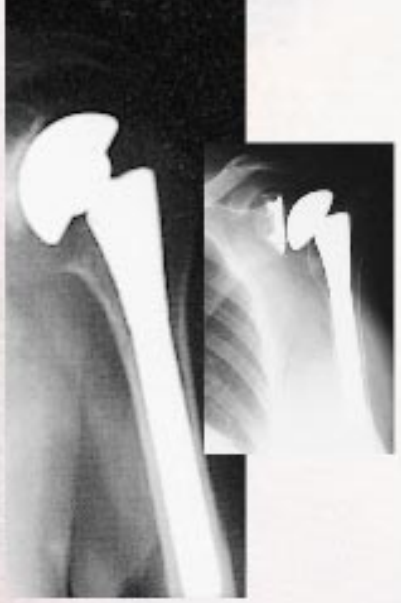


Bi-Angular BI-POLAR SHOULDER SYSTEM

FOR HEMI BI-POLAR AND
TOTAL SHOULDER ARTHROPLASTY

BIOMET INC®

Anterior, posterior and lateral holes permit suture placement for reconstruction of complex proximal humeral fractures

Proximal fins maximize rotational stability

Medial hole allows accurate version control during placement of the stem

Proximal plasma spray porous coating enhances immediate fixation

Secure RingLoc® polyethylene locking ring design

Distal cylindrical stem with smooth blast finish to better fill the humeral canal

The Bi-Polar humeral head is marketed for use in primary cases of noninflammatory degenerative joint disease, rheumatoid arthritis, correction of severe functional deformity and fracture. The device is intended for use with a humeral stem inserted with bone cement. (USA)

Bi-Polar Design Stability[1]

- Axial separation strength of over 170 lbs
- Cantilever separation strength of over 45 in-lbs[1]

Bi-Polar cobalt chrome shells are available in 40, 44, 48 and 52mm diameters

22.2mm Bi-Polar heads are available in Std., +2mm and +4mm neck lengths

Bi-Angular Bi-Polar System Features

- Multiple component combinations for optimal patient sizing
- Primary and revision length porous titanium stems
- Non-porous cobalt chrome stems
- Variety of Bi-Polar shell diameters and neck lengths
- Standard heads and glenoids for total shoulder replacement

WARNING: Porous coated components depicted in this brochure are marketed for use with bone cement in the United States.

This system has been developed in cooperation with Richard L. Worland, M.D., Medical Director, The Joint Replacement Center, Advanced Orthopaedic Centers, Richmond, Virginia.

[1]Data on file at Biomet, Inc.

Bi-Polar Features & Benefits

- Concentric contact with shoulder cavity, both subacromial and glenoid
- Potentially less glenoid-acromial wear due to bi-rotational head/shell motion
- Enhanced tensioning of deltoid lever arm in rotator cuff deficient shoulders

Bi-Polar Indications

- Rotator cuff arthropathy
- Rheumatoid arthritis
- Four-part fractures in young patients
- Deficient glenoid bone stock
- Revision arthroplasty
- Avascular necrosis
- Some osteoarthritis

Bi-Angular® Features & Benefits

STEMS

- Lateral offset facilitates tensioning of deltoid in rotator cuff deficient cases
- Rasps and broaches not required
- Tapered stems ensure accurate fit in humeral bone
- Cylindrical distal stems to better fill the humeral canal

Bi-Angular® Features & Benefits

GLENOIDS

- All polyethylene or metal backed design options
- Metal backed glenoid has porous coated pegs for enhanced fixation
- Glenoid instruments and implants are designed for a more anterior approach, allowing easier exposure and implantation

HEADS

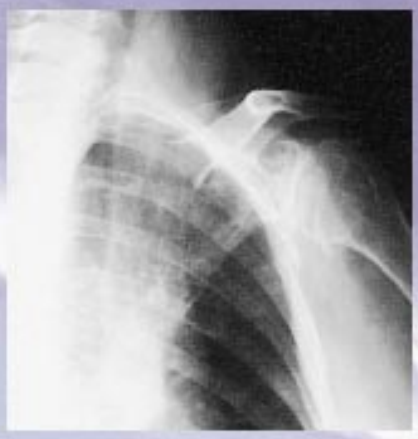
- Cobalt chrome heads provide excellent wear characteristics
- Three neck lengths optimize tissue tensioning

ADVANTAGES OF NON-COLLARED STEMS

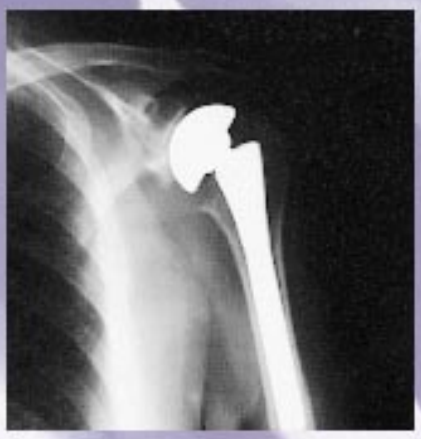
- Initial neck resection not critical
- No Bi-Polar shell impingement
- Ease of revision (stem removal)
- No subsidence reported in up to nine years follow-up on the Bi-Angular stem[2]

[2]Data on file at Biomet, Inc.

Bi-Polar Hemi Shoulder Replacement

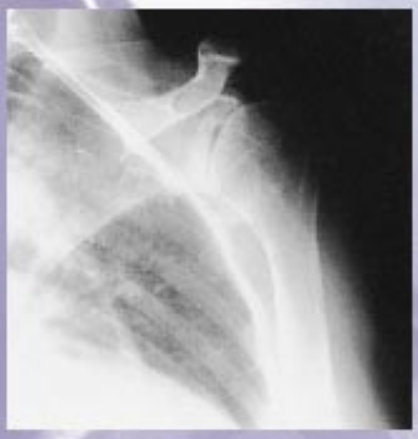


PREOPERATIVE
The patient is a 79-year-old female with a 12-year history of bilateral shoulder pain. She was unresponsive to injections and anti-inflammatory medications. The preoperative Swanson Shoulder Score was 13.2/30. Her forward flexion was 40° and external rotation was 0°.

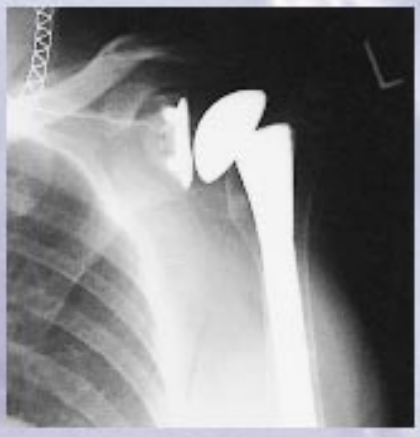


POSTOPERATIVE
A Bi-Polar Head with an 11mm Bi-Angular stem and 40mm shell was used. Six weeks postoperative, her shoulder score had improved to 30/30 with 150° of forward flexion and 30° of external rotation.

Bi-Angular Total Shoulder Replacement



PREOPERATIVE
The patient is a 68-year-old female with osteoarthritis. Forward flexion was 85˚, with a 10˚ internal rotation contracture resulting in -10˚ of external rotation. Internal rotation was present to the left hip pocket.



POSTOPERATIVE
Four years postoperative the patient has 150˚ of forward elevation, 85˚ external rotation, abduction to 120˚ and internal rotation to L4. The patient has no sign of glenoid loosening.

Surgical Technique

PREFACE

Shoulder joint replacement is widely performed and the expected results can be compared to hip and knee joint replacement. The operation can be difficult and should be performed by skilled shoulder surgeons who have considerable experience in total joint arthroplasty. Glenoid replacement has and continues to be the most problematic area in glenohumeral replacement. To address this concern, the Bi-Angular/Bi-Polar Shoulder was developed, making shoulder arthroplasty a relatively easy procedure to accomplish with potentially few complications and predictable patient outcomes. Patient selection is important since postoperative therapy is critical, and the surgeon, therapist and patient must work closely together to ensure a good result.

The humeral component should always be cemented especially if the prosthesis is used for a four-part fracture in elderly patients. Standard canal preparation should be performed, and the cement inserted with a gun. However, firm pressurization must be avoided to prevent cement from being forced out the nutrient foramina. Care should be taken not to allow the cement to pass too distal should the possibility of future total elbow arthroplasty exist. To ensure successful hemi-replacement for proximal humeral fractures, it is crucial that the tuberosities be sutured to each other and to the humeral shaft. The humeral fins provide rotational control and are perforated to allow passage of sutures for tuberosity reattachment. Non-absorbable sutures should be passed through drill holes in the humeral shaft prior to placement of the cement and prosthesis.

The Bi-Angular/Bi-Polar Shoulder System offers the advantage of easy and accurate component implantation. Six primary titanium stem sizes and three revision titanium stems, coupled with three neck lengths and four Bi-Polar shell diameters, permit a wide range of modularity to achieve accurate soft tissue tensioning. The bi-rotational head enhances implant stability and provides good fill of the entire shoulder space, both glenoid and subacromial.

The humeral stem design provides complete canal fill, and a medial through-hole accommodates a guide pin to permit accurate version control during stem placement. Proximal plasma spray porous coating on the titanium humeral components provides enhanced component fixation. Three nonporous cobalt chrome stem sizes are also available. Should glenoid replacement be elected, all polyethylene and metal-backed porous coated glenoid implants are available.

The modular design of the Bi-Angular/Bi-Polar Shoulder minimizes implant inventory and allows for a better anatomic fit. The stem is easily and accurately inserted after humeral canal preparation. This system does not require rasps to finalize the version of the humeral component. Concerns with glenoid loosening, screws, glenoid preparation and insertion, and glenoid fixation are avoided when the Bi-Polar head is used.

The surgical technique will vary somewhat depending on the individual clinical situation. The following technique description is intended solely as a general guide for shoulder joint replacement with the Bi-Angular/Bi-Polar Shoulder System.

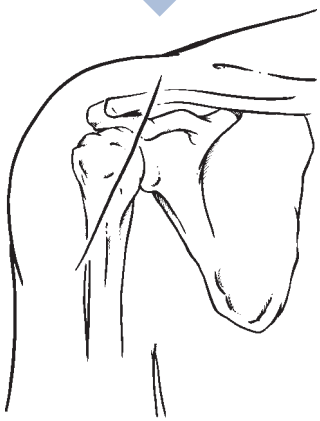
NOTE: This brochure describes the surgical technique used by Richard L. Worland, M.D. Biomet, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the prosthesis in each individual patient. Biomet is not responsible for selection of the appropriate surgical technique to be used for an individual patient.

Step 1

PATIENT PREPARATION

Administer general endotracheal or interscalene block anesthesia. Place the patient in the modified beach-chair position, lateralized on the table with a padded arm board to secure the patient's head. Use a folded towel to support the ipsilateral scapula. A shoulder chair is an excellent alternative, allowing good access about the shoulder should a posterior incision be required. The arm should be draped free.

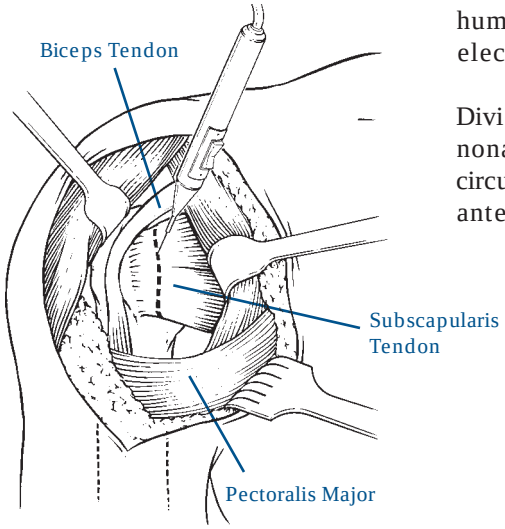
Step 2



SURGICAL APPROACH

Make the skin incision from the distal third of the clavicle, directed over the coracoid and ending over the deltoid insertion on the humerus. Bluntly develop the deltopectoral interval, sparing the cephalic vein. Retract the deltoid laterally with the cephalic vein without detaching any of its fibers proximally or distally, and divide the fascia longitudinally lateral to the coracoid.

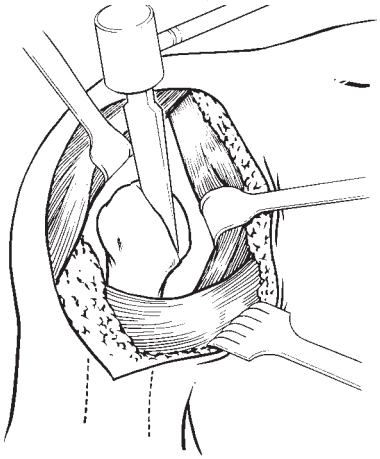
Step 3



Taking care to protect the musculocutaneous nerve, retract the short head of the biceps and coracobrachialis medially with a blunt retractor and place the arm into external rotation. To facilitate mobilization of the humerus, divide the upper portion of the pectoralis major insertion by electrocautery and identify the biceps tendon and subscapularis.

Divide the subscapularis 1cm medial to its insertion and tag it with a nonabsorbable suture for later repair. Cauterize the anterior humeral circumflex vessels and dissect the subscapularis back medial to the anterior glenoid rim.

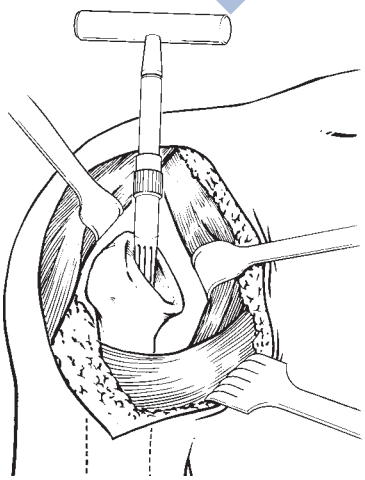
Step 4



HUMERAL OSTEOTOMY

Divide the capsule superiorly, being careful not to divide the long head of the biceps. Place the arm into further external rotation and position a Joker or Hohmann-type retractor below the capsule to protect the axillary nerve. Incise the anterior and inferior capsule from the six to the twelve o'clock position. Continue humeral external rotation and extension to dislocate the humeral head anteriorly so that osteophytes can be removed. Use a broad osteotome to remove the desired amount of humeral head, including all the articular surface, taking care not to damage the rotator cuff. Final trimming of the proximal humerus may be performed with a rongeur after the humeral stem is seated in the humeral canal. Provided the Bi-Polar shell does not impinge on the resected humeral bone, the exact angle of the neck cut is not critical.

Step 5



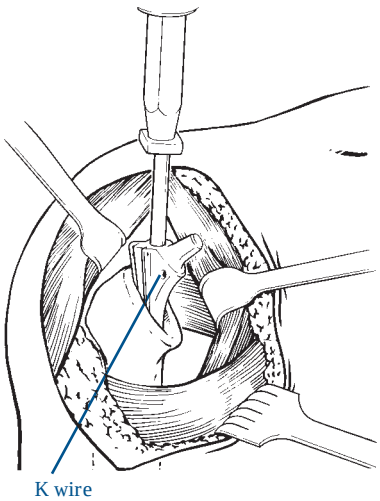
HUMERAL SELECTION AND IMPLANTATION

Identify the medullary canal with a small curette. Ream by hand, starting with the 6.5mm reamer and continuing sequentially until resistance from cortical bone is encountered (cortical chatter). Six diameters are available to appropriately match the individual patient anatomy.

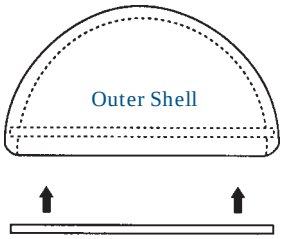
Attach the humeral inserter handle to the selected humeral stem. Carefully drive the component down into the humeral canal. Next, place a 7/64" K-wire into the version hole in the stem to determine the retroversion of the humeral component, referencing off the patient's forearm (usually 30-35˚).

If the stem is too tight, extract the prosthesis and use a curette to enlarge the proximal portion of the humerus. Then drive the prosthesis into place under direct vision, watching the three fins of the humeral component as they cut into the soft bone of the proximal humerus. A stem one size smaller than the last reamer should be chosen to allow room for an adequate cement mantle. Once the prosthesis is properly seated, remove the humeral inserter and trim the proximal humerus with a small rongeur.

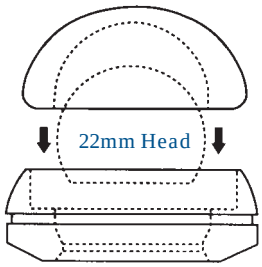
For Bi-Polar hemi arthroplasty, continue to Step 6.
For total shoulder arthroplasty, go to Step 7.



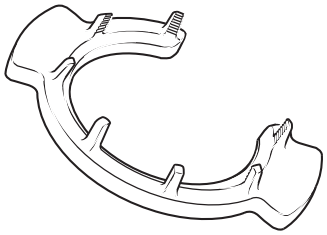
Step 6



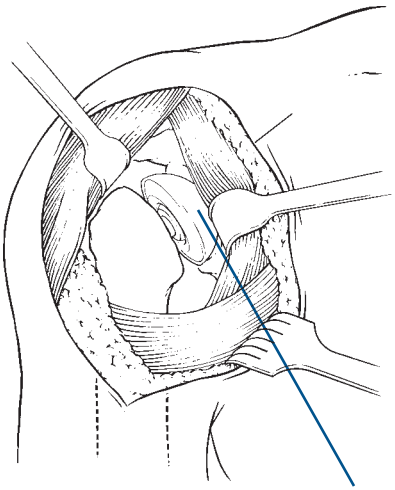
Metal Ring



Polyethylene Locking Ring



Bi-Polar Removal Tool



Bi-Polar Head

BI-POLAR HEMI ARTHROPLASTY

Position the trial head and shell components on the stem to determine the proper neck length and shell size. The top of the head must project above the greater tuberosity to prevent tuberosity-acromial impingement. Adequate soft tissue tension must also be restored. However, the component should not set too proud or range of motion may be decreased, resulting in less than optimal contact between the Bi-Polar shell and the true glenoid.

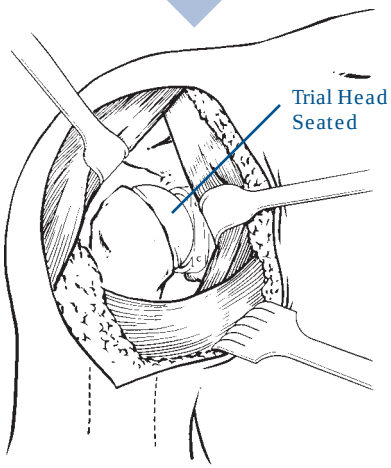
BI-POLAR HEAD ASSEMBLY:

1. Insert the metal locking ring into the groove in the Bi-Polar shell. (This is usually pre-assembled.)
2. Place the polyethylene locking ring over the stem trunion and impact the 22.2mm head.
3. Place the outer shell with polyethylene liner over the 22.2mm head.
4. Snap the polyethylene locking ring into the Bi-Polar shell.
5. Should the prosthesis ever need to be removed, use the locking ring removal tool to disassemble the Bi-Polar components, and the removal ramp to disengage the modular head. Then attach the slap-hammer extractor to the humeral stem to remove it.

Reattach the subscapularis with non-absorbable sutures. Then externally rotate the arm to see at what degree of external rotation the suture line comes under tension. This will be the maximum amount of external rotation permitted during the first six weeks following surgery.

Close in a routine manner and apply a sling at the conclusion of the procedure.

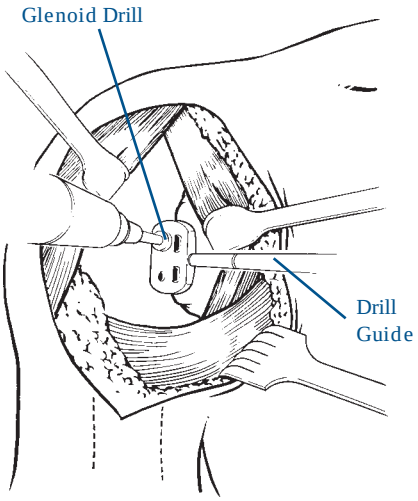
Step 7



TOTAL SHOULDER ARTHROPLASTY

Position the trial modular head components on the stem to determine the proper head height. The top of the head must project above the greater tuberosity to prevent tuberosity-acromial impingement. Adequate soft tissue tension must also be restored. Seat the selected trial head on the Morse taper of the humeral stem and reduce the shoulder. Once the correct head size has been chosen, dislocate the shoulder and remove the trial head.

Step 8



GLENOID PREPARATION

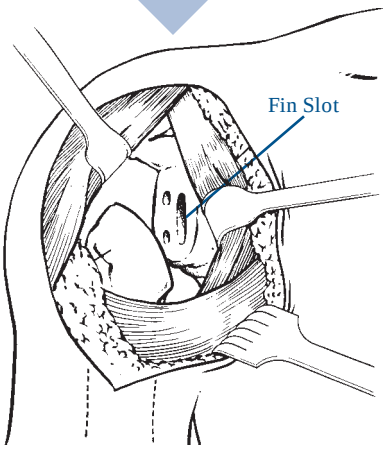
Abduct the arm to relax the deltoid, then retract the humerus posteriorly with a Fukuda-type retractor placed behind the glenoid. Further capsular release may be required. Inspect the glenoid to determine whether it needs resurfacing. Glenoid resurfacing may be indicated in osteoarthritic patients with good bone stock and a functioning rotator cuff.

Replacement of the glenoid is carried out by first excising the glenoid labrum and then debriding the surface of any cartilage and soft tissue remnants. Position the glenoid drill template with its keel resting on the anterior glenoid rim. Should exposure still be difficult, a portion of the conjoint tendon and coracoacromial ligament may be released.

If the all polyethylene glenoid is selected, simply develop the slot for the polyethylene fin.

If the metal backed glenoid is chosen, use the glenoid drill with depth stop to make pilot holes for the two posterior glenoid pegs. Leave the first glenoid drill bit with depth stop in the bone for stability while the second hole is being drilled. Then create a slot for the polyethylene fin.

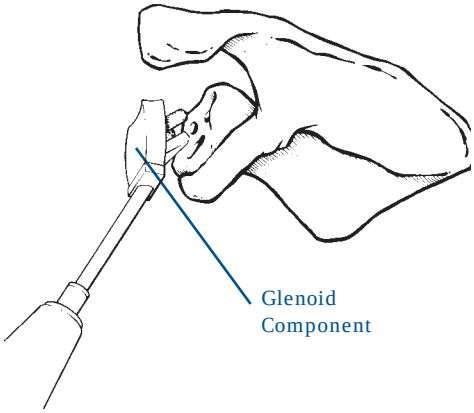
Step 9



Remove the drill guide and develop the fin slot with a burr and small curette. Use the glenoid broach to ensure that the trial glenoid can be fully seated. Take care not to penetrate the glenoid posteriorly. If the glenoid does not seat fully, the polyethylene fin of the actual glenoid component can be trimmed with bone scissors to allow full glenoid seating. (Avoid cutting the X-ray wire on the all polyethylene glenoid when trimming the component.)

Use a small drill bit to perforate the subchondral cortical bone of the glenoid surface in several places to permit additional cement fixation. Thoroughly cleanse the bone with pulsatile lavage and then dry it prior to applying the cement.

Step10



GLENOID PLACEMENT

Place a small amount of cement in the slot for the fin of the glenoid component. Fit the inserter into the glenoid component and place it into position. Remove all excess cement. Using firm pressure, impact the component into place and hold it until the cement has polymerized.

Step11

HUMERAL HEAD PLACEMENT

Seat the selected modular head component on the Morse taper of the humeral stem with multiple light hammer strikes, and then reduce the shoulder. Should the humeral component ever need to be extracted, remove the head from the humeral stem with the removal ramp, and attach the slap-hammer extractor to the humeral stem to remove it.

Step12

CLOSURE

Close in a routine manner using non-absorbable sutures to repair the subscapularis. Should lengthening of the tendon be necessary, sew the subscapularis back to the humerus through drill holes at the osteotomy site of the head fragment. Close the subcutaneous tissues with absorbable sutures, then close the skin with staples. It is not necessary to use a drain. Apply a sling at the conclusion of the procedure.

Post-op Care

Postoperative care is as important as correct implant placement. The surgeon, therapist and patient must work closely together on the rehabilitation program as defined by the surgeon based on the intraoperative range of motion achieved.

Permit the patient free swing of the arm out of the sling the first postoperative day, depending on discomfort. On the second day, passive and active assisted external rotation and forward flexion exercises should be initiated. Begin pulley exercises on the third day. Keep the patient in the hospital until at least 120˚ of active-assisted forward elevation has been attained. This usually requires a total of three or four days in the hospital. Continue exercises on an out-patient basis, usually at home, until recovery is complete.

It is first necessary to achieve range of motion, and later strength can be increased with purposeful use of the arm. Provide rubber tubing and a pulley to the patient upon discharge from the hospital, and instruct the patient to perform exercise sessions five times each day. A moist warm towel applied to the shoulder prior to exercise sessions will help relax the muscles and encourage circulation. Follow the patient's progress closely to see whether further professional physical therapy is indicated. The ultimate goal for shoulder joint replacement is near normal shoulder function.

Should a prosthesis be used to treat a proximal fracture, initiate passive exercises early if tuberosity fixation is secure. However, the patient should use a sling for six weeks or as long as it takes for tuberosity union to occur. At that point, initiate active-assisted exercises as described above.

Bi-Angular/Bi-Polar Shoulder System Ordering Information

IMPLANTS

Titanium Humeral Stems (Porous Coated)	
Part No.	Dia./Length (mm)
114065	6.5 x 115
114068	8.0 x 115
114066	9.5 x 115
114069	11.0 x 115
114067	12.5 x 115
114070	14.0 x 115

Titanium Revision Humeral Stems (Porous Coated)	
Part No.	Dia./Length (mm)
114071	8.0 x 205
114072	9.5 x 205
114073	11.0 x 205

CoCr Humeral Stems (Nonporous)	
Part No.	Dia./Length (mm)
114090	6.5 x 115
114092	9.5 x 115
114094	12.5 x 115

Humeral Heads	
Part No.	Dia./Neck Length (mm)
114022	15 x 40
114052	15 x 44
114053	19 x 44
114054	23 x 44
114024	19 x 48
114026	23 x 52

Part No.	Glenoids
114060	Standard Metal Backed
114061	Standard All Polyethylene

Bi-Polar Shell Components	
Part No.*	O.D./I.D. (mm)
113130	40 x 22.2
113131	44 x 22.2
113132	48 x 22.2
113133	52 x 22.2

*(Includes metal locking ring, poly liner, poly ring, and metal shell)

Bi-Angular®/Bi-Polar Modular Heads (Standard Morse Taper)	
Part No.	Dia./Neck Length (mm)
113101	22.2 / Standard
113141	22.2 / + 2
113142	22.2 / + 4

Bio-Modular®/Bi-Polar Modular Heads (Reverse Morse Taper)	
Part No.	Dia./Neck Length (mm)
113143	22.2 / Standard
113144	22.2 / + 2
113145	22.2 / + 4

INSTRUMENTATION

Humeral Stem Trials

	Dia./Length (mm)
414443	6.5 x 115
414446	8.0 x 115
414444	9.5 x 115
414448	11.0 x 115
414445	12.5 x 115
414450	14.0 x 115

Humeral Head Trials

	Neck Length/Dia. (mm)
414422	15 x 40
414415	15 x 44
414419	19 x 44
414423	23 x 44
414424	19 x 48
414426	23 x 52

Glenoid Trials

414430	Std. Metal Backed
414436	Std. All Polyethylene

Bi-Polar Shell Trials

	O.D./I.D. (mm)
408400	40 x 22.2
408402	44 x 22.2
408404	48 x 22.2
408406	52 x 22.2

Bi-Angular/Bi-Polar Modular Head Trials

	Dia./Neck Length (mm)
408408	22.2 / Standard
408410	22.2 / + 2
408412	22.2 / + 4

Bio-Modular/Bi-Polar Modular Head Trials

	Dia./Neck Length (mm)
408418	22.2 / Standard
408420	22.2 / + 2
408422	22.2 / + 4

Humeral Reamers

	Dia. (mm)
414437	6.5
414440	8.0
414438	9.5
414441	11.0
414439	12.5
414442	14.0

Bi-Polar Locking Ring Removal Tools

	Dia. (mm)
408435	40
408436	44
408437	48
408438	52

Other Humeral Instruments

31-473620	Tapered Reamer T-Handle
31-473600	Hammer Plate with Screw
31-473601	Humeral Trial Inserter/Extractor
31-473621	Slide Hammer
406514	Humeral Head Driver
408432	Humeral Head Removal Ramp
414447	Bi-Angular Shoulder X-Ray Templates
414449	Bi-Angular/Bi-Polar Shell Templates
406490	Bio-Modular/Bi-Polar Shell Templates

Glenoid Instruments

414429	Rasp
414433	Drill Guide
414434	Drill with Stop
414431	Inserter
414432	Pusher

P.O. Box 587 • Warsaw, Indiana 46581-0587 •219.267.6639
web site http://www.biomet.com • eMail: biomet@biomet.com
Form No. Y-BMT-500R/063097/M