Comprehensive® Reverse
Shoulder System

Surgical Technique

BIOMET®

Comprehensive® Reverse Shoulder System

Contents

Figure 1

Figure 2

Patient Positioning and Incision

Surgical Position

The arm and shoulder are prepped and draped free (Figure 1). Utilize a modified beach chair position at about 30–40 degrees of flexion.

Surgical Incision/Exposure

Utilize an extended deltopectoral anterior incision beginning immediately above the coracoid process and extending distally and laterally, following the deltopectoral groove along the anterior border of the deltoid (Figure 2). Laterally retract the deltoid muscle, avoiding release of the deltoid from the clavicle. The deltoid may be partially released from its distal insertion by subperiosteal dissection.

This brochure is presented to demonstrate the surgical technique utilized by John Sperling, M.D.; David Dines, M.D.; Russell Warren, M.D.; Edward Craig, M.D.; Donald Lee, M.D.; and Timothy Codd, M.D. Biomet, as a manufacturer of this device, does not practice medicine and does not recommend this device or technique. Each surgeon is responsible for determining the appropriate device and technique to utilize on each individual patient.

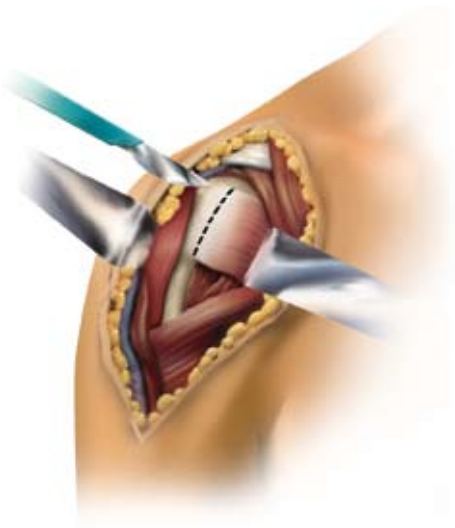

Figure 3

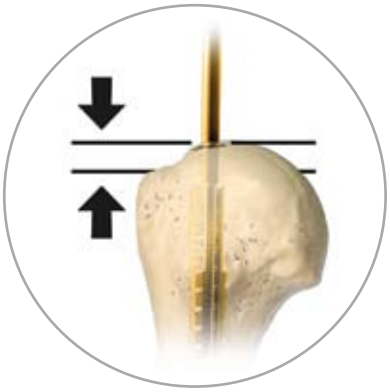

Figure 4a

Figure 4

Identify anterior structures and externally rotate the humerus. If the subscapularis is intact, make a longitudinal incision through the tendinous portion of the subscapularis muscle and capsule, just medial to the lesser tuberosity (Figure 3). In cases of severe contracture, subscapularis lengthening may be required.

Tag the subscapularis tendon with non-absorbable sutures for easy identification during closure. Externally rotate and extend the humerus to expose the humeral head, while protecting the axillary nerve.

Note: An optional biceps tenodesis may be performed to improve exposure.

Humeral Standard Stem

(Mini stem described later in technique.)

Humeral Preparation

Using the 4, 5 or 6mm trocar pointed reamer and ratcheting T-handle, bore a pilot hole through the humeral head along the axis of the humeral shaft (Figure 4), just lateral to the head's articular surface and just posterior to the bicipital groove. This pilot hole may also be created with a 4mm drill or high-speed burr. Insert the tapered humeral reamer until the engraved line above the cutting teeth is located between the top of the humeral head and the top of the greater tuberosity (Figure 4a). If unsure on where to sink reamer within this small window, it is advisable to reference the greater tuberosity. Continue reaming in 1mm increments until light cortical contact is achieved, sinking the reamer only to the engraved line. Note the reamer size for future reference.

Figure 5

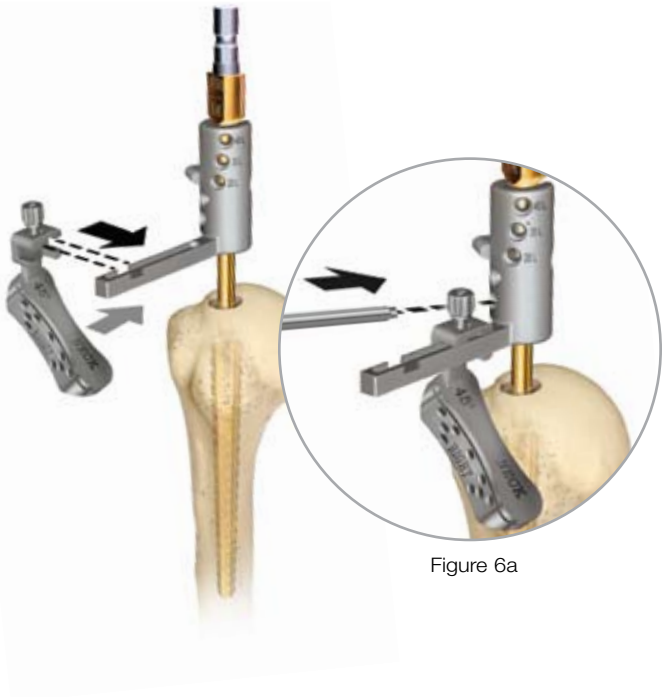

Figure 6a

Figure 6

Intramedullary Resection Guide Assembly

Place the resection guide boom onto the reamer shaft and slide it up until it rests against the top of the reamer, just below the sizing engrave (Figure 5).

Place the IM resection guide block onto the arm of the boom (Figure 6) and orient it for the proper resection (Figure 6a). For example, “right” should be visible for a right shoulder.

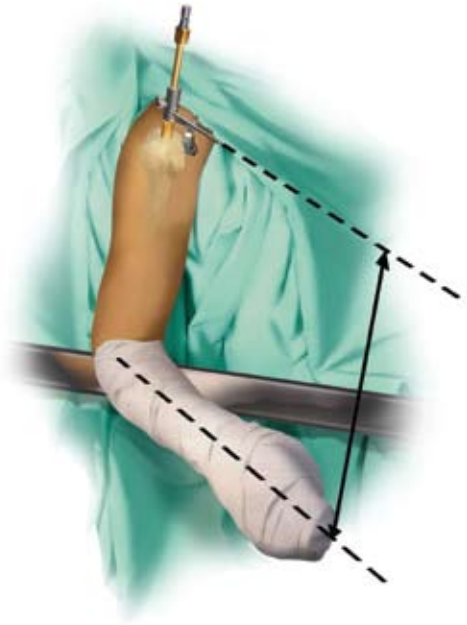

Figure 7

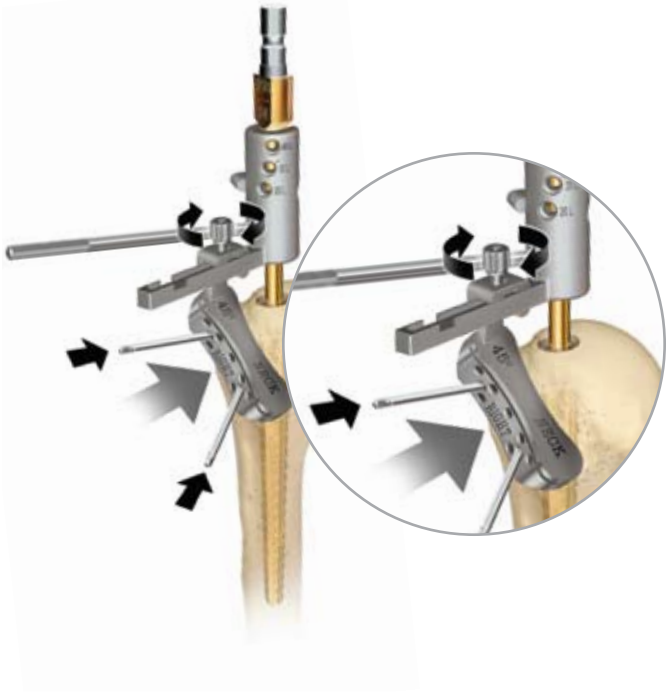

Figure 8

Screw the version control rod into the desired version hole (most common is 20 to 30 degrees), and align the rod with the forearm flexed at 90 degrees in external rotation (Figure 7). If less than 20 degrees of retroversion is desired, the arm of the IM resection guide is 0 degrees.

As an alternative to the intramedullary resection guide, an extramedullary resection guide is available in the instrument set.

Set the correct version using the amount of external rotation of the forearm, slide the resection guide against the humerus and finger tighten the thumbscrew. Place two threaded Steinmann pins through converging angled holes in the resection guide block and into the bone to secure the block to the bone (Figure 8).

Figure 9

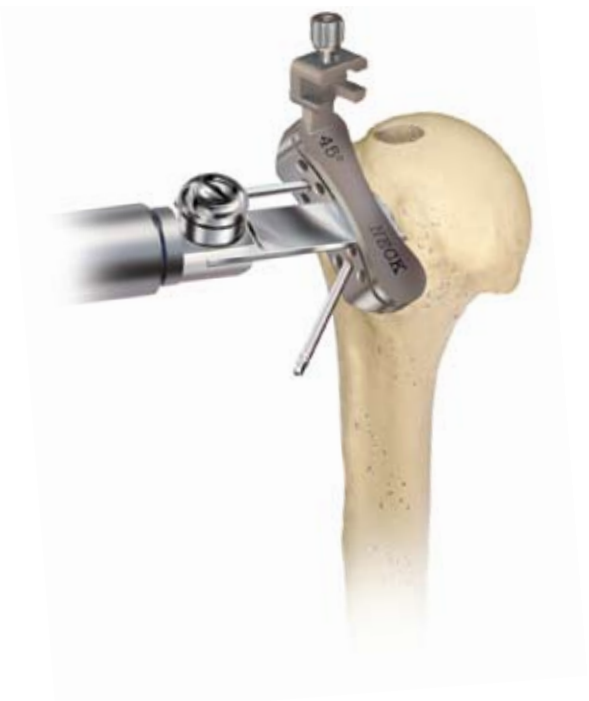

Figure 10

Loosen the thumbscrews on the resection guide block and the reamer shaft. Rotate the resection guide boom until the arm of the boom clears the resection block (Figure 9). Remove the reamer and guide boom.

Place a saw blade through the cutting slot in the guide. The saw blade should be moving when it comes in contact with the bone (Figure 10). Resect the humeral head, and then remove the Steinmann pins and cutting block. The removal of osteophytes at this stage will help with visualization of glenoid.

Figure 11

Figure 12

Humeral Broaching

Select a broach that is at least 2 to 3mm smaller than the last reamer used and attach it to the broach handle. Insert the version rod into the same position used during resection. Flex the forearm to 90 degrees, and externally rotate the arm to be parallel with the version control rod indicating the chosen amount of retroversion. Sequentially broach in 1mm increments until the broach size is equal to the "STD" size of the humeral reamer. For example, if the etching on the last reamer used indicated 10 STD/9 MI, broach up to 10mm (see stem sizing chart on page 30). Advance each broach into the humerus in several successive motions. The broach is fully seated when the collar on the broach inserter rests on the resected surface of the humerus (Figure 11). Remove the broach handle, leaving the last broach in place to be used as a trial.

Note: If broach feels too tight and will not seat, finish broaching with the next smaller size. There is approximately 1.5mm of PPS® porous plasma spray proximally on the definitive implants.

Calcar Planer

Use the calcar planer to refine the resected surface. Attach the planer blade that most closely matches the diameter of the resected surface to the barrel of the calcar planer. Insert the planer plunger into the female taper of the broach. **Begin rotation of the calcar planer before contacting the resected surface.** Apply slight pressure and plane the resected surface (Figure 12). An optional broach cover is recommended to protect the humerus while the glenoid is prepared.

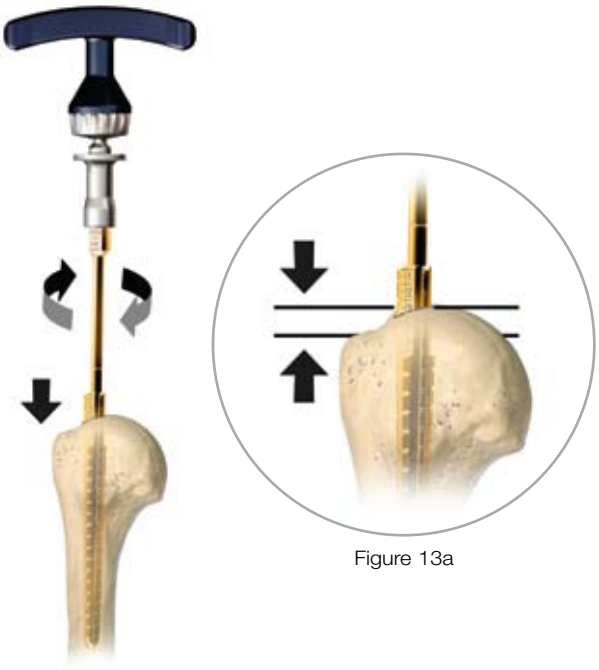

Figure 13a

Figure 13

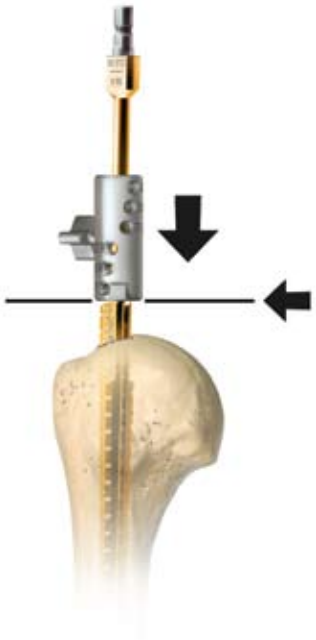

Figure 14

Humeral Mini Stem

(Standard stem described previously in technique.)

Humeral Preparation

Using the 4, 5 or 6mm trocar pointed reamer and ratcheting T-handle, bore a pilot hole through the humeral head along the axis of the humeral shaft (Figure 13), just lateral to the head's articular surface and just posterior to the bicipital groove. This pilot hole may also be created with a 4mm drill or high-speed burr. Insert the tapered humeral reamer until the large hashmark between the 3 and 4 on the reamer is located between the top of the humeral head and the top of the greater tuberosity (Figure 13a). If unsure on where to sink reamer within this small window, it is advisable to reference the greater tuberosity. Continue reaming in 1mm increments until light cortical contact is achieved, sinking the reamer only to the hashmark between 3 and 4. Note the reamer size for future reference.

Intramedullary Resection Guide Assembly

Place the resection guide boom onto the reamer shaft and slide it down until it rests against the base surface of the reamer, just above the cutting teeth (Figure 14).

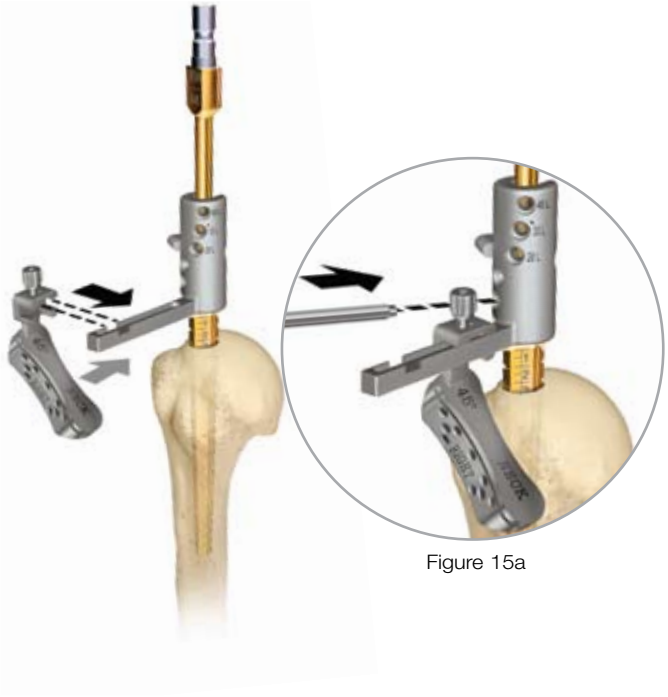

Figure 15a

Figure 15

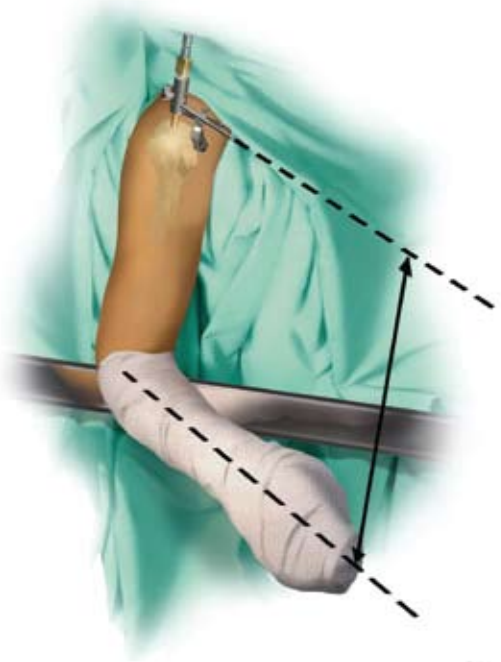

Figure 16

Place the IM resection guide block onto the arm of the boom (Figure 15) and orient it for the proper resection (Figure 15a). For example, “right” should be visible for a right shoulder.

Screw the version control rod into the desired version hole (most common is 20 to 30 degrees), and align the rod with the forearm flexed at 90 degrees in external rotation (Figure 16). If less than 20 degrees of retroversion is desired, the arm of the IM resection guide is 0 degrees.

As an alternative to the intramedullary resection guide, an extramedullary resection guide is available in the instrument set.

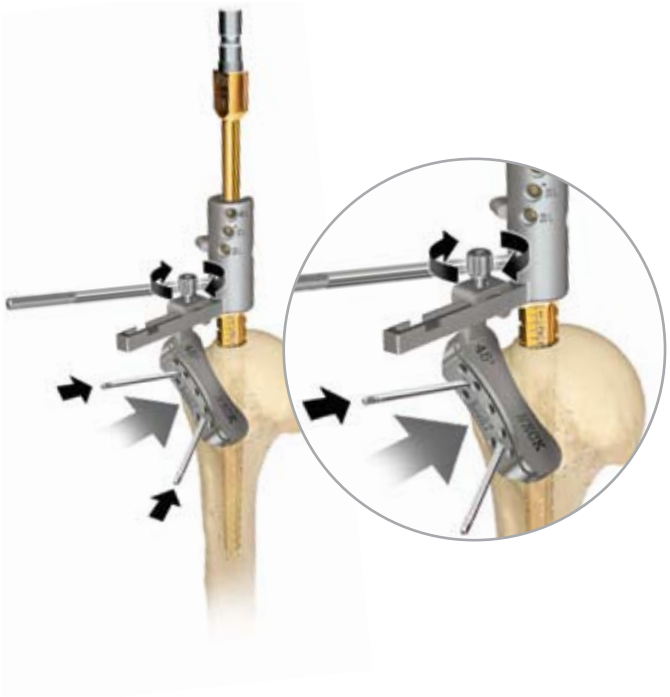

Figure 17

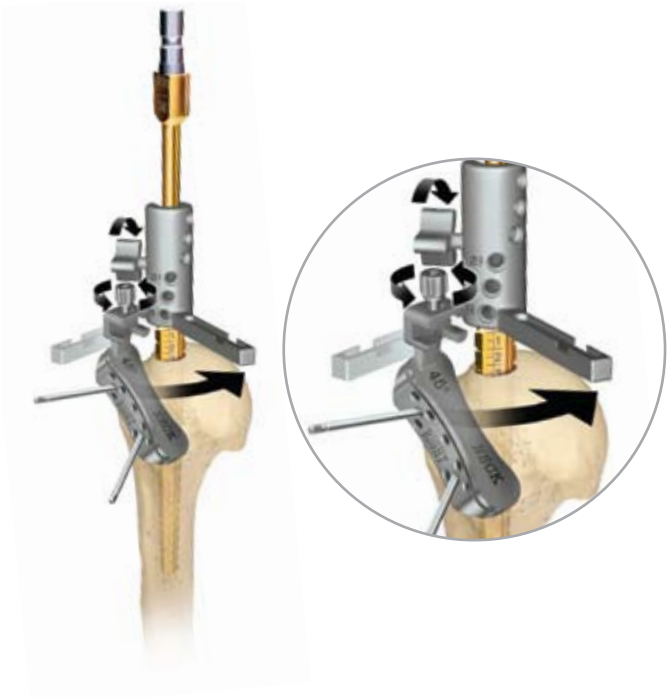

Figure 18

Set the correct version using the amount of external rotation of the forearm, slide the resection guide against the humerus and finger tighten the thumbscrew. Place two threaded Steinmann pins through converging angled holes in the resection guide block and into the bone to secure the block to the bone (Figure 17).

Loosen the thumbscrews on the resection guide block and the reamer shaft. Rotate the resection guide boom until the arm of the boom clears the resection block (Figure 18). Remove the reamer and guide boom.

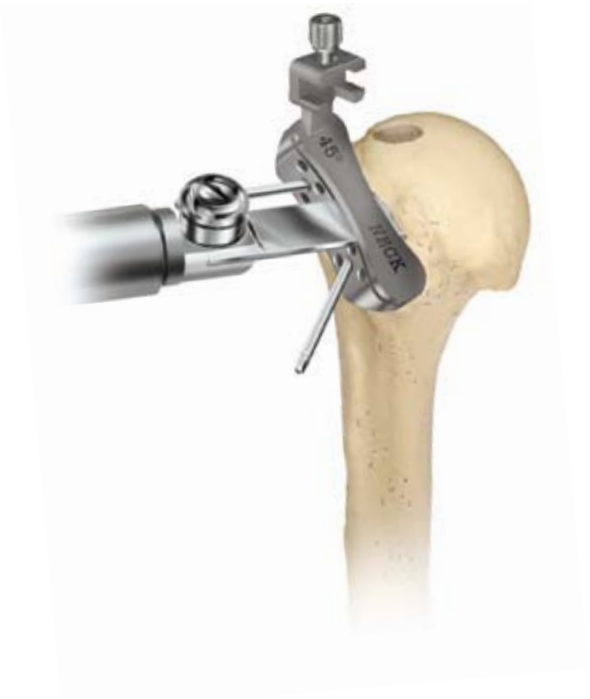

Figure 19

Figure 20

Place a saw blade through the cutting slot in the guide. Care should be taken not to resect the rotator cuff insertion on the humerus. The saw blade should be moving when it comes in contact with the bone (Figure 19). Resect the humeral head, and then remove the Steinmann pins and cutting block. The removal of osteophytes at this stage will help with visualization of glenoid.

Humeral Broaching

Select a broach that is at least 2 to 3mm smaller than the last reamer used and attach it to the broach handle. Insert the version rod into the same position used during resection. Flex the forearm to 90 degrees, and externally rotate the arm to be parallel with the version control rod indicating the chosen amount of retroversion. Sequentially broach in 1mm increments until the broach size is equal to the "MI" size of the humeral reamer. For example, if the etching on the last reamer used indicated 10 STD/9 MI, broach up to 9mm (see chart on page 30). Advance each broach into the humerus in several successive motions, tapping it up as well as down between advancements. The broach is fully seated when the collar on the broach handle rests on the resected surface of the humerus (Figure 20). Remove the broach handle, leaving the last broach in place to be used as a trial.

Note: If broach feels too tight and will not seat, finish broaching with the next smaller size. There is approximately 1.5mm of PPS® porous plasma spray proximally on the definitive implants.

Figure 21

Figure 22

Calcar Planer

Use the calcar planer to refine the resected surface. Attach the planer blade that most closely matches the diameter of the resected surface to the barrel of the calcar planer. Insert the planer plunger into the female taper of the broach. **Begin rotation of the calcar planer before contacting the resected surface.** Apply slight pressure and plane the resected surface (Figure 21). An optional broach cover can be used be used to protect the humerus while the glenoid is prepared.

Other Stem Options

The Comprehensive® Fracture, and Revision and Micro Stems (Figure 22) are compatible with the Comprehensive® Reverse Shoulder. For the complete Comprehensive® Fracture Stem Technique, please see BOI0274.0.

Note: If using the micro stem, special-order micro broaches are required.

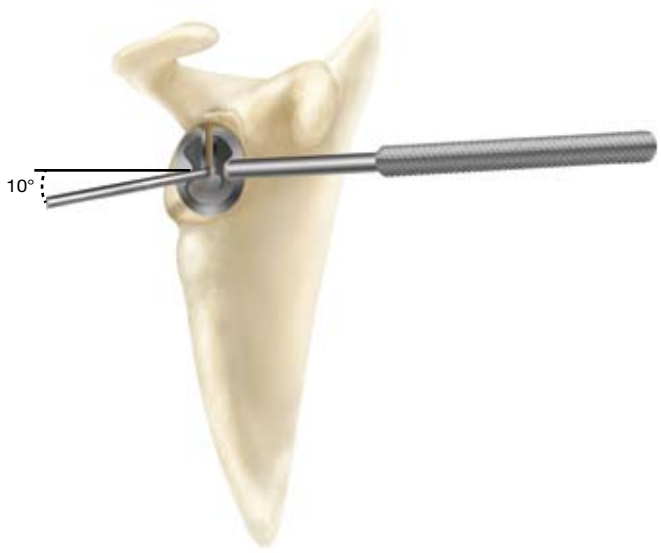

Figure 23

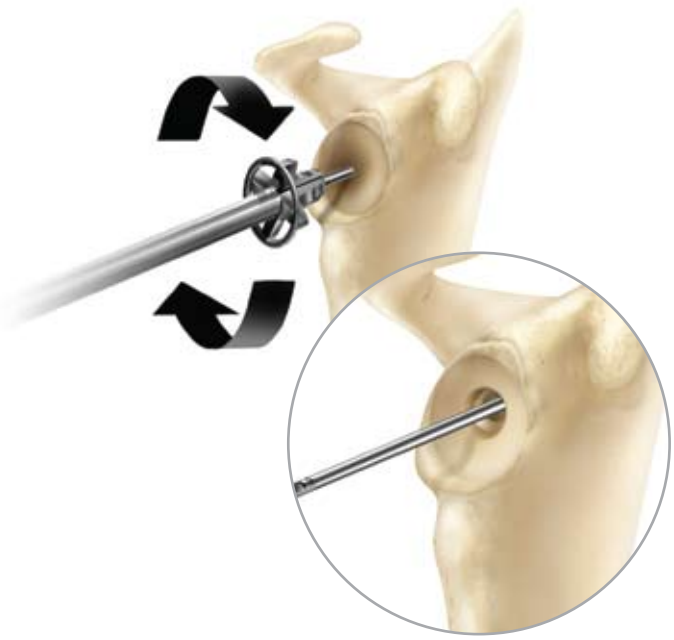

Figure 24a

Figure 24

Glenoid

Glenoid Preparation

Attach the threaded glenoid guide handle to the glenoid sizer. Insert a 3.2mm Steinmann pin into the glenoid at the desired angle and position, ensuring the pin engages or perforates the medial cortical wall (Figure 23). A 10 degree inferior tilt has been built into the glenoid sizer.

Ideally, the Steinmann pin should be placed into the best possible bone stock, keeping in mind the Versa-Dial® glenosphere can be offset up to 4.5mm in any direction.* It may be helpful to section off the glenoid into quadrants for ease of placement of the Steinmann pin, as the best bone is often located centrally.

* For the 36mm standard glenosphere, the offset range is 1.5–3.5mm. For the 31mm glenosphere, the offset is fixed.

Position the cannulated glenoid reamer over the top of the Steinmann pin (Figure 24). Ream the glenoid to the desired level, ensuring that the medial geometry of the glenoid baseplate is completely reamed and contained inside the glenoid. Due to the included 10 degree inferior tilt in the glenoid sizer, an inferior ridge should be evident first. A superior bone ridge should then follow. **It is critical that the glenoid is adequately reamed to ensure complete seating of the glenoid baseplate.** Depending on the condition of the glenoid, the baseplate can be partially counter-sunk. This is accomplished by sinking the glenoid reamer until the desired bone shelf is evident.

Remove the cannulated glenoid reamer, ensuring that the Steinmann pin remains securely positioned in the glenoid (Figure 24a).

Note: There is not a stop on the glenoid reamer, so continual attention to the reaming depth is important.

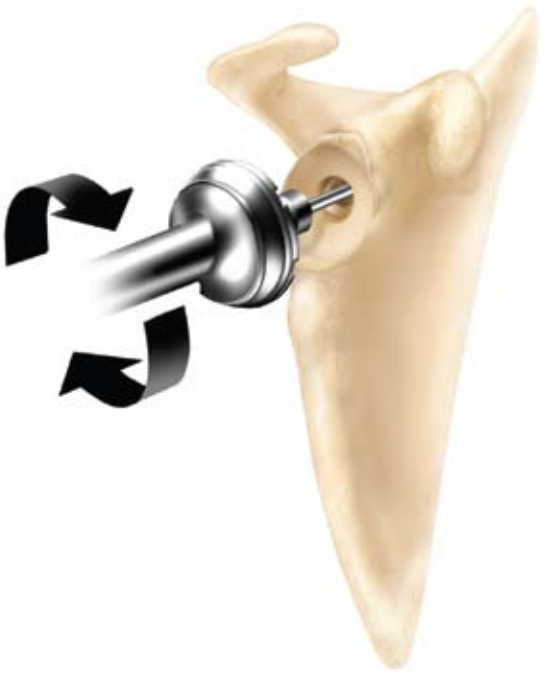

Figure 25

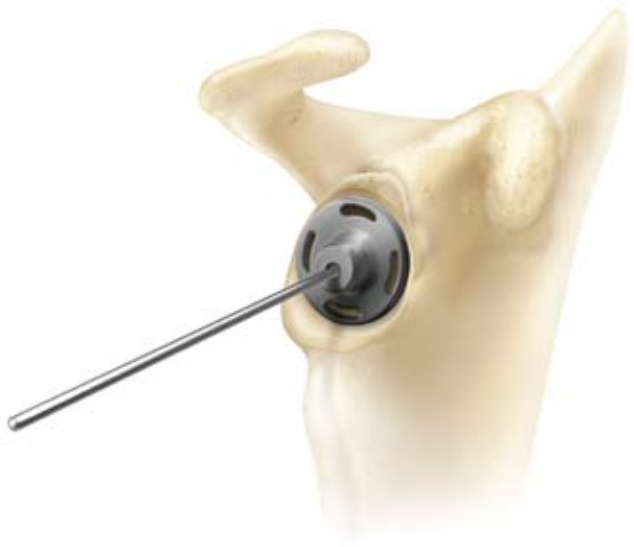

Figure 26

Depending on which size glenosphere is desired, select and attach the desired size planer blade to the planer. Position the cannulated glenoid planer over the top of the Steinmann pin. Concentrically plane the glenoid face, ensuring that any adhesions and soft tissues are removed from the face of the glenoid (Figure 25). Remove the cannulated glenoid planer, ensuring that the Steinmann pin remains securely positioned in the glenoid.

Using the cannulated trial glenoid baseplate, position the glenoid baseplate provisional over the Steinmann pin and into the prepared glenoid (Figure 26). If the glenoid baseplate provisional does not fully seat, the baseplate reamer should be used to completely prepare the baseplate geometry.

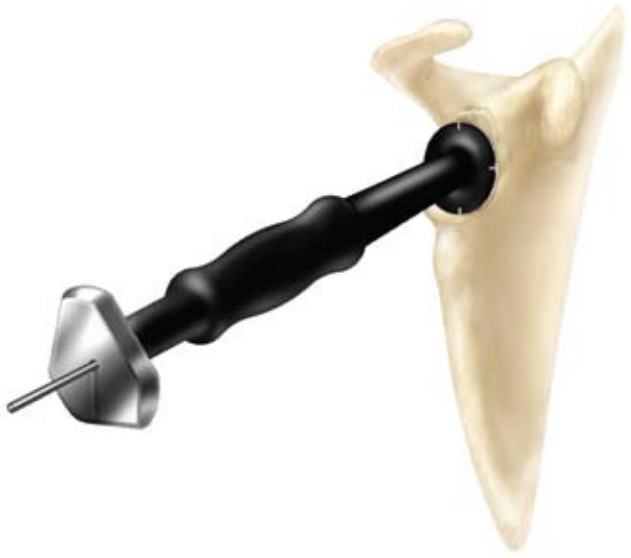

Figure 27

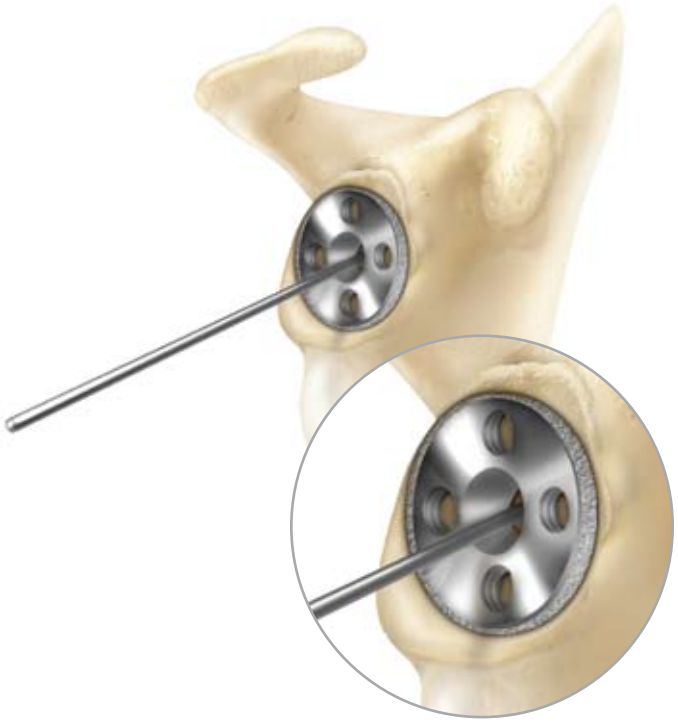

Figure 28

Baseplate Impaction

Place the glenoid baseplate implant onto the end of the cannulated baseplate impactor (Figure 27). Application of saline to impactor tip o-ring should aid in distraction of impactor from baseplate after impaction. Reference the screw hole indicator hashmarks on the impactor to align the peripheral hole screw position as desired. All peripheral screw holes on the baseplate are identical, which allows them to be placed in any desired location. Once aligned, impact the baseplate into the glenoid, and remove the baseplate impactor. The back of the baseplate should be flush, or slightly counter-sunk, relative to the glenoid surface. Visual confirmation can be attained by checking for gaps between the reamed glenoid surface and baseplate at the screw holes. A small nerve hook may aid in confirming complete seating of the baseplate.

The glenoid baseplate is now seated, and determination of the appropriate length 6.5mm central screw can be made (Figure 28).

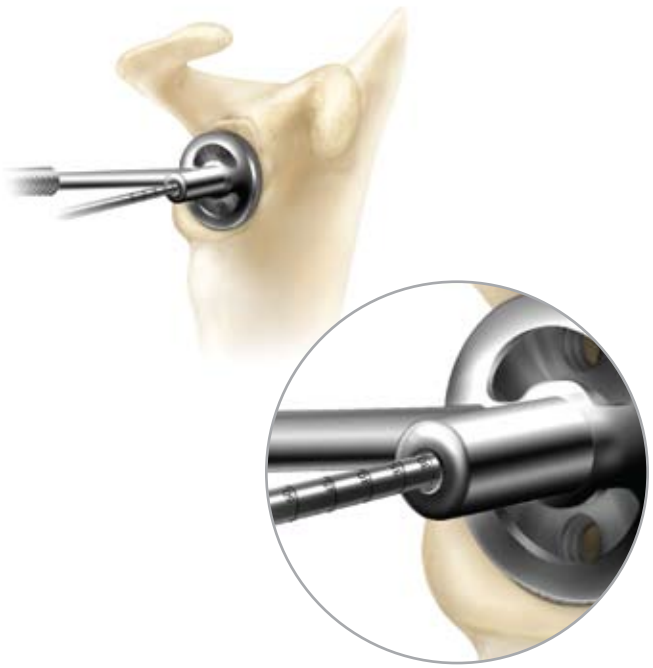

Figure 29

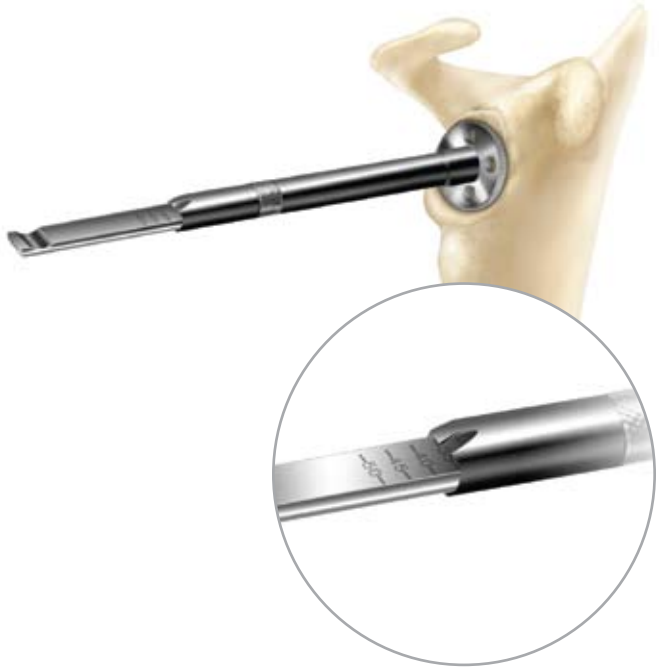

Figure 30

Baseplate Central Screw Selection/Insertion

6.5mm central screw length determination may be made in one of the three following methods:

1. With Steinmann pin in place, position the central screw drill guide over the pin and read the corresponding depth marking on the pin from the back of the drill guide (Figure 29).

2. If Steinmann pin is removed or falls out insert the central screw drill guide into the glenoid baseplate and drill a 3.2mm diameter hole to the desired depth. Read corresponding depth marking on the 3.2mm diameter drill from the back of the drill guide (Figure 29).

3. If Steinmann pin is removed or falls out, place the central screw depth gauge into the reverse Morse central taper of the glenoid baseplate and read the corresponding depth marking from the gauge (Figure 30).

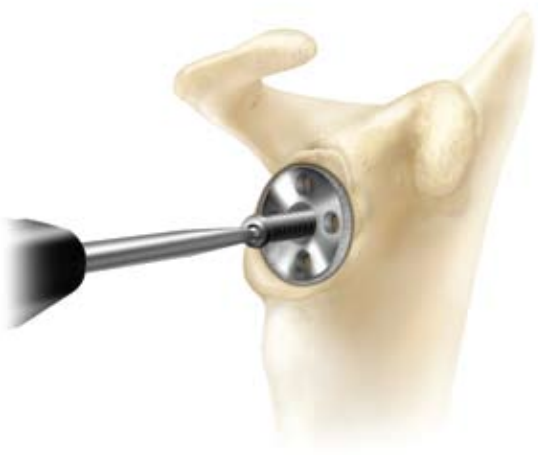

Figure 31

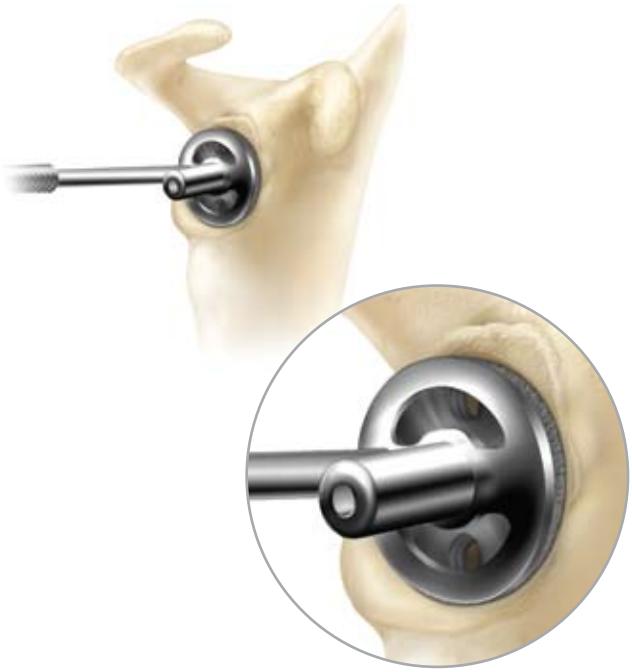

Figure 32

Insert the desired length 6.5mm central screw (Figure 31) and completely tighten with the 3.5mm hex driver. To verify the 6.5mm central screw is fully seated in the baseplate, a check with the central screw drill guide should be performed. Simply attach the central screw drill guide/ template to the glenoid handle, and insert the guide into the reverse Morse taper of the baseplate. If the guide sits flush on the baseplate without rocking or toggling, the central screw is completely and correctly seated (Figure 32).

If the guide does not sit flush, the central screw is not completely tightened. Additional effort should be made to inspect for unwanted soft tissue or debris behind the screw head; then fully seat the central screw. A fully seated central screw provides the best compression and fixation, as well as ensures the male taper of the glenosphere will fully engage.

Tip: The most common length of central screw is 30–35mm.

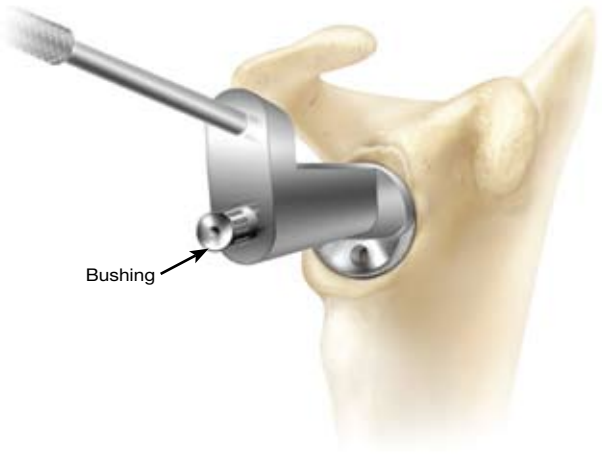

Figure 33

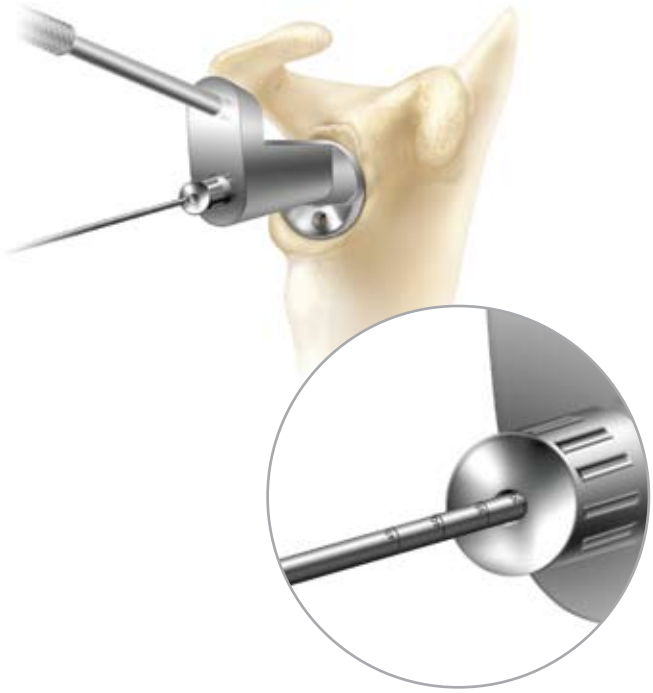

Figure 34

Peripheral Screw Selection/Insertion

Position the peripheral drill guide with bushing insert on the baseplate (Figure 33) and drill the superior hole using 2.7mm drill (Figure 34).

Ensure the drill bushing is flush with the guide when reading the depth markings. Remove the drill bushing insert from the guide.

As an alternative, a depth gauge is available. The peripheral screw depth gauge should be inserted directly into the desired baseplate peripheral hole noting the depth marking.

Note: The depth gauge marked “peripheral depth gauge” should not be used in conjunction with a drill guide.

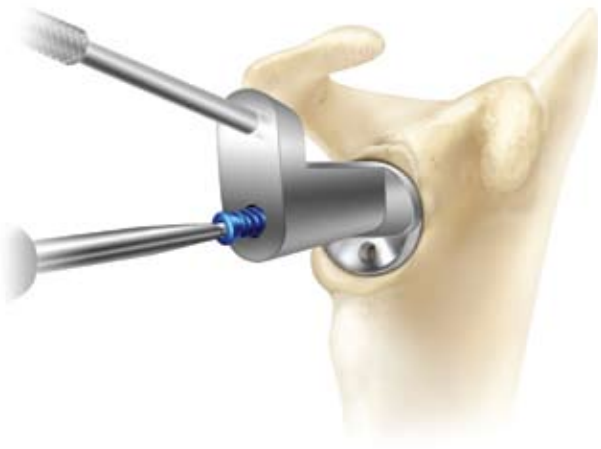

Figure 35

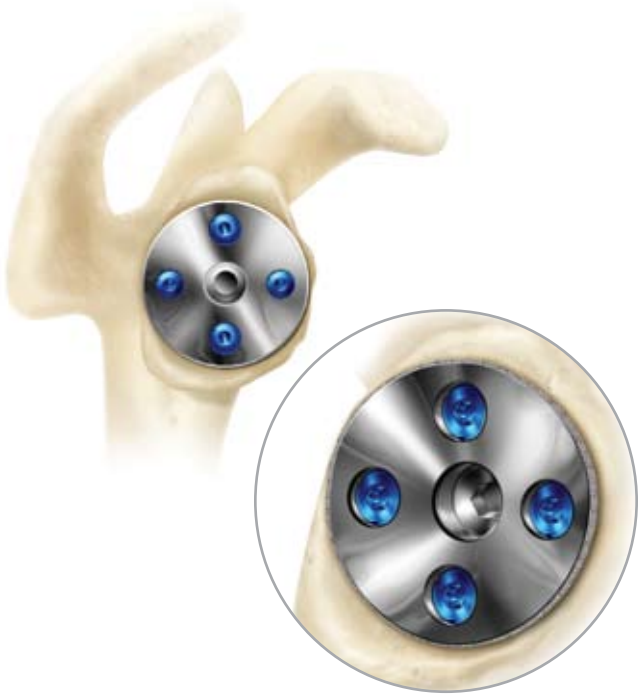

Figure 36

Select and tighten the appropriate length 4.75mm screw through the channel in the drill guide using the 2.5mm hex driver, and into the baseplate without completely tightening (Figure 35). Rotate the peripheral drill guide and bushing 180 degrees and repeat for opposing screw. Repeat these steps for the remaining two peripheral screws.

Warning: It is important to ensure the screw driver and screw are parallel with each other and fully engaged as you insert the screws. Deviation from this technique may lead to stripping of the driver and screw interface. Once the screws are fully seated in the baseplate, do not over-tighten.

Note: It is advisable to inspect all screw drivers after each surgery and replace as necessary.

Tighten all peripheral locking screws in an alternating fashion until fully seated to complete baseplate screw insertion (Figure 36).

Tip: The most common length of superior and inferior screws is 30–35mm. The most common length of anterior and posterior screws is 15mm. Typically, locking screws are used in the superior and inferior holes, while non-locking screws are used in the anterior and posterior holes.

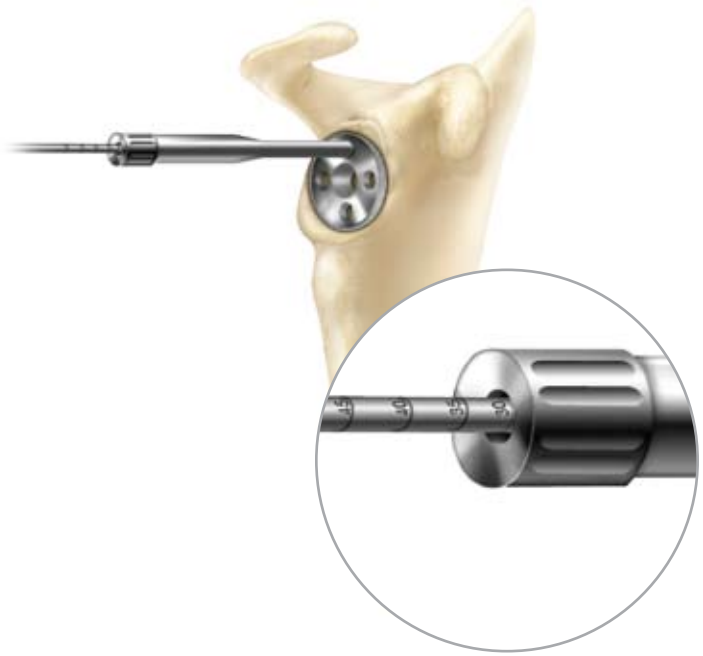

Figure 37

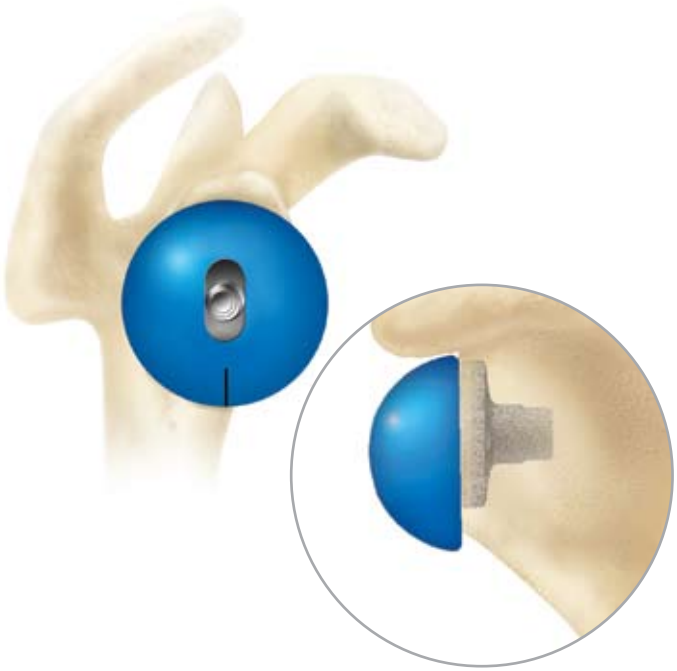

Figure 38

Peripheral Screw Selection/Insertion (Optional Method)

As an alternative to using the peripheral drill guide with bushing insert, the peripheral drill guides (fixed angle or variable angle) that thread into each baseplate peripheral hole may be used. The threaded peripheral drill guide is threaded into the baseplate (Figure 37). With the 2.7mm peripheral drill bit, drill the superior hole and read the desired depth marking at the end of the drill guide. Unscrew the threaded peripheral drill guide from the baseplate, and insert the appropriate peripheral screw. Repeat until all four peripheral screws are inserted, and fully tighten in an alternating fashion.

Note: If using the variable-angle threaded peripheral drill guide, the non-locking 4.75mm peripheral screw must be used. Twelve degrees of angulation is possible.

Note: If using the fixed-angle threaded peripheral drill guide, either the locking or non-locking 4.75mm peripheral screws may be used.

Glenosphere Selection

Select the appropriately sized glenosphere trial and assemble to a trial taper adaptor. Determine the amount and orientation of glenosphere offset, keeping in mind that a fully inferior offset glenosphere provides the best opportunity to minimize or eliminate scapular notching (Figure 38). However, it is possible to orient the glenosphere offset in any direction including anterior/posterior, which may help with extreme instability. Glenosphere provisionals are marked with an arrow to show offset direction.

In addition to the amount and direction of offset, medialized or lateralized center of rotation glenospheres are available depending on preference.

Tip: The most common glenospheres used are 36mm.

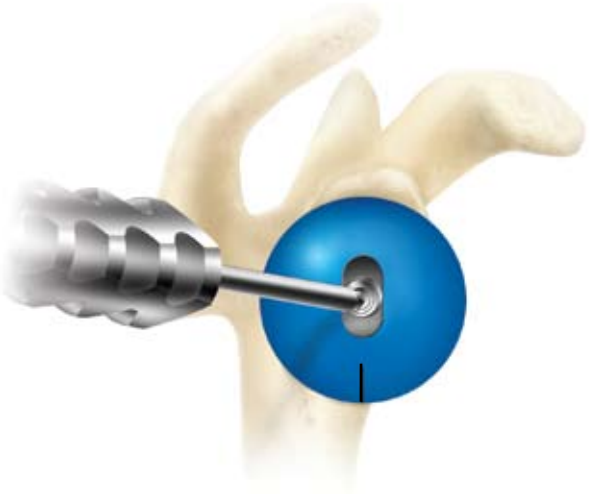

Figure 39

Figure 40

After desired positioning of glenosphere trial is achieved, tighten the taper adaptor trial in the head trial with the 5⁄32 inch Versa-Dial® hex driver (Figure 39).

Note: It may be helpful to use the trial glenosphere wrench for optimal positioning and ease of use of the trial glenosphere.

Glenosphere Offset

Remove the glenosphere trial assembly from the glenoid baseplate. Determine the amount of offset needed by referencing the A, B, C, D, and E* indications on the underside of the trial glenosphere and trial adaptor (Figure 40). This offset indicator will be referenced when preparing the definitive implant.

Note: The glenosphere removal fork may be required to remove the trial glenosphere from the glenoid baseplate.

Note: There is no variability in the offset of the 31mm glenospheres, however the fixed offset may be positioned in any orientation relative to the glenoid baseplate.

*The 36mm standard glenosphere provisional is marked with B, C, D indications as the offset range is 1.5mm to 3.5mm for the definitive implant.

Figure 41

Figure 42

Glenosphere Assembly

Place the glenosphere implant into the impactor base. Ensuring the components are clean and dry, insert the taper adaptor into the glenosphere (Figure 41). Rotate the taper adaptor until the trial offset is replicated. For example, if trialing indicated a fully offset glenosphere (position E), the implant taper adaptor is aligned so that the hashmark is positioned at position E on the definitive glenosphere head.

Offset Indicator	Offset*
A	0.5mm
B	1.5mm
C	2.5mm
D	3.5mm
E	4.5mm

*For 36mm Standard Glenosphere, the offset range is 1.5–3.5mm.

Engage the Morse taper with two firm strikes, using the taper impactor tool and mallet (Figure 42). The taper/glenosphere assembly is now secure.

Note: In the event the taper has been engaged in an incorrect position, the Versa-Dial® taper extractor may be used to remove the taper adaptor from the glenosphere. After removal of the taper adaptor, a new taper adaptor should be used.

Note: The 31mm glenospheres are a one-piece construct, with a fixed offset.

Figure 43

Figure 44

Glenosphere/Taper Adaptor Offset Direction Determination

Place the glenosphere into the orientation block for determination of offset direction. Rotate the glenosphere until the implant reaches the point that is furthest on the orientation block scale. This orientation will represent the direction of the offset (Figure 43).

Place the inserter with the suction cup attachment over the top of the glenosphere so the white indicator on the suction cup is pointing toward the direction of the offset (Figure 44).

As an alternative to the suction cup, a surgical marker can be used to note the direction of the offset on the rim of the glenosphere. The glenosphere can then be inserted into the baseplate by hand.

Figure 45

Figure 46

Glenosphere Orientation/Impaction

Once the reverse Morse taper of the baseplate has been cleaned and dried using the included taper swabs, engage the glenosphere with the suction mechanism, and implant the glenosphere in the same orientation as the trial (Figure 45). It is recommended to hold the glenosphere while it is positioned within the baseplate. With two firm strikes, a concave glenosphere impactor should be used to engage the glenosphere into the baseplate.

A screw is not needed to attach the glenosphere to the baseplate. The design of the Morse tapers provide a secure mode of fixation.

Humeral Tray and Bearing

Humeral Tray and Bearing Preparation

Select the appropriately sized one-piece trial humeral tray/bearing. Noting the "SUPERIOR" and "INFERIOR" markings on the humeral tray, place the trial humeral tray/bearing into the Comprehensive® broach/trial (Figure 46) and perform a trial reduction to assess range of motion and implant size selection. The included shoe horn may be helpful in reducing the joint. The trial reduction should show very limited distraction (1mm or less).

In cases of extreme instability, +3mm retentive humeral bearings are available. Retentive bearings capture more of the glenosphere and have polyethylene walls which are 2–3mm higher than standard bearings, but do not add any additional joint space.

Note: Additional humeral resection and subsequent re-reaming and re-broaching may be required if the joint is extremely difficult to reduce.

Note: Glenospheres and humeral bearings have been color coded to ensure only matching curvatures are used together.

Tip: The most common thickness of the tray and bearing is standard.

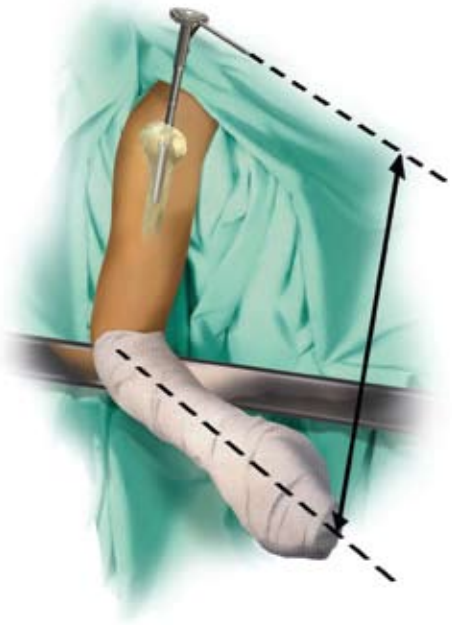

Figure 47

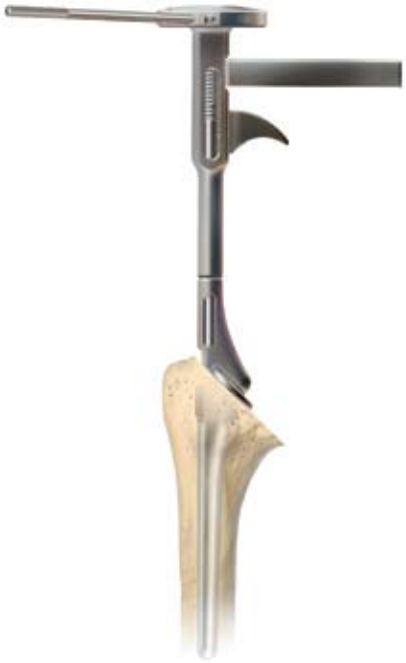

Figure 48

Standard Stem Insertion—Uncemented

Attach the broach handle to the broach/trial, and remove it from the humeral canal. In situations where fluid build-up prevents the broach inserter from engaging the broach, the broach extractor will enable removal of the broach.

Select a humeral stem which matches the final broach/trial used. Assemble the humeral stem onto the humeral stem inserter. Place the version control rod into the appropriate version hole and align it with the forearm flexed at 90 degrees in external rotation (Figure 47). Insert the stem into the humeral canal (Figure 48), impacting if necessary. The implant is fully seated when the collar on the implant inserter rests on the resected surface of the humerus.

Standard Stem Insertion—Cemented

Attach the broach handle to the broach/trial, and remove it from the humeral canal. Select a humeral stem 2mm smaller than the final broach/trial used. Assemble the humeral stem onto the humeral stem inserter.

Use a pulse lavage/suction unit to thoroughly clean the humeral canal. Dry the canal with absorbent gauze and inject doughy cement in a retrograde manner, completely filling the humeral canal.

Place the version control rod into the appropriate version hole and align it with the forearm flexed at 90 degrees in external rotation (Figure 47). Introduce the implant into the humeral canal (Figure 48), keeping the alignment rod in line with the forearm, until the desired position is attained. Remove excess cement. The implant is fully seated when the collar on the implant inserter rests on the resected surface of the humerus.

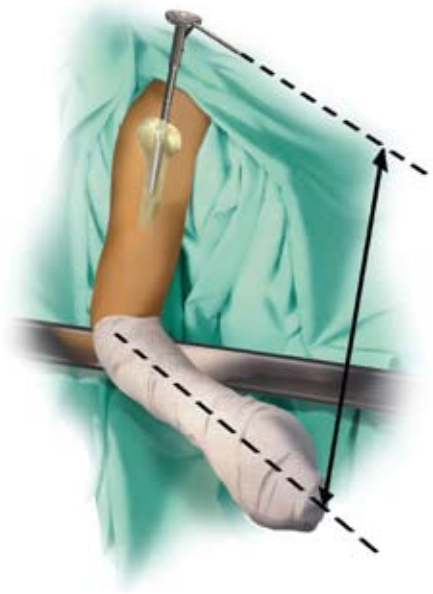

Figure 49

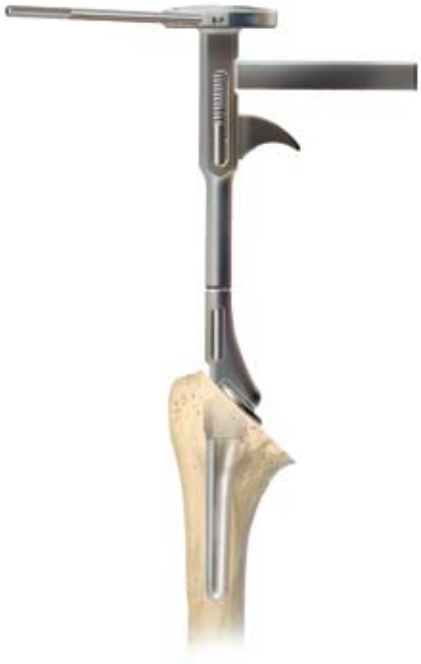

Figure 50

Mini Stem Insertion—Uncemented

Attach the broach handle to the broach/trial, and remove it from the humeral canal. In situations where fluid build-up prevents the broach inserter from engaging the broach, the broach extractor will enable removal of the broach.

Select a humeral stem which matches the final broach/trial used. Assemble the humeral stem onto the humeral stem inserter. Place the version control rod into the appropriate version hole and align it with the forearm flexed at 90 degrees in external rotation (Figure 49). Insert the stem into the humeral canal (Figure 50), impacting if necessary. The implant is fully seated when the collar on the implant inserter rests on the resected surface of the humerus.

Mini Stem Insertion—Cemented

Attach the broach handle to the broach/trial, and remove it from the humeral canal. Select a humeral stem 2mm smaller than the final broach/trial used. Assemble the humeral stem onto the humeral stem inserter.

Use a pulse lavage/suction unit to thoroughly clean the humeral canal. Dry the canal with absorbent gauze and inject doughy cement in a retrograde manner, completely filling the humeral canal.

Place the version control rod into the appropriate version hole and align it with the forearm flexed at 90 degrees (Figure 49). Introduce the implant into the humeral canal (Figure 50), keeping the alignment rod in line with the forearm, until the desired position is attained. Remove excess cement. The implant is fully seated when the collar on the implant inserter rests on the resected surface of the humerus.

Figure 51

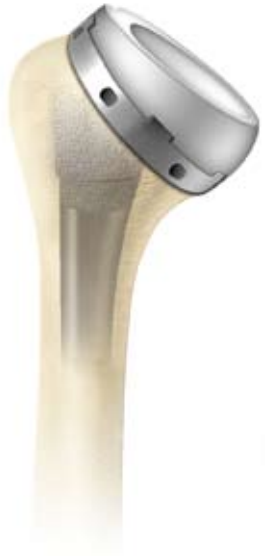

Figure 52

Humeral Tray and Bearing Assembly

Position the definitive humeral bearing in the definitive humeral tray, ensuring that the laser etching on the bearing aligns with the laser etching on the humeral tray. This alignment assures engagement of the RingLoc® locking mechanism between the tray and bearing. Snap the humeral bearing into the humeral tray (Figure 51). An audible "click" will be heard when the bearing is properly engaged.

Tip: Assembly of humeral tray and bearing may be aided by using index fingers and thumbs to compress and snap into place.

Humeral Tray/Bearing Impaction

Clean and dry the reverse Morse taper of the stem with the included taper swabs. With two firm strikes of the humeral tray/bearing impactor, impact the assembled definitive humeral tray/bearing into the Comprehensive® stem. The humeral tray is marked "SUPERIOR" to aid in positioning the tray/bearing with respect to the stem. Reduce the joint with the aid of the shoe horn and assess the final range of motion (Figure 52). The final reduction should show very limited distraction (1mm or less). Impingement should not be present in either adduction or abduction. If impingement occurs in abduction, a greater tuberosity osteotomy or tuberoplasty may be necessary.

Figure 53

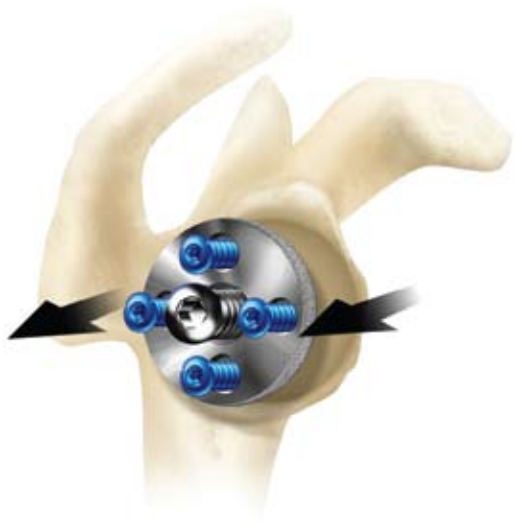

Figure 54

Subscapularis Repair

There is some evidence that the subscapularis improves the stability of the implant. Therefore, when possible, the subscapularis should be repaired at the completion of the procedure, as long as it does not significantly reduce external rotation. If the tissue at the lesser tuberosity is poor, place sutures through the bone prior to implantation of the stem.

Salvage Hemi-arthroplasty

In the event a Comprehensive® Reverse Shoulder fails, a salvage hemi-arthroplasty may be the only option for a patient. While expectation for pain relief and/or function should be reduced, a salvage reverse to hemi-arthroplasty conversion may be done without removing a Comprehensive® stem.

Removal of Glenosphere/Baseplate

Remove the Versa-Dial® glenosphere with the low-profile head removal fork. Once the glenosphere is removed, the peripheral and central screws should be backed-out and removed (Figure 54). Finally, the baseplate should be completely removed using the baseplate extractor. It may be desirable to use autograft/allograft material on the glenoid at this time, before proceeding to complete the salvage hemi-arthroplasty.

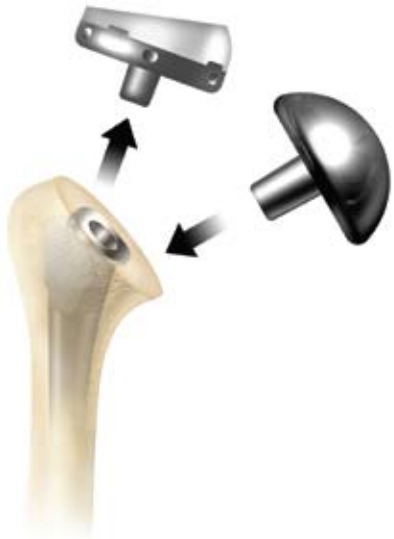

Figure 55

Figure 56

Removal of the Humeral Tray/Bearing

The humeral tray/bearing assembly may be removed by sliding the low-profile humeral removal fork between the assembly and the humeral stem. Once the humeral tray/bearing assembly is removed and the stem taper has been cleaned and dried with the included taper swabs, a large Versa-Dial® or EAS™ humeral head may be inserted and engaged into the Comprehensive® stem (Figure 55).

Polyethylene Humeral Bearing Removal/Exchange

If a humeral bearing ever needs to be replaced, the RingLoc® locking mechanism of the humeral tray will allow for exchange/revision of bearings without tray removal (Figure 56). To remove a humeral bearing, simply expand the locking ring using the Ringloc® liner removal tool. Position the curved portion of the tip towards the bearing and insert between the open portion of the locking ring. This will expand the ring. Once the ring has been expanded, slide the removal tool down and then underneath the bearing. The humeral bearing is now released. Whenever a bearing is removed, a new locking ring should be placed into the humeral tray before the new bearing is locked in place.

Humeral Stem Sizing

Standard Stem

Last Reamer Used	Broach to Size	Implant Size
20 STD / 19 MI	20mm	20mm
19 STD / 18 MI	19mm	19mm
18 STD / 17 MI	18mm	18mm
17 STD / 16 MI	17mm	17mm
16 STD / 15 MI	16mm	16mm
15 STD / 14 MI	15mm	15mm
14 STD / 13 MI	14mm	14mm
13 STD / 12 MI	13mm	13mm
12 STD / 11 MI	12mm	12mm
11 STD / 10 MI	11mm	11mm
10 STD / 9 MI	10mm	10mm
9 STD / 8 MI	9mm	9mm
8 STD / 7 MI	8mm	8mm
7 STD / 6 MI	7mm	7mm
6 STD / 5 MI	6mm	6mm
5 STD / 4 MI**	5mm	5mm
4 STD**	4mm	4mm
4 STD**	4mm	4mm

** Since there are no numeric hashmarks on the teeth of these reamers, ream to the horizontal hashmark.

Mini Stem

Last Reamer Used	Broach to Size	Implant Size
20 STD / 19 MI*	20mm	20mm
20 STD / 19 MI	19mm	19mm
19 STD / 18 MI	18mm	18mm
18 STD / 17 MI	17mm	17mm
17 STD / 16 MI	16mm	16mm
16 STD / 15 MI	15mm	15mm
15 STD / 14 MI	14mm	14mm
14 STD / 13 MI	13mm	13mm
13 STD / 12 MI	12mm	12mm
12 STD / 11 MI	11mm	11mm
11 STD / 10 MI	10mm	10mm
10 STD / 9 MI	9mm	9mm
9 STD / 8 MI	8mm	8mm
8 STD / 7 MI	7mm	7mm
7 STD / 6 MI	6mm	6mm
6 STD / 5 MI	5mm	5mm
5 STD / 4 MI**	5mm	5mm
4 STD**	4mm	4mm

* Ream to horizontal hashmark in order to implant the 20mm mini stem, as there is not a larger reamer to facilitate reaming to a point between the 3 and 4 hashmark.

** Since there are no numeric hashmarks on the teeth of these reamers, ream to the horizontal hashmark.

Implants

Product	Part Number	Description	Size
	**115300**	Fixed Offset Glenosphere Standard	31mm
	115306	Fixed Offset Glenosphere +6mm	31mm
	115310	Versa-Dial® Glenosphere Standard	36mm
	115313	Versa-Dial® Glenosphere +3mm	36mm
	115316	Versa-Dial® Glenosphere +6mm	36mm
	115320	Versa-Dial® Glenosphere Standard	41mm
	115323	Versa-Dial® Glenosphere +3mm	41mm
	115326	Versa-Dial® Glenosphere +6mm	41mm
	**118001**	Versa-Dial® Taper Adaptor	—
	**115330**	Glenoid Baseplate	28mm
	**115340**	Humeral Tray Standard	44mm
	115345	Humeral Tray +5mm	44mm
	115348	Humeral Tray +10mm	44mm
	**XL-115360**	ArComXL® Standard Humeral Bearing	44–31
	XL-115361	ArComXL® +3mm Humeral Bearing	44–31
	XL-115362	ArComXL® Retentive +3mm Humeral Bearing	44–31
	XL-115363	ArComXL® Standard Humeral Bearing	44–36
	XL-115364	ArComXL® +3mm Humeral Bearing	44–36
	XL-115365	ArComXL® Retentive +3mm Humeral Bearing	44–36
	XL-115366	ArComXL® Standard Humeral Bearing	44–41
	XL-115367	ArComXL® +3mm Humeral Bearing	44–41
	XL-115368	ArComXL® Retentive +3mm Humeral Bearing	44–41
—	**106021**	RingLoc® Replacement Humeral Tray Ring	—

Implants, continued

Product	Part Number	Description	Size
	**113604**	Comprehensive® Humeral Stem—Micro	4mm
	113605	Comprehensive® Humeral Stem—Micro	5mm
	113606	Comprehensive® Humeral Stem—Micro	6mm
	113607	Comprehensive® Humeral Stem—Micro	7mm
	113608	Comprehensive® Humeral Stem—Micro	8mm
	113609	Comprehensive® Humeral Stem—Micro	9mm
	113610	Comprehensive® Humeral Stem—Micro	10mm
	113611	Comprehensive® Humeral Stem—Micro	11mm
	113612	Comprehensive® Humeral Stem—Micro	12mm
	113613	Comprehensive® Humeral Stem—Micro	13mm
	113614	Comprehensive® Humeral Stem—Micro	14mm
	113615	Comprehensive® Humeral Stem—Micro	15mm
	113616	Comprehensive® Humeral Stem—Micro	16mm
	113617	Comprehensive® Humeral Stem—Micro	17mm
	113618	Comprehensive® Humeral Stem—Micro	18mm
	113619	Comprehensive® Humeral Stem—Micro	19mm
	113620	Comprehensive® Humeral Stem—Micro	20mm
	**113624**	Comprehensive® Humeral Stem—Mini	4mm
	113625	Comprehensive® Humeral Stem—Mini	5mm
	113626	Comprehensive® Humeral Stem—Mini	6mm
	113627	Comprehensive® Humeral Stem—Mini	7mm
	113628	Comprehensive® Humeral Stem—Mini	8mm
	113629	Comprehensive® Humeral Stem—Mini	9mm
	113630	Comprehensive® Humeral Stem—Mini	10mm
	113631	Comprehensive® Humeral Stem—Mini	11mm
	113632	Comprehensive® Humeral Stem—Mini	12mm
	113633	Comprehensive® Humeral Stem—Mini	13mm
	113634	Comprehensive® Humeral Stem—Mini	14mm
	113635	Comprehensive® Humeral Stem—Mini	15mm
	113636	Comprehensive® Humeral Stem—Mini	16mm
	113637	Comprehensive® Humeral Stem—Mini	17mm
	113638	Comprehensive® Humeral Stem—Mini	18mm
	113639	Comprehensive® Humeral Stem—Mini	19mm
	113640	Comprehensive® Humeral Stem—Mini	20mm

Product	Part Number	Description	Size
	113644	Comprehensive® Humeral Stem—Standard	4mm
	113645	Comprehensive® Humeral Stem—Standard	5mm
	113646	Comprehensive® Humeral Stem—Standard	6mm
	113647	Comprehensive® Humeral Stem—Standard	7mm
	113648	Comprehensive® Humeral Stem—Standard	8mm
	113649	Comprehensive® Humeral Stem—Standard	9mm
	113650	Comprehensive® Humeral Stem—Standard	10mm
	113651	Comprehensive® Humeral Stem—Standard	11mm
	113652	Comprehensive® Humeral Stem—Standard	12mm
	113653	Comprehensive® Humeral Stem—Standard	13mm
	113654	Comprehensive® Humeral Stem—Standard	14mm
	113655	Comprehensive® Humeral Stem—Standard	15mm
	113656	Comprehensive® Humeral Stem—Standard	16mm
	113657	Comprehensive® Humeral Stem—Standard	17mm
	113658	Comprehensive® Humeral Stem—Standard	18mm
	113659	Comprehensive® Humeral Stem—Standard	19mm
	113660	Comprehensive® Humeral Stem—Standard	20mm
	11-113554	Comprehensive® Humeral Stem—Fracture	4mm
	11-113556	Comprehensive® Humeral Stem—Fracture	6mm
	11-113558	Comprehensive® Humeral Stem—Fracture	8mm
	11-113560	Comprehensive® Humeral Stem—Fracture	10mm
	11-113562	Comprehensive® Humeral Stem—Fracture	12mm
	11-113564	Comprehensive® Humeral Stem—Fracture	14mm
	113664	Comprehensive® Humeral Stem—Revision	4mm
	113665	Comprehensive® Humeral Stem—Revision	5mm
	113666	Comprehensive® Humeral Stem—Revision	6mm
	113667	Comprehensive® Humeral Stem—Revision	7mm
	113668	Comprehensive® Humeral Stem—Revision	8mm
	113669	Comprehensive® Humeral Stem—Revision	9mm
	113670	Comprehensive® Humeral Stem—Revision	10mm
	113671	Comprehensive® Humeral Stem—Revision	11mm
	113672	Comprehensive® Humeral Stem—Revision	12mm
	113673	Comprehensive® Humeral Stem—Revision	13mm
	113674	Comprehensive® Humeral Stem—Revision	14mm
	113675	Comprehensive® Humeral Stem—Revision	15mm

Implants, continued

Product	Part Number	Description	Size
	**115380**	6.5mm Central Screw	20mm length
	115381	6.5mm Central Screw	25mm length
	115382	6.5mm Central Screw	30mm length
	115383	6.5mm Central Screw	35mm length
	115384	6.5mm Central Screw	40mm length
	115385	6.5mm Central Screw	45mm length
	115386	6.5mm Central Screw	50mm length
	**180500**	4.75mm Fixed Locking Screw	15mm length
	180501	4.75mm Fixed Locking Screw	20mm length
	180502	4.75mm Fixed Locking Screw	25mm length
	180503	4.75mm Fixed Locking Screw	30mm length
	180504	4.75mm Fixed Locking Screw	35mm length
	180505	4.75mm Fixed Locking Screw	40mm length
	180506	4.75mm Fixed Locking Screw	45mm length
	**180507**	4.75 Fixed Non-Locking Screw	15mm length
	180508	4.75 Fixed Non-Locking Screw	20mm length
	180509	4.75 Fixed Non-Locking Screw	25mm length
	180510	4.75 Fixed Non-Locking Screw	30mm length
	180511	4.75 Fixed Non-Locking Screw	35mm length
	180512	4.75 Fixed Non-Locking Screw	40mm length
	180513	4.75 Fixed Non-Locking Screw	45mm length

Instruments

Product	Part Number	Description	Size
	**405902**	Baseplate Provisional	28mm
	**405903**	Glenosphere Provisional Standard	31mm
	405905	Glenosphere Provisional +6mm	31mm
	405810	Glenosphere Provisional Standard	36mm
	405813	Glenosphere Provisional +3mm	36mm
	405816	Glenosphere Provisional +6mm	36mm
	405820	Glenosphere Provisional Standard	41mm
	405823	Glenosphere Provisional +3mm	41mm
	405826	Glenosphere Provisional +6mm	41mm

Product	Part Number	Description	Size
	**405910**	Humeral Bearing/Tray Trial, 44STD–31STD	31mm
	405915	Humeral Bearing/Tray Trial, 44+5–31STD	
	405918	Humeral Bearing/Tray Trial, 44+10–31STD	
	405920	Humeral Bearing/Tray Trial, 44STD–31+3	
	405925	Humeral Bearing/Tray Trial, 44+5–31+3	
	405928	Humeral Bearing/Tray Trial, 44+10–31+3	
	405930	Humeral Bearing/Tray Trial,44STD–31RET+3	
	405935	Humeral Bearing/Tray Trial,44+5–31RET+3	
	405938	Humeral Bearing/Tray Trial, 44+10–31RET+3	
	**405940**	Humeral Bearing/Tray Trial, 44STD–36STD	36mm
	405945	Humeral Bearing/Tray Trial, 44+5–36STD	
	405948	Humeral Bearing/Tray Trial, 44+10–36STD	
	405950	Humeral Bearing/Tray Trial, 44STD–36+3	
	405955	Humeral Bearing/Tray Trial, 44+5–36+3	
	405958	Humeral Bearing/Tray Trial, 44+10–36+3	
	405960	Humeral Bearing/Tray Trial, 44STD–36RET+3	
	405965	Humeral Bearing/Tray Trial, 44+5–36RET+3	
	405968	Humeral Bearing/Tray Trial, 44+10–36RET+3	
	**405970**	Humeral Bearing/Tray Trial, 44STD–41STD	41mm
	405975	Humeral Bearing/Tray Trial, 44+5–41STD	
	405978	Humeral Bearing/Tray Trial, 44+10–41STD	
	405980	Humeral Bearing/Tray Trial, 44STD–41+3	
	405985	Humeral Bearing/Tray Trial, 44+5–41+3	
	405988	Humeral Bearing/Tray Trial, 44+10–41+3	
	405990	Humeral Bearing/Tray Trial, 44STD–41RET+3	
	405995	Humeral Bearing/Tray Trial, 44+5–41RET+3	
	405998	Humeral Bearing/Tray Trial, 44+10–41RET+3	
	**405906**	Taper Adaptor Provisional	—
	405800	9 inch Steinmann Pin	3.2mm Ø
	**405802**	Sizer with 10 Degree Inferior Tilt	—
	406849	Guide Handle	—
	**405806**	Glenoid Baseplate Reamer	—

Instruments, continued

Product	Part Number	Description	Size
	**405890**	Glenoid Planer with Blades	—
	**405880**	Fixed Angle Drill Guide	—
	**405881**	Variable Angle Drill Guide	—
	405889	Peripheral Screw Drill	2.7mm Ø
	405883	Central Screw Drill	3.2mm Ø
	**405884**	Drill Guide/Template	3.2mm Ø
	**405885**	Peripheral Screw Hex Driver	2.5mm
	**405808**	Glenoid Tray Impactor	—
	**405886**	Trial Glenosphere Wrench	—
	**405898**	Central Screw Hex Driver	3.5mm
	**405887**	Offset Orientation Block	—
	**405830**	Peripheral Screw Depth Gauge Assembly	—
	**405831**	Central Screw Depth Gauge Assembly	—
	**405882**	Peripheral Drill and Screw Guide	—
	**405833**	Peripheral Drill Guide Insert	2.7mm
	**405835**	Humeral Bearing/Tray Impactor	—
	**407297**	Glenosphere Impactor	—
	**405832**	Glenosphere Removal Fork	—

Product	Part Number	Description	Size
	**405899**	Glenosphere Inserter Handle/Suction	—
	**31-424206**	RingLoc® Liner Release Tool	—
	**405904**	Baseplate Extractor	—
	**406668**	Baseplate Extraction Bar	—
	**405901**	Shoehorn	—
	**407296**	Versa-Dial® Trial Screwdriver	—
	**407280**	Versa-Dial® Taper Impactor	—
	**407281**	Versa-Dial® Impactor Base	—
	**32-420160**	Steinmann Pin Puller	—
	**405908**	Ratcheting Handle	—
	**994500850**	Bent Ring Fukuda	—
	**406699**	Large Ring Fukuda	—
	**405891**	Golf Club Retractor	—
	**405892**	Thin Glenoid Retractor	—

Instruments, continued

Product	Part Number	Description	Size
	**405893**	Wide Glenoid Retractor	—
	**402852**	2-Prong Capsular Retractor	—
	**405895**	Modified Darrach Retractor	—
—	**405801**	Comprehensive® Reverse X-ray Templates	—
—	**595510**	Comprehensive® Reverse Shoulder Total Instrument Case	—
—	**595505**	Comprehensive® Retractor Set Total Instrument Case	—
—	**595509**	Comprehensive® Reverse Shoulder Instrument Case Shell (With Lid)	—
—	**595501**	Comprehensive® Reverse Shoulder Instrument Case 1	—
—	**595502**	Comprehensive® Reverse Shoulder Instrument Case 2	—
—	**595503**	Comprehensive® Reverse Shoulder Instrument Case 3	—

Biomet Orthopedics, Inc
P.O. Box 587
56 East Bell Drive
Warsaw, Indiana 46581 USA

01-50-0903
Date: 06/08

Biomet® Comprehensive™ Reverse Shoulder Products

ATTENTION OPERATING SURGEON

DESCRIPTION
Biomet® Comprehensive™ Reverse Shoulder products are intended for total shoulder replacement in a reverse configuration.

MATERIALS

Baseplates	Titanium Alloy
Baseplate Screws	Titanium Alloy
Humeral Tray	Titanium Alloy
Snap Ring	Titanium Alloy
Glenospheres	CoCrMo Alloy
Humeral Bearings	UHMWPE
Surface Coating	Titanium Alloy / Hydroxyapatite (HA)
Taper Adaptor	Titanium Alloy

INDICATIONS
Biomet® Comprehensive™ Reverse Shoulder products are indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Comprehensive™ Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Interlok™ finish humeral stems are intended for cemented use and the MacroBond™ coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

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. The use of a reverse shoulder prosthesis in patients with a deficient rotator cuff could increase the risk of component loosening due to non-anatomic loading conditions. 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. Humeral and glenosphere components should be used only when there is good quality bone.
2. Disassociations of modular components have 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 components to avoid crevice corrosion and improper seating. All additional locking screws must be adequately tightened.
3. 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.

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 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
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, and the patient must have a functional deltoid muscle.

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, incorrect 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 that 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. If glenoid component is not securely fixed, micromotion can lead to peripheral screw failure.
6. Periarticular calcification or ossification, with or without impediment of joint mobility.
7. Inadequate range of motion due to improper selection or positioning of components, lack of rotator cuff, and inadequate function of the deltoid.
8. Undesirable shortening or lengthening of limb.
9. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity or excessive activity can also contribute to these conditions.
10. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
11. Fretting and crevice corrosion can occur at interfaces between components.
12. Wear and/or deformation of articulating surfaces.
13. Intraoperative or postoperative bone fracture and/or postoperative pain.
14. Scapular notching and bone erosion has been reported with the use of reverse shoulder implants. Scapular notching may lead to early failure of glenoid fixation.

STERILITY
Titanium/CoCrMo/E-Poly components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation.

ArComXL™ components are sterilized by exposure to one of the following methods:
- Ethylene Oxide Gas (EtO)
- Gas Plasma.

Do not resterilize Do not use any component from an opened or damaged package. Do not use implants past expiration date.

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

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. 587, Warsaw, IN 46581 USA, FAX: 574-372-3968.

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Biomet at the contact information provided herein.

Biomet Orthopedics, Inc
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

01-50-0944
Date: 01/08

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 adaptors, and bipolar heads.

MATERIALS

Humeral Stems	CoCrMo Alloy or Titanium Alloy
Humeral Head	CoCrMo Alloy/ Titanium Alloy
Glenoid Components	Ultra-High Molecular Weight Polyethylene (UHMWPE)/Tantalum/ 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 Adaptor	CoCrMo Alloy or Titanium 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™ 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.

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. The use of a glenoid prosthesis in patients with a deficient rotator cuff could increase the risk of glenoid component loosening due to non-anatomic loading conditions. 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. Uncemented glenoid components should be used only when there is good quality bone and no significant shoulder instability.
2. 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.
3. 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.
4. 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.
5. The use of Bio-Modular™ MI stems and the shorter Comprehensive™ (micro and mini) primary 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

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.

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, incorrect 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.

Intraoperative and early postoperative complications can include: (1) damage to blood vessels, (2) temporary or permanent nerve damage resulting in pain or numbness to the affected limb, (3) cardiovascular disorders including venous thrombosis, pulmonary embolism or myocardial infarction, (4) hematoma, and (5) delayed wound healing.

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, distribution, or use by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-3968

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA, U.K.

CE 0086

For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert herein and Biomet's website.

BIOMET® ORTHOPEDICS

One Surgeon. One Patient.℠

P.O. Box 587, Warsaw, IN 46581-0587 • 800.348.9500 ext. 1501

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