

GLOBAL[®] APG+ INSTRUMENTATION

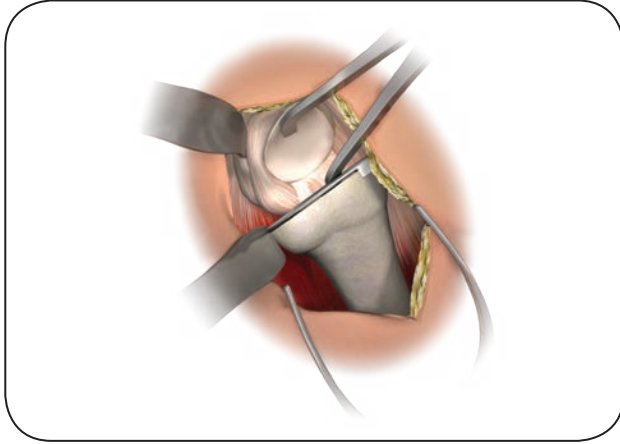


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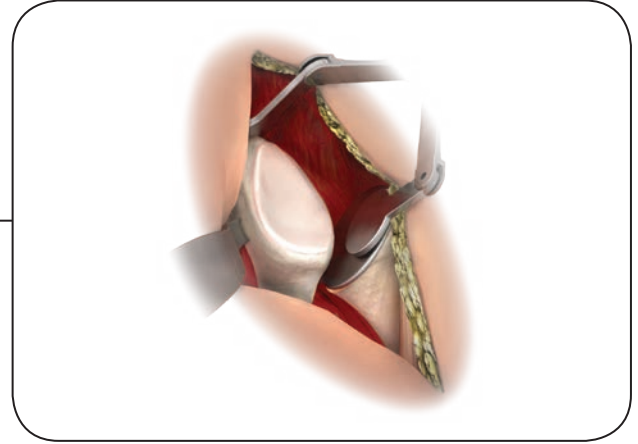
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GLOBAL® APG+ SYSTEM KEY SURGICAL STEPS

GLENOID EXPOSURE



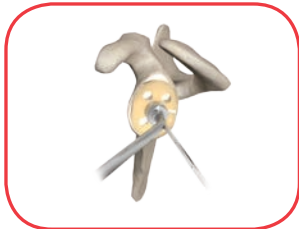
1. Release Capsule



2. Expose Glenoid

GLENOID PREPARATION AND IMPLANTATION

Sizer Pin Guides (No Version)



Fixed Pin Guide (Version or No Version)



Sizer Pin Guides (Version)

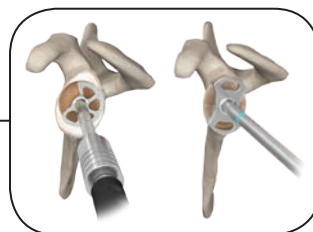


1. Pin Placement, Sizing and Retroversion Correction

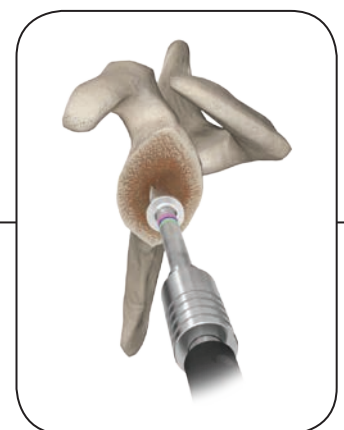
Normal Exposure



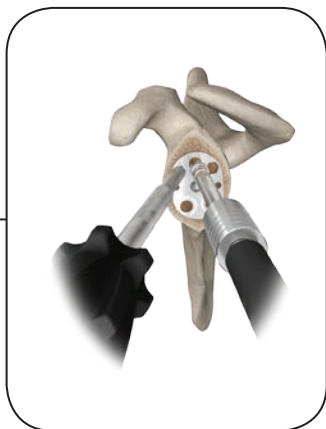
Challenging Exposure



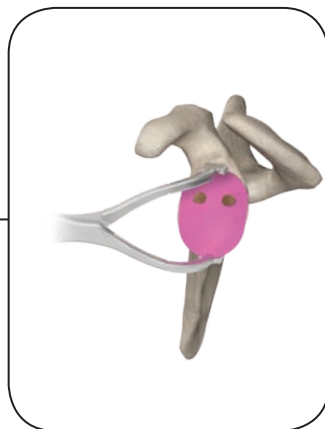
2. Reaming



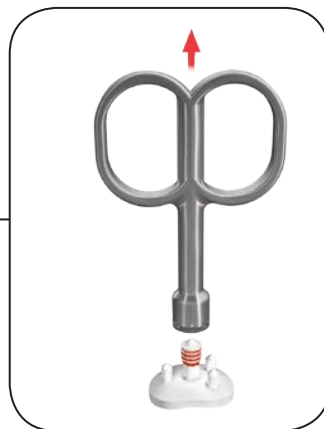
3. Drilling Central Peg Hole



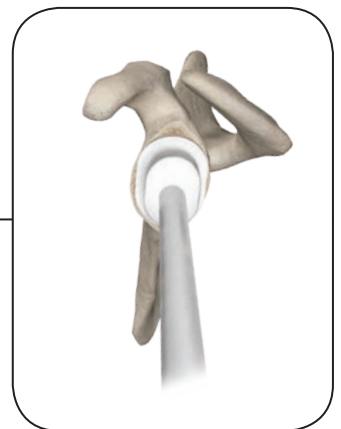
4. Drilling Peripheral Peg Holes



5. Trialing



6. Applying Bone Paste



7. Seating the Implant

PRE-OPERATIVE PLANNING

Pre-Operative Templating

Initial assessments of the glenoid bone should be carried out using radiographic imaging to determine if the patient is suitable for treatment (Figure 1). Additional information obtained from CT imaging can help determine appropriate treatment as well. At this stage, measurements can be identified for the angle of the plane of the scapula, the plane of the glenoid fossa, glenoid version, as well as size of the glenoid vault. One major pre-operative goal is to determine how much (if any) retroversion correction is necessary (refer to Table 1 on page 13). Corresponding information from the humeral component of the joint is also assessed at this time.



Figure 1

Surgical Approach

The patient rests in the beach chair position for the surgical procedure (Figures 2 and 3). The GLOBAL® Anchor Peg Glenoid Implant should be implanted using the delto-pectoral approach, humeral head resection, and canal preparation as described in the GLOBAL® ADVANTAGE® or GLOBAL® AP® System surgical techniques. This allows for a good view of the inferior part of the glenoid, and is also advantageous for revision surgery where the difficult task of removal of the humeral stem can be accomplished. Using this approach, a full 360 degree exposure of the bony glenoid should be achieved. Sufficient posterior displacement of the proximal humerus is required to provide necessary exposure for implanting the GLOBAL Anchor Peg Glenoid Implant. This degree of posterior humeral displacement frequently requires a posterior capsule release from the posterior glenoid rim in addition to an anterior and inferior capsular excision. To maintain this exposure a Modified Sonnabend humeral head retractor, or a Lamina Spreader retractor is used to lever against the humeral broach or osteotomy cover, which is left in place to protect the proximal humerus.



Figure 2



Figure 3

Note: Failure to resect the entire humeral head at its anatomic neck may limit glenoid exposure.

GLENOID EXPOSURE

Before beginning glenoid exposure for preparation of the glenoid, it is very useful to inspect the posterior aspect of the capsule and glenohumeral space. Place the arm in a position so that the humeral osteotomy is parallel to the glenoid fossa. This is generally with the forearm perpendicular to the floor and the humerus in slight abduction. Using an osteotomy cover to protect the resected humeral surface, position a lamina spreader retractor and laterally displace the proximal humerus to create a space between the osteotomy surface and the glenoid. Open the blades of the lamina spreader and have an assistant hold the retractor to prevent rotation. Use a **Double Prong Gelpi** (2245-10-001) to retract the superficial soft tissues while placing a **Reverse Hohmann Retractor** (2245-10-040) between the remaining inferior capsule and neurovascular structures (axillary nerve and posterior humeral circumflex vessels) to achieve a clear view of the interval between the humerus and glenoid to the back surface of the capsule.

The posterior capsule is then released from the posterior glenoid rim (Figure 4). In cases with a very tight posterior capsule (prior surgery or post traumatic arthritis), it can be excised with this exposure. In addition, the posterior labrum can be easily visualized for excision along with removal of the remaining part of the long head of the biceps. Most importantly, this step will allow for complete removal of the anterior inferior capsule with excellent visualization and protection of the axillary nerve. At this step, any osteophytes are removed, and the tissue is then placed back into physiologic tension thereby facilitating increased access and safety.

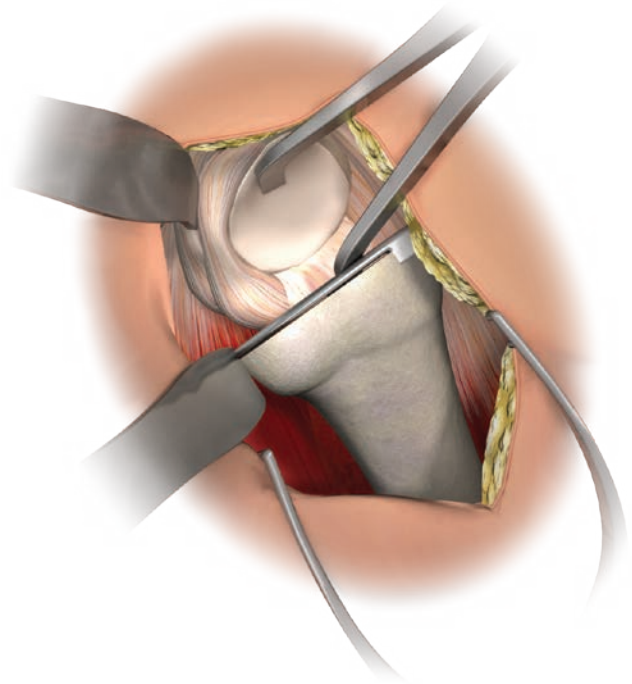


Figure 4

GLENOID EXPOSURE

Final exposure of the glenoid requires the use of a select set of deep retractors. A **Small Anterior Glenoid Neck Retractor** (2810-17-000) is placed over the anterior glenoid rim and is used to retract the subscapularis and the anterior soft tissues. The arm is then gradually positioned in extension, external rotation, and abduction. A **Proximal Humerus Spreader** (2245-10-100) is positioned with the medial foot plate at the base of the coracoid and the lateral plate on the resected surface of the humerus to provide improved glenoid exposure (Figure 5). With ideal exposure the resected surface of the humerus is parallel to the posterior wall of the glenoid as well as posterior to the posterior glenoid rim thereby allowing full 360 degree exposure of the glenoid fossa. If needed, a **Reverse Hohmann Retractor**, is placed on the superior glenoid within the supraspinatus fossa to retract the superior part of the deltoid.

Full 360 degree exposure of the glenoid fossa is difficult in patients who have revision surgery, soft tissue scarring from a prior surgery, or malunions resulting from post traumatic cases. Patients who are very muscular or obese can also present exposure problems. In these cases, less than ideal exposure needs to be managed with respect to the instrumentation, alternative methods of retraction, and arm positioning to facilitate adequate exposure of the glenoid.

Note: Extensive capsular excision and release, along with proper resection of the humeral head, will correct most loss of motion commonly due to osteoarthritis, post capsulorrhaphy arthropathy, and post traumatic arthritis (including malunions). Soft tissue release often includes release of the long head of the biceps. These releases are essential for optimal glenoid exposure. Additional details surrounding glenoid exposure can be found in the GLOBAL® ENABLE™ System surgical technique.

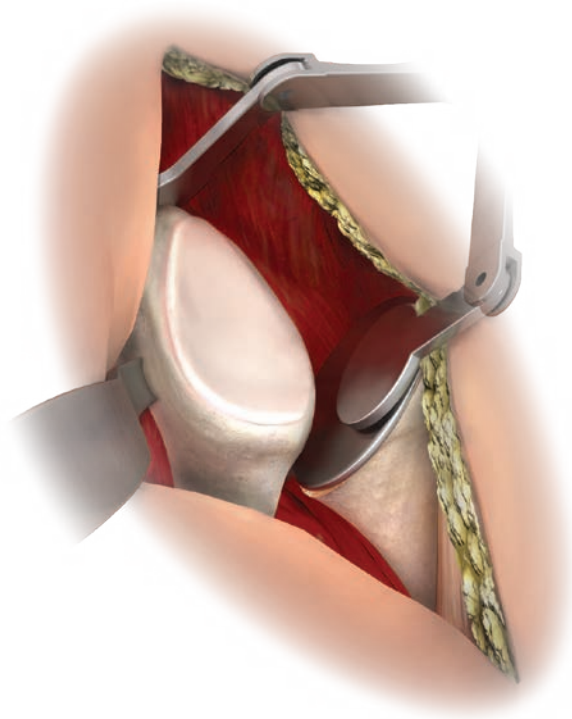


Figure 5

SIZING – SIZER PIN GUIDES

The 2.5mm Breakaway Guide Pin is set in an orientation that may allow for an appropriate amount of retroversion correction (if necessary), and is placed using one of two pin placement devices – Sizer Pin Guides (+0, +3, or +5mm), or a Fixed Pin Guide. The 2.5mm Breakaway Guide Pin is scored in three locations (3, 4, and 5 inches from the tip) allowing smooth and controlled breakage. This feature allows the pin to be customized to a length appropriate to the patient and surgeon preference.

No Version Correction

Identify which **Sizer Pin Guide (40+0, 44+0, 48+0, 52+0, or 56+0mm)** covers as much of the glenoid surface as possible without overhanging the periphery of the bone surface.

Version Correction

Identify which **Sizer Pin Guide (40+3, 40+5, 44+3, 44+5, 48+3, 48+5, 52+3, 52+5, 56+3, or 56+5mm)** covers as much of the glenoid surface as possible without overhanging the periphery of the bone surface, and has the appropriate step height (+3 or +5mm) (Figure 6) that will provide the amount of version correction required (5 or 10 degrees) based on preoperative planning or intra-operative assessment (See Table 1 and Figure 7).

Note: An implant that is too large will lack glenoid bone support and interfere with normal rotator cuff function.

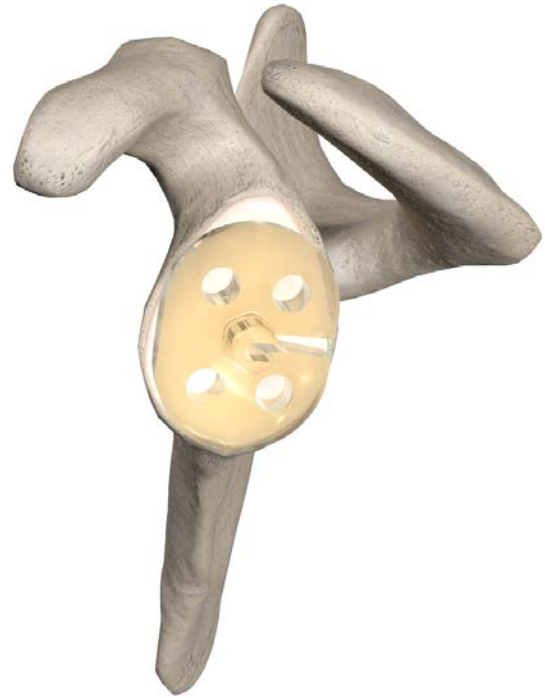


Figure 6

Step Height (mm)	Version Correction
+0	None
+3	5°
+5	10°



Figure 7

PIN PLACEMENT – SIZER PIN GUIDES

Use the selected **Sizer Pin Guide** for the glenoid surface that allows placement of the **2.5mm Breakaway Guide Pin** (Figure 8) in the center of the glenoid fossa. The viewing holes in the Sizer Pin Guide allow for visualization of position and fit. If there is intraoperative difficulty in glenoid sizing, reference the planned size for the humeral head to determine which side of the joint needs to be adjusted.

Attach the cannulated **Curved Handle** to the hexagonal boss on the correct Sizer Pin Guide and center on the glenoid fossa. This connection keeps the Sizer Pin Guide from rotating when held in place.

Insert a 2.5mm Breakaway Guide Pin through the Curved Handle/Sizer Pin Guide assembly and drill securely into the glenoid fossa using a power drill (Figure 9). Remove the Curved Handle/Sizer Pin Guide assembly over the 2.5mm Breakaway Guide Pin. The 2.5mm Breakaway Guide Pin length may be adjusted at this point by placing the guide pin through the hole in the top of the Curved Handle just below the chosen score line and snapping the guide pin using the Curved Handle as a lever. The guide pin is now ready for the other cannulated instrumentation.

Note: 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.

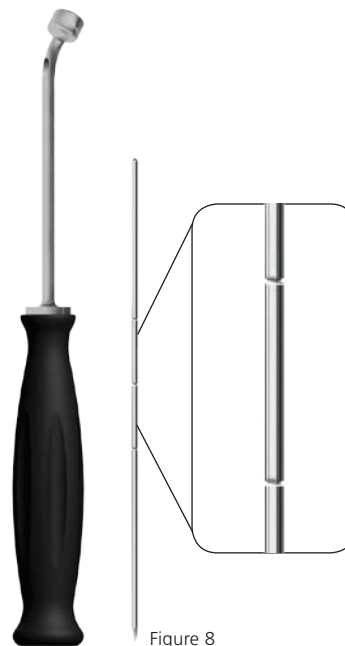


Figure 8

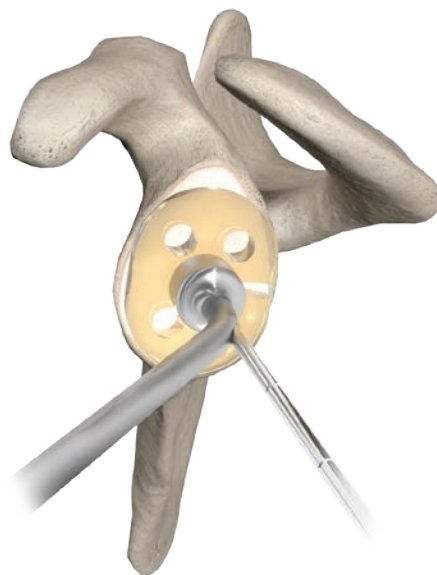


Figure 9

PIN PLACEMENT AND SIZING – FIXED PIN GUIDE

Insert the tip of the **Straight Handle Hex Driver** through the top of the **Fixed Pin Guide** and engage it in the bottom portion. Tighten the **Internal Rod** of the Straight Handle Hex Driver through the external handle, which expands the hexagonal tip securing the driver to the Fixed Pin Guide.

Place the guide along the anterior wall of the glenoid until its tip reaches the lateral aspect of the subscapularis fossa. Identify the hole in the upper portion of the Fixed Pin Guide that corresponds to the center of the glenoid fossa. Care needs to be taken that the inclination angle of the Fixed Guide Pin is set appropriately.

Insert a **2.5mm Breakaway Guide Pin** through the chosen hole of the Fixed Pin Guide directly and drill securely into the glenoid fossa using a power drill (Figure 10). Loosen the Internal Rod (Figure 11) of the Straight Handle Hex Driver to disengage from the Fixed Pin Guide. Remove the Fixed Pin Guide from the glenoid. The lower portion of the guide is designed to pivot away from the anterior glenoid for easy removal over the 2.5mm Breakaway Guide Pin. The 2.5mm Breakaway Guide Pin length may be adjusted at this point by placing the guide pin through the hole in the top of the Curved Handle just below the chosen score line and snapping the guide pin using the Curved Handle as a lever. The guide pin is now ready for the other cannulated instrumentation.

Identify which **Sizer Pin Guide (40, 44, 48, 52 or, 56 – +0, +3, +5)** covers as much of the glenoid surface as possible without overhanging the periphery of the bone surface (See Table 1 and Figure 7 on page 13).

Note: The Fixed Pin Guide is designed to place the guide pin straight down the axis of the glenoid regardless of version. Inclination must be independently determined and set by the surgeon.



Figure 10

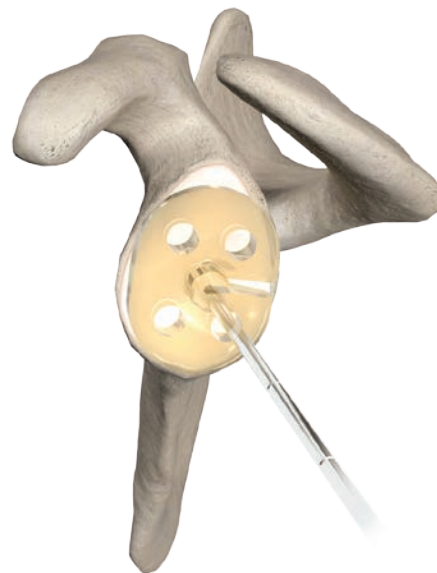


Figure 11

REAMING – NORMAL EXPOSURE

Attach the appropriately sized **Access Reamer (40, 44, 48, 52, or 56mm)** to the Quick Connect Driver Shaft, and advance over the **2.5mm Breakaway Guide Pin** (Figures 12 and 13). Remove unwanted cartilage and bone from the surface of the center portion of the glenoid fossa making sure to remove only as much bone as necessary (Figure 14). Remove the Access Reamer and Quick Connect Driver Shaft over the 2.5mm Breakaway Guide Pin. Detach the Access Reamer from the Quick Connect Driver Shaft to ready the driver for the drilling step.

Note: It is important to prepare the surface completely before moving on to the next step. Care needs to be taken that there is congruent contact between the bone and the back side of the implant. The appropriately sized Sizer Pin Guide (+0) may be used to check contact.

! Caution: Over-reaming decreases the surface area of the glenoid, decreases the depth of the glenoid vault, and removes the subchondral bone. All of these conditions can lead to suboptimal seating and support of the implant.

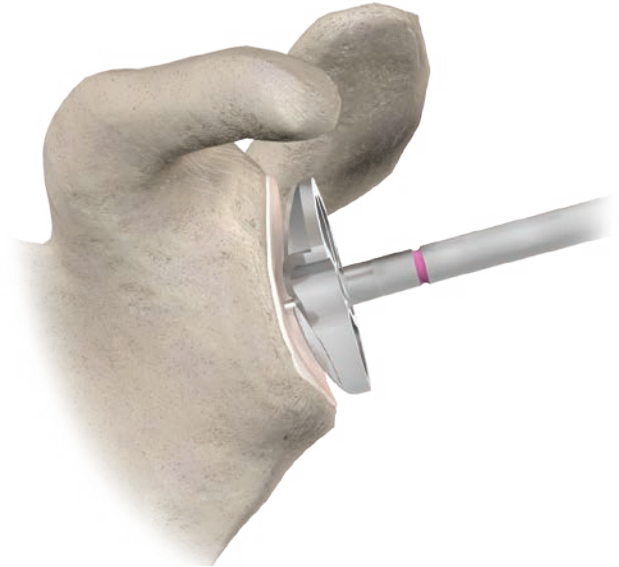


Figure 12

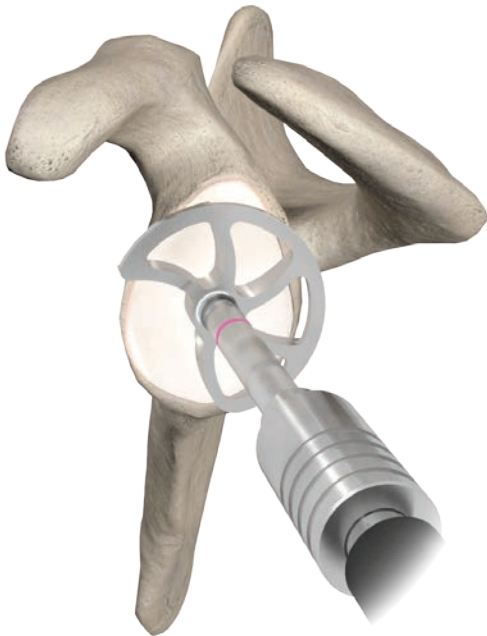


Figure 13



Figure 14

REAMING – CHALLENGING EXPOSURE

Attach the appropriately sized **Low Profile Central Reamer (40/44mm or 48/52/56mm)** to the **Quick Connect Driver Shaft**, and advance over the **2.5mm Breakaway Guide Pin**. The size and shape of the Low Profile Central Reamer is designed to prepare the anterior/posterior portion of the glenoid fossa only, and a second step is needed to remove unwanted cartilage and bone from the superior/inferior portions. Remove unwanted cartilage and bone from the surface of the center portion of the glenoid fossa making sure to remove only as much bone as necessary (Figure 15). Remove the Low Profile Central Reamer and Quick Connect Driver Shaft over the 2.5mm Breakaway Guide Pin. Detach the Low Profile Central Reamer from the Quick Connect Driver Shaft to ready the driver for the drilling step.

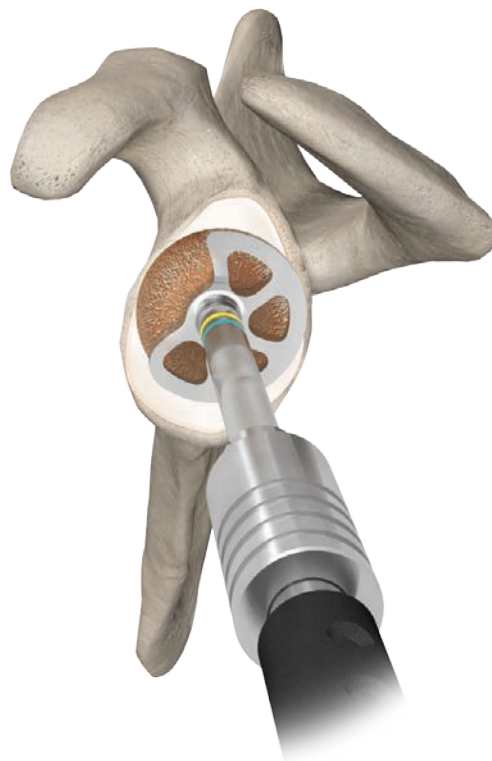


Figure 15

REAMING – CHALLENGING EXPOSURE

Select the appropriately sized **Low Profile Peripheral Reamer (40, 44, 48, 52, or 56mm)**, and attach to the **Ratchet T-Handle** from either the GLOBAL ADVANTAGE or GLOBAL AP Instrument Set. Finish creating a uniform, concave surface across the entire glenoid fossa by manually operating the Low Profile Peripheral Reamer (Figure 16) until its depth-stop bottoms out on the center portion of the glenoid.

Note: It is important to prepare the surface completely before moving on to the next step. Care needs to be taken that there is congruent contact between the bone and the back side of the implant. The appropriately sized Sizer Pin Guide (+0) may be used to check contact.

Tip: Remove all retractors and use reamer shaft to retract soft tissue for extra room during challenging exposure cases.

- ⚠ **Caution:** Over-reaming decreases the surface area of the glenoid, decreases the depth of the glenoid vault, and removes the subchondral bone. All of these conditions can lead to suboptimal seating and support of the implant.
- ⚠ **Caution:** The Low Profile Peripheral Reamer is NOT intended for use with power. If hard bone impedes bone removal, a Hand Burr may be used to conservatively remove problem areas. Care should be taken to avoid removal of too much subchondral bone as this may compromise implant stability.

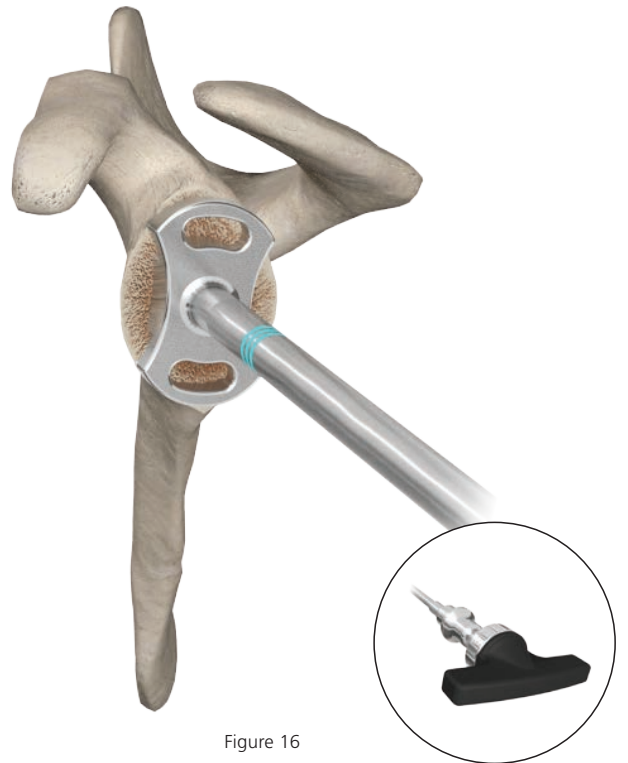


Figure 16

DRILLING CENTRAL PEG HOLE AND GUIDE PIN EXTRACTION

Drilling Central Peg Hole

Attach the appropriately sized cannulated **Quick Connect Central Drill Bit (40/44mm or 48/52/56mm)** to the **Quick Connect Driver Shaft**, and introduce over the **2.5mm Breakaway Guide Pin**.

Advance the bit until it bottoms out on the reamed surface of the glenoid (Figure 17). The morselized bone captured during drilling the central hole should be saved for use as bone paste between the flutes of the GLOBAL Anchor Peg Glenoid. Remove the Quick Connect Central Drill Bit and Quick Connect Driver Shaft over the 2.5mm Breakaway Guide Pin.

Note: Use Quick Connect Central Drill Bit 40/44mm for implanting a 40mm or a 44mm Anchor Peg Glenoid. Use Quick Connect Central Drill Bit 48/52/56mm for implanting a 48mm, 52mm, or 56mm GLOBAL Anchor Peg Glenoid.

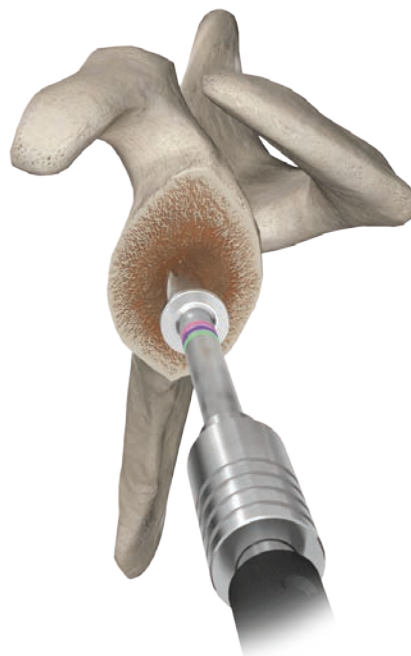


Figure 17

Guide Pin Extraction

Grasp and remove the **2.5mm Breakaway Guide Pin** using the **Pin Extractor** (Figure 18).

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 18

DRILLING PERIPHERAL PEG HOLES

Insert the tip of the **Straight Handle Hex Driver** into one of the hexagonal holes on the **Peripheral Drill Guide**. Tighten the **Internal Rod** of the Straight Handle Hex Driver expanding the hexagonal tip and securing the driver to the Peripheral Drill Guide. Insert the Peripheral Drill Guide into the central hole. It should fully contact the prepared bone surface on the glenoid fossa.

Connect the **Quick Connect Peripheral Drill Bit** to the **Quick Connect Driver Shaft** to prepare for drilling of the peripheral holes. The peripheral holes should not penetrate the base of the scapula (Figure 19).

Place an **Anti-Rotation Peg** into the newly drilled peripheral hole using the **Anti-Rotation Peg Inserter/Remover** (Figure 20). The peg will help prevent the Peripheral Drill Guide from shifting or rotating during the drilling of subsequent holes. This will ultimately enable the resulting peripheral hole pattern to precisely accommodate the peripheral pegs of the implant. Prepare the anterior and posterior holes using the same Quick Connect Peripheral Drill Bit.

Remove the Anti-Rotation Peg using the Anti-Rotation Peg Inserter/Remover.

Option: An alternative to holding the Peripheral Drill Guide in place is to use a 2.5mm x 70mm Fixation Pin. Insert a 2.5mm x 70mm Fixation Pin through one of two angled holes in the Peripheral Drill Guide directly and securely into the glenoid fossa (Figure 21). This alleviates the need to hold the Peripheral Drill Guide in place by hand, and allows for better visibility and maneuverability in the joint space.

Note: Check each peripheral hole to determine whether it penetrates the cortical wall of the glenoid vault. Penetrating holes are cemented but extra care is exercised to avoid pressurizing the cement.

Note: The recommended order of peripheral peg hole preparation is: 1) anterior-inferior 2) anterior-posterior 3) superior (Figure 21).



Figure 19



Figure 20

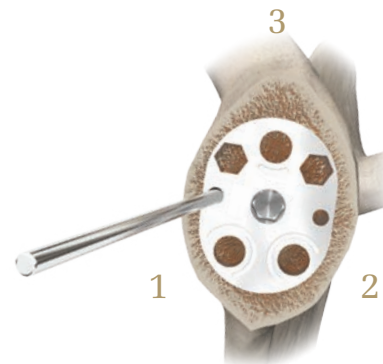


Figure 21

TRIALING

Insert the appropriate implant **Trial (40, 44, 48, 52, or 56mm)** (Figure 22) into the prepared glenoid using the **Glenoid Grasper** (Figure 23). Assess the fit to determine that the Trial sits flush with the prepared surface of the glenoid. There should be full and concentric contact between the back side of the Trial and the prepared surface of the bone. If there is not full and concentric contact between Trial and prepared bone surface, some or all of the prior bone preparation steps may need to be repeated. If the fit is adequate, remove the Trial, and finalize the bone preparation with pulsatile lavage or other means of thorough irrigation to remove any blood clots from the four drilled holes.

Note: Check the quality of the glenoid bone preparation by determining if the component is directly supported by precisely contoured bone, which should prevent the component from rocking, even when an eccentric load is applied to the rim of the implant.

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



Figure 22

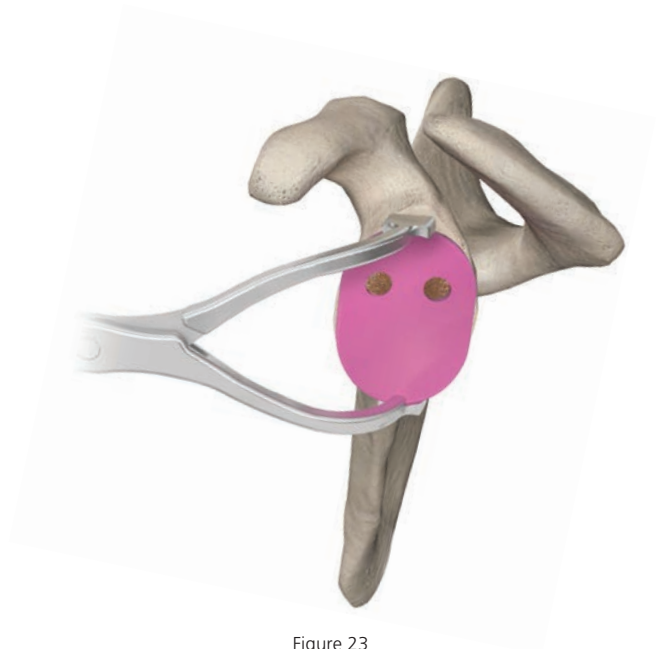


Figure 23

APPLYING BONE PASTE

Use the **Bone Graft Applicator** to apply cancellous bone paste between the flutes of the appropriately sized **GLOBAL Anchor Peg Glenoid Implant (40, 44, 48, 52, or 56mm)** to help facilitate tissue integration. Place the GLOBAL Anchor Peg Glenoid Implant on a table with the articular surface down and the central peg flutes up. Place the circular opening of the Bone Graft Applicator over the flutes and open the handles to expose the central peg flutes. Place the bone paste collected from drilling the central peg hole, or from drilling the underneath side of the humeral head, into the Bone Graft Applicator on both sides of the central peg flutes (Figure 24). Close and hold the Bone Graft Applicator. At the same time, hold the GLOBAL Anchor Peg Glenoid Implant at its base, and twist the Bone Graft Applicator several times back and forth (Figure 25). Pull the Bone Graft Applicator straight off leaving bone interposed evenly between the central peg flutes (Figure 26).

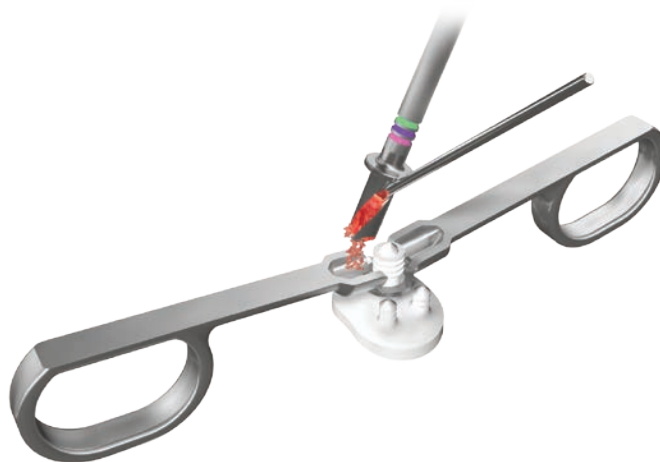


Figure 24

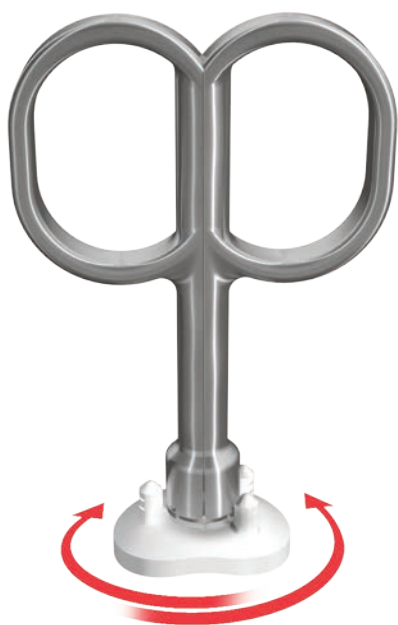


Figure 25



Figure 26

CEMENT APPLICATION

Obtain hemostasis in each of the three peripheral holes.

Mix cement as indicated in **SMARTMIX® Mini System** protocol (Figure 27). Replace mixing blade with plunger. Orient the mixing cartridge horizontally with the syringe port facing up. Remove any unwanted air from the cartridge by advancing the cement until it has reached the port. Securely connect the syringe to the port. Fill the syringe with cement (Figure 28). When cement has reached a doughy state and no longer sticks to surgical gloves, it is ready for use.



Figure 27

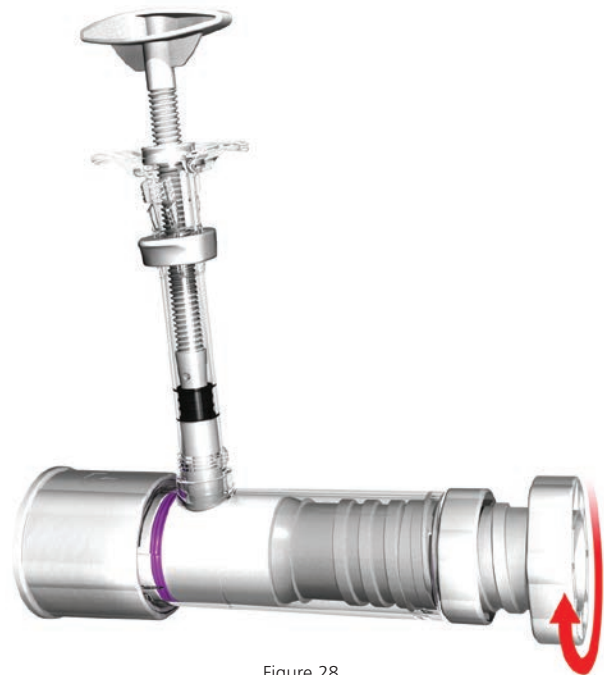


Figure 28

CEMENT APPLICATION

Use the **SMARTMIX Mini Cement Applicator** to place three measured half turns of **SMARTSET® HV** cement into each peripheral hole (Figure 29). Only a small amount of cement is necessary in each hole to provide the proper 1mm cement mantle around each **GLOBAL Anchor Peg** **Glenoid Implant** peripheral peg (Figure 30). Make sure no cement is in the central hole or on the backside of the implant that could inhibit proper seating.

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

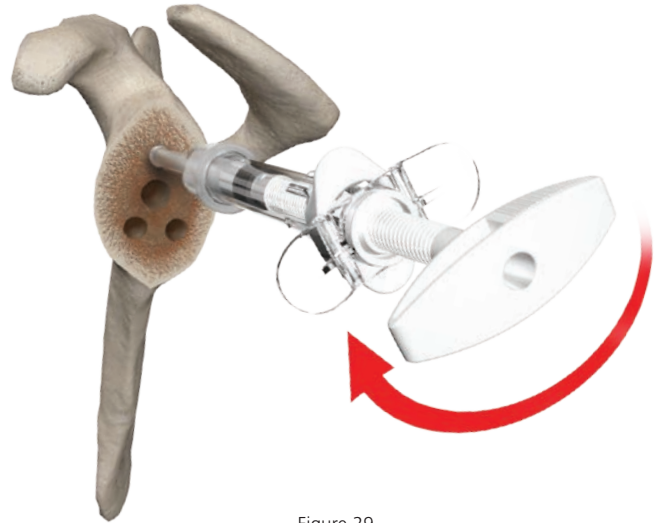


Figure 29



Figure 30

SEATING THE IMPLANT AND WOUND CLOSURE

Seating the Implant

Insert the final implant using the **Glenoid Grasper** (Figure 31).

Use both the **Universal Glenoid Handle** and the polyethylene **Glenoid Impactor Tip** to seat the implant until there is complete contact between the back side of the implant and the prepared glenoid surface (Figure 32). The implant will be most stable when supported by precisely contoured bone. This support should prevent rocking even with unbalanced loads applied to the rim of the implant. Maintain direct pressure on the implant until the cement has hardened.

Note: Confirm that the central hole is clear prior to implant insertion.



Figure 31

Wound Closure

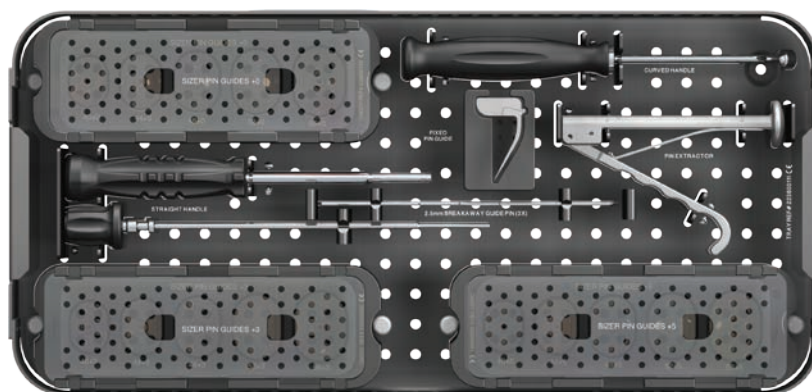
Verify soft tissue tension and range of motion after completing the humeral procedure according to the GLOBAL ADVANTAGE or GLOBAL AP System surgical technique. Thoroughly irrigate the wound with antibiotic solution. After repairing the biomechanical aspects of the joint, take measures to manage short-term pain and limit formations of post-operative hematoma. The wound is closed according to surgeon preference.



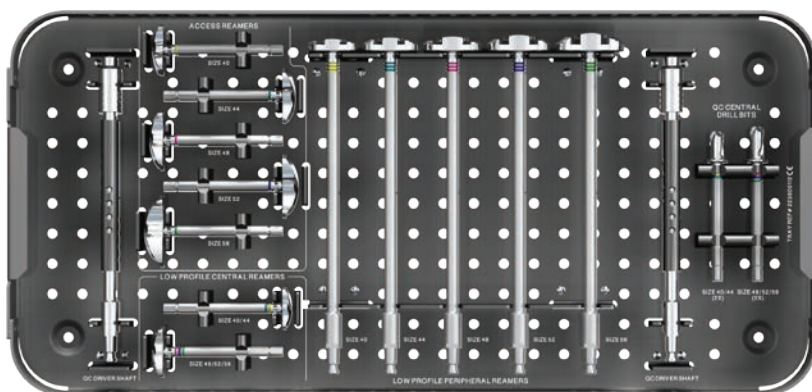
Figure 32

INSTRUMENT CASE LAYOUT

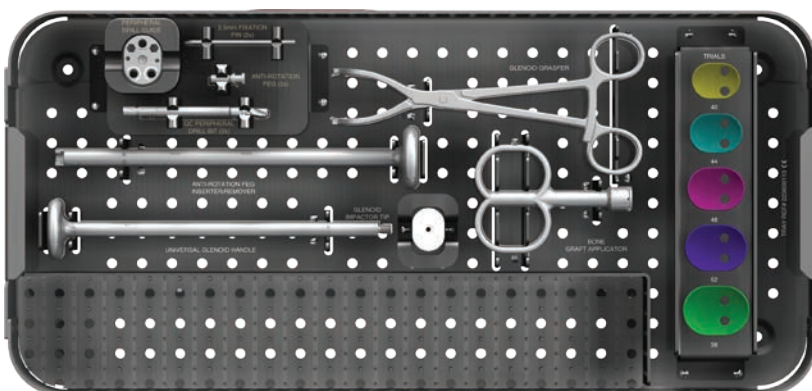
Tray 1 - Pin Placement



Tray 2 - Surface Prep

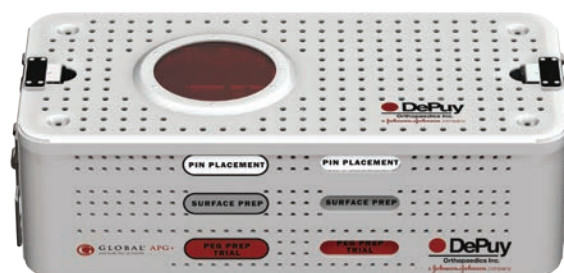


Tray 3 - Peg Prep and Trial



ORDERING INFORMATION

Part Number	Description
2236-00-100	CASE COMPLETE
2236-00-110	CASE
2236-00-111	PIN PLACEMENT TRAY
2236-00-112	SURFACE PREP TRAY
2236-00-113	PEG PREP AND TRIAL TRAY
2236-00-120	SIZER PIN GUIDE +0 CADDY
2230-00-320	SIZER PIN GUIDE +3 CADDY
2230-00-321	SIZER PIN GUIDE +5 CADDY
2236-00-300	LID



ORDERING INFORMATION

Part Number	Description	Usage Diagram					
2236-80-098	GLOBAL ANCHOR PEG GLENOID TEMPLATE						
2236-00-001	SIZER PIN GUIDE 40+0	Red	Brown				
2236-00-002	SIZER PIN GUIDE 44+0	Red	Brown				
2236-00-003	SIZER PIN GUIDE 48+0	Red	Brown				
2236-00-004	SIZER PIN GUIDE 52+0	Red	Brown				
2236-00-005	SIZER PIN GUIDE 56+0	Red	Brown				
2230-00-023	CURVED HANDLE	Red	Dark Grey				
2230-00-003	SIZER PIN GUIDE 40+3			Dark Grey			
2230-00-004	SIZER PIN GUIDE 40+5			Dark Grey			
2230-00-006	SIZER PIN GUIDE 44+3			Dark Grey			
2230-00-007	SIZER PIN GUIDE 44+5			Dark Grey			
2230-00-009	SIZER PIN GUIDE 48+3			Dark Grey			
2230-00-010	SIZER PIN GUIDE 48+5			Dark Grey			
2230-00-012	SIZER PIN GUIDE 52+3			Dark Grey			
2230-00-013	SIZER PIN GUIDE 52+5			Dark Grey			
2230-00-015	SIZER PIN GUIDE 56+3			Dark Grey			
2230-00-016	SIZER PIN GUIDE 56+5			Dark Grey			
2230-00-018	FIXED PIN GUIDE			Brown			
2230-00-024	STRAIGHT HANDLE HEX DRIVER (INTERNAL ROD)			Brown	Orange		
2230-00-025	STRAIGHT HANDLE HEX DRIVER (EXTERNAL HANDLE)			Brown	Orange		
2230-00-019	2.5mm BREAKAWAY GUIDE PIN	Red	Dark Grey	Brown	Black	Yellow	
2230-00-029	QUICK CONNECT DRIVER SHAFT			Brown	Black	Yellow	
2236-00-008	ACCESS REAMER 40			Brown			
2236-00-009	ACCESS REAMER 44			Brown			
2236-00-010	ACCESS REAMER 48			Brown			
2236-00-011	ACCESS REAMER 52			Brown			
2236-00-012	ACCESS REAMER 56			Brown			
2230-00-030	LOW PROFILE CENTRAL REAMER 40/44			Black			
2230-00-031	LOW PROFILE CENTRAL REAMER 48/52/56			Black			
2230-00-032	LOW PROFILE PERIPHERAL REAMER 40			Black			
2230-00-033	LOW PROFILE PERIPHERAL REAMER 44			Black			
2230-00-034	LOW PROFILE PERIPHERAL REAMER 48			Black			
2230-00-035	LOW PROFILE PERIPHERAL REAMER 52			Black			
2230-00-036	LOW PROFILE PERIPHERAL REAMER 56			Black			
2128-61-070	RATCHET T-HANDLE			Black			
2236-00-014	QUICK CONNECT CENTRAL DRILL BIT 40/44				Yellow		
2236-00-015	QUICK CONNECT CENTRAL DRILL BIT 48/52/56				Yellow		
2307-99-004	PIN EXTRACTOR				Green		
2236-00-016	PERIPHERAL DRILL GUIDE				Orange		
2230-00-095	QUICK CONNECT PERIPHERAL DRILL BIT				Orange		
2230-00-099	ANTI-ROTATION PEG				Orange		
2230-00-021	ANTI-ROTATION PEG INSERTER/REMOVER				Orange		
8555-06-000	2.5mm X 70mm FIXATION PIN				Orange		
2236-00-018	TRIAL 40				Purple		
2236-00-019	TRIAL 44				Purple		
2236-00-020	TRIAL 48				Purple		
2236-00-021	TRIAL 52				Purple		
2236-00-022	TRIAL 56				Purple		
2236-00-017	GLENOID GRASPER				Purple	Dark Grey	
2236-00-023	BONE GRAFT APPLICATOR					Dark Grey	
3092020	SMARTSET HV 20g					Dark Grey	
5401-39-000	SMARTMIX MINI SYSTEM					Dark Grey	
2236-03-000	UNIVERSAL GLENOID HANDLE					Dark Grey	
2236-21-000	GLENOID IMPACTOR TIP					Dark Grey	
1136-40-026	GLOBAL ANCHOR PEG GLENOID 40mm					Dark Grey	
1136-41-026	GLOBAL ANCHOR PEG GLENOID 44mm					Dark Grey	
1136-42-026	GLOBAL ANCHOR PEG GLENOID 48mm					Dark Grey	
1136-43-026	GLOBAL ANCHOR PEG GLENOID 52mm					Dark Grey	
1136-44-026	GLOBAL ANCHOR PEG GLENOID 56mm					Dark Grey	
2128-99-060	GLOBAL ANCHOR PEG GLENOID DNI					Dark Grey	

INSTRUMENT USAGE DIAGRAM KEY

Sizing and Pin Placement (No Version)	Reaming Challenging Exposure	Trialing
Sizing and Pin Placement (Version)	Drilling Central Peg Hole	Seating the Implant
Fixed Pin Placement and Sizing	Guide Pin Extraction	
Reaming Normal Exposure	Drilling Peripheral Peg Holes	

Important

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

Indications

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

Hemi-shoulder replacement is also indicated for: 1) Ununited humeral head fractures; 2) Avascular necrosis of the humeral head; 3) Rotator cuff tear arthropathy. **GLOBAL® CAP® System is indicated for intact or repairable rotator cuff.** 4) Deformity and/or limited motion.

- **GLOBAL® AP® CTA System heads are indicated for hemi-shoulder replacement only and are to be used with GLOBAL AP Humeral Stems only.**
- **GLOBAL® CAP® CTA System heads are indicated for hemi-shoulder replacement only.**
- **GLOBAL CAP and GLOBAL CAP CTA Systems are intended for cementless use only.**

Porocoat® Porous-Coated Components

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

Cemented Components

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

Press-fit or Cemented Components

Humeral stem prostheses without porous coating and labeled "For Press-fit or Cemented Use Only" are indicated for press-fit uncemented use or for use with bone cement.

Contraindications

The following conditions are contraindications for total shoulder and hemi-shoulder arthroplasty. 1) Active local or systemic infection; 2) Inadequate bone stock in the proximal humerus or glenoid fossa for supporting the components; 3) Poor bone quality, such as osteoporosis, where there could be considerable migration of the prosthesis and/or a chance of fracture of the humerus or glenoid.

The following condition is a contraindication for total shoulder arthroplasty. 1) Absent, irreparable or nonfunctional rotator cuff or other essential muscles.

Warnings and Precautions

The use of a glenoid prosthesis in patients with cuff tear arthropathy could increase the risk of glenoid component loosening due to non anatomic loading conditions. The following conditions tend to adversely affect shoulder replacement implants: excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, disabilities of other joints.

Adverse Events

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



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