DePuy Synthes
JOINT RECONSTRUCTION
COMPANIES OF Johnson & Johnson

GLOBAL® UNITE® ANATOMIC

Platform Shoulder System

SURGICAL TECHNIQUE

GLOBAL® | UNITE®
PLATFORM SHOULDER SYSTEM

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PLATFORM SHOULDER SYSTEM

Introducing the GLOBAL® UNITE® Platform Shoulder Arthroplasty System, a modular shoulder system that provides surgeons principled adaptability within the operating room to restore valuable biomechanical function.

Every shoulder procedure provides unique challenges to the surgeon. That is why *DePuy Synthes Joint Reconstruction** created the GLOBAL UNITE System, a next generation platform system. The modular proximal bodies allow the surgeon to restore proper joint height and anatomic alignment utilizing a streamlined surgical procedure.

In the event that the GLOBAL UNITE System requires conversion to a reverse shoulder, it does so by implementing the reverse shoulder principles described by Professor Paul Grammont. Removal of the proximal body allows the epiphysis to attach to a well-fixed distal stem within the humerus at the proper height and version to optimize deltoid function, thus allowing the deltoid to compensate for the deficient rotator cuff muscles.

The GLOBAL UNITE System truly provides the surgeon *Principled Adaptability* within the operating room.

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CONTENTS

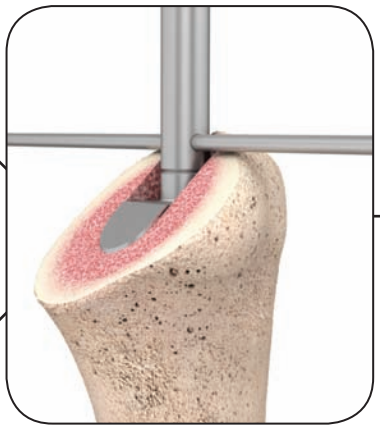
KEY SURGICAL STEPS

PRIMARY OR ANATOMIC

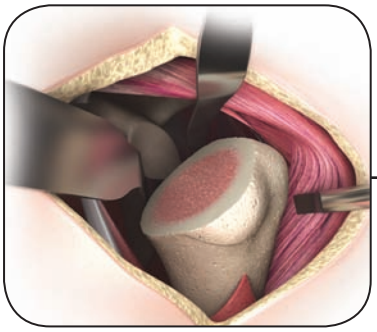
INTERMEDULLARY RESECTION

Ream the Humeral Canal

Resect the Humeral Head



Prepare the Proximal Humeral Bone



Resect the Humeral Head

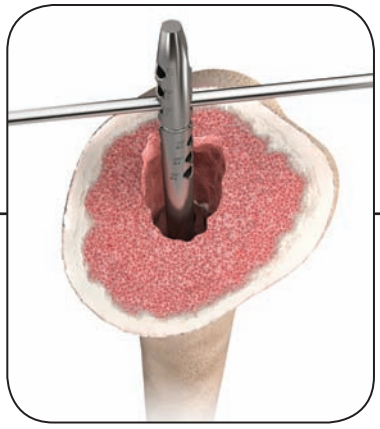
Ream the Humeral Canal and Verify Osteotomy Angulation

FREEHAND RESECTION

CONVERSION TO REVERSE

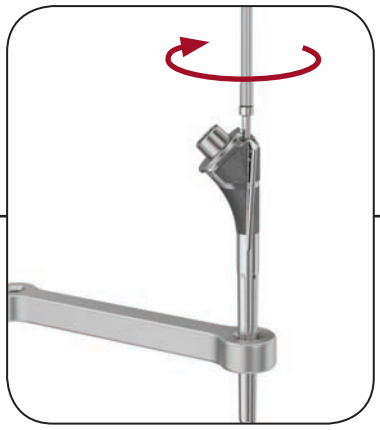
Remove the Humeral Head

Remove the Proximal Component



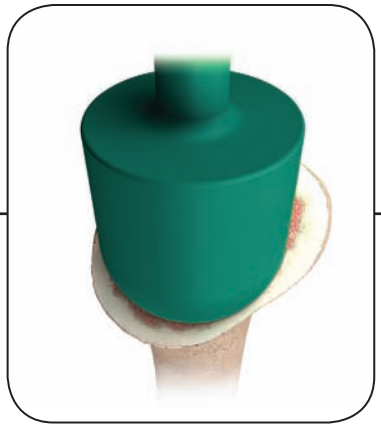
Establish Epiphysis Version

Insert Humeral Trial Stem

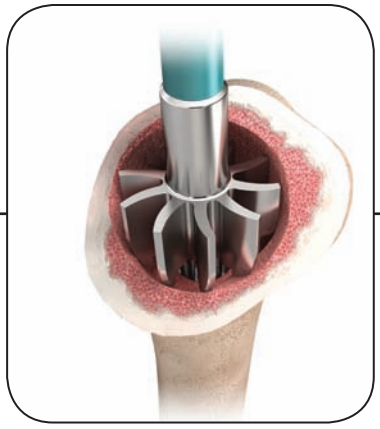


Assemble Final Implant

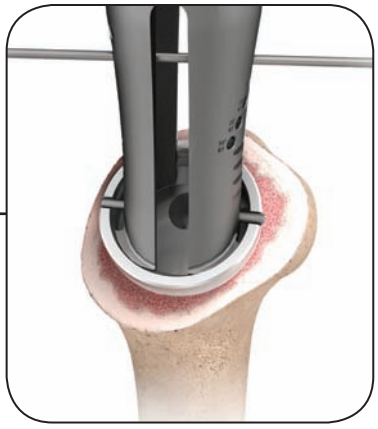
Impact Head and Insert Final Construct



Size the Proximal Humerus



Prepare the Proximal Humerus



Implant Epiphysis

PRE-OPERATIVE TEMPLATING

Pre-operative Planning
Pre-operative planning should be carried out using AP and lateral shoulder radiographs of known magnification and the available **GLOBAL UNITE System** implant template to help the surgeon determine the size and alignment of the implant. The final decision should be made intraoperatively.

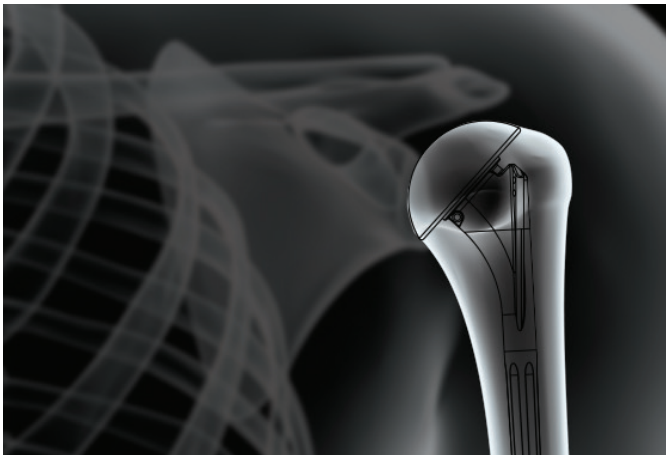


Figure 1

RESECTION METHODS

Option 1: Intermedullary Technique
Starting with the 6mm **Bullet Tip Reamer**, sequentially ream the humeral canal until the reamer begins to bite on cortical bone distally.

Assemble the appropriate right or left **Anatomic Resection Guide** to the **Quick Clamp** and attach it to the reamer shaft. The posterior cuff guide will aid in identifying and protecting the posterior rotator cuff attachment sites.

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.

Remove the reamer and quick clamp assembly and resect the humeral head utilizing an oscillating power saw (Figure 2).

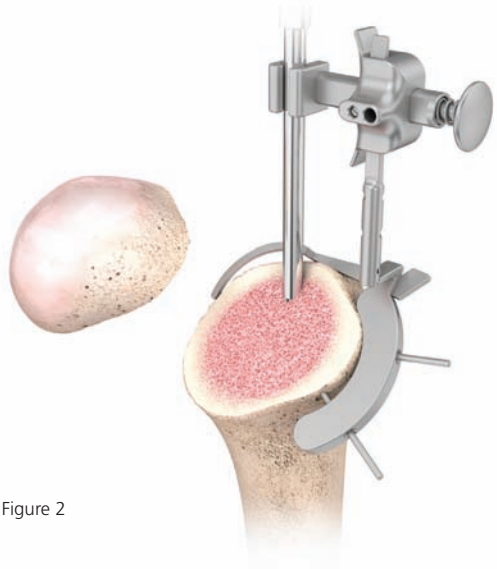


Figure 2

Option 2: Freehand Technique
Place the **Plastic Resection Guides** on the anterior aspect of the arm parallel with the humerus.

Utilize the appropriate angle of the resection guide (128, 135 or 142) that best matches the patient's anatomy and mark the desired angle on the humerus using electrocautery.

Resect the humeral head along the marked neck angle (Figure 3). Once the head has been removed, sequentially ream the humeral canal.

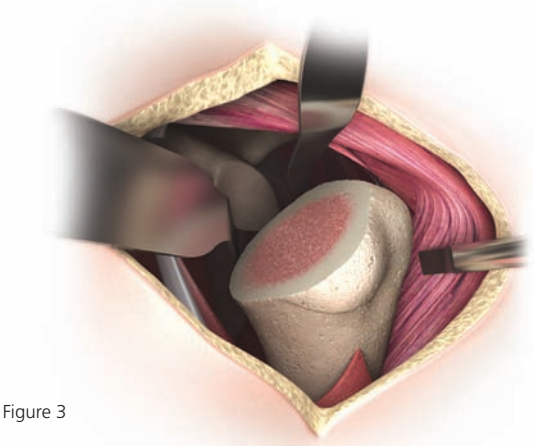


Figure 3

To verify the resection angle, do not remove the final reamer. Place the **Plastic Resection Guides** upside down on the resection and compare the alignment of the reamer shaft to the resection guide handles. Parallel alignment indicates the proper angle (Figure 4). The final determination of proper angle will be verified during the implant trialing process.

NOTE: If the reamers are not advanced to the appropriate position, the brosteotome, humeral trial or definitive implant may not fully seat in the humerus and could increase the risk of humeral fracture.

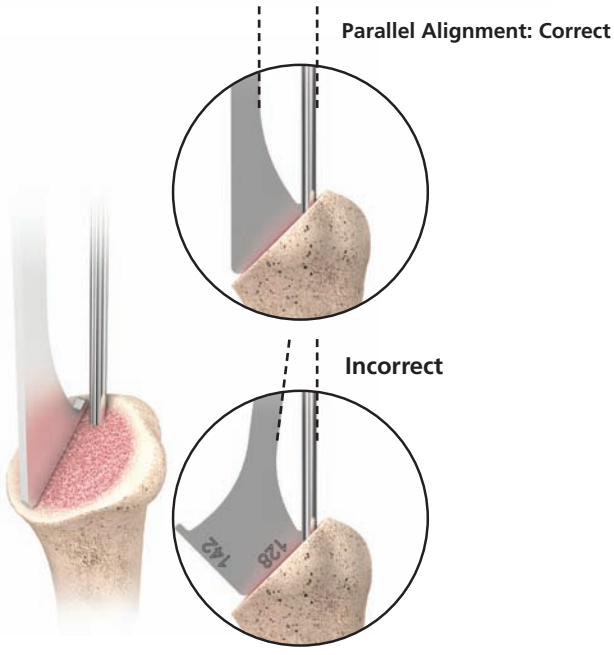


Figure 4

HUMERAL HEAD SIZING AND PROXIMAL HUMERAL BONE PREPARATION

Humeral Head Sizing

The humeral head can be provisionally sized using the GLOBAL UNITE System **Anatomic Head Gauge**. The gauge can be utilized to measure both the diameter and height of the resected humeral head (Figure 5).

Figure 5

Glenoid Preparation

Place a **Cover Plate** over the resected surface and prepare the glenoid.

Note: Please refer to the GLOBAL® APG+ System surgical technique (0612-13-509) for the detailed information regarding glenoid preparation.

Proximal Humeral Bone Preparation

Select the **Proximal Body Brosteotome** that matches the diameter of the final reamer used to prepare the humeral canal. If an odd number reamer was used as the final reamer, select the brosteotome that is one size smaller.

Place the Proximal Body Brosteotome into the humeral canal. Correct version is achieved by aligning an orientation guide pin positioned in the hole below the cutting fins of the brosteotome with the plane of the resection (Figure 6a). Alternative, the humeral preparation version can be determined by aligning an orientation guide pin placed in the superior version holes with the axis of the forearm.

Once the desired version is achieved, remove the pin and reinsert it into the depth stop hole located above the proximal body of the brosteotome (Figure 6b). Advance the brosteotome into the humerus using a mallet. Continue advancing the brosteotome until the depth stop pin touches the resection.

Note: If the brosteotome is difficult to advance, remove it and clean any bone from the teeth using the Posterior Cuff Guide. Additional bone removal with manual instruments (rongeur, burr, ect.) may be required if hard bone is encountered.

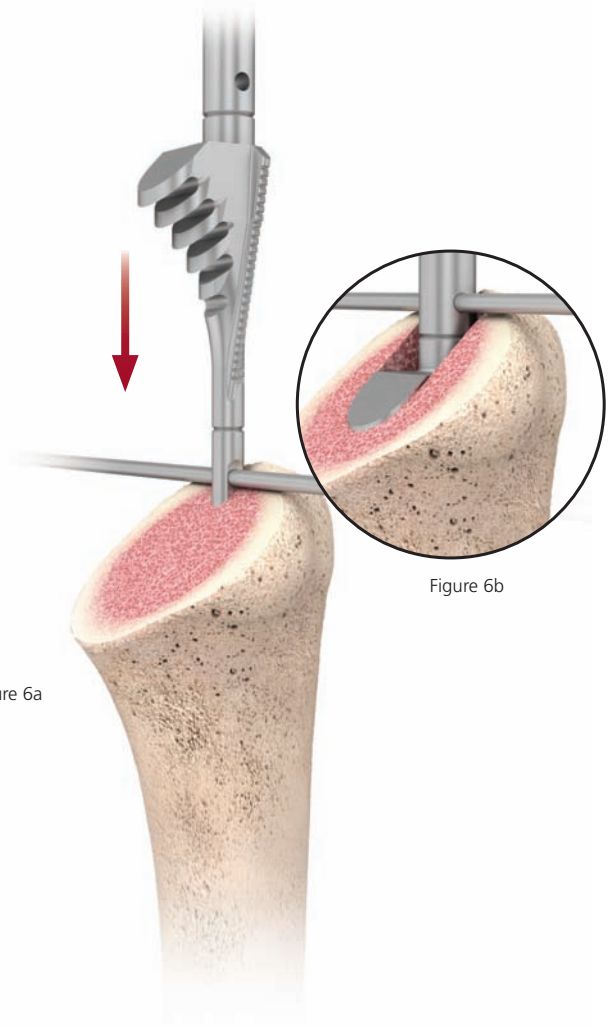


Figure 6b

Figure 6a

TRIAL IMPLANTATION

Trial Insertion
Assemble the matching size and angle **Proximal Trial Body** to the **Distal Trial Stem** using the **Female Hex Screw Driver** and **Distal Stem Wrench**. Attach the assembled trial to the **Implant Holder** (Figure 7).

Align the trial with previous preparation steps and advance into the proximal humerus. Version can be verified using the orientation guide pin and the alignment holes on the handle of the implant holder. The trial is seated when the collar is flush with the resected humerus (Figure 8).

Note: It is acceptable to modify the neck resection for a more precise fit by free hand cutting the resection with a saw or adding bone augments.

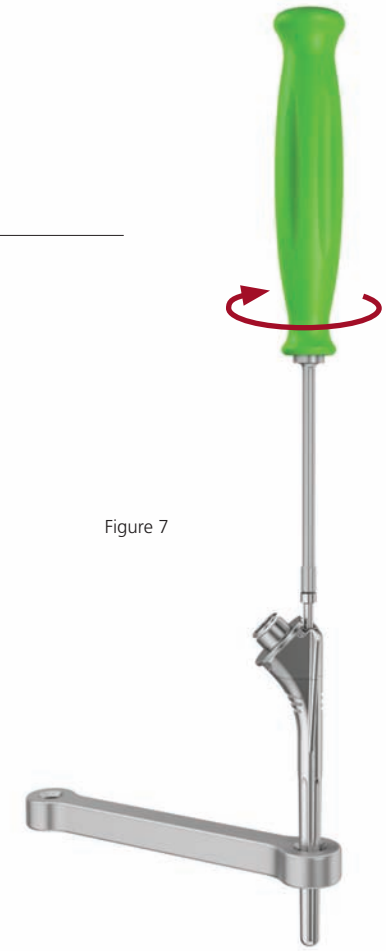


Figure 7

Figure 8

TRIAL IMPLANTATION

Humeral Head Sizing and Trialing

Select the **Humeral Head Trial** previously measured. Place the trial head onto the taper of the proximal body. The selected trial head should provide coverage of the resected humerus and should transition smoothly with the superior cuff insertion site (Figure 9).

If an eccentric trial head is used, register the position of the eccentricity by placing a skin marker through the eccentricity hole and marking on the collar of the proximal body trial (Figure 10).

Once the trialing process is complete, remove the trial construct from the humerus using the implant holder.

Figure 9

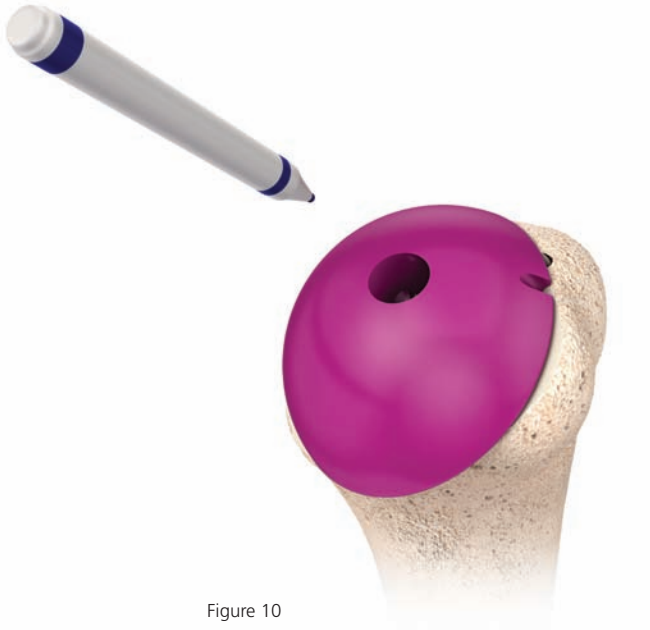


Figure 10

FINAL IMPLANT ASSEMBLY AND IMPLANTATION

Final Implant Assembly and Insertion
When the final implant stem and humeral head size have been determined, assemble the definitive implant stem and proximal body together using the female hex driver and the stem wrench. Securely tighten the bolt. Place the assembled implant into the Impaction Stand using the correct **Impaction Slide** that matches the size of the implant. If an eccentric head was selected during the trialing process, the trial stem must be placed into the impaction stand and the eccentricity recorded on the clock face prior to placing the final implant into the impaction stand (Figure 11).

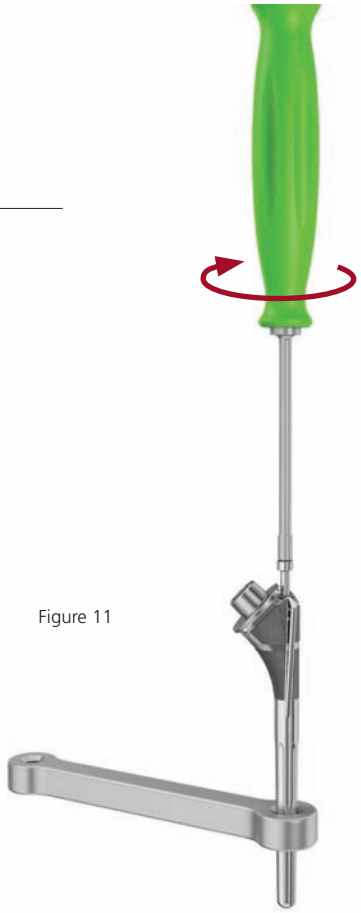


Figure 11

Place the appropriate sized humeral head onto the taper of the proximal body. If an eccentric head is selected, verify eccentricity alignment using the mark registered on the clock face of the impaction stand. Impact the humeral head onto the stem using the **Head Impactor** (Figure 12).

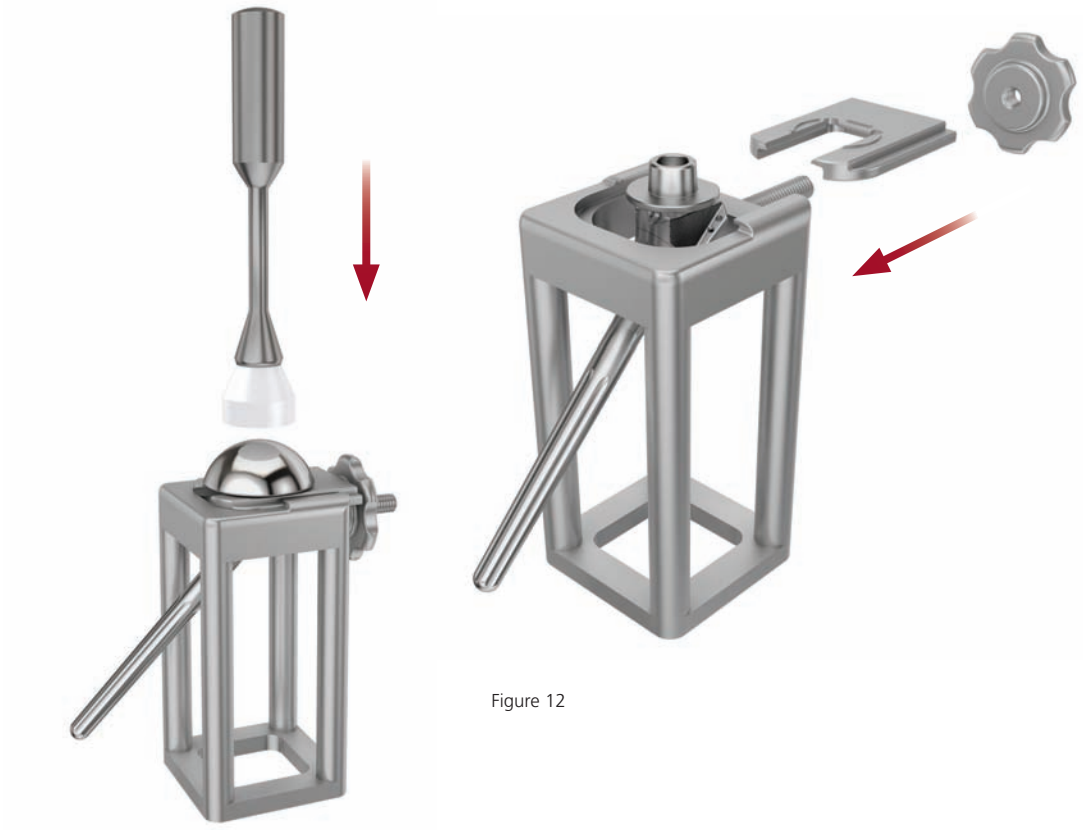


Figure 12

FINAL IMPLANT ASSEMBLY AND IMPLANTATION

Final Implant Insertion

The final prosthesis is porous coated and **1.5mm larger** than the trial stem assembly so that in the majority of cases, a firm press-fit can be obtained without the use of bone cement.

Align the prosthesis with the prepared bone and impact the construct with the **Head Impactor** until the collar sits flush with the resection (Figure 13).

The humeral head can also be impacted after the humeral stem has been implanted allowing the surgeon to retrial the humerus. To perform this method attach the final stem construct to the Implant Holder and insert the stem into the humerus in the intended version. Version can be verified by placing the orientation guide pin in the proper version hole of the Implant Holder and aligning with the axis of the forearm. Implant the definitive humeral stem using the Implant Holder. Advance the implant until the collar is flush with the resected surface. After trialing is complete, position and seat the selected humeral head implant in the desired orientation on the humeral implant using the Head Impactor.

Figure 13

Removing the Humeral Head
Place the **Humeral Head Distractor** in the anterior slot between the head of the prosthesis and the collar. Tap on the end of the distractor to disengage the taper (Figure 14).

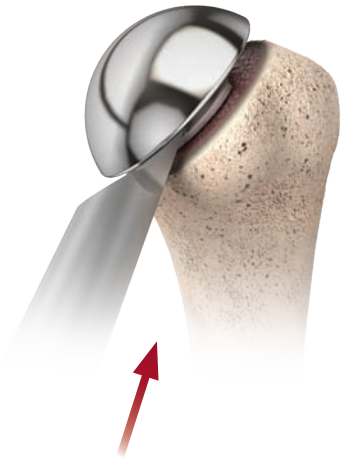


Figure 14

Removing the Proximal Component
Use an appropriately sized thin osteotome from DePuy Synthes' Shoulder Extraction Instrument Set to remove the bone on-growth surrounding the proximal body.

Use the **Female Hex Screwdriver** to unscrew the proximal bolt (Figure 15).

Attach the implant inserter to the proximal body and remove it from the humerus leaving the well-fixed distal stem.

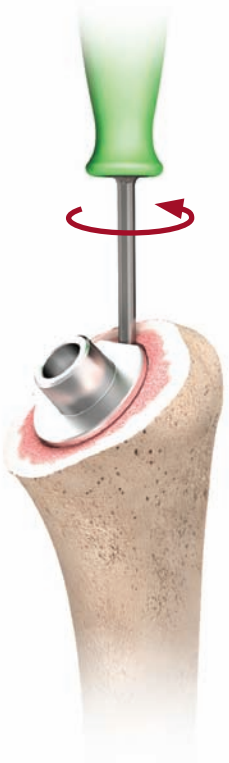


Figure 15

Humeral Reaming
Insert the orientation guide pin through the reaming guide at the desired epiphysis version.

Place the assembled **Epiphyseal Reaming Guide** and orientation guide pin on the stem by aligning the guide pin to the forearm while keeping the reaming guide on the stem spigot (Figure 16).

Tighten the reaming guide screw to the stem using the 3.5mm **Male Hex Screwdriver**. Place the **Sizing Guides** onto the reaming guide in order to determine the correct reverse epiphysis size. The correct size will be contained within the cortical wall (Figure 17).

Note: The GLOBAL UNITE System allows eccentric reaming and preparation of the proximal humerus to better match anatomy. Assure that the proper reamer guide is utilized (Right, Center or Left) to achieve the desired outcome.

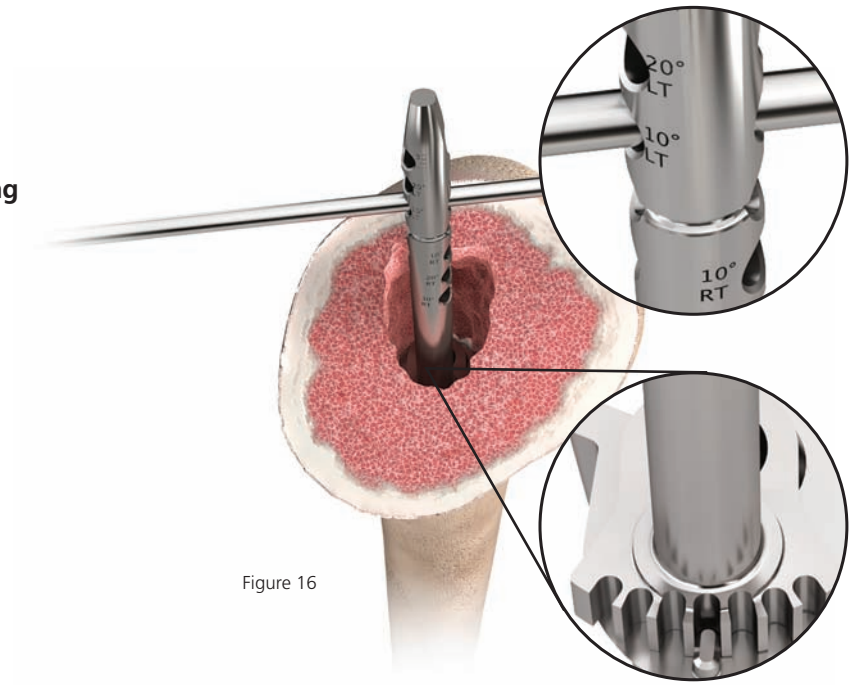


Figure 16

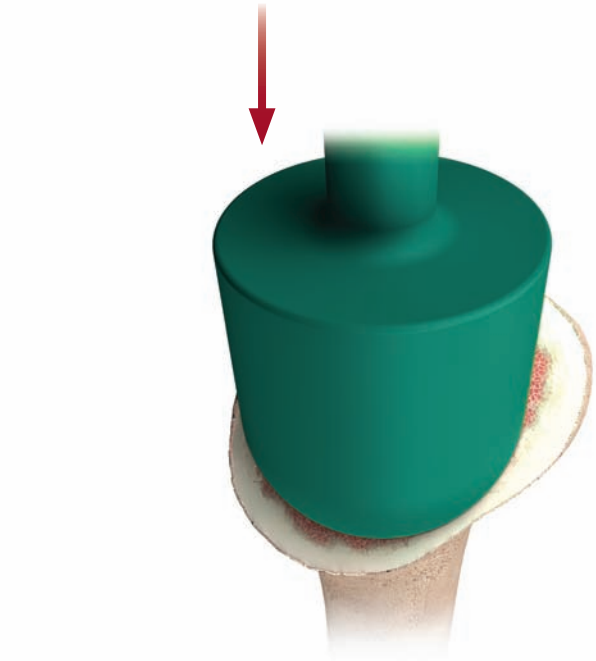


Figure 17

Select the color coded **Epiphyseal Reamer** (red or green) determined during the sizing exercise and prepare the proximal humerus by using power (Figure 18). Once the reaming process has been completed the reamer guide can be removed utilizing the 3.5mm hex screwdriver (yellow handle).

Utilize an osteotome or ronguer to remove any bone that may remain around the proximal portion of the distal stem that can prevent the proximal component from completely engaging with the stem (Figure 19).

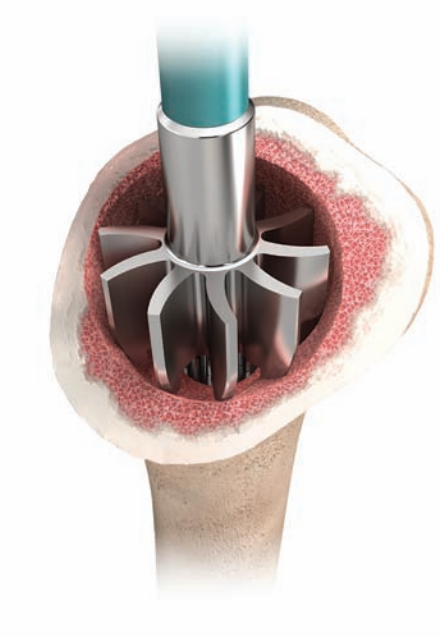


Figure 18

Figure 19

Attaching the Trial Epiphysis Component to the Distal Stem

Attach the DELTA XTEND™ Reverse Shoulder System trial epiphysis to the **Reverse Epiphysis Holder** by squeezing the distal portion and placing it within the epiphysis. Align the pins on the outside of the epiphyseal holder with the notches on the implant and release the holder, this will lock the two components together (Figure 20).

Figure 20

Place the **Orientation Guide Pin** through the retroversion hole that was originally determined during the reaming process (Figure 21). Align the trial epiphysis to the stem and align the pin to the forearm.

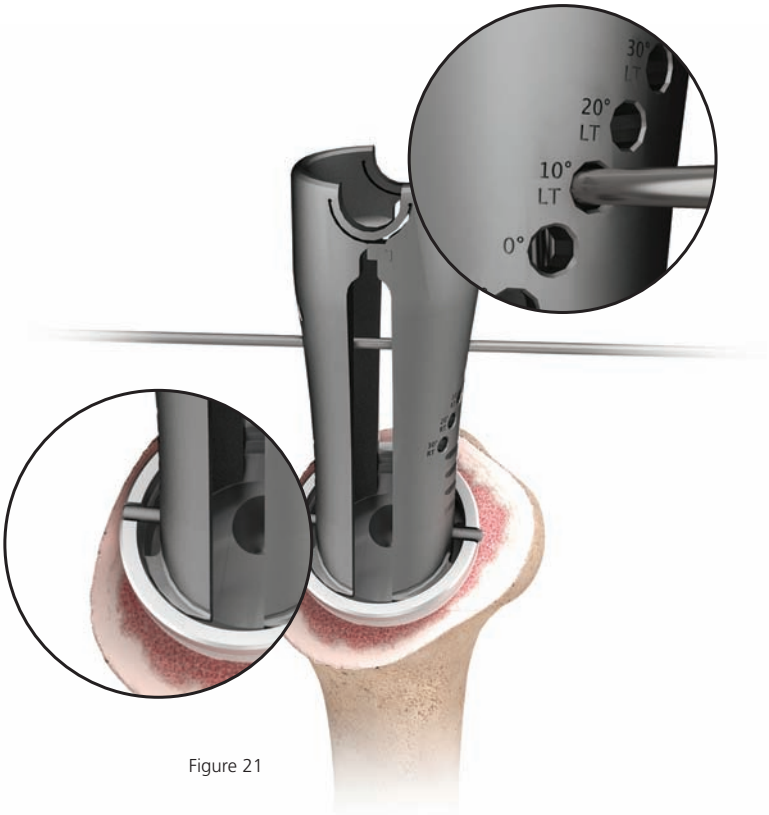


Figure 21

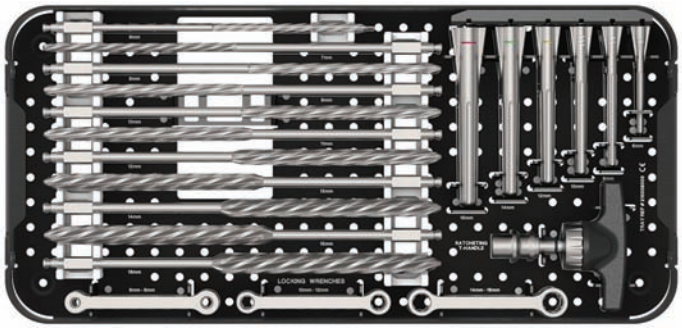
Once the component is in proper orientation, place the 3.5mm **Male Hex Screwdriver** (yellow handle) through the inner portion of the reverse epiphysis holder and securely tighten the bolt. Remove the reverse epiphyseal holder when this step has been completed (Figure 22). Remove any bone on the superior aspect of the trial epiphysis that could cause impingement with the final implant. This can be done with an oscillating saw while using the trial epiphysis as a guide.

Once the proximal component has been secured to the stem, complete all other steps of the procedure consistent with the **DELTA XTEND** Reverse Shoulder System through final implantation.

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

Figure 22

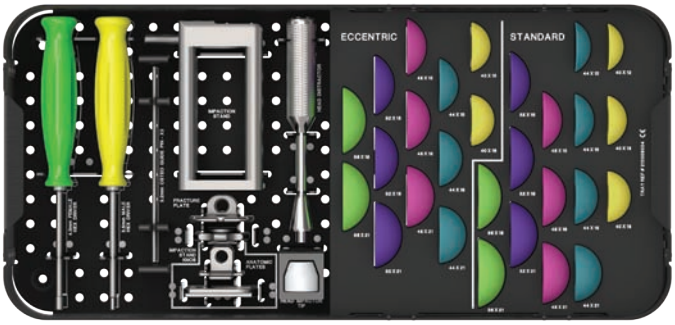
INSTRUMENT ORDERING INFORMATION
COMMON CASE



Top Tray – Humeral Preparation

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

INSTRUMENT ORDERING INFORMATION
COMMON CASE

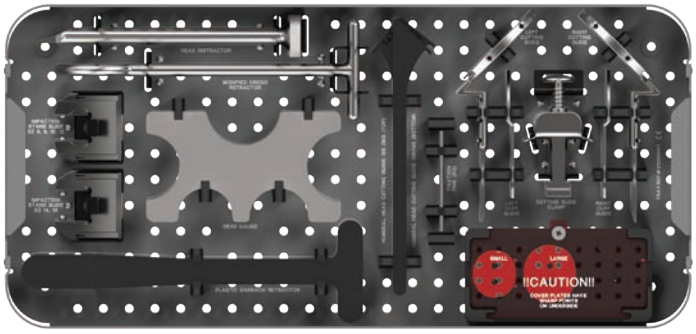


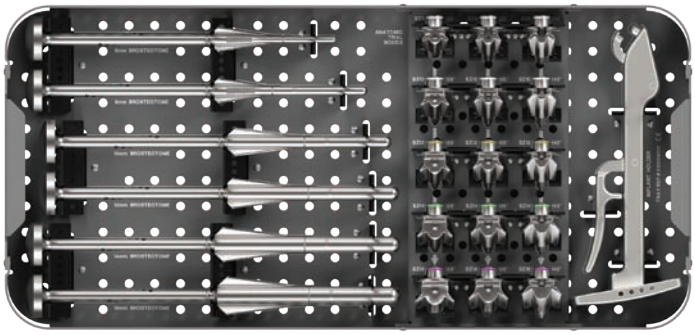
Bottom Tray – Trial Heads

2130-20-000	3.2mm Osteotomy Guide Pin – Long
2100-70-155	4.0mm Female Hex Screwdriver
2100-70-150	3.5mm Hex Screwdriver
2001-65-000	Humeral Head Impactor
2100-01-022	Impaction Stand
2100-11-400	Common Humeral Head 40 X 12 Trial
2100-11-401	Common Humeral Head 40 X 15 Trial
2100-11-402	Common Humeral Head 40 X 18 Trial
2100-11-440	Common Humeral Head 44 X 12 Trial
2100-11-441	Common Humeral Head 44 X 15 Trial
2100-11-442	Common Humeral Head 44 X 18 Trial
2100-11-443	Common Humeral Head 44 X 21 Trial
2100-11-481	Common Humeral Head 48 X 15 Trial
2100-11-482	Common Humeral Head 48 X 18 Trial
2100-11-483	Common Humeral Head 48 X 21 Trial
2100-11-521	Common Humeral Head 52 X 15 Trial
2100-11-522	Common Humeral Head 52 X 18 Trial
2100-11-523	Common Humeral Head 52 X 21 Trial
2100-11-562	Common Humeral Head 56 X 18 Trial
2100-11-563	Common Humeral Head 56 X 21 Trial

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

INSTRUMENT ORDERING INFORMATION
ANATOMIC CASE





Top Tray – Anatomic

2128-01-021	Humeral Head Distractor
2236-26-000	Modified Crego Retractor
2100-70-005	Impaction Slide - Anatomic Stems 6 - 12
2100-70-006	Impaction Slide - Anatomic Stems 14 - 16
2100-01-020	Anatomic Head Guage
2236-31-000	Plastic Darrach
2100-61-071	Celcon Cutting Guide 128 & 142 Degree
2128-61-071	Celcon Cutting Guide 135 Degree
2490-95-000	3.2mm Fixation Pins Qty 3
2128-62-110	Anatomic Resection Guide - Right
2128-62-130	Posterior Cuff Guide - Right
2128-62-150	Cutting Guide Quick Clamp
2128-62-120	Posterior Cuff Guide - Left
2128-62-100	Anatomic Resection Guide - Left
2128-65-200	Small Cover Plate
2128-65-250	Large Cover Plate

Bottom Tray – Anatomic

2100-05-006	Proximal Humeral Brosteotome 6
2100-05-008	Proximal Humeral Brosteotome 8
2100-05-010	Proximal Humeral Brosteotome 10
2100-05-012	Proximal Humeral Brosteotome 12
2100-05-014	Proximal Humeral Brosteotome 14
2100-05-016	Proximal Humeral Brosteotome 16
2100-20-016	Trial Body 6/8 – 128 Degree
2100-30-016	Trial Body 10 – 128 Degree
2100-40-016	Trial Body 12 – 128 Degree
2100-50-016	Trial Body 14 – 128 Degree
2100-60-016	Trial Body 16 – 128 Degree
2100-20-015	Trial Body 6/8 – 135 Degree
2100-30-015	Trial Body 10 – 135 Degree
2100-40-015	Trial Body 12 – 135 Degree
2100-50-015	Trial Body 14 – 135 Degree
2100-60-015	Trial Body 16 – 135 Degree
2100-20-017	Trial Body 6/8 – 142 Degree
2100-30-017	Trial Body 10 – 142 Degree
2100-40-017	Trial Body 12 – 142 Degree
2100-50-017	Trial Body 14 – 142 Degree
2100-60-017	Trial Body 16 – 142 Degree
2100-01-135	Anatomic Implant Holder

INSTRUMENT ORDERING INFORMATION
REVISION CASE

Top Tray

2100-70-500	Epiphyseal Sizer 1
2100-70-510	Epiphyseal Sizer 2
2100-70-600	Epiphyseal Reamer 1
2100-70-610	Epiphyseal Reamer 2
2100-70-410	Epiphyseal Reamer Guide
2100-70-415	Epiphyseal Reamer Guide Left
2100-70-420	Epiphyseal Reamer Guide Right
2100-70-700	Reverse Epiphyseal Holder
2130-01-120	Humeral Head Distractor
2307-99-002	Extraction T-Handle
2130-20-000	3.2mm Osteotomy Guide Pin – Long
2100-70-155	4.0mm Female Hex Screwdriver
2100-70-150	3.5 Male Hex Screwdriver

IMPLANT ORDERING INFORMATION

Standard Humeral Stem Components

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

Humeral Long Stem Components

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

Anatomic Proximal Bodies

110020000	Anatomic Proximal Body 135 SZ 6/8
110030000	Anatomic Proximal Body 135 SZ 10
110040000	Anatomic Proximal Body 135 SZ 12
110050000	Anatomic Proximal Body 135 SZ 14
110060000	Anatomic Proximal Body 135 SZ 16
110020010	Anatomic Proximal Body 128 SZ 6/8
110030010	Anatomic Proximal Body 128 SZ 10
110040010	Anatomic Proximal Body 128 SZ 12
110050010	Anatomic Proximal Body 128 SZ 14
110060010	Anatomic Proximal Body 128 SZ 16
110020020	Anatomic Proximal Body 142 SZ 6/8
110030020	Anatomic Proximal Body 142 SZ 10
110040020	Anatomic Proximal Body 142 SZ 12
110050020	Anatomic Proximal Body 142 SZ 14
110060020	Anatomic Proximal Body 142 SZ 16

Humeral Head Components

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

Anchor Peg Glenoid Implants Featuring PREMERON® X-Linked Polyethylene

1136-40-026	Cross-linked Anchor Peg Glenoid 40mm
1136-41-026	Cross-linked Anchor Peg Glenoid 44mm
1136-42-026	Cross-linked Anchor Peg Glenoid 48mm
1136-43-026	Cross-linked Anchor Peg Glenoid 52mm
1136-44-026	Cross-linked Anchor Peg Glenoid 56mm

IMPLANT ORDERING INFORMATION

Metaglene Components

1307-60-000	Metaglene
1407-60-020	+10mm Long Peg Metaglene
1407-60-025	+15mm Long Peg Metaglene

Glenosphere Components

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

Metaglene Screw Components

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

Modular Epiphyseal Components

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

Polyethylene Cup and Humeral Spacer

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

IMPORTANT

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

INDICATIONS

Total shoulder or hemi-shoulder replacement is indicated for:

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

Hemi-shoulder replacement is also indicated for:

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

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

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

CONTRAINDICATIONS

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

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

Please review the full labeling for DELTA XTEND System Metaglene when converting to a reverse.

WARNINGS AND PRECAUTIONS

- Implants and trial components from different manufacturers should never be used together.
- DePuy Synthes' single use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.
- Always use a trial prosthesis for trial purposes. Trials should never be used as an implant.
- Do not alter or modify implants in any way.
- GLOBAL UNITE System Standard and Eccentric Humeral Heads are intended to be used with either GLOBAL UNITE or GLOBAL® AP® System Humeral Components. DO NOT USE the 40x12 mm or 44x12 mm GLOBAL UNITE Standard Humeral Heads with the GLOBAL AP humeral components, as their compatibility has not been established.
- The use of a glenoid prosthesis in patients with cuff tear arthropathy could increase the risk of glenoid component loosening due to non-anatomic loading conditions.
- When used with multiple components of a total shoulder replacement system, the MR compatibility and safety of the entire system of implants has not been evaluated and the entire system of implants has not been tested together for heating or migration in the MR environment. The risks of exposure to MR include heating and/or displacement of a metallic implant. Image artifacts including dead zones and distortion may occur, especially in the immediate area around the implant, requiring optimization of imaging parameters. In line with the recommendations of the American College of Radiology, DePuy Synthes Joint Reconstruction recommends that a professional familiar with the specific MRI apparatus to be used assess the patient prior to any MRI examination or therapy.

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

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

ADVERSE EVENTS AND COMPLICATIONS

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

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

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

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

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

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