

Comprehensive Fracture System

Surgical Technique



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 Modular Hybrid Glenoid is intended to be implanted with bone cement. The optional porous titanium peg may be inserted without bone cement. The optional polyethylene peg should be inserted with bone cement.

The Comprehensive Humeral Positioning Sleeves are for cemented use only and are intended for use with the Comprehensive Fracture Stem.

The Comprehensive Shoulder Stems (Fracture, Primary and Revision) are intended for use with the Bio-Modular Humeral Heads and glenoid components and Versa-Dial Humeral Heads.

The Versa-Dial Humeral Head Prosthesis is intended for use only with the Comprehensive Shoulder Stems (Fracture, Primary and Revision), the Bio-Modular Shoulder Stems, the glenoid components of the Bio-Modular Shoulder System, and the glenoid components of the Comprehensive 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.

The Titanium Versa-Dial Humeral Head Prosthesis is indicated for patients with suspected cobalt alloy sensitivity. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy. A Titanium humeral head is not recommended for patients who lack suspected material sensitivity to cobalt alloy.

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.

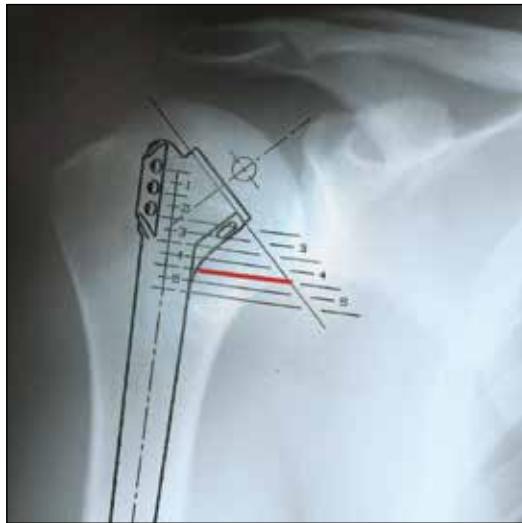


Figure 1



Figure 2

Preoperative Planning

Evaluate X-rays of both the fractured shoulder and the contralateral shoulder. Ensure both X-rays are at the same degree of external rotation. Determine amount of comminution and proximal bone loss on X-ray and/or CT scans. Find a bony landmark along the fracture line that can be used as a reference and draw a line on the X-ray at that exact point. In many instances, the medial calcar can be used (Figure 1).

Flip the fracture X-ray and align it over the chosen bony landmark on the contralateral shoulder X-ray.

The Comprehensive Fracture System templates are then placed over the contralateral shoulder and the proper stem size is selected.

Using the selected stem size, note the previously drawn line and the hashmark to which it corresponds. For example, if the line made on the medial calcar aligns with the line between the 4 and 5 hashmark, the fracture stem will be inserted to that depth. The height determined here will be used throughout the surgical technique.

The humeral head size can be estimated by overlaying the head templates over the contralateral humeral head. A second check in proper placement of the stem is performed by overlaying the head and stem together at the appropriate position within the humeral canal.

Patient Positioning

Place the patient in a modified beach chair position at 30–45 degrees after general or regional anesthetic has been induced and a prophylactic dose of a broad-spectrum antibiotic has been administered. Lateralize the patient on the edge of the table so that the arm can be extended off the side (Figure 2).



Figure 3



Figure 4



Figure 5

Approach

Mark the skin incision for an extended deltopectoral approach (Figure 3). Begin the incision over the clavicle, directly superior to the coracoid process, and pass over the coracoid, sweeping laterally and distally to end at the insertion of the deltoid onto the humerus (Figure 4). This approach allows for detachment of part of the distal deltoid insertion if further mobilization of the deltoid is required.

As dissection proceeds, identify the cephalic vein, a landmark of the deltopectoral interval. This vein is usually identified by its surrounding fatty tissue (Figure 5).



Figure 6

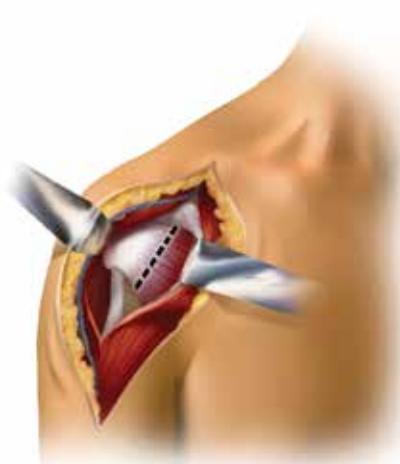


Figure 7

Dissection of Soft Tissue

The cephalic vein is usually firmly embedded in the deltoid, with many feeders from the deltoid to the cephalic vein. The vein may either be sacrificed or reflected. The distal deltoid may be partially released from its humeral insertion, but the proximal origin should not be violated.

In fracture cases, it is especially important to identify and protect the musculocutaneous and axillary nerves. Palpate the musculocutaneous nerve as it comes from the plexus into the posteromedial aspect of the conjoined tendon (Figure 6). With further dissection, the medial branches of the cephalic vein that cross the incision are identified, divided and cauterized.

Next, divide the clavipectoral fascia and retract the conjoined tendon, avoiding traction on the musculocutaneous nerve, which lies distal to the coracoid process (Figure 7). The nerve usually penetrates the muscle one to two inches inferior to the tip of the coracoid process, but in some instances the nerve has a higher penetration into the conjoined muscle tendon unit. It is important to remember the location of this nerve when retracting the conjoined tendon. A partial tenotomy may be considered to reduce the tension during exposure.

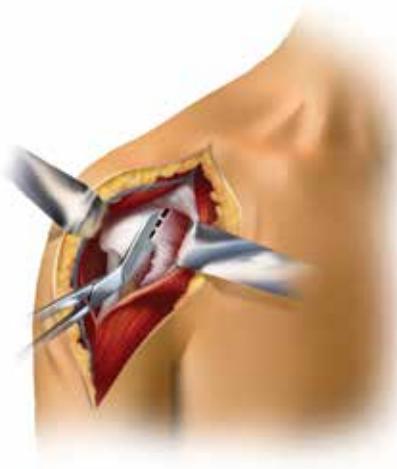


Figure 8

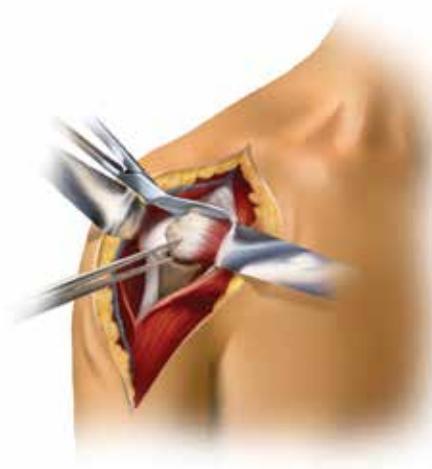


Figure 9

Identifying the Lesser and Greater Tuberosity Fragments Using the Biceps Tendon

The biceps tendon and bicipital groove afford the most useful anatomic landmark for identification of the fractured tuberosity fragments. Place a pair of scissors into the sheath of the biceps tendon and use them to divide the transverse ligament (Figure 8).

Continuing proximally with the scissors, open the interval between the subscapularis and the supraspinatus tendons all the way up to the insertion of the biceps tendon into the supraglenoid tubercle. Even if the biceps tendon is ruptured, place the scissors into the bicipital groove and use them to open the interval between the subscapularis and the supraspinatus tendon. Free up the lesser tuberosity from the underlying humeral head and soft tissue (Figure 9).

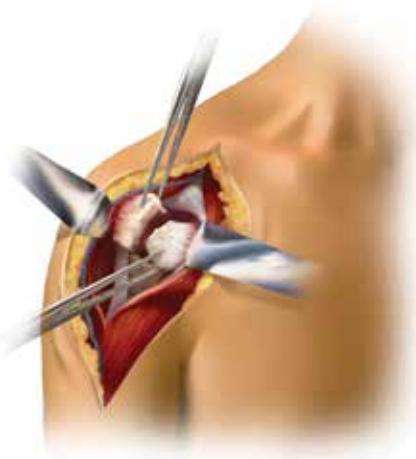


Figure 10



Figure 11

Identifying the Lesser and Greater Tuberosity Fragments Using the Biceps Tendon (cont.)

The fracture may need to be completed with an osteotome or elevator. Protect the axillary nerve during mobilization of both the lesser and greater tuberosities and the attached rotator cuff muscle tendon unit. Once the tuberosities have been identified, place three nonabsorbable #5 sutures through the attached tendon. The greater and lesser tuberosity fragments must be sufficiently freed so they can be easily repaired around the prosthesis and to each other at the time of closure (Figure 10). By retracting the greater and lesser tuberosities, improved access is provided to the glenohumeral joint.

Humeral Head Retrieval

Identify and remove the articular segment of the humeral head using the tuberosity clamps. Size the head with calipers or by direct comparison to the modular head trials (Figure 11). Assess the proximal humerus for shortening due to proximal metaphyseal comminution. This must be considered in placement of the prosthesis. Evaluate the glenoid surface. If it is damaged significantly, or if chronic cartilage loss is present, glenoid replacement may be performed.

Note: Multiple humeral head options are available to help achieve the most accurate fit.

- Standard
- Offset
- EAS Extended Articular Surface Head
- Versa-Dial Head



Figure 12a



Figure 12b



Figure 13

Shaft Preparation of the Humerus

Step 1 – Ream

Humeral shaft preparation is facilitated by extension, adduction and external rotation of the humerus. If a chronic fixed posterior dislocation with associated humeral head fracture of greater than 50% is being treated, less retroversion will be necessary.

Attach the T-handle to the 4 mm reamer and sequentially ream in 1 mm increments until cortical contact has been achieved, being careful to not overream. Depth of reaming is determined by aligning the appropriate hashmark on the reamer with the predetermined bony landmark of the humerus as determined in preoperative planning (Figures 12a and 12b). For example, if the medial calcar was shown preoperatively to line up with the line between the 4 and 5 hashmark, continue reaming to that depth.

Note: The 4 mm and 5 mm reamers do not have hashmarks for depth. They are designed to open the canal to accept the 6 mm reamer and larger.

Reaming should allow the shaft to accept the correct size stem in approximately 20–40 degrees of retroversion. The reamer that achieves cortical contact is the basis on which the final implant size is determined.

Step 2 – Tap

Note: If the stem will be press-fit please skip steps 2 and 3 and proceed to humeral head trialing and insertion (page 13) as the positioning sleeve will not be utilized.

Remove the T-handle from the reamer and attach it to the corresponding tap. For example, if the 8 mm reamer was the final reamer used in Step 1, select the 8 mm tap and insert down the shaft to the predetermined hashmark (Figure 13). A clockwise rotation will feed the tap into the intramedullary canal. A counterclockwise rotation will draw the tap from the canal.

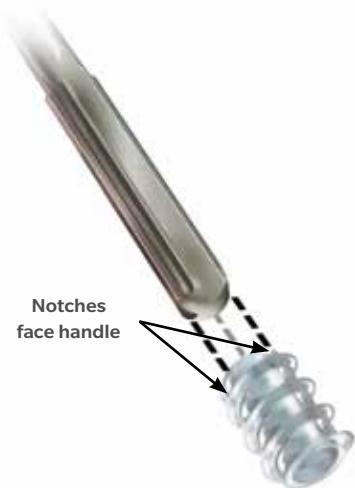


Figure 14



Figure 15

Shaft Preparation of the Humerus (cont.)

Step 2 – Tap (cont.)

If a cement plug is desired, it should be placed down the canal before tapping. It is recommended to use a size just big enough to occlude the flow of cement, yet small enough to avoid any extra pressure on the cortical walls.

Note: The tap will thread the canal distally an extra 12.7 mm, or one full sleeve's length, to allow for any necessary height adjustment when trialing.

Caution: Do not attempt to force the bone tap down the humeral canal. If necessary, use a tap that is 1 mm smaller than the last reamer used.

Step 3 – Insert Sleeve

Choose the sleeve inserter that corresponds with the respective reamer/tap used. For example, if the 8 mm reamer and tap are used, the 8 mm positioning sleeve is selected and inserted (see sizing chart on page 18). The implant positioning sleeve is placed onto the inserter with the sleeve notches facing the T-handle (Figure 14). Insert the sleeve down the shaft with a clockwise motion to the predetermined hashmark (Figure 15). Once the sleeve is positioned at the appropriate depth, pull the sleeve inserter out of the humerus.

Note: Sleeve adjustments can be made by re-engaging the sleeve and inserter. Use the same clockwise/counterclockwise rotation as described previously.



Figure 16a

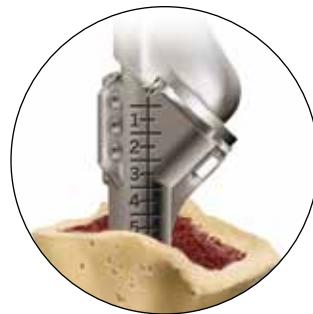


Figure 16b



Figure 17

Humeral Stem Insertion

In order to allow for a 2–3 mm cement mantle, select a trial stem 2–3 mm smaller than the size of the final reamer used in canal preparation (see sizing chart on page 18). Attach the trial prosthesis to the inserter handle and place in the canal (Figures 16a and 16b). Check for correct sizing, version and humeral length. Stem should be positioned at the exact hashmark used during the reaming, tapping and sleeve insertion process.

Note: If the stem will be press-fit, keep in mind the 2 mm sizing increments of 4 to 14. Ream line to line and utilize the corresponding stem size. It is also important to note the 1.5 mm circumferential PPS coating on the proximal portion of the stem. Standard impaction bone grafting may be utilized when between implant sizes to enhance implant stability.

The version rod may be attached to the inserter handle and aligned parallel to the long axis of the forearm (Figure 17). This will place the trial in the desired amount of retroversion. Select the humeral head trial that most closely replicates the original articular segment.



Figure 18



Figure 19

Humeral Stem Insertion (cont.)

With the forearm at neutral, or zero degrees rotation, the head should point at the glenoid (Figure 18). Test humeral length intraoperatively by attempting to sublux the humerus inferiorly. Normally, the humeral component should travel only 25 to 50% of the length of the glenoid with inferior traction. If more than that is possible, the prosthesis is seated too low. In this case, the deltoid function will likely be poor due to inadequate length and tension. If there is no inferior play, the humerus is too high and should be sunk deeper into the shaft or it will be prone to impingement and may place undue stress on the glenoid.

Proper tension can also be evaluated by measuring the distance between the pectoralis tendon insertion to the top of the prosthetic head which should be approximately 5.6 cm. If adjustments are needed, the sleeve can be screwed up or down in the canal to modify the height of the humeral trial.

Radiography or fluoroscopy may be used at this time to determine if implant size and positioning are correct.

The anterolateral fin is immediately lateral to the bicipital groove. Therefore, the lateral edge of the bicipital groove may be directly lined up with the leading fin. Before cementing the appropriate stem, drill two holes in the humeral shaft, medial and lateral to the bicipital groove.

Pass one #5 nonabsorbable suture front to back through these holes to be used later as a figure-of-eight tension band. Pass a second #5 nonabsorbable suture through the lateral hole for longitudinal fixation of the greater tuberosity (Figure 19). After final check of the stem fit with the trial implant, prepare and dry the canal.

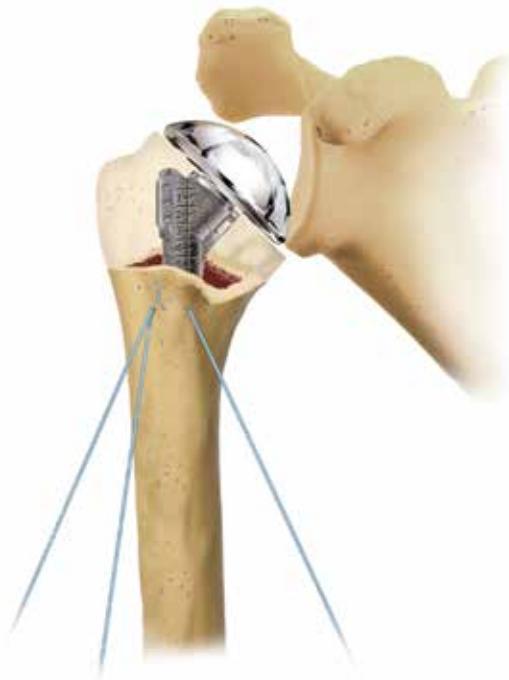


Figure 20

Cementing the Humeral Component

The internal positioning sleeve is designed to be used with cement. Once in the desired position, cement is introduced into the canal and the stem is placed at the pre-determined hashmark with the desired amount of retroversion. There will be less retroversion in cases of fixed posterior dislocation.

Note: The humeral shaft does not need to be pressurized during cement insertion with a distal plugging device. Humeral shaft bone stock may be extremely thin and pressurization can result in either fractures of the proximal shaft during cementing or cement extruding from the humeral shaft and endangering the radial nerve. If a cement plug was inserted prior to tapping, ensure the size is just big enough to occlude the flow of cement, yet small enough to avoid any extra pressure on the cortical walls.

Trialing and Insertion of the Humeral Head

Once the stem has been cemented, place the selected head trial on the stem and reduce the joint. With tension maintained in the tuberosities, assess anterior stability, posterior stability and range of motion. Attempt to recreate a 50% translation relative to the glenoid anteriorly, posteriorly and inferiorly (Figure 20). In addition, a full range of forward flexion and abduction should be possible without tuberosity impingement. Continue to trial until all criteria are fulfilled.

Remove the trial and adequately clean and dry the reverse Morse taper with the swabs packaged with the implant. Use the humeral head impactor to impact the head onto the humeral stem.

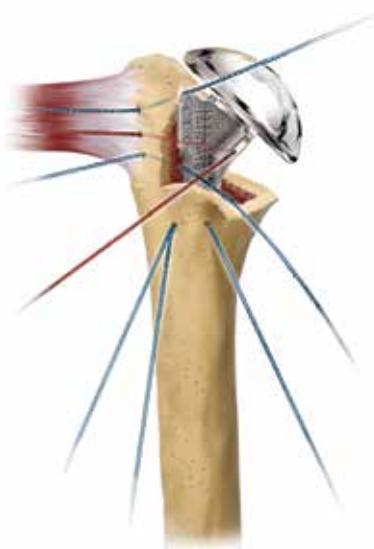


Figure 21

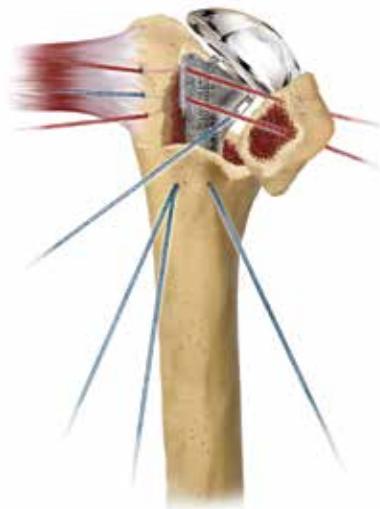


Figure 22

Tuberosity Reattachment

This is the most critical part of the procedure. There are many acceptable variations. However, the goal is to securely fix the greater and lesser tuberosities to the shaft and to each other. Tuberosity clamps can be used to secure tuberosities during reconstruction.

Place three #5 nonabsorbable sutures through the bone tendon interface of the greater tuberosity. Place the middle greater tuberosity suture through the suture hole on the medial neck of the prosthesis (Figure 21).

Next, place the superior and inferior greater tuberosity sutures through the superior and inferior holes in the prosthesis fin. Continue with these sutures through the bone tendon interface of the lesser tuberosity at corresponding levels (Figure 22).

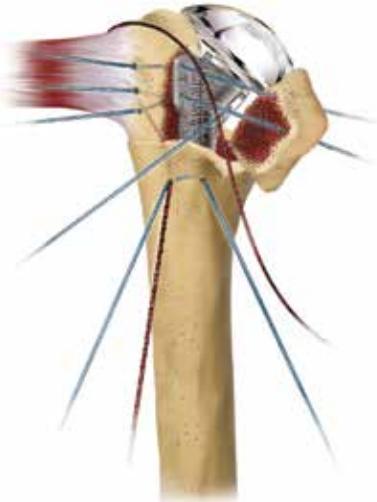


Figure 23

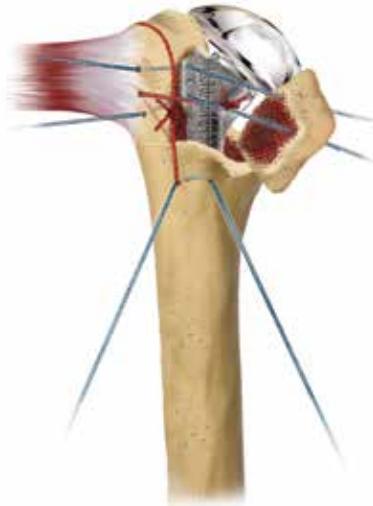


Figure 24

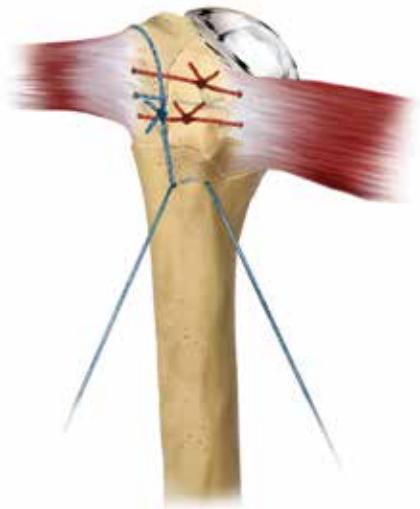


Figure 25

Tuberosity Reattachment (cont.)

Pass the longitudinal suture, previously placed through the lateral hole in the humeral shaft, inside out through the superior portion of the supraspinatus tendon above the greater tuberosity. Continue with this suture underneath the greater tuberosity sutures (Figure 23).

Tie these sutures in the appropriate order to first secure the greater tuberosity to the humeral shaft and to the prosthesis (Figure 24) and then to secure the lesser tuberosity to the humeral shaft and to the greater tuberosity (Figure 25).



Figure 26

Tuberosity Reattachment (cont.)

Place the figure-of-eight suture that was placed prior to stem insertion from back to front through the rotator cuff and close above the tuberosities, fixing the tuberosities to the humeral shaft (Figure 26). Insert bone graft from the humeral head below the tuberosities for improved healing. The tuberosities should be positioned a few millimeters below the top of the humeral head component. Improper positioning will cause abnormal tensioning on the rotator cuff and could lead to impingement. Place the shoulder through a range of motion, noting stability of the tuberosities. This will allow guidance for the postoperative rehabilitation program.

Closure

Close the wound over a wound drain system. Place the arm in a sling and swathe. Begin physical therapy on the first postoperative day.

Rehabilitation

The initial phase is aimed at achieving full, passive ROM. The precise exercises, safe ranges of motion and timing of initiation and progression of exercises should be individualized. This is typically based on intraoperative testing of tension on the tuberosities, tuberosity repair and security of tuberosity fixation.

Initial phases of rehabilitation may include therapist assisted passive flexion. The patient may also perform passive flexion of the arm using the other arm as the power source or by use of a pulley and rope system. Each passive exercise should include five repetitions and be performed four to six times per day. The patient should perform pendulum exercises four to six times per day when out of bed. External rotation stretching exercises using a 3 ft stick may also be utilized. If the patient does not have sufficient passive motion after several weeks of rehabilitation, additional stretching exercises may be instituted, such as wall climbing, additional overhead stretching with a pulley, posterior capsule stretching, etc.

Rehabilitation (cont.)

Nonisometric resistance exercises using rubber tubing may be started at approximately six weeks when there is earlier X-ray evidence of tuberosity healing.

During all phases of rehabilitation, the patient should be instructed on appropriate shoulder stretching exercises and activities of daily living. Strengthening exercises of the deltoid and rotator cuff are gradually begun with Thera-Band Band Loops. Exercise with light hand weights is introduced when appropriate. The goal of rehabilitation should be gradual rather than rapid improvement in ROM. Attempt to gain 150 degrees of passive ROM in forward elevation within the first four weeks. A major goal should be 90 degrees active forward flexion achieved by the second month. Rehabilitation should continue for up to a year, and improvement is anticipated throughout this time.

Conclusion

The reproduction of normal humeral length, appropriate retroversion of the humerus, tuberosity fixation and ultimate union are mandatory for a successful result in hemiarthroplasty for acute fractures of the proximal humerus. Successful results can only be expected if the patient agrees to undergo extensive rehabilitation after surgery.

Appendix—Humeral Stem Sizing

Comprehensive Fracture System Sizing Chart (when utilizing the fracture sleeve)

Reamer	Bone Tap	Positioning Sleeve	Sleeve Inserter	Fracture Stem
6 mm	6 mm	6 mm	20 mm 19 mm	20 mm 19 mm
7 mm	7 mm	7 mm		
8 mm	8 mm	8 mm	18 mm 17 mm	18 mm 17 mm
9 mm	9 mm	9 mm		
10 mm	10 mm	10 mm	16 mm 15 mm	16 mm 15 mm
11 mm	11 mm	11 mm		
12 mm	12 mm	12 mm	14 mm 13 mm	14 mm 13 mm
13 mm	13 mm	13 mm		
14 mm	14 mm	14 mm	12 mm 11 mm	12 mm 11 mm
15 mm	15 mm	15 mm		
16 mm	16 mm	16 mm	10 mm 9 mm	10 mm 9 mm
17 mm	17 mm	17 mm		

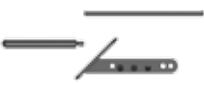
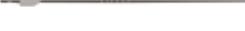
EAS/Stem Size Combinations

Implants and Trials

Product	Description	Size	Trial Part Number	Implant Part Number
	Comprehensive Fracture Stem (Macrobond)	4 x 122 mm 6 x 122 mm 8 x 122 mm 10 x 122 mm 12 x 122 mm 14 x 122 mm	31-406904 31-406906 31-406908 31-406910 31-406912 31-406914	11-113554 11-113556 11-113558 11-113560 11-113562 11-113564
	Comprehensive Fracture Stem (PPS)	4 x 122 mm 6 x 122 mm 8 x 122 mm 10 x 122 mm 12 x 122 mm 14 x 122 mm	31-406904 31-406906 31-406908 31-406910 31-406912 31-406914	12-113554 12-113556 12-113558 12-113560 12-113562 12-113564
	Comprehensive Positioning Sleeve	6 mm 7 mm 8 mm 9 mm 10 mm 11 mm 12 mm 13 mm 14 mm 15 mm 16 mm 17 mm	— — — — — — — — — — — —	113574 113575 113576 113577 113578 113579 113580 113581 113582 113583 113584 113585
	Standard Humeral Head	40 x 15 mm 40 x 20 mm 40 x 22 mm 44 x 15 mm 44 x 17 mm 44 x 22 mm 44 x 27 mm 48 x 19 mm 48 x 24 mm 48 x 27 mm 54 x 22 mm 54 x 24 mm 54 x 27 mm	406530 406532 406528 406533 406534 406536 406538 406529 406540 406531 406537 406535 406539	113760 113762 113757 113763 113764 113766 113768 113769 113770 113771 113772 113775 113774

The Comprehensive Fracture System is compatible with offset and EAS heads from the Bio-Modular Choice Shoulder System, as well as Versa-Dial heads from the Comprehensive Shoulder System. For compatibility information, reference the sizing chart on page 18.

Instrumentation and Accessories

Product	Description	Size	Part Number
	Bio-Modular Humeral Head Impactor	—	406514
	Humeral Head Removal Fork	—	406515
	Comprehensive Extramedullary Resection Guide with Version Rod	—	407392
	Comprehensive Intramedullary Resection Guide Block	—	407396
	Comprehensive Intramedullary Resection Guide Boom with Version Rod	—	407397
	Threaded Steinmann Pins (pk. 2)	1/8 x 2.5"	406669
	Fracture Stem Inserter	—	31-406901
	Fracture Stem Extractor	—	406997
	Tuberosity Clamp	—	406994
	Comprehensive Cement Plug Inserter	—	407099

Instrumentation and Accessories (cont.)

Product	Description	Size	Part Number
	Ratcheting T-handle	—	406801
	Humeral Reamer	4 mm 5 mm 6 mm 7 mm 8 mm 9 mm 10 mm 11 mm 12 mm 13 mm 14 mm 15 mm 16 mm 17 mm	41-406804 41-406805 41-406806 41-406807 41-406808 41-406809 41-406810 41-406811 41-406812 41-406813 41-406814 41-406815 41-406816 41-406817
	Comprehensive Positioning Sleeve Taps	6 mm 7 mm 8 mm 9 mm 10 mm 11 mm 12 mm 13 mm 14 mm 15 mm 16 mm 17 mm	407004 407005 407006 407007 407008 407009 407010 407011 407012 407013 407014 407015

Instrumentation and Accessories (cont.)

Product	Description	Size	Part Number
	Comprehensive Positioning Sleeve Insters	6 mm or 7 mm 8 mm or 9 mm 10 mm or 11 mm 12 mm or 13 mm 14 mm or 15 mm 16 mm or 17 mm	407024 407026 407028 407030 407032 407034
	Comprehensive Fracture Stem X-ray Templates	—	TMP406996
	Comprehensive Fracture Instrument Case	—	592221

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Biomet Orthopedics
P.O. Box 587
56 E. Bell Drive
Warsaw, Indiana 46581-0587
USA

www.zimmerbiomet.com