Bi-Angular®

bi-polar

SHOULDER SYSTEM

Surgical Technique

BIOMET

ORTHOPEDICS, INC.

Bi-Angular® Hemi and Total Shoulder Arthroplasty

- Proximal fins maximize rotational stability
- Anterior, posterior, and lateral fin holes allow for suture placement when reconstructing complex proximal humeral fractures.
- Proximal titanium alloy plasma sprayed porous coating enhances immediate fixation.
- Distal cylindrical stem to better fill the humeral canal.
- A 7/64" K-wire placed through the medial stem hole allows for version control during stem insertion.

Features & Benefits

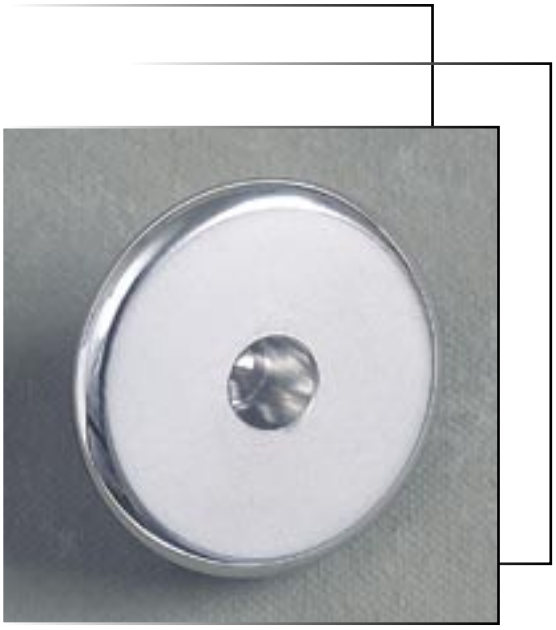
- Multiple sizing combinations for optimal patient fit
- Primary and revision length porous-coated titanium alloy stems
- Primary length cobalt chrome alloy stems
- Standard heads and glenoids for total shoulder replacement
- Ream and trial system
- One instrument tray

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

[1] Data on file at Biomet, Inc.
[2] Data on file at Biomet, Inc.

Stems

- Porous-coated humeral stem FDA cleared for press-fit and cemented applications
- Proximal flare ensures accurate fit in humeral bone
- Non-collared stems:
  - Initial neck resection angle not critical
  - Ease of revision (stem removal)
  - No subsidence reported in up to fifteen years follow-up on the Bi-Angular® stem[2]
- Titanium-Porous Coated
- Cobalt Chrome Avaliable



Standard Heads

- Heads made from cobalt chrome alloy provide excellent wear characteristics
- Four neck lengths optimize tissue tensioning

Indications

- Rheumatoid arthritis
- Some four-part fractures and some three part fractures
- Deficient glenoid bone stock
- Revision arthroplasty
- Avascular necrosis
- Most osteoarthritis
- Cuff tear arthropathy

Absolute® Bi-Polar Head

The Bi-Polar humeral head is designed for use in primary cases of non-inflammatory degenerative joint disease, rheumatoid arthritis, correction of severe functional deformity and fracture. The device is intended for use with a humeral stem.

The modular design of the Bi-Angular® 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. This helps to avoid iatrogenic humeral fractures. *Concerns with glenoid loosening, screws, glenoid preparation and insertion, and glenoid fixation are avoided when the Bi-Polar head is used.*

The Bi-Angular® Shoulder System offers the advantage of easy and accurate component implantation. Six primary titanium stem sizes, three Cobalt Chrome stem sizes, and three revision titanium stem sizes, coupled with *three neck lengths and six 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 in cases of cuff arthropathy.

Absolute® Bi-Polar Head

Indications

- Rotator cuff arthropathy
- Rheumatoid arthritis
- Four-part fractures
- Deficient glenoid bone stock
- Revision arthroplasty
- Avascular necrosis
- Most osteoarthritis

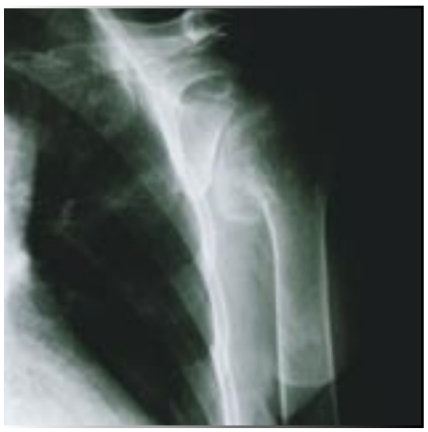
Features and Benefits

- 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

Design Mechanics

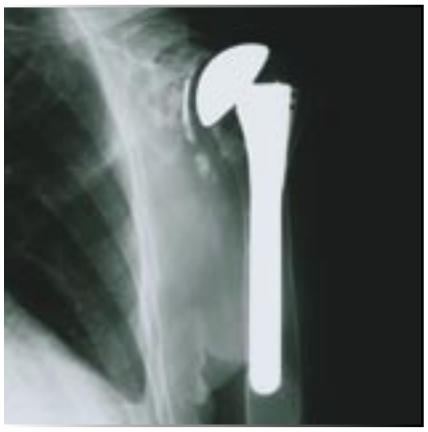
- Thick locking ring design to provide axial separation strength
- Thick locking ring design to provide cantilever separation strength
- Cobalt chrome alloy shells: 40, 44, 48, 52, 56 and 60mm diameters
- 22.2mm inner heads: Std., +2mm and +4mm neck lengths

Bi-Angular® Total Shoulder Replacement



Preoperative

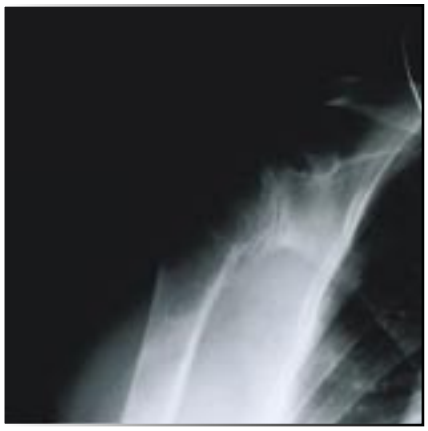
The patient is a 76 year old female with severe bilateral glenohumeral osteoarthritis and marked pain. Range of motion was severely restricted.



Postoperative

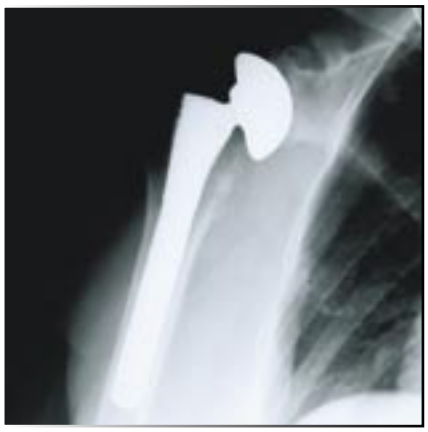
There was no pain postoperatively and function was excellent with improved forward flexion to 120˚ and external rotation to 40˚.

Bi-Polar Hemi Shoulder Replacement



Preoperative

The patient is a 65 year old female with left glenohumeral osteoarthritis unresponsive to conservative measures. Forward flexion was 95˚ and external rotation 10˚. Pain was severe.



Postoperative

Pain was completely gone postoperatively with forward flexion of 170˚ and external rotation measuring 45˚. Function was normal.

Surgical Technique

Preface

Shoulder joint replacement, a widely performed surgery, has expected results that can be compared to hip and knee joint replacement. Glenoid replacement has, and continues to be, the most problematic area in shoulder replacement. To address this concern, the Bi-Angular®/Bi-Polar Shoulder System was developed, making shoulder arthroplasty a relatively easy procedure to accomplish with potentially fewer complications and more consistent patient outcomes. Patient selection is important since postoperative therapy is critical. The surgeon, therapist and patient must work closely together for optimal results.

To successfully repair fractures, it is crucial that the tuberosities be sutured to each other and to the humeral shaft. The humeral fins provide rotational control and the suture holes allow for tuberosity reattachment. Non-absorable sutures should be passed through drill holes in the humeral shaft prior to placement of cement and the prosthesis.

Proximal titanium alloy plasma-sprayed porous coating on the titanim alloy humeral components provides enhanced component fixation. An all-polyethylene glenoid implant is available to resurface the glenoid.

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

This brochure describes the surgical technique used by Richard L. Worland, M.D. Biomet, as the maunufacturer 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 reponsible for determining and using the appropriate surgical technique to be used for an individual patient.

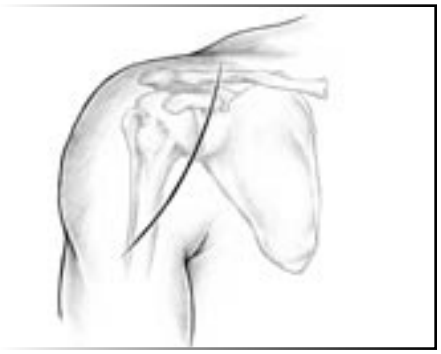
Surgical Technique

Step 1 Patient Preparation

Administer general endotracheal or interscalene block anesthesia. Place the patient in the modified beachchair position, lateralized on the table with a padded foam 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 to the shoulder should a posterior incision be required. The arm should be draped free.

Step 2 Surgical Approach

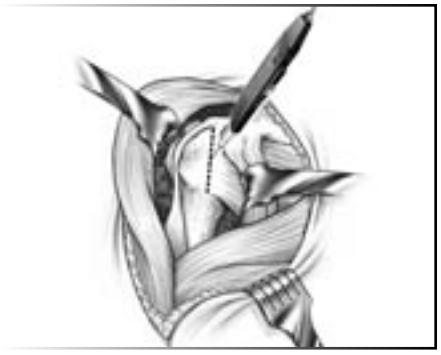
Make the skin incision from the AC joint or distal third of the clavicle, directed over the coracoid and ending over the deltoid insertion on the humerus. Bluntly develop the deltopectoral interval, sparing the cephalic vein. Retract the deltoid laterally along with the cephalic vein without detaching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



Step 3 Surgical Approach

Take 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 vessles 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 the humeral head, including all of the articular surface, at the humeral anatomic neck 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.

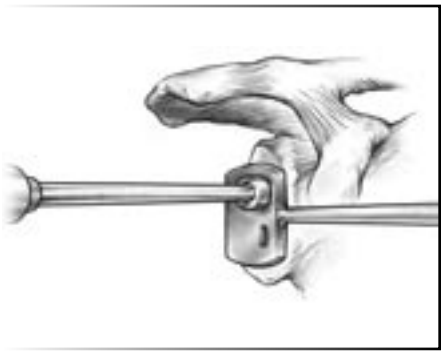
Step 5 Humeral Selection and Implantation

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). Seven diameters of humeral stems are available to appropriately match the individual patient anatomy.

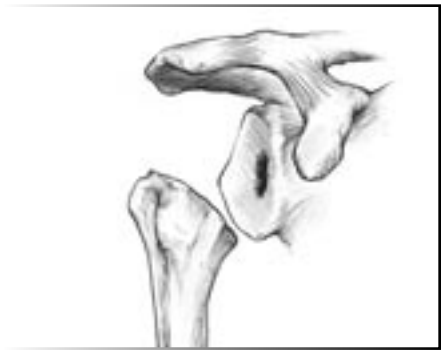
Attach the humeral inserter handle to the selected humeral stem. Next, place the 7/64" K-wire into the version hole in the stem to determine the retroversion of the humeral component, referencing off the patient's forearm (usually 25°–30°). Carefully drive the component down into the humeral canal.

If the stem is too tight, extract the prosthesis and use a curette to enlarge the proximal portion of the humerus. 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. **If using cement, a stem one size smaller than the last reamer used should be chosen to allow room for an adequate cement mantle.**

Step 6 Total Shoulder Arthroplasty



Position the trial modular head component 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. Once the correct head size has been chosen, dislocate the shoulder to remove the trial head.



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 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.

Drill through anterior slots of guide to approximate fin location.

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 glenoid component may 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).

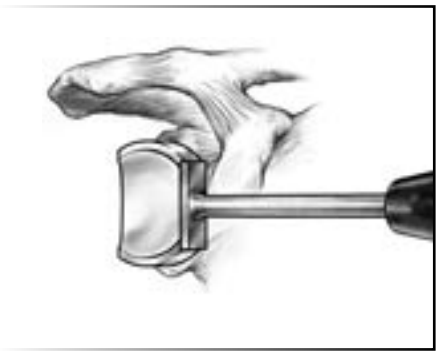
Use a small drill bit to perforate the subchondral cortical bone of the glenoid surface in several places to permit additional cement fixation. Throroughly cleanse the bone with pulsatile lavage and then dry it prior to applying the cement.

Step 7 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. The angled keeled glenoid uses Bi-Angular® instrumentation. The straight keeled glenoid can be implanted with the Bio-Modular® instrumentation. All Bio-Modular® glenoids are compatible with all Bi-Angular® heads. See Bio-Modular® Choice Technique Y-BMT-827.

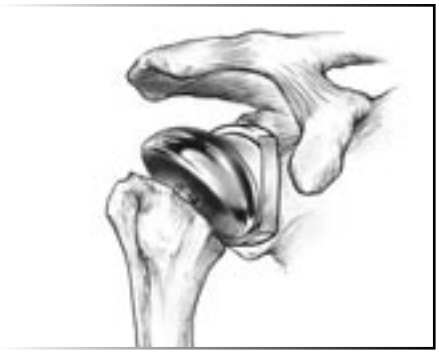
Step 8 Humeral Head Placement

Thoroughly clean and dry the Morse taper. Seat the selected modular head component on the Morse taper of the humeral stem with multiple 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.



Step 9 Closure

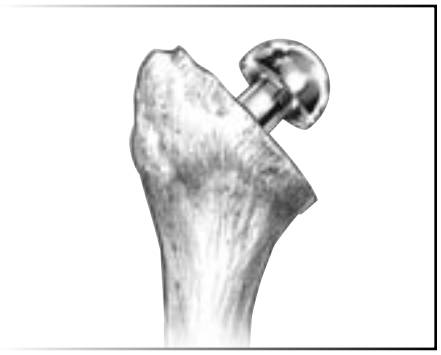
Close in a routine manner using non-absorbable sutures to repair the subscapularis. Should lengthening of the tendon be necessary, suture the subscapularis back to the humerus through drill holes at the osteotomy site of the head fragment. Close the subcutaneous tissues with absorbable sutures, then close the skin with staples. It is not necessary to use a drain. Apply a sling at the conclusion of the procedure. In most cases a 360˚ release of the subscapularis will allow suturing to the remnant of the subscapularis permitting the desired lengthening with a strong repair using non-absorbable suture.



Absolute® Bi-Polar Surgical Technique

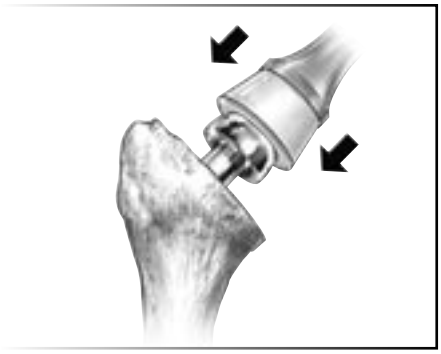
Step 1

Thoroughly clean and dry the Morse taper. This is important because any foreign materials will impede the establishment of a "cold weld" between the humeral component and the cobalt chrome inner head.



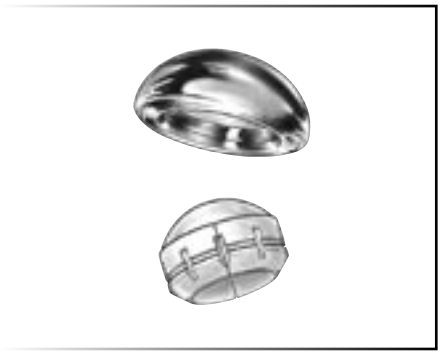
Step 2

Impact the cobalt chrome inner head onto the stem with 8–10 taps on the inner head using the impacting tool. Be sure the impacting is not done at an angle.



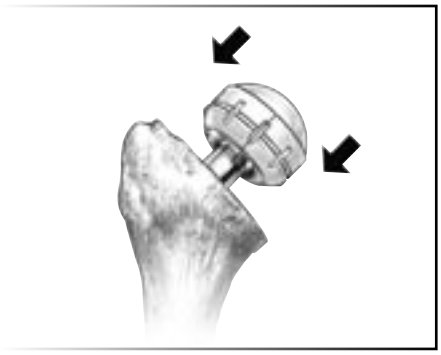
Step 3

Unpack the box containing the proper diameter Bi-Polar shell and also the box containing the ArCom® polyethylene component.



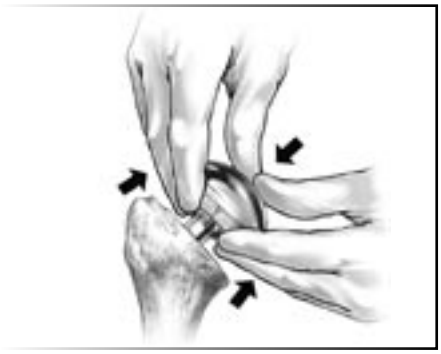
Step 4

Snap the polyethylene liner onto the inner head. **Do not snap the polyethylene component into the shell without first snapping the polethylene component over the inner head.**



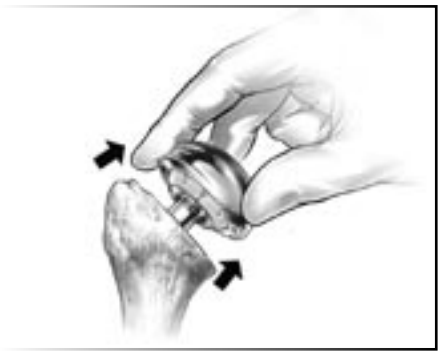
Step 5

Ensure the titanium locking ring is in place inside the cobalt chrome Bi-Polar shell, then slide the shell over the polyethylene liner. A "snap" sound will be heard to confirm the complete seating of the polyethylene into the shell. *Rotate the shell around and with a rongeur remove any impinging bone.*



Step 6

Test the assembly by gently pulling on the shell portion. If secure, relocate the shoulder and reduce the joint. If disassembly is necessary, a removal ramp is available to remove the Bi-Polar assembly and inner head from the stem. An inner head holder and liner removal tool can then be used to disassemble the inner head and outer shell.



Postoperative 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's free swing of the arm out of the sling the first post-operative 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 achieved. 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. 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 determine 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.

Ordering Information

Titanium Humeral Stems (Porous Coated)		
Part No.	**Trials**	**Description**
114065	434443	6.5 x 125mm
114068	434444	8.0 x 125mm
114066	434445	9.5 x 125mm
114069	434446	11.0 x 125mm
114067	434447	12.5 x 125mm
114070	434448	14.0 x 125mm
114064	414452	15.5 x 125mm

Absolute® Bi-Polar Shell Components		
Part No.	**Trials**	**Description**
113150	408450	40mm
113153	408453	44mm
113156	408456	48mm
113159	408459	52mm
113162	408462	56mm
113165	408465	60mm

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

CoCr Humeral Stems (Interlock™)	
Part No.	**Description**
114090	6.5 x 125mm
114092	9.5 x 125mm
114094	12.5 x 125mm

Bi-Angular® Bi-Polar Modular Head (Standard Morse Taper 22.2mm dia.)		
Part No.	**Trials**	**Description**
113101	408408	Standard
113141	408410	+2mm
113142	408412	+4mm

Bi-Angular® Humeral Heads		
Part No.	**Trials**	**Description**
114022	414422	40 x 15mm
114023	414425	40 x 19mm
114052	414415	44 x 15mm
114053	414419	44 x 19mm
114054	414423	44 x 23mm
114024	414424	48 x 19mm
114028	414428	48 x 23mm
114029	414421	48 x 27mm
114025	414420	52 x 19mm
114026	414426	52 x 23mm
114027	414427	52 x 27mm

Bi-Angular® All-Poly Glenoid (76mm Spherical Diameter)		
Part No.	**Trials**	**Description**
114061	414436	45˚ Angled Keel

All-Poly Straight Keel Glenoid (60mm Spherical Diameter)		
Part No.	**Trials**	**Description**
114063	414453	90˚ Straight Keel

Absolute® Bi-Polar Components	
Part No.	**Description**
113169	Absolute® Bi-Polar Liner (Universal)
105420	Replacement Locking Ring

Ordering Information

Bi-Angular® Instrumentation

Bi-Angular®/Bi-Polar New Case

595036	

Bi-Angular® New Upper tray for old case

595036-97	

Bi-Angular® Humeral Reamer

414437	6.5mm
414440	8.0mm
414438	9.5mm
414441	11.0mm
414439	12.5mm
414442	14.0mm
414451	15.5mm

Glenoid Instruments

414429	Rasp
414433	Drill Guide
414434	Drill w/stop
414431	Inserter
414432	Pusher

Humeral Instruments

31-473600	Hammer Plate w/screw
31-473601	Inserter/Extractor for trial stems and implants
31-473620	T-Handle (Standard)
31-473621	Slide Hammer w/thread tip
406514	Humeral Head Impactor

Bi-Angular® Shoulder X-Ray Template

414447	

Absolute® Bi-Polar Instrumentation

Instruments

408433	Bi-Polar Head Removal Ramp
408449	Bi-Polar Inner Head Holder

Bi-Polar Locking Ring Removal Tool

408446	

Bi-Angular®/Bi-Polar Template Set

414458	

BIOMET
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