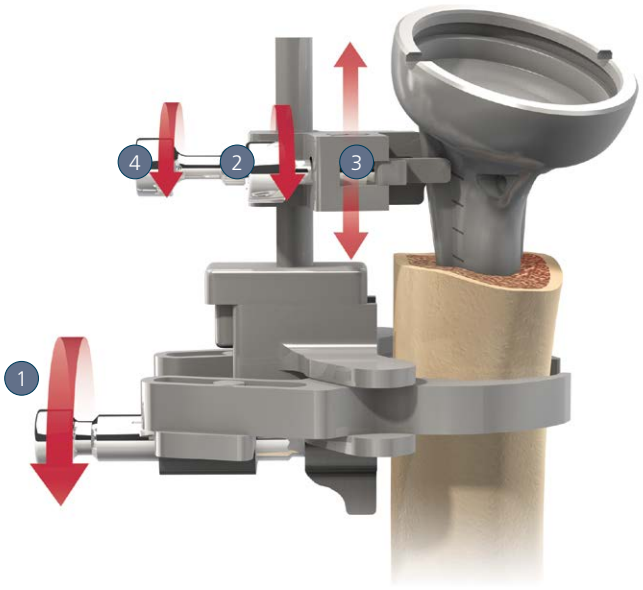


Figure 92

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 93).

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 94). 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.

Note: This will have to be done by estimating when you are between 0 to 10 degrees.

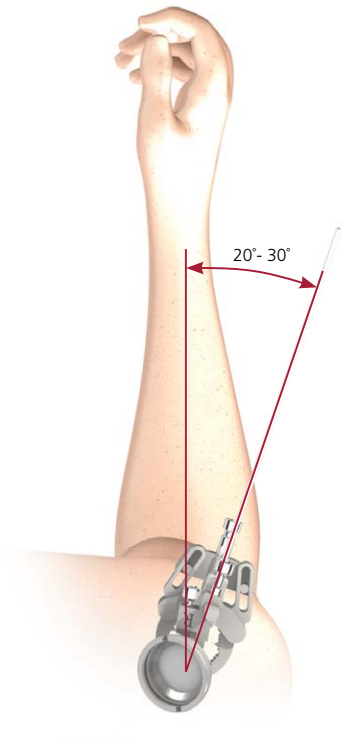


Figure 93

Figure 94

DELTA XTEND SYSTEM Revision to Hemi-Arthroplasty

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-prothesis as a salvage procedure. Specific hemi-heads with lateral head coverage, DELTA XTEND CTA System heads, are available. This is also indicated for intraoperative glenoid fracture.

Remove the glenosphere using the 3.5mm hex head screwdriver. Remove the metaglene locking screws using the locking screwdriver and the non-locking screw using the 3.5mm hex head screwdriver. Remove the metaglene using the extraction T-Handle and remove the humeral cup using the cup extraction clamp (Figure 95).

Place the DELTA XTEND CTA System Head Reamer Guide in the epiphysis (Figure 96). 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 System Head Reamer with the T-Handle. Ream the area around the epiphysis manually (Figure 97). If the DELTA XTEND CTA System Trial Head does not obtain perfect seating on the epiphysis, finish the preparation using a rongeur.

Choose the appropriate size of DELTA XTEND CTA System Head using the trial heads.

Gently impact the appropriate final head using the humeral head impactor (Figure 98). 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 Systemhead should be chosen to match the patient's anatomy. This requires that the head is placed in the proper orientation before impacting.

Figure 95

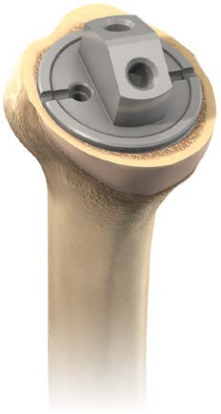


Figure 96

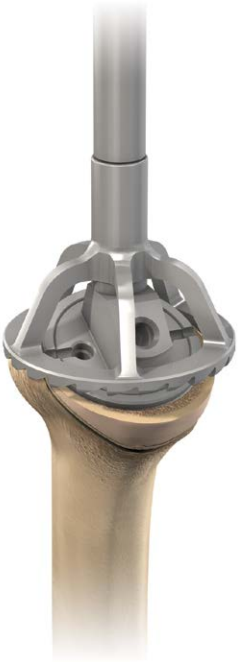


Figure 97

Figure 98

DELTA XTEND System Long Peg Metaglenes and DELTA CTA® High Strength Orthopaedic Suture Hybrid Cups

DELTA | XTEND™
REVERSE SHOULDER SYSTEM

DELTA XTEND System Glenoid Bone Defects

In case of a significant glenoid bone defect, or abnormal medialization of the glenoid bone:

- In order to restore the glenoid joint line, a long peg metaglene can be used (with possible associated bone grafting technique). Two long peg options (+10mm and +15mm) are available in addition to the existing standard metaglene peg (13.5mm)
- To implant the long peg metaglenes please refer to the glenoid section in the DELTA XTEND System Surgical Technique beginning on page 14. Dedicated drill bits are offered for each size (13.5mm, +10mm and +15mm)

DELTA XTEND/DELTA CTA System Glenoid Revisions

Revision of any DELTA CTA or DELTA XTEND System glenoid component due to loosening:

- To remove a DELTA or DELTA XTEND System Glenosphere use the Hexagonal Cannulated 3.5mm Screwdriver (2307-93-000) per page 41 of this technique
- To remove System CTA Metaglene Screws and DELTA XTEND System Non-Locking Screws use the Hexagonal Cannulated 3.5mm Screwdriver (2307-93-000)
- To remove DELTA XTEND System Metaglene Locking Screws use the Locking Screwdriver (2307-92-003) with Internal Rod (2307-92-004)
- To remove any type of metaglene from either DELTA System once all screws are removed, use the Monobloc Extraction T-handle (2307-99-002)
- Finally, replace with DELTA XTEND System Glenoid Components using the surgeon's preferred bone grafting technique and follow the DELTA XTEND System Surgical Technique

DELTA CTA System Glenoid Revision with Fixed Humeral Component

DELTA CTA System Hybrid Humeral Cups

In case of revision of a DELTA CTA System Glenoid Component where the humeral component is well fixed, different options are provided:

- In case of a DELTA CTA System 36mm epiphysis, use 38mm or 42mm hybrid cups consistent with the glenoid diameter used. Hybrid cups are available in three different heights (+3mm, +6mm and +9mm)
- In case of a DELTA CTA System 42mm epiphysis, DELTA CTA System 42mm diameter cups are compatible with 42mm DELTA XTEND System Glenospheres
- In more extreme cases, a modular humeral spacer +9mm can be used

DELTA CTA System Revision to Hemi-Arthroplasty

In cases of intra-operative fracture of the glenoid cavity, or revision of the DELTA CTA System Glenoid, for example, a hemi-arthroplasty may be considered. Intermediate metallic heads are provided within the DELTA CTA System to complete this procedure. Two epiphyseal diameters, 36mm and 42mm, are available in standard and +4mm offset. The hemi heads can be assembled either directly onto the epiphysis or onto the metallic spacer. These should be introduced using the humeral head impactor per the DELTA CTA Surgical Technique (DSUS/JRC/0915/1012).

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 program. 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 Stem Epiphysis Size 1 8mm Standard
1307-10-100	Monobloc Humeral Cemented Stem Epiphysis Size 1 10mm Standard
1307-12-100	Monobloc Humeral Cemented Stem Epiphysis Size 1 12mm Standard
1307-14-100	Monobloc Humeral Cemented Stem Epiphysis Size 1 14mm Standard
1307-10-200	Monobloc Humeral Cemented Stem Epiphysis Size 2 10mm Standard
1307-12-200	Monobloc Humeral Cemented Stem Epiphysis Size 2 12mm Standard
1307-14-200	Monobloc Humeral Cemented Stem Epiphysis Size 2 14mm Standard

Cementless Modular Humeral Implants

1100-06-100	PC HUMERAL STEM 6X83
1100-08-100	PC HUMERAL STEM 8X107
1100-10-100	PC HUMERAL STEM 10X113
1100-12-100	PC HUMERAL STEM 12X121
1100-14-100	PC HUMERAL STEM 14X130
1100-16-100	PC HUMERAL STEM 16X138
1100-06-600	LONG PC HUMERAL STEM 6X143
1100-08-600	LONG PC HUMERAL STEM 8X177
1100-10-600	LONG PC HUMERAL STEM 10X183
1100-12-600	LONG PC HUMERAL STEM 12X191
1307-10-000	Modular Humeral Stem 10mm HA
1307-12-000	Modular Humeral Stem 12mm HA
1307-14-000	Modular Humeral Stem 14mm HA
1307-16-000	Modular Humeral Stem 16mm HA
1307-20-101	Modular Centered Epiphysis Size 1 HA
1307-20-102	Modular Eccentric Epiphysis Size 1 Left HA
1307-20-103	Modular Eccentric Epiphysis Size 1 Right HA
1307-20-201	Modular Centered Epiphysis Size 2 HA
1307-20-202	Modular Eccentric Epiphysis Size 2 Left HA
1307-20-203	Modular Eccentric Epiphysis Size 2 Right HA
1307-20-111	Modular Centered 145 Epiphysis Size 1 POROCOAT®
1307-20-112	Modular Eccentric 145 Epiphysis Size 1 Left POROCOAT®
1307-20-113	Modular Eccentric 145 Epiphysis Size 1 Right POROCOAT®
1307-20-221	Modular Centered 145 Epiphysis Size 2 POROCOAT®
1307-20-222	Modular Eccentric 145 Epiphysis Size 2 Left POROCOAT®
1307-20-223	Modular Eccentric 145 Epiphysis Size 2 Right POROCOAT®
1307-40-101	Modular Centered 155 Epiphysis Size 1 POROCOAT®
1307-40-102	Modular Eccentric 155 Epiphysis Size 1 Left POROCOAT®
1307-40-103	Modular Eccentric 155 Epiphysis Size 1 Right POROCOAT®
1307-30-201	Modular Centered 155 Epiphysis Size 2 POROCOAT®
1307-30-202	Modular Eccentric 155 Epiphysis Size 2 Left POROCOAT®
1307-30-203	Modular Eccentric 155 Epiphysis Size 2 Right POROCOAT®

Centered

Eccentric

145° PC Epi

155° PC Epi

Polyethylene Cup and Humeral Spacer

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

High Mobility Cups

1307-38-703	High Mobility PREMIERON® X-Linked PE Humeral Cup Diameter 38mm +3mm
1307-38-706	High Mobility PREMIERON® X-Linked PE Humeral Cup Diameter 38mm +6mm
1307-38-709	High Mobility PREMIERON® X-Linked PE Humeral Cup Diameter 38mm +9mm
1307-42-703	High Mobility PREMIERON® X-Linked PE Humeral Cup Diameter 42mm +3mm
1307-42-706	High Mobility PREMIERON® X-Linked PE Humeral Cup Diameter 42mm +6mm
1307-42-709	High Mobility PREMIERON® X-Linked PE Humeral Cup Diameter 42mm +9mm

Glenoid Implants - Glenospheres (worldwide codes)

Standard Eccentric

1307-60-038	Eccentric Glenosphere 38mm
1307-60-042	Eccentric Glenosphere 42mm
1307-60-138	Standard Glenosphere 38mm
1307-60-142	Standard Glenosphere 42mm
1307-61-038	Eccentric Glenosphere 38mm, +0 Lateralization
1307-61-042	Eccentric Glenosphere 42mm, +0 Lateralization
1307-61-138	Standard Glenosphere 38mm, +0 Lateralization
1307-61-142	Standard Glenosphere 42mm, +0 Lateralization
1307-62-038	Eccentric Glenosphere 38mm, +2mm Lateralization
1307-62-042	Eccentric Glenosphere 42mm, +2mm Lateralization
1307-62-138	Standard Glenosphere 38mm, +2mm Lateralization
1307-62-142	Standard Glenosphere 42mm, +2mm Lateralization
1307-64-038	Eccentric Glenosphere 38mm, +4mm Lateralization
1307-64-042	Eccentric Glenosphere 42mm, +4mm Lateralization
1307-64-138	Standard Glenosphere 38mm, +4mm Lateralization
1307-64-142	Standard Glenosphere 42mm , +4mm Lateralization
1307-66-038	Eccentric Glenosphere 38mm, +6mm Lateralization
1307-66-042	Eccentric Glenosphere 42mm, +6mm Lateralization
1307-66-138	Standard Glenosphere 38mm, +6mm Lateralization
1307-66-142	Standard Glenosphere 42mm, +6mm Lateralization
1307-68-038	Eccentric Glenosphere 38mm, +8mm Lateralization
1307-68-042	Eccentric Glenosphere 42mm, +8mm Lateralization
1307-68-138	Standard Glenosphere 38mm, +8mm Lateralization
1307-68-142	Standard Glenosphere 42mm, +8mm Lateralization

Glenoid Implants - Metaglene and Screws

1307-60-000	Standard Metaglene 13.5mm
1307-70-018	Non-Locking Metaglene Screw 4.5mm x 18mm
1307-70-024	Non-Locking Metaglene Screw 4.5mm x 24mm
1307-70-030	Non-Locking Metaglene Screw 4.5mm x 30mm
1307-70-036	Non-Locking Metaglene Screw 4.5mm x 36mm
1307-70-042	Non-Locking Metaglene Screw 4.5mm x 42mm
1307-90-024	Locking Metaglene Screw 4.5mm x 24mm
1307-90-030	Locking Metaglene Screw 4.5mm x 30mm
1307-90-036	Locking Metaglene Screw 4.5mm x 36mm
1307-90-042	Locking Metaglene Screw 4.5mm x 42mm
1307-90-048	Locking Metaglene Screw 4.5mm x 48mm

Revision Implant Codes

DELTA XTEND Long Peg Metaglene

1307-60-020	+10mm Long Peg Metaglene (US ONLY)
1307-60-025	+15mm Long Peg Metaglene (US ONLY)
1307-60-010	+10mm Long Peg Metaglene (OUS ONLY)
1307-60-015	+15mm Long Peg Metaglene (OUS ONLY)

Cemented Monobloc Long Stems

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

CTA Heads

1307-48-021	DELTA XTEND CTA Head 48mm x 21mm
1307-48-026	DELTA XTEND CTA Head 48mm x 26mm
1307-52-021	DELTA XTEND CTA Head 52mm x 21mm
1307-52-026	DELTA XTEND CTA Head 52mm x 26mm

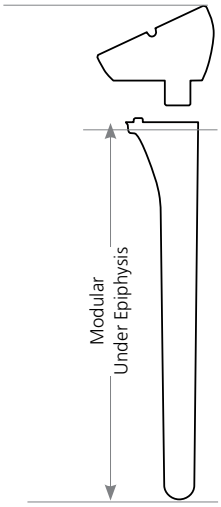
DELTA CTA Revision Components

1407-38-303	Hybrid PE Humeral Cup EPI36 D38 +3mm
1407-38-306	Hybrid PE Humeral Cup EPI36 D38 +6mm
1407-38-309	Hybrid PE Humeral Cup EPI36 D38 +9mm
1407-42-503	Hybrid PE Humeral Cup EPI36 D42 +3mm
1407-42-506	Hybrid PE Humeral Cup EPI36 D42 +6mm
1407-42-509	Hybrid PE Humeral Cup EPI36 D42 +9mm
1407-38-406	Retentive PE Humeral Cup EPI36 D38 +6 mm
RTH236	Humeral Spacer Diameter 36 +9mm
RTH242	Humeral Spacer Diameter 42 +9mm
4CHL336	Humeral Cup Diameter 36 +3mm
4CHL636	Humeral Cup Diameter 36 +6mm
4CHL936	Humeral Cup Diameter 36 +9mm
4CHL342	Humeral Cup Diameter 42 +3mm
4CHL642	Humeral Cup Diameter 42 +6mm
4CHL942	Humeral Cup Diameter 42 +9mm
4CHL636R	Humeral Cup Diameter 36 +6mm
4CHL642R	Humeral Cup Diameter 42 +6mm
TIH036	DELTA Humeral Head 36mm
TIH042	DELTA Humeral Head 42mm
TIH436	DELTA Humeral Head 36 +4mm
TIH442	DELTA Humeral Head 42 +4mm
GSC242	Glenosphere Diameter 42mm

Stem Sizes

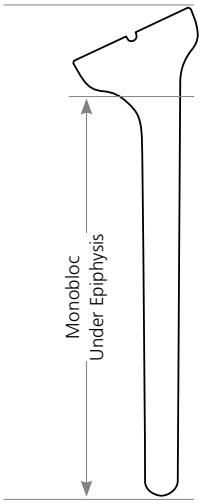
Length of Cementless Modular Humeral Implants

Size	Under Epiphysis	Total Length	Epiphysis Options
10mm	110mm	138mm	Epi 1 Cent Ecc-L Ecc-R Epi 2 Cent Ecc-L Ecc-R
12mm	117mm	145mm	Epi 1 Cent Ecc-L Ecc-R Epi 2 Cent Ecc-L Ecc-R
14mm	126mm	153mm	Epi 1 Cent Ecc-L Ecc-R Epi 2 Cent Ecc-L Ecc-R
16mm	135mm	162mm	Epi 1 Cent Ecc-L Ecc-R Epi 2 Cent Ecc-L Ecc-R



Length of Cemented Monobloc Humeral Implants

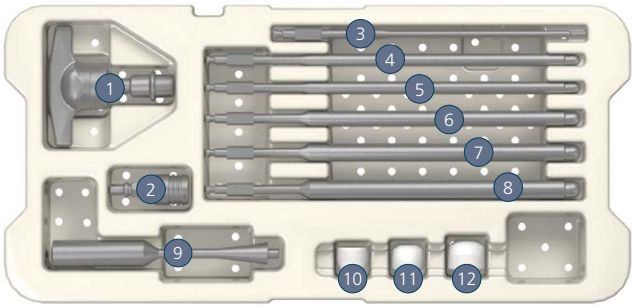
Designation	Cat Number	Under Epiphysis	Total Length
Monobloc Humeral Cemented Epiphysis 1 8 Std	1307-08-100	105mm	132mm
Monobloc Humeral Cemented Epiphysis 1 10 Std	1307-10-100	110mm	137mm
Monobloc Humeral Cemented Epiphysis 1 12 Std	1307-12-100	117mm	144mm
Monobloc Humeral Cemented Epiphysis 1 14 Std	1307-14-100	126mm	153mm
Monobloc Humeral Cemented Epiphysis 2 10 Std	1307-10-200	110mm	137mm
Monobloc Humeral Cemented Epiphysis 2 12 Std	1307-12-200	117mm	145mm
Monobloc Humeral Cemented Epiphysis 2 14 Std	1307-14-200	126mm	154mm
Monobloc Humeral Cemented Epiphysis 1 8 Long	1307-08-110	170mm	197mm
Monobloc Humeral Cemented Epiphysis 1 10 Long	1307-10-110	180mm	207mm
Monobloc Humeral Cemented Epiphysis 1 12 Long	1307-12-110	182mm	209mm
Monobloc Humeral Cemented Epiphysis 1 14 Long	1307-14-110	196mm	223mm
Monobloc Humeral Cemented Epiphysis 2 10 Long	1307-10-210	180mm	207mm
Monobloc Humeral Cemented Epiphysis 2 12 Long	1307-12-210	182mm	210mm
Monobloc Humeral Cemented Epiphysis 2 14 Long	1307-14-210	196mm	224mm



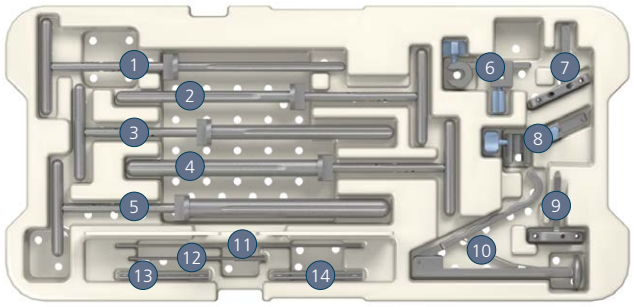
Humeral Instruments

2307-99-005 DELTA XTEND Humeral 1 Case Complete

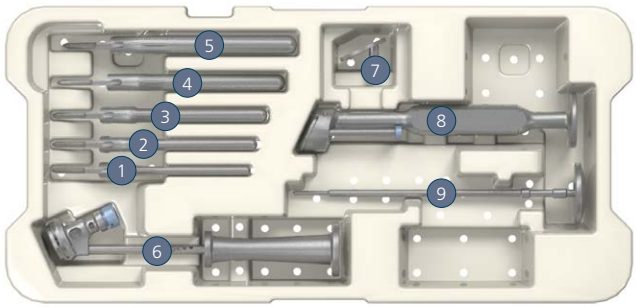
1	2128-61-070	Standard Hudson T-handle
2	1524-00-000	Hudson AO Converter
3	2128-01-006	Medulary Canal Reamer 6mm
4	2128-01-008	Medulary Canal Reamer 8mm
5	2128-01-010	Medulary Canal Reamer 10mm
6	2128-01-012	Medulary Canal Reamer 12mm
7	2128-01-014	Medulary Canal Reamer 14mm
8	2128-01-016	Medulary Canal Reamer 16mm
9	2001-65-000	Humeral Head Impactor
10	2001-66-000	Head Impactor Tip
11	2307-67-000	Humeral Cup Impactor Tip
12	2307-68-000	Spacer Impactor Tip



1	2307-70-008	Handle for Cutting Guide 8mm
2	2307-70-010	Handle for Cutting Guide 10mm
3	2307-70-012	Handle for Cutting Guide 12mm
4	2307-70-014	Handle for Cutting Guide 14mm
5	2307-70-016	Handle for Cutting Guide 16mm
6	2307-72-003	Delto-pectoral Cutting Guide
7	2307-72-004	Delto-pectoral Cutting Plate
8	2307-73-003	Superior-lateral Cutting Guide
9	2307-73-004	Superior-lateral Cutting Plate
10	2307-99-004	Pin Extractor
11	2307-71-000	Orientation Pin 2.5mm x 200mm
12	2555-89-000	Drill Bit 3.2mm x 127mm
13	2490-95-000	Cutting Guide Fixation Pin 3.2mm x 2
14	2490-95-000	Cutting Guide Fixation Pin 3.2mm x 2

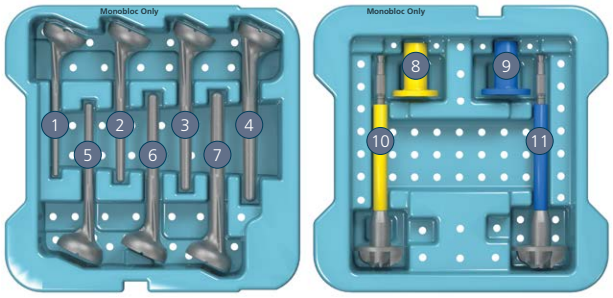


1	2307-74-008	Proximal Reaming Guide 8mm
2	2307-74-010	Proximal Reaming Guide 10mm
3	2307-74-012	Proximal Reaming Guide 12mm
4	2307-74-014	Proximal Reaming Guide 14mm
5	2307-74-016	Proximal Reaming Guide 16mm
6	2307-83-000	Humeral Implant Driver
7	2307-85-000	Humeral Resection Protection Plate
8	2307-74-001	Proximal Reaming Guide Holder
9	2307-74-002	Proximal Reaming Guide Holder Internal Rod

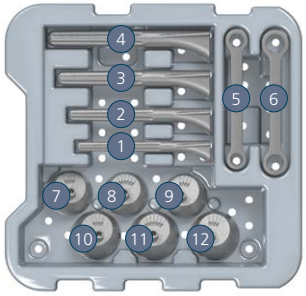


2307-99-006 DELTA XTEND Humeral 2 Case Complete

1	2307-08-100	Monobloc Humeral Trial Epiphysis Size 1 8mm Standard
2	2307-10-100	Monobloc Humeral Trial Epiphysis Size 1 10mm Standard
3	2307-12-100	Monobloc Humeral Trial Epiphysis Size 1 12mm Standard
4	2307-14-100	Monobloc Humeral Trial Epiphysis Size 1 14mm Standard
5	2307-10-200	Monobloc Humeral Trial Epiphysis Size 2 10mm Standard
6	2307-12-200	Monobloc Humeral Trial Epiphysis Size 2 12mm Standard
7	2307-14-200	Monobloc Humeral Trial Epiphysis Size 2 14mm Standard
8	2307-80-003	Monobloc Epiphyseal Disk Size 1
9	2307-80-004	Monobloc Epiphyseal Disk Size 2
10	2307-81-003	Monobloc Proximal Reamer Epiphysis Size 1
11	2307-81-004	Monobloc Proximal Reamer Epiphysis Size 2
1	2307-10-001	Modular Humeral Stem Trial 10mm
2	2307-12-001	Modular Humeral Stem Trial 12mm

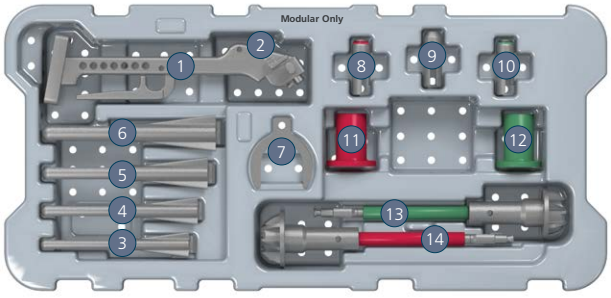


3	2307-14-001	Modular Humeral Stem Trial 14mm
4	2307-16-001	Modular Humeral Stem Trial 16mm
5	2307-84-001	Modular Implant Locking Wrench 10-12mm
6	2307-84-002	Modular Implant Locking Wrench 14-16mm
7	2307-20-102	Modular Eccentric Trial Epiphysis Size 1 Left
8	2307-20-101	Modular Centred Trial Epiphysis Size 1
9	2307-20-103	Modular Eccentric Trial Epiphysis Size 1 Right
10	2307-20-202	Modular Eccentric Trial Epiphysis Size 2 Left
11	2307-20-201	Modular Centred Trial Epiphysis Size 2
12	2307-20-203	Modular Eccentric Trial Epiphysis Size 2 Right



13	2307-38-403	Standard Humeral Cup Trial 38mm +3mm
14	2307-38-406	Standard Humeral Cup Trial 38mm +6mm
15	2307-38-409	Standard Humeral Cup Trial 38mm +9mm
16	2307-42-403	Standard Humeral Cup Trial 42mm +3mm
17	2307-42-406	Standard Humeral Cup Trial 42mm +6mm
18	2307-42-409	Standard Humeral Cup Trial 42mm +9mm
19	2307-30-009	Humeral Spacer Trial +9mm
20	2307-38-506	Retentive Humeral Cup Trial 38mm +6mm
21	2307-42-506	Retentive Humeral Cup Trial 42mm +6mm
22	2307-38-303	High Mobility Humeral Cup Trial 38mm +3mm
23	2307-38-306	High Mobility Humeral Cup Trial 38mm +6mm
24	2307-38-309	High Mobility Humeral Cup Trial 38mm +9mm
25	2307-42-303	High Mobility Humeral Cup Trial 42mm +3mm
26	2307-42-306	High Mobility Humeral Cup Trial 42mm +6mm
27	2307-42-309	High Mobility Humeral Cup Trial 42mm +9mm

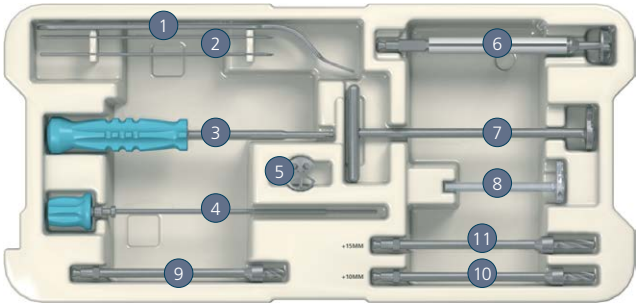
1	2307-01-030	Broach Handle
2	2307-01-031	Goniometer
3	2307-79-010	Humeral Broach 10mm
4	2307-79-012	Humeral Broach 12mm
5	2307-79-014	Humeral Broach 14mm
6	2307-79-016	Humeral Broach 16mm
7	2307-01-032	Broach Handle Plate
8	2307-76-002	Eccentric Proximal Reaming Adaptor Size 2
9	2307-76-000	Centred Proximal Reaming Adaptor
10	2307-76-001	Eccentric Proximal Reaming Adaptor Size 1
11	2307-77-004	Epiphyseal Disk for Modular Implant Size 2
12	2307-77-003	Epiphyseal Disk for Modular Implant Size 1
13	2307-78-003	Proximal Reamer for Modular Implant Size 1
14	2307-78-004	Proximal Reamer for Modular Implant Size 2



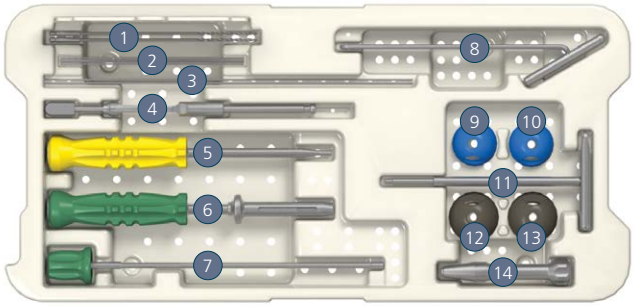
Glenoid Instruments

2307-99-007 DELTA XTEND Glenoid Case Complete

1	2307-86-002	Forked Retractor
2	2307-87-004	Metaglene Central Guide Pin 2.5mm x 2
	2230-00-019	2.5mm Breakaway Guide Pin*
3	2307-87-005	Metaglene Holder
4	2307-87-002	Metaglene Holder Internal Rod
5	2307-87-003	Metaglene Positioning Plate
6	2307-88-027	Glenoid Resurfacing Reamer 27mm
7	2307-88-242	Glenoid Manual Reamer 42mm
8	2307-88-300	Glenoid Reaming Level Checker
9	2307-89-000	Glenoid Cannulated Stop Drill Standard
10	2407-89-010	Glenoid Cannulated Stop Drill +10mm
11	2407-89-015	Glenoid Cannulated Stop Drill +15mm



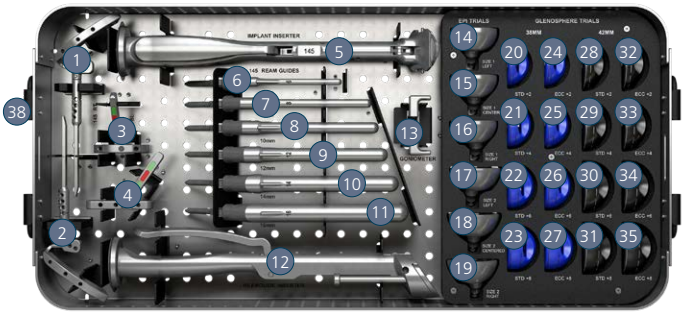
1	2307-90-005	Drill Bit 2.5mm x 170mm x 2
2	2307-90-004	Screw Guide Pin 1.2mm x 150mm x 5
3	2307-96-000	Glenosphere Guide Pin 1.5mm x 300mm
4	2307-91-001	Screw Depth Gauge
5	2307-93-000	3.5mm Cannulated Hex Screwdriver
6	2307-92-003	Locking Screwdriver
7	2307-92-004	Locking Screwdriver Internal Rod
8	2307-90-003	Glenoid Drill Guide 2.5mm
9	2307-60-038	Eccentric Glenosphere Trial 38mm
10	2307-60-138	Standard Glenosphere Trial 38mm
11	2307-99-002	Extraction T-handle
12	2307-60-042	Eccentric Glenosphere Trial 42mm
13	2307-60-142	Standard Glenosphere Trial 42mm
14	2307-95-000	Glenosphere Orientation Guide

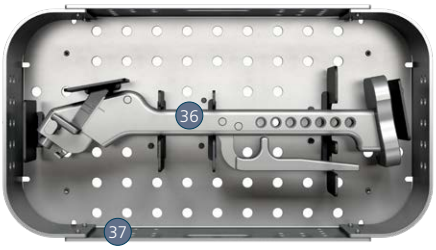


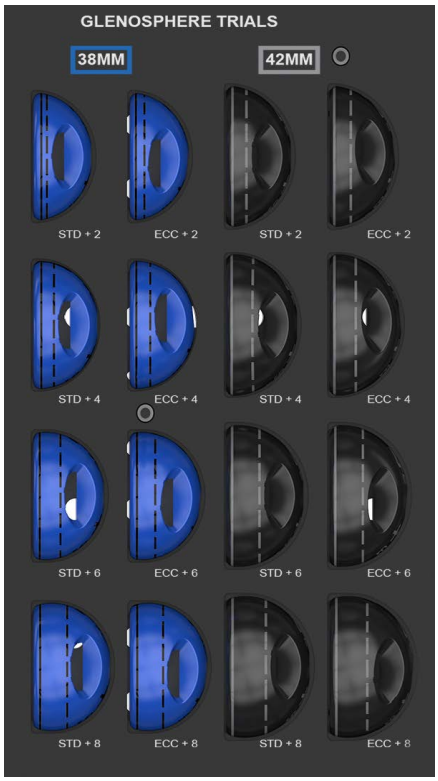
*Special order only

Lateralized and 145° Epiphysis Instruments

1	212862101	145 RSA Cutting Guide Left
2	212862111	145 RSA Cutting Guide Right
3	230773104	145 RSA Superior-lateral Cutting Guide
4	230772104	145 RSA Delto-pectoral Cutting Guide
5	230784000	145 RSA Implant Inserter
6	230774106	145 RSA Proximal Reaming Guide 6mm
7	230774108	145 RSA Proximal Reaming Guide 8mm
8	230774110	145 RSA Proximal Reaming Guide 10mm
9	230774112	145 RSA Proximal Reaming Guide 12mm
10	230774114	145 RSA Proximal Reaming Guide 14mm
11	230774116	145 RSA Proximal Reaming Guide 16mm
12	230774101	145 RSA Ream Guide Inserter
13	230701131	145 RSA Goniometer
14	230720112	145 RSA Modular Eccentric Trial Size 1 Left
15	230720111	145 RSA Modular Centered Trial Size 1
16	230720113	145 RSA Modular Eccentric Trial Size 1 Right
17	230720222	145 RSA Modular Eccentric Trial Size 2 Left
18	230720221	145 RSA Modular Centered Trial Size 2
19	230720223	145 RSA Modular Eccentric Trial Size 2 Right
20	230762138	Standard Glenosphere Trial 38mm +2
21	230764138	Standard Glenosphere Trial 38mm +4
22	230766138	Standard Glenosphere Trial 38mm +6
23	230768138	Standard Glenosphere Trial 38mm +8
24	230762038	Eccentric Glenosphere Trial 38mm +2
25	230764038	Eccentric Glenosphere Trial 38mm +4
26	230766038	Eccentric Glenosphere Trial 38mm +6
27	230768038	Eccentric Glenosphere Trial 38mm +8
28	230762142	Standard Glenosphere Trial 42mm +2
29	230764142	Standard Glenosphere Trial 42mm +4
30	230766142	Standard Glenosphere Trial 42mm +6
31	230768142	Standard Glenosphere Trial 42mm +8
32	230762042	Eccentric Glenosphere Trial 42mm +2
33	230764042	Eccentric Glenosphere Trial 42mm +4
34	230766042	Eccentric Glenosphere Trial 42mm +6
35	230768042	Eccentric Glenosphere Trial 42mm +8
36	230774111	XTEND 145 BROACH HANDLE
37	2100-09-250	145 155 DX BROACH HANDLE BASE
	2100-09-255	145 155 DX BROACH HANDLE LID
38	2100-09-050	145 Alt Angle Lat Tray #1 Base
	2100-09-055	145 Alt Angle Lat Tray #1 Lid



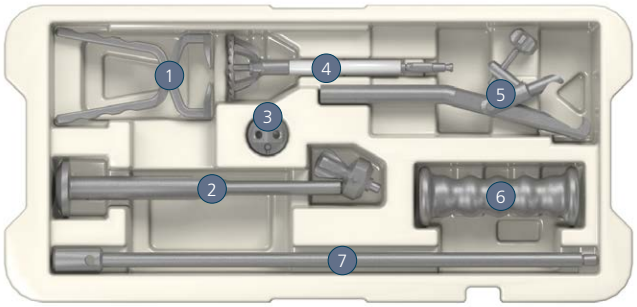




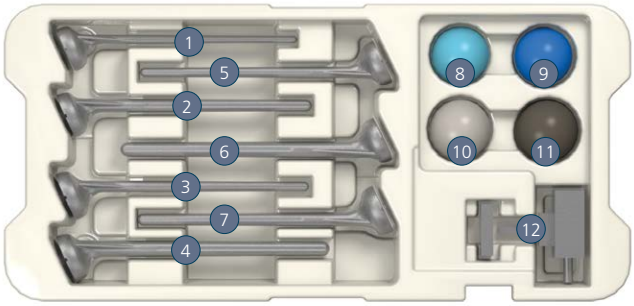
Revision Instruments

2307-99-008 DELTA XTEND Revision Case Complete

1	2307-99-001	Humeral Cup Extraction Clamp
2	ITH003	Stem Impactor/Extractor
3	2307-82-001	DELTA XTEND CTA Head Reamer Guide
4	2307-82-003	DELTA XTEND CTA Head Reamer
5	ETH001	Standard Humeral Prosthesis Extractor
6	MAI001	Slap Hammer
7	MDE001	Extraction Rod



1	2307-08-110	Monobloc Humeral Trial Epiphysis Size 1 8mm Long
2	2307-10-110	Monobloc Humeral Trial Epiphysis Size 1 10mm Long
3	2307-12-110	Monobloc Humeral Trial Epiphysis Size 1 12mm Long
4	2307-14-110	Monobloc Humeral Trial Epiphysis Size 1 14mm Long
5	2307-10-210	Monobloc Humeral Trial Epiphysis Size 2 10mm Long
6	2307-12-210	Monobloc Humeral Trial Epiphysis Size 2 12mm Long
7	2307-14-210	Monobloc Humeral Trial Epiphysis Size 2 14mm Long
8	2307-48-121	DELTA XTEND CTA Trial Head 48mm x 21mm
9	2307-48-126	DELTA XTEND CTA Trial Head 48mm x 26mm
10	2307-52-121	DELTA XTEND CTA Trial Head 52mm x 21mm
11	2307-52-126	DELTA XTEND CTA Trial Head 52mm x 26mm
12	2128-01-035	GLOBAL® FX Positioning Jig



1	2407-38-203	Hybrid Trial Humeral Cup EPI36 D38 +3 mm
	2407-38-206	Hybrid Trial Humeral Cup EPI36 D38 +6 mm
	2407-38-209	Hybrid Trial Humeral Cup EPI36 D38 +9 mm
	2407-42-203	Hybrid Trial Humeral Cup EPI36 D42 +3 mm
	2407-42-206	Hybrid Trial Humeral Cup EPI36 D42 +6 mm
	2407-42-209	Hybrid Trial Humeral Cup EPI36 D42 +9 mm
	2407-38-106	Hybrid Retentive Trial Humeral Cup EPI36 D38 +6 mm
2	REH236	Humeral Spacer Trial, Dia. 36
	REH242	Humeral Spacer Trial, Dia. 42
3	A5469	Lateralized Humeral Cup Trial, +3 mm Dia. 36
	A5264	Lateralized Humeral Cup Trial, +6 mm Dia. 36
	A5468	Lateralized Humeral Cup Trial, +9 mm Dia. 36
4	A5467	Lateralized Humeral Cup Trial, +3 mm Dia. 42
	A5261	Lateralized Humeral Cup Trial, +6 mm Dia. 42
	A5466	Lateralized Humeral Cup Trial, +9 mm Dia. 42
5	A5263	Lateralized Humeral Retentive Cup Trial, +6 mm Dia. 36
	A5260	Lateralized Humeral Retentive Cup Trial, +6 mm Dia. 42
6	TEH036	Standard Humeral Head Trial, Dia. 36
	TEH042	Standard Humeral Head Trial, Dia. 42
	TEH436	Standard Humeral Head Trial, Dia. 36 +4 mm
	TEH442	Standard Humeral Head Trial, Dia. 42 +4 mm

Essential Product Information

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

INTENDED USE:
The DePuy Synthes DELTA XTEND Shoulder Prosthesis is intended for use in total shoulder or hemi-shoulder replacement procedures in patients with non-functional rotator cuffs, with or without bone cement. HA components are for cementless use only.

INDICATIONS FOR USE:
The DELTA Xtend Shoulder Prosthesis is indicated for use in treatment of a grossly deficient rotator cuff joint with:

- severe arthropathy and/or;
- a previously failed joint replacement and/or;
- 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

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.

DELTA XTEND hemi-shoulder replacement is also indicated for hemi-arthroplasty if the glenoid is fractured intraoperatively or for the revision of a previously failed DELTA XTEND Reverse Shoulder.

Porous-coated epiphysis are indicated for use in total shoulder replacement only.The metaglene component is HA coated and is intended for cementless use with the addition of screws for fixation.

The metaglene component is HA coated and is intended for cementless use with the addition of screws for fixation.

The modular humeral stem is HA coated and is intended for cementless use. The HA coated humeral epiphysis is intended for cementless use. The porous-coated epiphysis is intended for cemented or cementless use.

All other metallic components are intended for cemented use only.

CONTRAINDICATIONS:
Joint replacements may be contraindicated where the patient is overweight, where there is infection, poor bone stock, severe deformity, drug abuse, overactivity, tumor, mental incapacity, muscle, nerve or vascular disease.

Note: Diabetes, at present, has not been established as a contraindication. However, because of increased risk for complications such as infection, slow wound healing, etc., the physician should carefully consider the advisability of shoulder replacement in the severely diabetic patient.

WARNINGS AND PRECAUTIONS:

CAUTION

- Implants and trial components from different manufacturers or implant systems should never be used together, with the exception of GLOBAL UNITE™ Humeral Stems and DELTA CTA™ as described below.
  - The GLOBAL UNITE™ Humeral Stems, in conjunction with existing DELTA XTEND™ epiphyseal components, can be used in reverse shoulder arthroplasty in the treatment of a grossly deficient rotator cuff joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff joint.
  - When well-fixed DELTA CTA™ stem, the DELTA XTEND™ glenosphere and metaglene can be used with DELTA CTA™ Hybrid Humeral Cups, Humeral PE Cups dia 42mm and/or spacers described in the DELTA XTEND™ Surgical Technique.
- Shoulder prosthesis components should never be reimplanted. Even though the implant appears undamaged, the implant may have developed microscopic imperfections, which could lead to failure. DePuy's Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.
- Always use a trial prosthesis for trial purposes. Trials should not be assembled with any components intended for permanent implantation. Trials must have the same configuration size, etc., as the corresponding components to be implanted.

- Do not alter or modify implants in any way.
- 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.

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

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

The following conditions singularly or concurrently, 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.

WHEN THE SURGEON DETERMINES THAT TOTAL SHOULDER OR HEMI-SHOULDER REPLACEMENT IS THE BEST MEDICAL OPTION AVAILABLE AND DECIDES TO USE THIS PROSTHESIS IN A PATIENT WHO HAS ANY OF THE ABOVE CONDITIONS OR WHO IS SIMPLY YOUNG AND ACTIVE, IT IS IMPERA-TIVE THAT THE PATIENT BE INSTRUCTED ABOUT THE STRENGTH LIMITATIONS OF THE MATERIALS USED IN THE DEVICE AND FOR FIXATION AND THE RESULTANT NEED TO SUBSTANTIALLY REDUCE OR ELIMINATE ANY OF THE ABOVE CONDITIONS.

The surgical and postoperative management of the patient must be carried out with due consideration for all existing conditions. Mental attitudes or disorders resulting in a patient's failure to adhere to the surgeon's orders may delay postoperative recovery and/or increase the risk of adverse effects including implant or implant fixation failure. The functional life expectancy of prosthetic shoulders is, at present, not clearly established.

MRI SAFETY INFORMATION:

- Non-clinical testing has demonstrated the DELTA XTEND™ Shoulder Prosthesis is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:
  - Static magnetic field of 1.5 T or 3.0 T
  - Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
  - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
- Under the scan conditions defined above, the DELTA XTEND Shoulder Prosthesis is expected to produce a maximum temperature rise of 4.1°C (1.5 T and 3.0 T) after 15 minutes of continuous scanning.
- In non-clinical testing, the image artifact caused by the device extends approximately 92.2mm from the DELTA XTEND™ Shoulder Prosthesis when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

References

1. Van Seymortier, P., et. al., "The Reverse Shoulder Prosthesis (Delta III) in Acute Shoulder Fractures: Technical Considerations with Respect to Stability", *Acta Orthopaedica Belgica* 2006.
2. ORTHOCORD® Suture is a registered trademark of DePuy Synthes Mitek Sports Medicine.

Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

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

Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.

For recognized manufacturer and model designation, refer to product label.

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