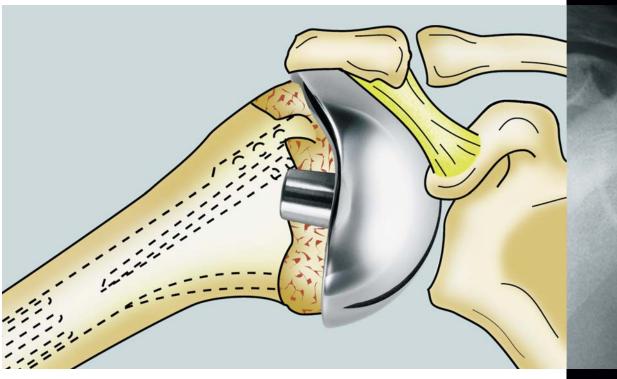
DESIGN RATIONALE AND SURGICAL TECHNIQUE

Global Advantage.

CTA HUMERAL HEAD

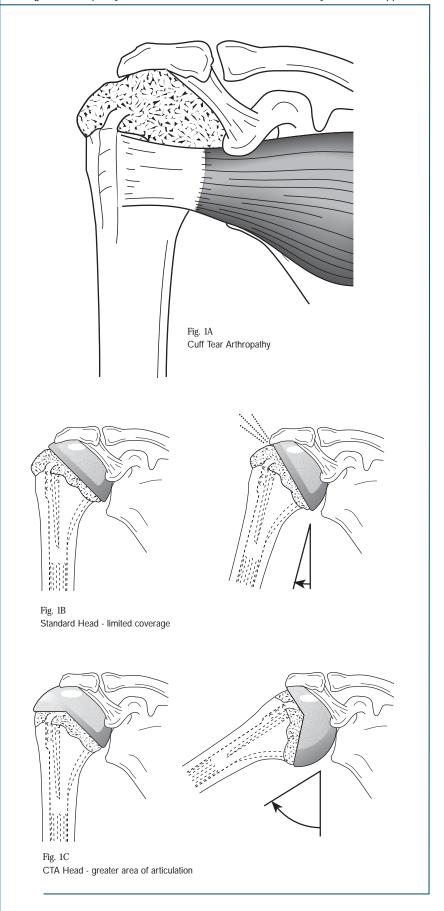




COMBINING SCIENCE,
SIMPLICITY AND
CLINICAL SUCCESS



The DePuy Global Advantage® Cuff Tear Arthropathy (CTA) humeral head prosthesis is indicated for use in patients with a massive, irreparable rotator cuff tear and arthritis (Figure 1A). Unlike other humeral heads, this prosthesis has a larger area of lateral articulation. Since most patients with massive rotator cuff tears have proximal migration of the humerus, the CTA extended head allows a surface with a low coefficient of friction to articulate with the acromion. In comparison to a standard humeral head, the CTA head provides a greater area of articulation in abduction and also in external rotation (Figures 1B & 1C).



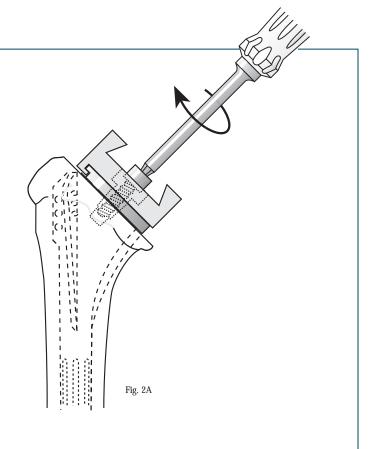
Surgical Technique

Step 1

Begin by performing a resection of the humeral head and humeral canal preparation, as noted in the standard Global Advantage Surgical Technique (Cat. No. 0601-69-050). The surgical technique is available through your local DePuy sales representative. Once the appropriate size humeral broach/trial is inserted into the humerus, perform appropriate sizing of the humeral head using standard trial heads.

It is imperative that the humeral stem not be placed in a varus orientation. This will cause the head to sit too far medially and may result in excessive resection of the greater tuberosity and medial offset of the CTA head relative to the tuberosity. If it appears that the trial stem is in varus, convert to a cemented stem to allow proper seating of the prosthesis.

Upon determining that the rotator cuff tear is irreparable, debride the frayed edges of the remaining cuff and bursa. Do not perform an acromioplasty or release the coracoacromial ligament, since this may compromise postoperative prosthesis stability.



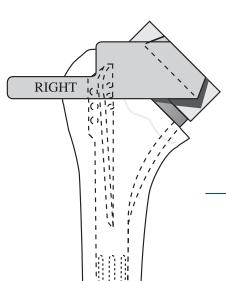
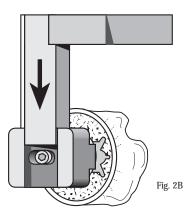


Fig. 2C

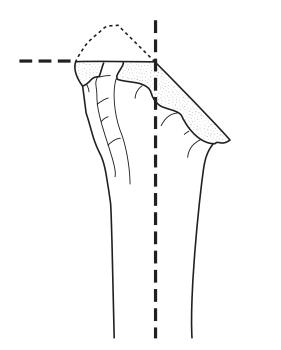


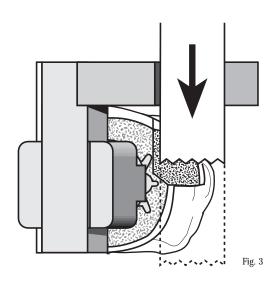
Step 2

With the humeral broach/trial in place and the humerus dislocated, secure the CTA head resection clamp onto the humeral broach/trial and attach the left or right cutting guide (Figures 2A, 2B & 2C).

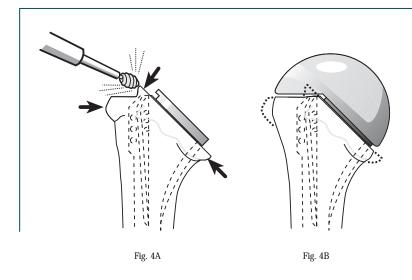
Step3

Using an oscillating saw or osteotome, remove bone from the greater tuberosity. Use caution not to contact the broach with the saw blade or osteotome (Figure 3).





Step4



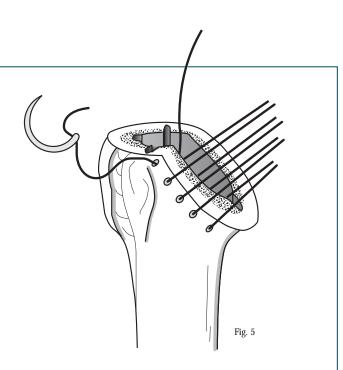
Once the jig has been removed, the transverse cut that was started with the cutting guide needs to be extended medially to the original oblique cut. It is important that no extra bone be left where these two cuts intersect, as this will prevent the head from fully seating into the humeral stem (Figure 4A). Also, remove prominent bone with a rasp or rongeur lateral to the CTA head (Figure 4B). Bony protuberances can affect stem orientation and hinder proper implant seating.

Place an appropriate-sized CTA trial head onto the humeral broach/trial. Reduce, then assess the shoulder and soft tissue balancing as described in the Global Advantage Surgical Technique.

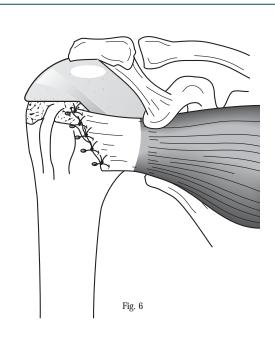
Step 5

Remove the trial humeral head and broach. Pass sutures for the repair of the subscapularis tendon through the metaphyseal bone just distal to the humeral neck cut (Figure 5).

On the back table, impact the final head onto the final body using the delrin-tipped impactor and a one or two-pound mallet. Strike the head three to four times to ensure proper seating. Next, insert the final component assembly into the humerus to the proper seating position.



Step 6



Reduce the shoulder, then repair the subscapularis tendon back to the humerus using the previously placed sutures. In patients with sufficient bone stock, the sutures previously placed in the subscapularis tendon can be placed through drill holes in the lesser tuberosity to reattach the tendon (Figure 6).

Postoperative Care

The postoperative care of the patient is the same as outlined in the Global Advantage Surgical Technique (Cat. No. 0601-69-050).

Global Advantage.

Implant Cat. No.	Description
1128-65-010	Global Advantage CTA Head 44x18
1128-65-020	Global Advantage CTA Head 44x23
1128-65-030	Global Advantage CTA Head 48x18
1128-65-040	Global Advantage CTA Head 48x23
1128-65-050	Global Advantage CTA Head 52x18
1128-65-060	Global Advantage CTA Head 52x23
1128-65-070	Global Advantage CTA Head 56x18
1128-65-080	Global Advantage CTA Head 56x23

Instrument Cat. No.	Description
2128-65-000	Advantage CTA Resection Clamp
2128-65-001	Advantage CTA Resection Guide Right
2128-65-002	Advantage CTA Resection Guide Left
2128-65-010	Global Advantage CTA Head 44x18 Trial
2128-65-020	Global Advantage CTA Head 44x23 Trial
2128-65-030	Global Advantage CTA Head 48x18 Trial
2128-65-040	Global Advantage CTA Head 48x23 Trial
2128-65-050	Global Advantage CTA Head 52x18 Trial
2128-65-060	Global Advantage CTA Head 52x23 Trial
2128-65-070	Global Advantage CTA Head 56x18 Trial
2128-65-080	Global Advantage CTA Head 56x23 Trial
2128-65-090	Global Advantage CTA Base & Lid
2128-65-190	Global Advantage CTA Head Overlay

Global Advantage Cat. No.	Description
Standard stems	
1137-06-000	Global Advantage Stem 6mm
1137-08-000	Global Advantage Stem 8mm
1137-10-000	Global Advantage Stem 10mm
1137-12-000	Global Advantage Stem 12mm
1137-14-000	Global Advantage Stem 14mm
1137-16-000	Global Advantage Stem 16mm
Long stems	
1137-08-010	Global Advantage Stem 8x200mm
1137-10-010	Global Advantage Stem 10x210mm
1137-12-010	Global Advantage Stem 12x220mm
1137-14-010	Global Advantage Stem 14x220mm

Global Fx Cat. No.	Description
Standard stems	
1128-06-000	Global Fx Stem 6mm
1128-08-000	Global Fx Stem 8mm
1128-10-000	Global Fx Stem 10mm
1128-12-000	Global Fx Stem 12mm
Long stems	
1128-06-010	Global Fx Stem 6x160mm
1128-08-010	Global Fx Stem 8x200mm
1128-10-010	Global Fx Stem 10x210mm
1128-12-010	Global Fx Stem 12x220mm



Preoperative patient with Cuff Tear Arthropathy.



Postoperative patient with CTA humeral head and Global Advantage humeral stem.

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 C.A.P.™ is indicated for intact or repairable rotator cuff.
- 4. Deformity and/or limited motion.

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.

Global C.A.P. is intended for cementless use only.

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.
- 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 ioints

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

US Patent 5,665,090.

For more information about the Global Advantage Cuff Tear Arthropathy Humeral Head, visit our web site at www.jnjgateway.com/globaladvantage.



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