DESIGN RATIONALE AND SURGICAL TECHNIQUE





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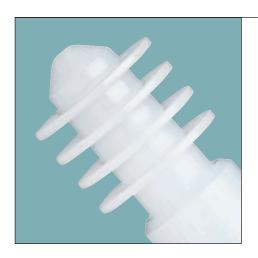
ANCHOR PEG GLENOID

DESIGN RATIONALE

In total shoulder arthroplasty, most cases of clinical and radiographic loosening involve failure of the fixation of the glenoid component. In traditional cemented glenoid components, "Radiolucent lines at the bone cement interface of glenoid stems are common (30 to 96 percent). The appearance or progression of these radiolucent lines may coincide with symptomatic component loosening."

ANCHOR PEG GLENOID PROSTHESIS

DePuy's Anchor Peg Glenoid is an all-polyethylene, minimally cemented, pegged glenoid prosthesis. It features a circumferentially fluted, central, interference-fit peg for tissue integration and three small, cemented peripheral pegs. This glenoid is designed to improve long-term fixation, compared to conventional all-polyethylene keeled and pegged glenoids.





Radiographic, histologic and mechanical tests were performed at three postoperative intervals (zero, three and six months) in a canine model. The central, fluted peg of the Anchor Peg Glenoid achieved bone ingrowth around the peg flanges in all cases (*FIGURE A*). This result was confirmed histologically (*FIGURE B*) and radiographically. Mechanical results indicated that mean fixation strength increases significantly between zero and three months after surgery and remains strong through six months.

Results showed that the anchor peg design improved implant fixation, compared to conventional all-polyethylene, keeled glenoid designs. Also, the central, fluted peg of the Anchor Peg Glenoid was superior to a conventional cemented keel design in achieving tissue integration and fixation in a weight-bearing animal model.²

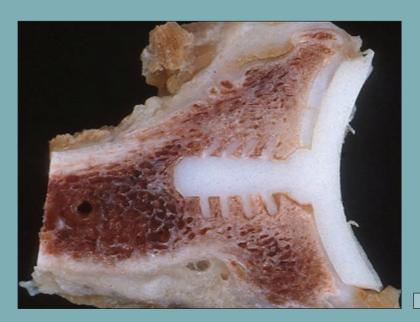


FIGURE A



FIGURE B



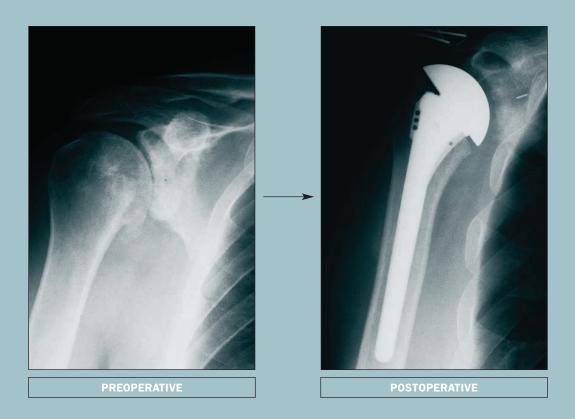
ANCHOR PEG GLENOID

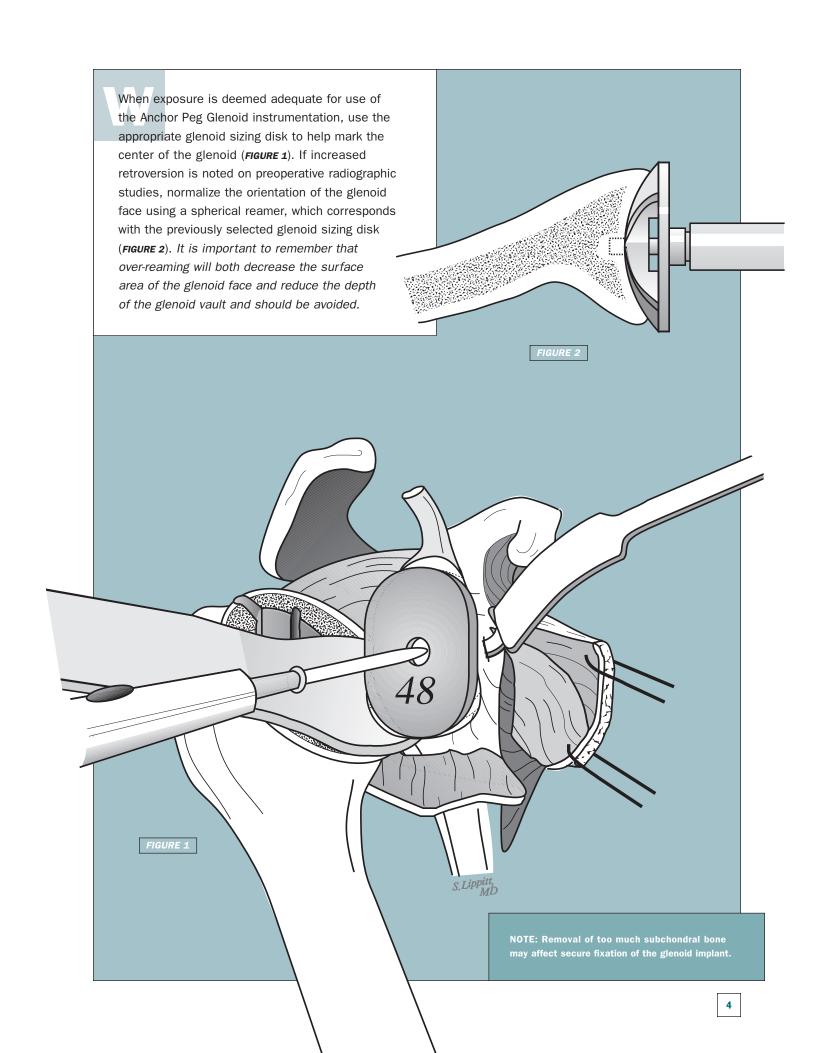
SURGICAL TECHNIOUE

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ANCHOR PEG GLENOID PREPARATION

Perform glenoid exposure and sizing as outlined on pages 16 and 17 of the DePuy Global™ Advantage® Shoulder Arthroplasty System surgical technique (Cat. No. 0601-69-050). Sufficient posterior displacement of the proximal humerus is required to provide necessary exposure for implanting the Anchor Peg Glenoid. This degree of posterior humeral displacement frequently requires a posterior capsule release from the posterior glenoid rim in addition to the anterior and inferior capsular excision. Use a Fukuda-type humeral head retractor (Cat. No. 2245-10-003 or 2245-10-004) to lever against the humeral broach, which is left in place to protect the proximal humerus after broaching is completed. Alternatively, use a bone hook in the Morse taper of the broach to retract the proximal humerus by applying lateral traction to facilitate exposure of the posterior capsule.

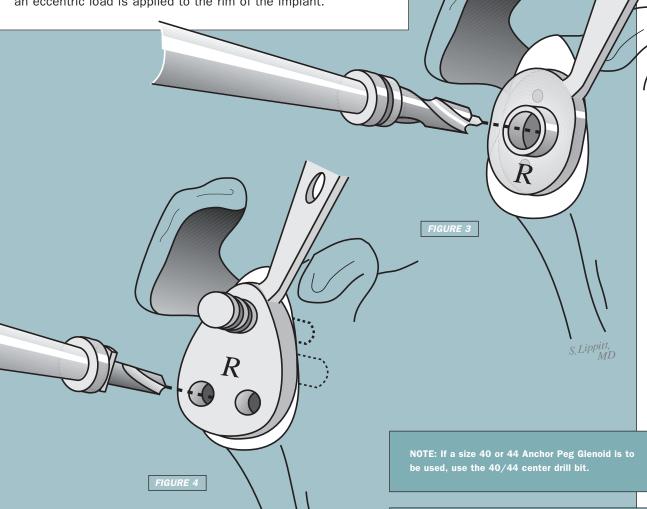




ANCHOR AND PERIPHERAL PEG HOLES

Using the gold central guide and the appropriate size anchor peg center drill bit, align the drill guide hole with the previously created central drill hole that was used to ream the glenoid. Drill the central anchor peg hole (FIGURE 3). Insert the tip of the peripheral drill guide into the anchor peg hole. Use the smaller peripheral drill bit to create the peripheral drill holes.

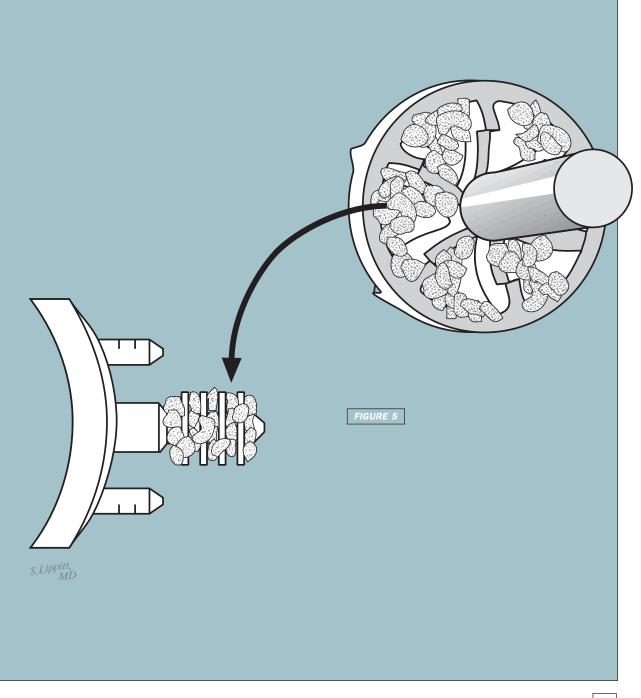
After each peripheral hole is drilled, insert a derotation peg to maintain alignment of the guide while the subsequent holes are completed (FIGURE 4). Check each peripheral hole to determine whether it penetrates the scapula at its base. Penetrating holes are cemented but the cement is not pressurized. 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.



ANCHOR PEG GLENOID PREPARATION

Finely morselized bone retrieved during the glenoid preparation (reaming and drilling) may be used to create a "bone paste."

Interpose the bone paste between the flanges of the central anchor peg to help facilitate tissue integration (FIGURE 5).



ANCHOR PEG GLENOID INSERTION

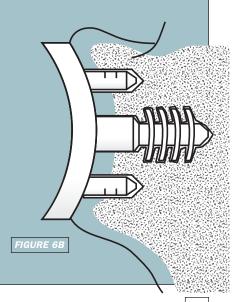
Use pulsatile lavage or another means of thorough irrigation to remove any blood clots from the four drill holes. While cement is being prepared, obtain hemostasis by packing each of the three peripheral holes with thrombin and Surgicel® gauze (Ethicon). Mix cement, using DePuy 1 or 2 cement if packing by hand or DePuy 3 or Endurance® cement if using a syringe. When the cement has reached a "doughy" state and no longer sticks to the surgeon's gloves, remove the Surgicel gauze and pressurize a small amount of cement into each peripheral hole using a fingertip. Only a small amount of cement is necessary in each hole to provide the proper 1 mm cement mantle around each peripheral peg.

FIGURE 6A

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

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Insert the Anchor Peg Glenoid prosthesis and use the glenoid impactor to seat the component until there is complete contact with the perimeter of the glenoid (FIGURES 6A AND 6B). Maintain pressure directly on the glenoid component until the cement has hardened.



NOTE: Cement injected under high pressure by a syringe technique may result in cement extruding from the cancellous walls of the peripheral holes into the central anchor peg hole, which could preclude proper seating of the component.



ANCHOR PEG GLENOID

ORDERING INFORMATION

Instruments	
Cat. No.	Description
2236-80-000	Anchor Peg Glenoid 40 Trial
2236-80-010	Anchor Peg Glenoid 44 Trial
2236-80-020	Anchor Peg Glenoid 48 Trial
2236-80-030	Anchor Peg Glenoid 52 Trial
2236-80-040	Anchor Peg Glenoid 56 Trial
2236-80-050	Anchor Peg Glenoid 56 XL Trial
2236-80-060	Anchor Peg Glenoid Center Drill Guide
2236-80-070	Anchor Peg Glenoid Center Drill Bit 48, 52, 56
2236-80-075	Anchor Peg Glenoid Center Bit 40/44
2236-80-080	Anchor Peg Glenoid Peripheral Guide
2236-80-090	Anchor Peg Glenoid Peripheral Bit
2236-80-091	Anchor Peg Glenoid Anti-rotation Post
2236-80-095	Anchor Peg Glenoid Case
2236-80-098	Anchor Peg Glenoid Overlay

Ancillary Products	
Cat. No.	Description
2245-10-000	Global Shoulder Retractor System
3800-00-000	Global Shoulder Rehabilitation Kit
5220-60-000	Patient Shoulder Modesty Drape
5300-10-000	KamVac® Suction Tube, Mini
5401-30-000	Prism® Vacuum Mixing Bowl, Single
5401-32-000	Prism Vacuum Pump
5401-60-000	UltraMix™ Vacuum Mixing Bowl, Single
5401-64-000	UltraMix Monomer Introducer
5401-65-000	UltraMix Vacuum Pump
5450-31-000	DePuy 1 Bone Cement (40 g)
5450-32-000	DePuy 2 Bone Cement (20 g)
5450-33-000	DePuy 3 Bone Cement (40 g)
5450-49-000	Endurance Bone Cement (20 g)
5450-50-000	Endurance Bone Cement (40 g)
5461-28-000	Cup Currette (10/box)
5461-30-000	Spatula/Ring Currette (10/box)



Global Shoulder Rehabilitation Kit



Essential Product Information

IMPORTANT

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

INDICATIONS

Total shoulder or hemi-shoulder replacement is indicated for:

- A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis
- 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
- 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:

- · Ununited humeral head fractures
- Avascular necrosis of the humeral head
- · Rotator cuff tear arthropathy

POROCOAT® POROUS-COATED COMPONENTS

Porocoat porous-coated humeral stem prostheses are indicated for cemented or cementless use with fixation provided by biological tissue ingrowth 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:

- Active local or systemic infection
- 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

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 nonanatomic loading conditions.

Components labeled "for cemented use only" are to be implanted only with bone cement. 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 and 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.

REFERENCES

1. Wirth, M.A., et al. "Current Concepts Review: Complications of Total Shoulder Replacement Arthroplasty." *The Journal of Bone and Joint Surgery* April 1996: 603-616.
2. Wirth, M.A., et al. "Radiologic, mechanical, and histologic evaluation of 2 glenoid prosthesis designs in a canine model." *Journal of Shoulder and Elbow Surgery* March/April 2001: 140-148.

The Anchor Peg Glenoid is intended for cemented use only.

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

Consult the package insert for complete product information.

For more information about the Anchor Peg Glenoid, visit our web site at www.jnjgateway.com.

Contact your local DePuy sales representative for additional information about DePuy shoulder products, including the Global Total Shoulder System, Global Advantage Shoulder Arthroplasty System, Global Fx Shoulder Fracture System and Global Rehabilitation Kit. DePuy also offers an entire range of implants for both upper and lower extremity joint replacement, and a complete line of bone cement products.



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