Comprehensive®
FRACTURE STEM

Positioning Sleeve
Surgical Technique

BIOMET®
ORTHOPEDICS, INC.

Surgical Technique

The Comprehensive® Fracture System offers a unique tool to evaluate and re-establish humeral height, which can be critical to restoring proper biomechanics and achieving adequate range of motion in proximal humeral fracture cases.

- This internal positioning sleeve is simply inserted into the tapped humeral canal at a pre-selected position. Fine adjustments are then made, if needed, by raising or lowering the positioning sleeve along the tapped path.
- The completely internal design eliminates the need for external fracture jigs that may be cumbersome and also destructive to soft tissue and bone and interfere with range of motion assessments.
- Made of PMMA, the positioning sleeve secures the fracture prosthesis at the desired height and remains within the humeral canal.

Step 1

Determine insertion depth for positioning sleeve

Determine desired height of the prosthesis for proper placement of Fracture Positioning Sleeve. This is done by evaluating x-rays of the fracture and the opposite normal shoulder as well as intra-operative identification of proximal bone loss.

Determine amount of comminution and proximal bone loss on x-ray and/or CT scans.

Later confirm amount of humeral shortening by intra-operative observation of pathology.

Measure “normal” humeral height (length) by evaluating the opposite normal x-ray with template (Figure 1).

Draw a perpendicular line at “normal” articular margin and read “height number” off template. This number is adjusted by amount of bone loss. Template the fracture x-ray for proper diameter of Fracture Positioning Sleeve implant (Figure 2). The humeral stem will be 2 or 3mm smaller than the fracture sleeve (allowing for a 2–3mm cement mantel). The height determined here will be used throughout the surgical technique.

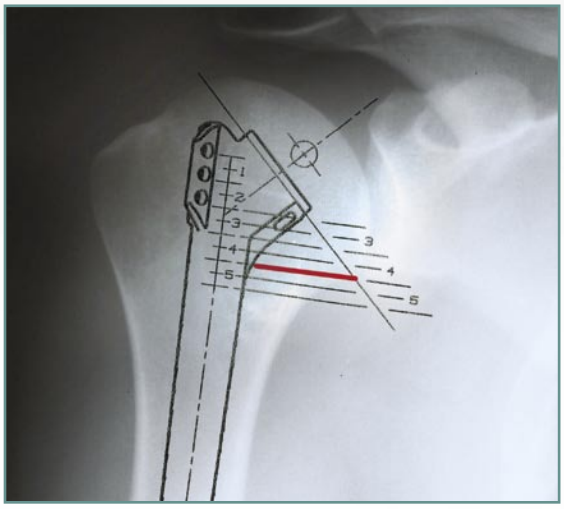


Figure 1

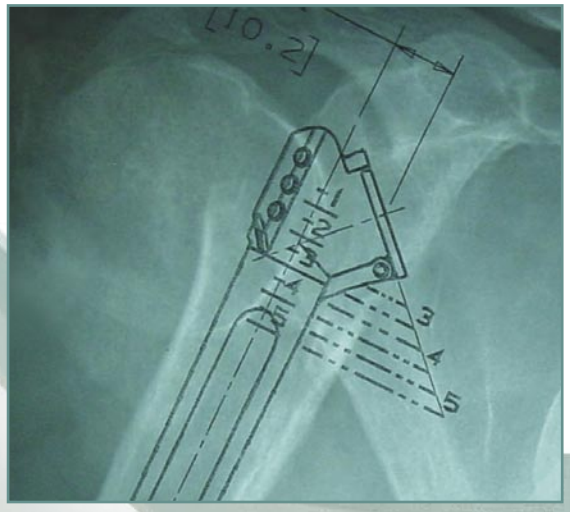


Figure 2

Step 2
Prepare the humeral canal

Ream sequentially in 1mm increments to the predetermined depth defined in Step 1, until cortical contact is achieved (Figures 3a and 3b). Utilize the predetermined diameter only as a guide. Final implant size is determined by the reamer that achieves good cortical contact.

Figure 3a

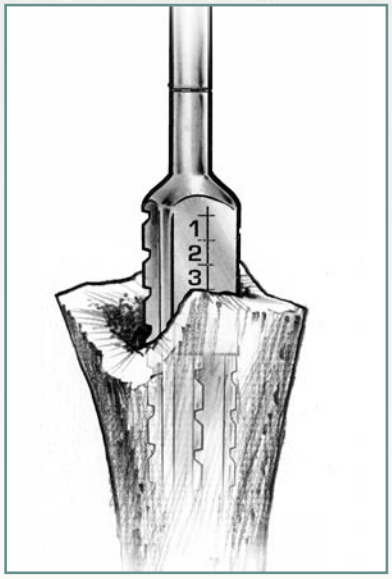


Figure 3b

Step 3
Tap the humeral canal

Using the T-handle tap the humeral canal to the predetermined depth defined in Step 1 (noted by the hashmark on the reamers and taps). (i.e. If cortical contact was achieved with an 11mm reamer, select an 11mm tap.) Tap size corresponds to the last reamer used (Figure 4).

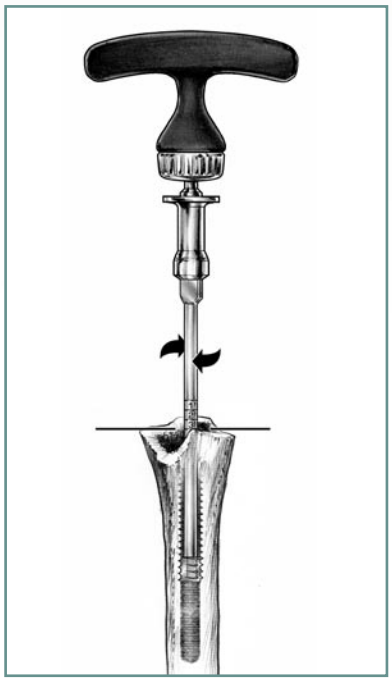


Figure 4

Step 4
Positioning sleeve selection

Select the proper sized positioning sleeve based on the size of the tap used in Step 3. (i.e. following the example from Step 3, if an 11mm tap was used, select an 11mm positioning sleeve implant.)

Step 5
Insertion of the positioning sleeve

Utilize the proper sized inserter for the chosen positioning sleeve selected in Step 4. (Example, if you used an 11mm sleeve you will need to use the "10mm or 11mm" inserter) (Figure 5).

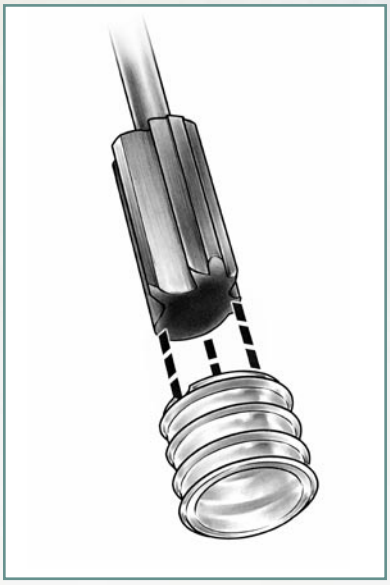


Figure 5

Attach the T-handle to the proper sleeve inserter. Slide the sleeve onto the inserter with the notch pointing towards the T-handle.

Insert the sleeve to the chosen depth identified by the hash marks (Figure 6).

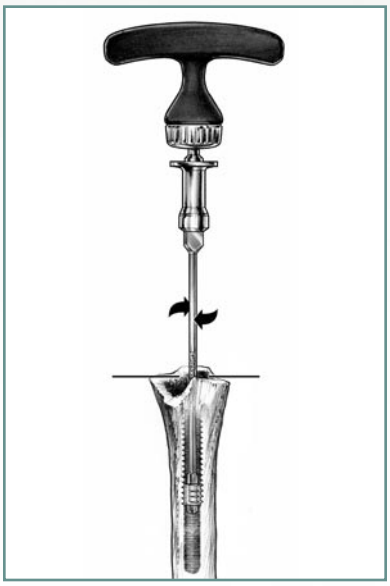


Figure 6

Step 6
Insert trial stem

Trial reduction with correct stem and head combination will ensure that proper height (length) has been achieved (Figure 7). If adjustments are needed, they should be accomplished before continuing to the next step. The sleeve can be screwed up or down in the canal as necessary to adjust the height of the humeral trial.

Step 7
Cementing fracture stem

Cement proper humeral stem component with proper technique. Low pressure and viscous cementing is recommended.

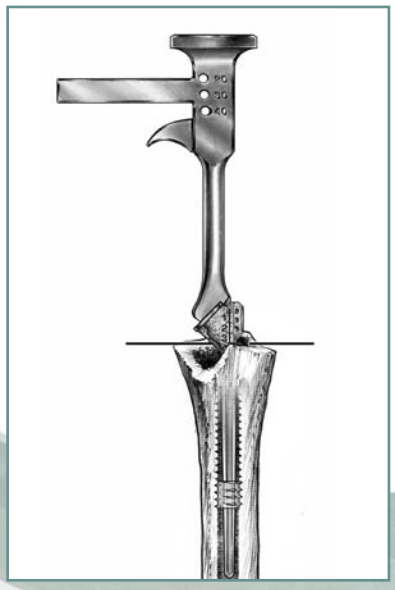
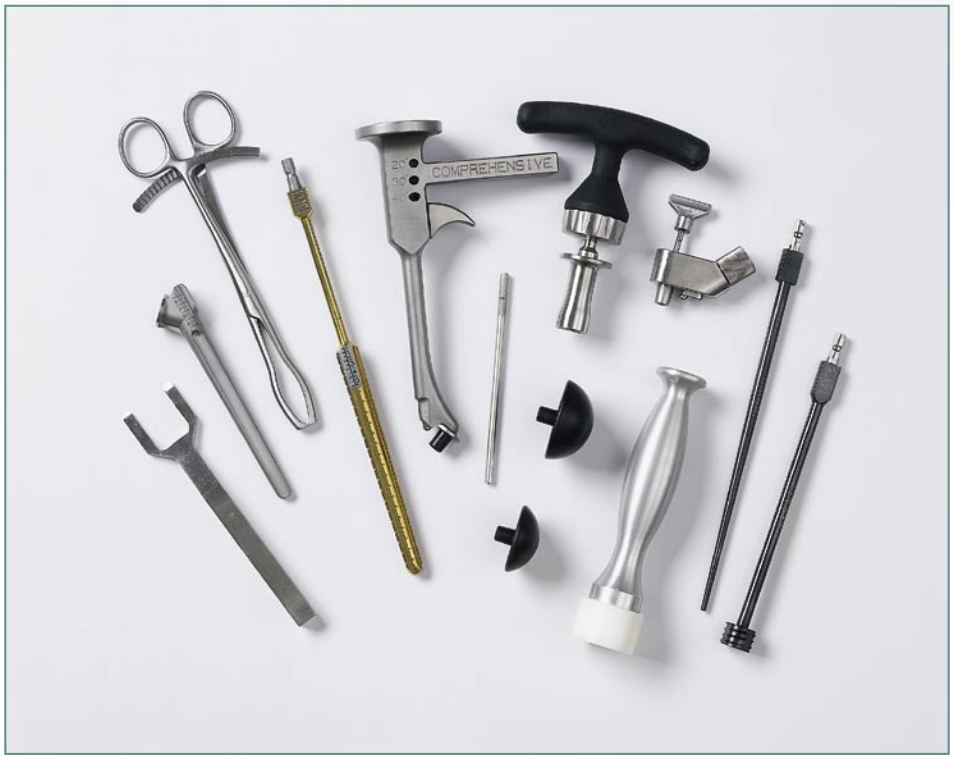


Figure 7

Comprehensive® Sizing Chart

Reamer	Bone Tap	Sleeve Inserter	Positioning Sleeve	Fracture stem
6mm	6mm	6mm or 7mm 4mm Stem	6mm	4mm
7mm	7mm		7mm	
8mm	8mm	8mm or 9mm 6mm Stem	8mm	6mm
9mm	9mm		9mm	
10mm	10mm	10mm or 11mm 8mm Stem	10mm	8mm
11mm	11mm		11mm	
12mm	12mm	12mm or 13mm 10mm Stems	12mm	10mm
13mm	13mm		13mm	
14mm	14mm	14mm or 15mm 12mm Stems	14mm	12mm
15mm	15mm		15mm	
16mm	16mm	16mm or 17mm 14mm Stem	16mm	14mm
17mm	17mm		17mm	



Ordering Information

Implants

Comprehensive® Positioning Sleeve Implants	
Part No.	**Description**
113574	6mm
113575	7mm
113576	8mm
113577	9mm
113578	10mm
113579	11mm
113580	12mm
113581	13mm
113582	14mm
113583	15mm
113584	16mm
113585	17mm

Instrumentation

Comprehensive® Positioning Sleeve Inserters

407024	6mm or 7mm
407026	8mm or 9mm
407028	10mm or 11mm
407030	12mm or 13mm
407032	14mm or 15mm
407034	16mm or 17mm

Comprehensive® Positioning Sleeve Cement Plug Inserter

407099

Ratcheting T-Handle Z–H

406801

ET Humeral Reamer

31-406804	4mm
31-406805	5mm
31-406806	6mm
31-406807	7mm
31-406808	8mm
31-406809	9mm
31-406810	10mm
31-406811	11mm
31-406812	12mm
31-406813	13mm
31-406814	14mm
31-406815	15mm
31-406816	16mm
31-406817	17mm

Comprehensive® Positioning Sleeve Taps

407004	6mm
407005	7mm
407006	8mm
407007	9mm
407008	10mm
407009	11mm
407010	12mm
407011	13mm
407012	14mm
407013	15mm
407014	16mm
407015	17mm

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Date: 04/05

Biomet® Shoulder Joint Replacement Prostheses

Attention Operating Surgeon

DESCRIPTION
Biomet manufactures a variety of shoulder joint replacement prostheses intended for partial or total shoulder joint arthroplasty for use in cemented and uncemented biological fixation applications. Shoulder joint replacement components include humeral stems, humeral heads, and glenoid components. Components are available in a variety of designs and size ranges for both primary and revision applications. Specialty components include glenoid screws, centering sleeves, taper adapters, and bipolar heads.

Materials	
Humeral Stems	CoCrMo Alloy or Titanium Alloy
Humeral Head	CoCrMo Alloy or Titanium Alloy
Glenoid Components	Ultra-High Molecular Weight Polyethylene (UHMWPE) / Titanium Alloy / 316 LVM Stainless Steel / CoCrMo Alloy
Glenoid Screws	Titanium Alloy
Centering Sleeves	Polymethylmethacrylate (PMMA)
Positioning Sleeves	Polymethylmethacrylate (PMMA)
Bipolar Heads	CoCrMo Alloy / UHMWPE / Titanium Alloy
Surface Coating	Titanium Alloy / Hydroxyapatite (HA)
Taper Adapter	CoCrMo Alloy

INDICATIONS
1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Revision where other devices or treatments have failed.
4. Correction of functional deformity.
5. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
6. Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

Humeral components with a Macrobond® surface coating are indicated for either cemented or uncemented press-fit applications.

Humeral/glenoid components with a porous coated surface coating are indicated for either cemented or uncemented biological fixation applications. (Metal backed glenoid components offer optional screw fixation.)

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. (Metal backed glenoid components offer optional screw fixation.)

Humeral components with a non-coated (Interlok®) surface are indicated for cemented application only.

Polyethylene glenoid components not attached to a metal back are indicated for cemented application only.

The Comprehensive® Humeral Positioning Sleeves are for cemented use only.

The Comprehensive® Humeral Fracture Stem is intended for use with the Bio-Modular® humeral heads and glenoid components.

The Versa-Dial™ Humeral Head Prosthesis is intended for use only with the Comprehensive® Humeral Fracture Stem and the glenoid components of the Bio-Modular® Shoulder System.

In addition to those specified above, the Proximal Shoulder Replacement prostheses are indicated for use in oncology applications, complex humeral fractures and revisions.

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity levels, 3) a good nutritional state of the patient and 4) the patient must have reached full skeletal maturity.

CONTRAINDICATIONS
Absolute contraindications include infection, sepsis, and osteomyelitis.
Relative contraindications include:
1. Uncooperative patient or patient with neurologic disorders who is incapable or unwilling to follow directions
2. Osteoporosis
3. Metabolic disorders which may impair bone formation
4. Osteomalacia
5. Distant foci of infections which may spread to the implant site
6. Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram

WARNINGS
Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissue have lower adhesion strength to cement than implants handled with clean gloves. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

1. Once the Atlas® proximal component and distal stems have been assembled, they should not be unscrewed and reassembled. Doing so may compromise the secondary locking function of the polyethylene plug inserted in the screw threads of the stem. Should disassembly become necessary, a new distal stem extension must be used.
2. Uncemented glenoid components should be used only when there is good quality bone and no significant shoulder instability.
3. Disassociation of the humeral head component from the humeral stem component has been reported. Failure to properly align and completely seat the components together can lead to disassociation. Thoroughly clean and dry tapers prior to attachment of modular head component to avoid crevice corrosion and improper seating.
4. Dislocation of the bipolar shoulder component has been reported. Closed reduction should be attempted with caution to prevent disassociation of the bipolar component. Do not use excessive force during closed reduction. The bipolar component may impinge against the glenoid component.
5. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations that may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.
6. The use of Bio-Modular®MI stems is not recommended for fractures of the proximal humerus.

Biomet® joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals, they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight and excessive weight bearing have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

PRECAUTIONS

Specialized instruments are designed for Biomet® joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.

POSSIBLE ADVERSE EFFECTS

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
2. Early or late postoperative, infection, and allergic reaction.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4. Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption and/or excessive activity.
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
10. Fretting and crevice corrosion can occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Accelerated wear of glenoid articular cartilage.
13. Intraoperative or postoperative bone fracture and/or postoperative pain.

STERILITY

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, P.O. 587, Warsaw, IN 46581 USA, FAX: 574-372-1683.

Authorized Representative:

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CE 0086

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Driven By Engineering

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