COMPREHENSIVE®

SHOULDER SYSTEM

SURGICAL TECHNIQUE

BIOMET® ORTHOPEDICS

KNEES • HIPS • EXTREMITIES • CEMENT AND ACCESSORIES • PMI • TECHNOLOGY

TABLE OF CONTENTS

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.

Comprehensive®
SHOULDER SYSTEM

PATIENT POSITIONING AND INCISION

PATIENT POSITIONING AND INCISION

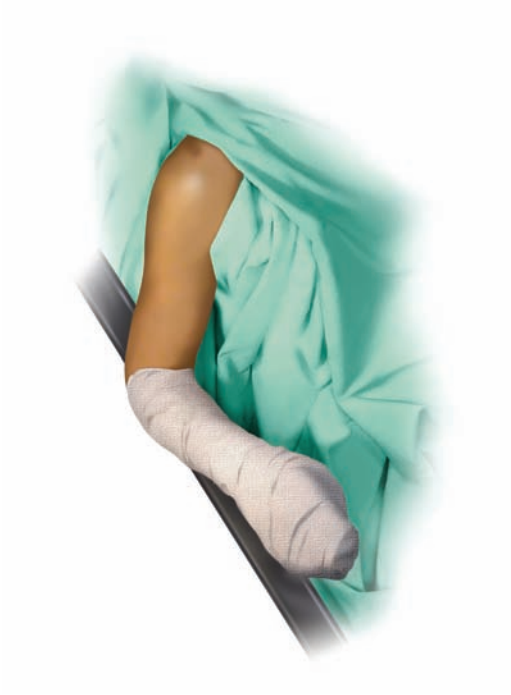


Figure 1

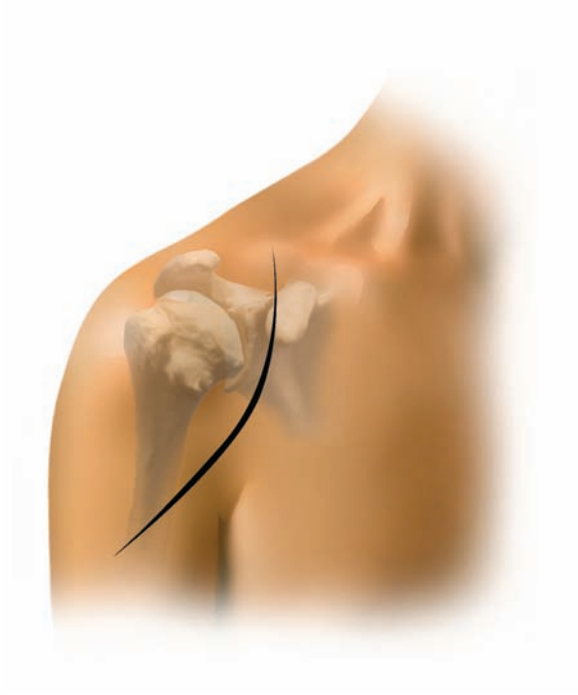


Figure 2

SURGICAL POSITION

The arm and shoulder are prepped and draped free (Figure 1). Utilize a modified beach chair position.

SURGICAL INCISION

Utilize an extended deltopectoral anterior incision with an optional biceps tenodesis 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. Make a partial relaxing incision through the proximal coracoid tendon and medially retract the conjoined tendon.

PATIENT POSITIONING AND INCISION

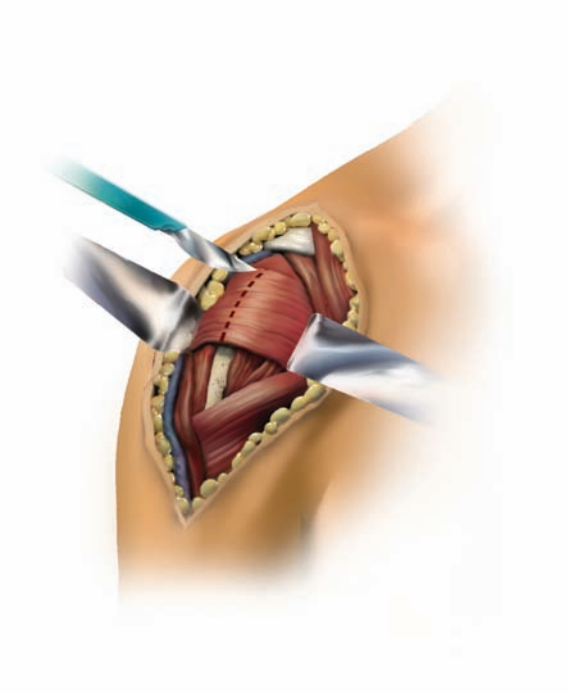


Figure 3

Identify anterior structures and externally rotate the humerus. 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-absorbent sutures. Externally rotate and extend the humerus to expose the humeral head, while protecting the axillary nerve.

Comprehensive®
SHOULDER SYSTEM

MINI STEM TECHNIQUE

MINI STEM TECHNIQUE

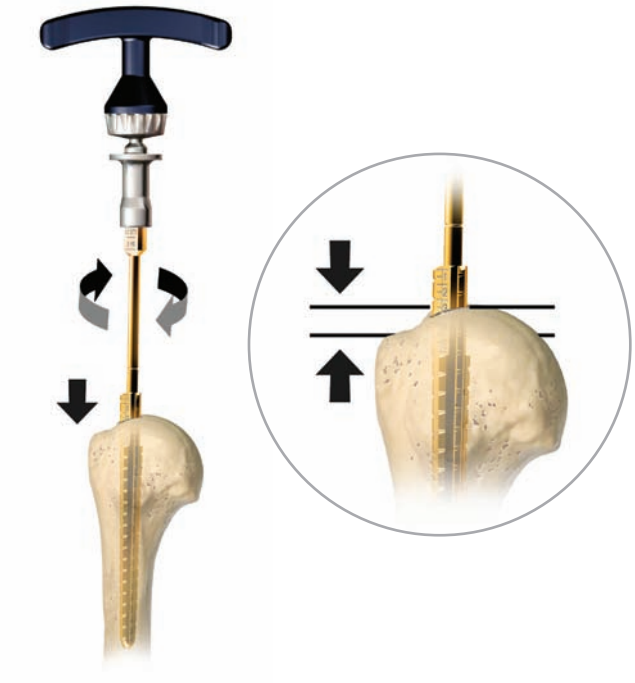


Figure 4

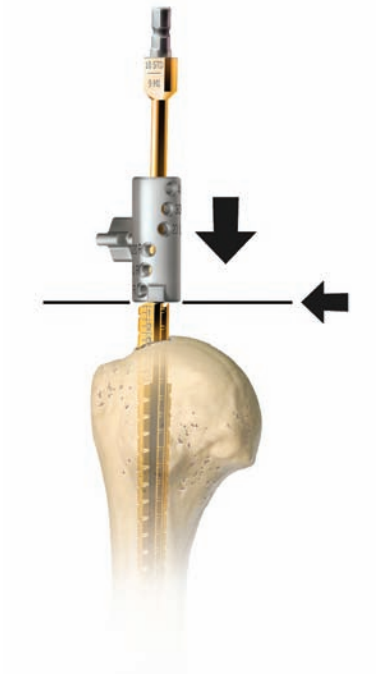


Figure 5

HUMERAL PREPARATION

Using the 4, 5 or 6mm 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 medial to the rotator cuff attachment. Insert the 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 4 inset). Continue reaming in 1mm increments until 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 5).

Figure 6

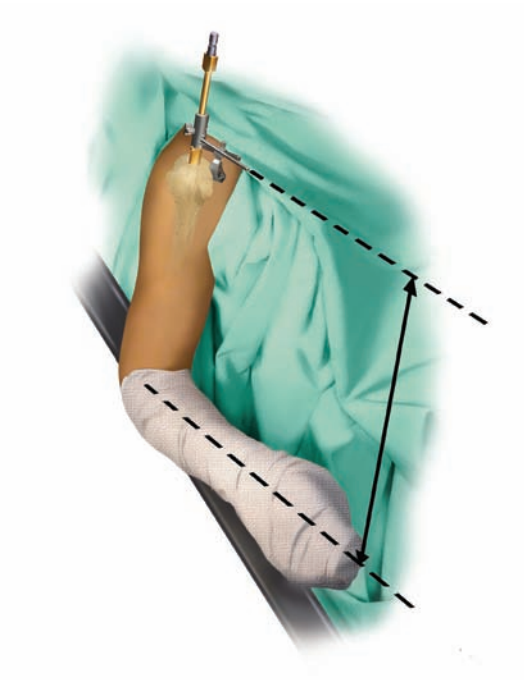


Figure 7

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

Screw the version control rod into the appropriate version hole, and align the rod with the forearm flexed at 90 degrees (Figure 7).

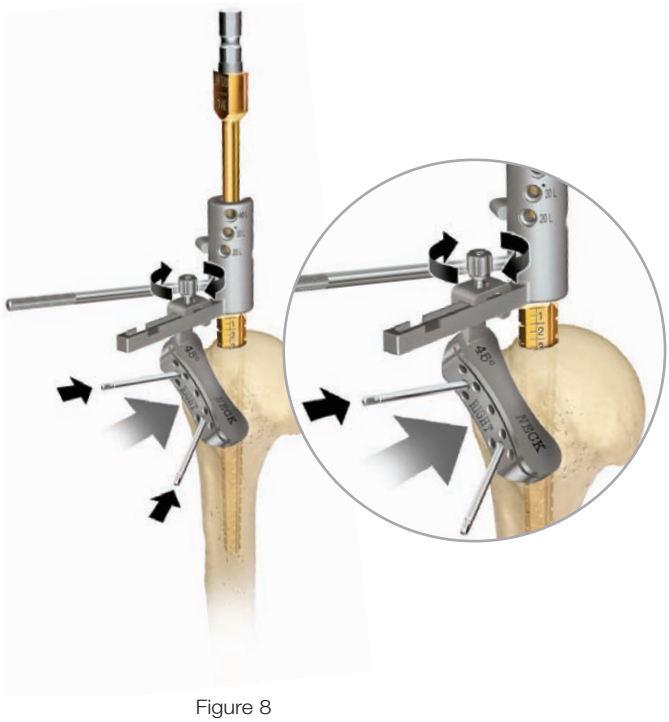


Figure 8

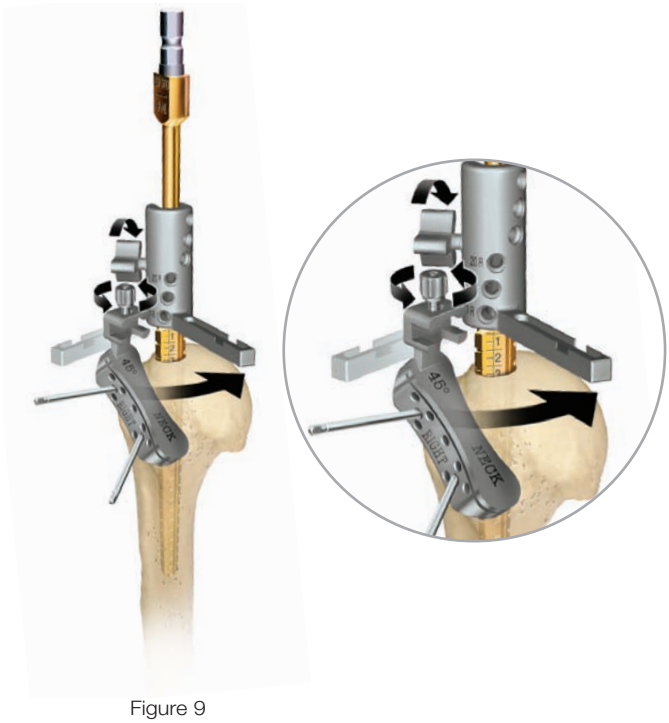


Figure 9

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).

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

Figure 10

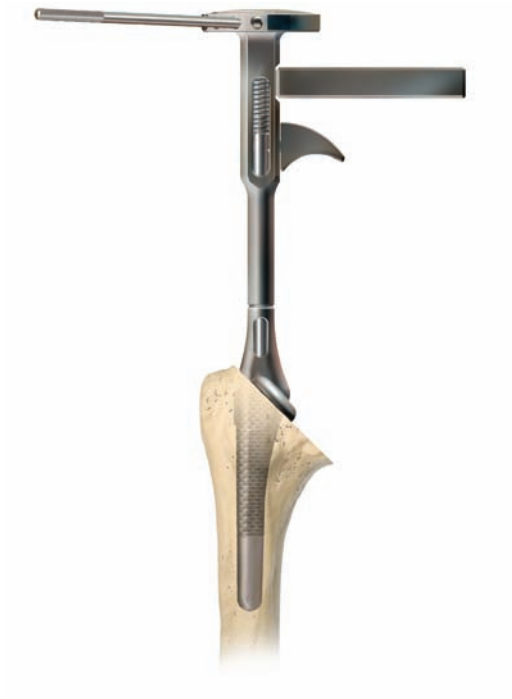


Figure 11

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. Remove the Steinmann pins and the cutting block.

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 37). (Tip: 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 11).* Remove the broach handle, leaving the last broach in place to be used as a trial.

*Caution: If broach feels too tight and will not seat, finish broaching with next smaller size.

Figure 12

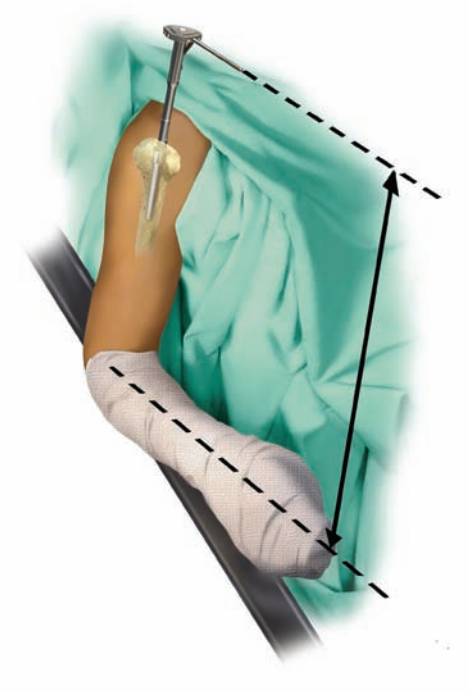


Figure 13

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).

HUMERAL STEM INSERTION– PRESS-FIT TECHNIQUE

Attach the broach handle to the broach/trial, and remove it from the humeral canal. 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 (Figure 13). Insert the stem into the humeral canal (Figure 14), impacting if necessary.

MINI STEM TECHNIQUE

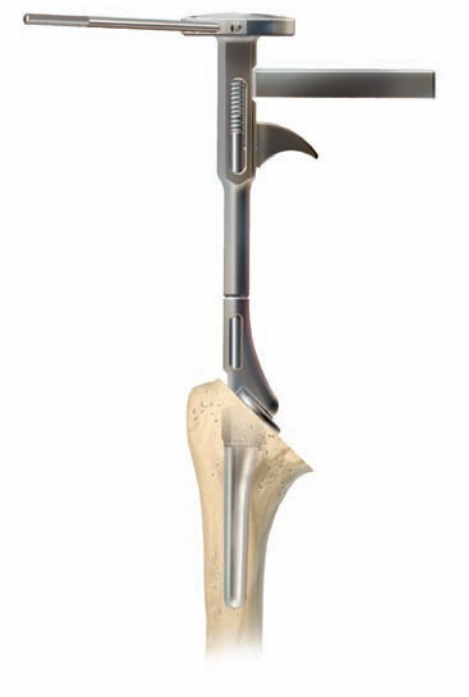


Figure 14

HUMERAL STEM INSERTION– CEMENTED TECHNIQUE

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 13). Introduce the implant into the humeral canal (Figure 14), keeping the alignment rod in line with the forearm, until the desired position is attained. Remove excess cement.

Comprehensive®
SHOULDER SYSTEM

STANDARD STEM TECHNIQUE

STANDARD STEM TECHNIQUE

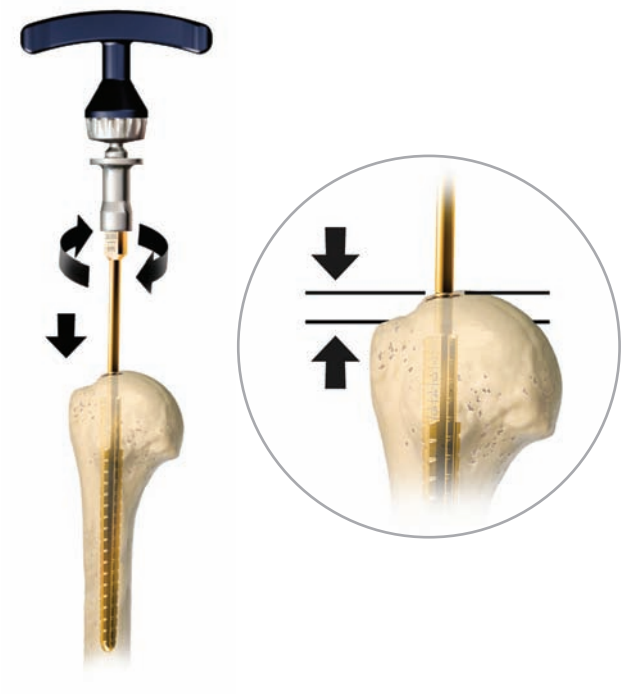


Figure 15

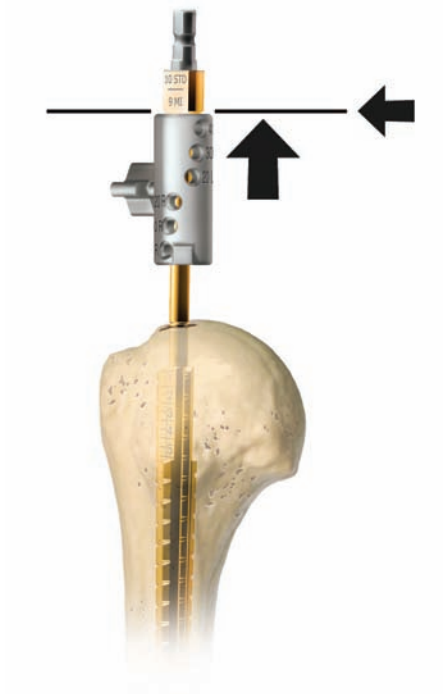


Figure 16

HUMERAL PREPARATION

Using the 4, 5 or 6mm reamer and ratcheting T-handle, bore a pilot hole through the humeral head along the axis of the humeral shaft (Figure 15), just lateral to the head's articular surface and just medial to the rotator cuff attachment. Insert the 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 15 inset). Continue reaming in 1mm increments until cortical contact is achieved, sinking the reamer only to the engraved line. Note the reamer size for future reference.

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 16).

Figure 17

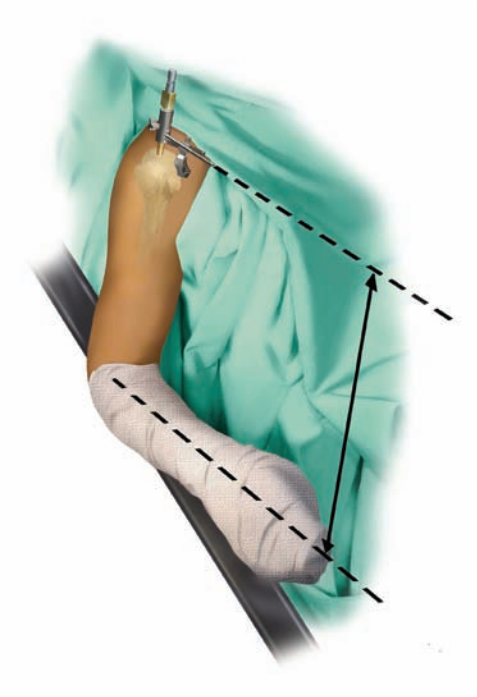


Figure 18

Place the IM resection guide block onto the arm of the boom (Figure 17) and orient it for the proper resection (Figure 17 inset). For example, “right” should be visible for a right shoulder.

Screw the version control rod into the appropriate version hole, and align the rod with the forearm flexed at 90 degrees (Figure 18).

STANDARD STEM TECHNIQUE

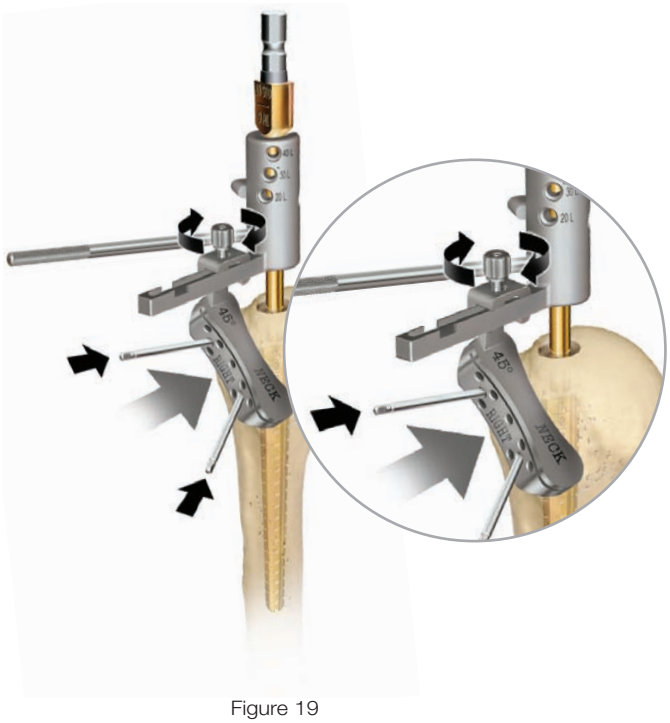


Figure 19

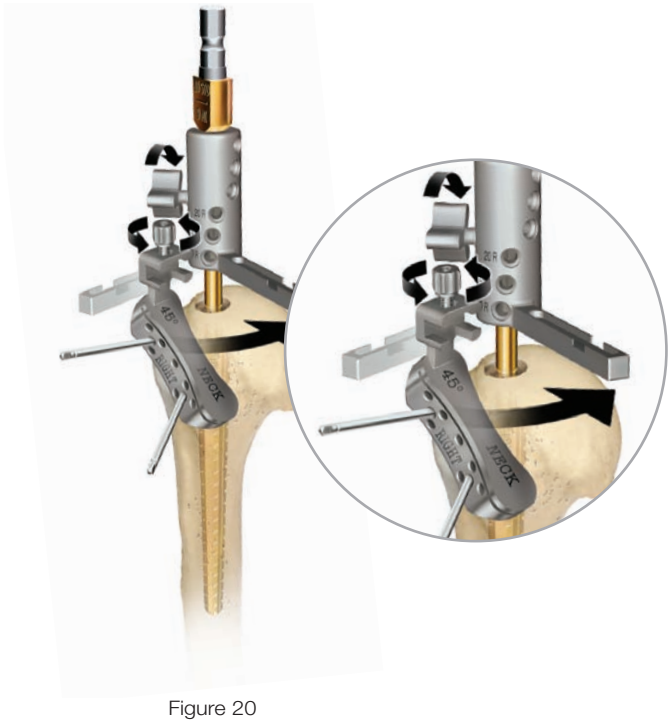


Figure 20

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 19).

Loosen the thumbscrews on the resection guide block and the reamer shaft. Rotate the resection guide boom until the arm clears the resection block (Figure 20). Remove the reamer and guide boom.

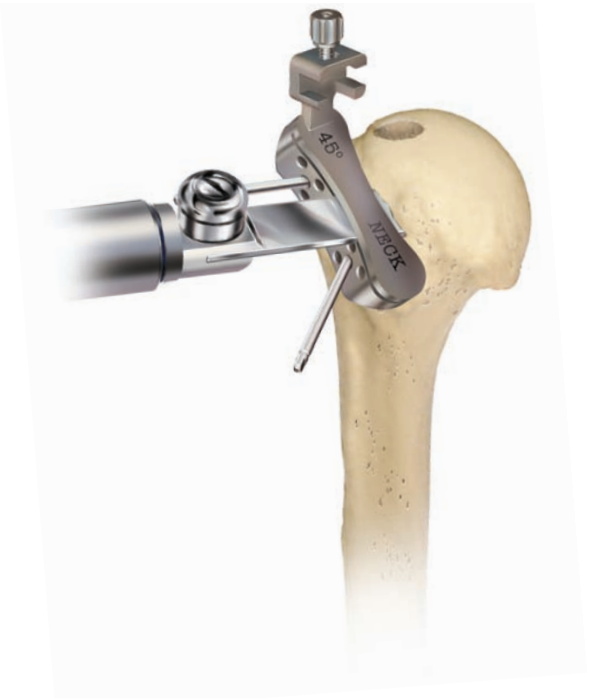


Figure 21

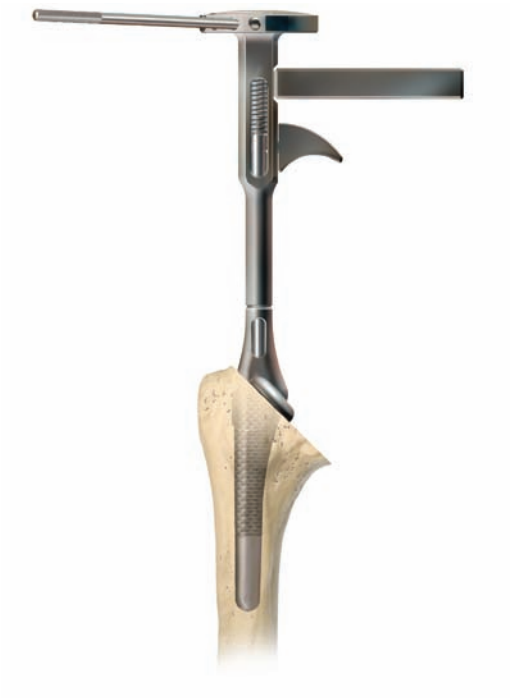


Figure 22

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 21). Resect the humeral head. Remove the Steinmann pins and the cutting block.

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 chart on page 37). (Tip: 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 22).* Remove the broach handle, leaving the last broach in place to be used as a trial.

*Caution: If broach feels too tight and will not seat, finish broaching with next smaller size.

STANDARD STEM TECHNIQUE

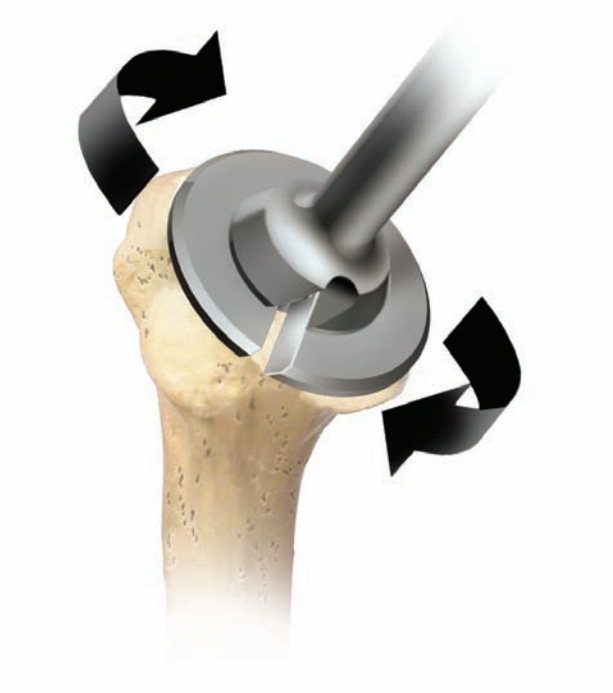


Figure 23

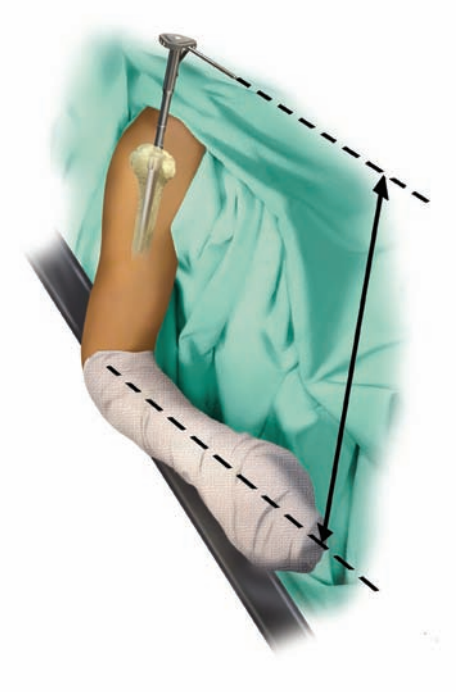


Figure 24

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 23).

HUMERAL STEM INSERTION– PRESS-FIT TECHNIQUE

Attach the broach handle to the broach/trial, and remove it from the humeral canal. 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 (Figure 24). Insert the stem into the humeral canal (Figure 25), impacting if necessary.

STANDARD STEM TECHNIQUE

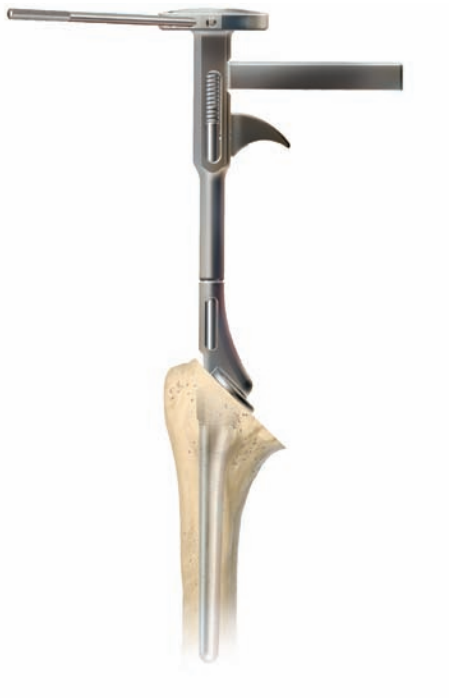


Figure 25

HUMERAL STEM INSERTION– CEMENTED TECHNIQUE

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 24). Introduce the implant into the humeral canal (Figure 25), keeping the alignment rod in line with the forearm, until the desired position is attained. Remove excess cement.

Comprehensive®
SHOULDER SYSTEM

VERSA-DIAL™ HEAD TECHNIQUE

VERSA-DIAL™ HEAD TECHNIQUE

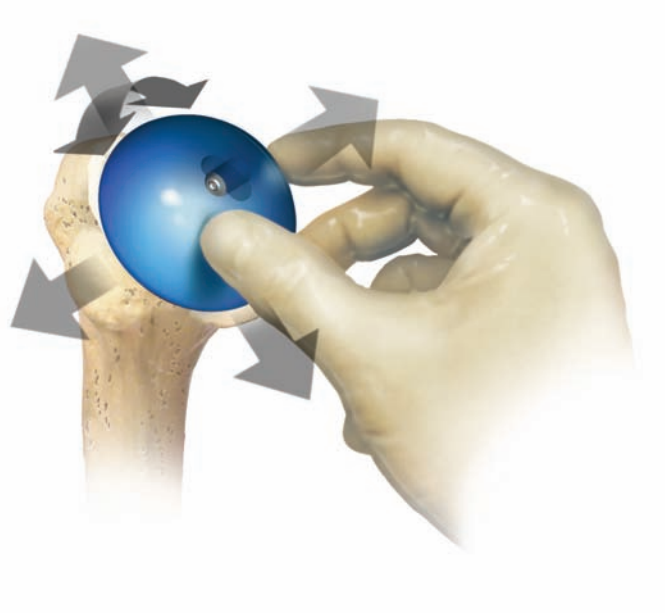


Figure 26

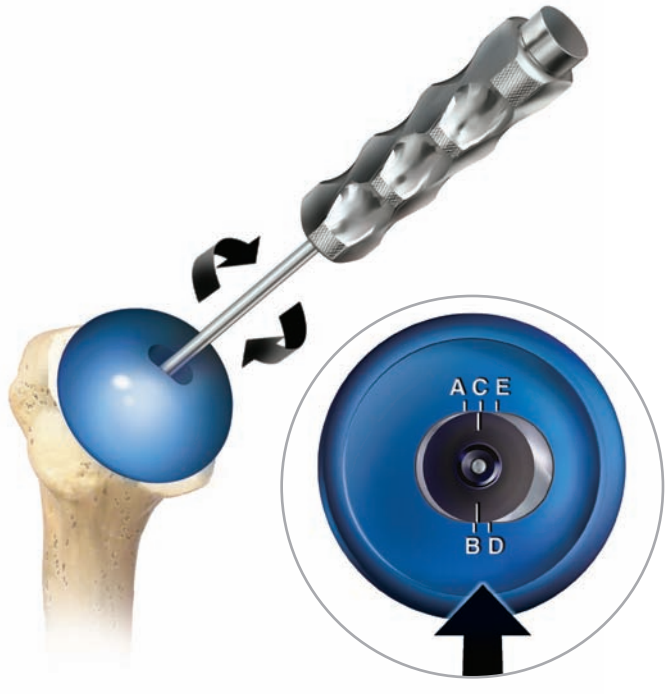


Figure 27

HEAD SELECTION

Using the resected humeral head for comparison, select an appropriately sized head trial and assemble to a standard trial taper adaptor. Determine the amount of desired offset by maximizing the coverage of the Versa-Dial™ provisional over the resected surface of the humerus (Figure 26). After maximum coverage of the resected surface is achieved, tighten the taper adaptor trial in the head trial with a hex driver (Figure 27). Reduce the joint and perform a trial range of motion.

HEAD OFFSET

Remove the Versa-Dial™ trial assembly from the humeral stem. Determine the amount of offset needed by referencing the indications on the underside of the trial head and trial adaptor (Figure 27 inset).

VERSA-DIAL™ HEAD TECHNIQUE

Figure 28

Figure 29

HEAD ASSEMBLY

Place the Versa-Dial™ head into the impactor tray. Ensuring the components are clean and dry, insert the Versa-Dial™ taper adaptor into the head (Figure 28). Rotate the taper adaptor until the trial offset is replicated. For example, if trialing indicated halfway between the B and C hashmarks, the implant taper adaptor is aligned so its hashmark is halfway between the B and C on the head.

Engage the Morse taper with two strikes, using the taper impactor tool and mallet (Figure 29). The taper/head assembly is now securely fastened.

VERSA-DIAL™ HEAD TECHNIQUE

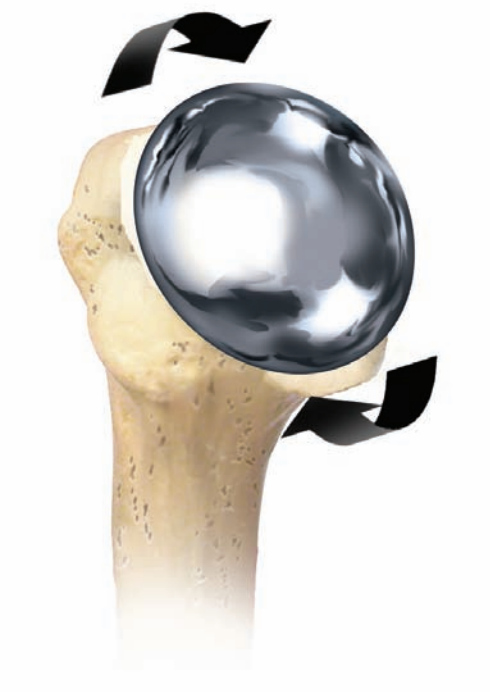


Figure 30

HEAD INSERTION

Clean and dry the reverse Morse taper with the taper swabs packaged with the stem. Gently place the Versa-Dial™ head onto the stem and rotate to achieve maximum coverage of the resected surface (Figure 30). Impact the head onto the stem to complete humeral head implantation by using at least two blows with an appropriately sized surgical mallet and the head impactor tool.

Comprehensive®
SHOULDER SYSTEM

MODULAR HYBRID GLENOID TECHNIQUE

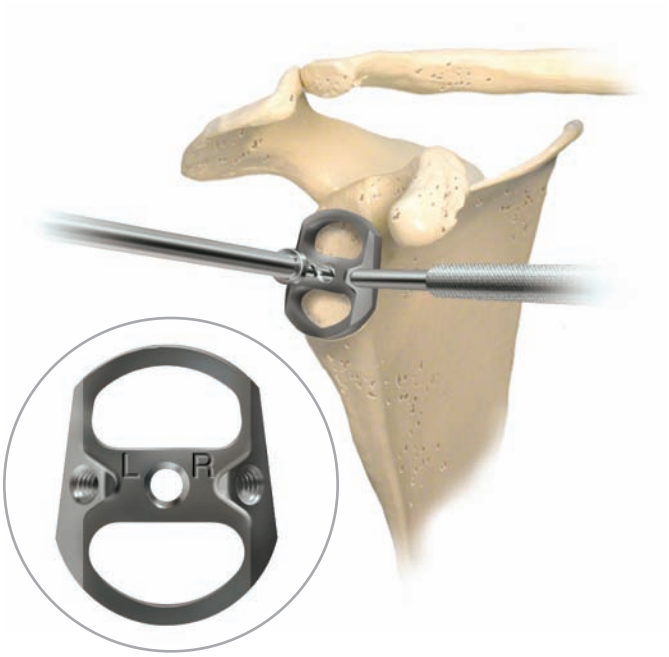


Figure 31

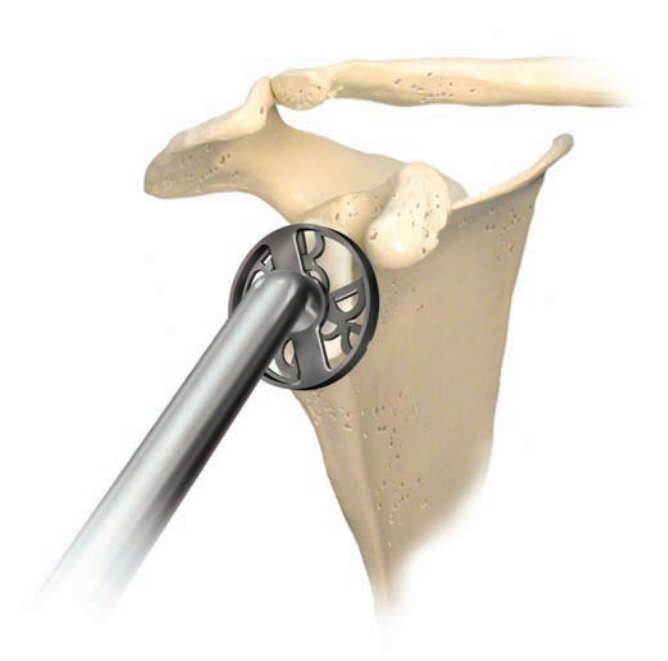


Figure 32

SIZING AND REAMING

Based on the operative shoulder, attach the threaded guide handle to the appropriate anatomic glenoid sizer. Place the sizer in the center of the glenoid with the wide side inferior and firmly seated against the face of the glenoid to give the appropriate position for the centering hole to be drilled. Drill the hole for the centering peg until the stop is engaged (Figure 31).

Attach the appropriate size glenoid reamer to the angled or straight reamer shaft. Position the reamer's center peg in the center hole on the glenoid. Ream the face of the glenoid until concentric reshaping is achieved (Figure 32). When finished, the glenoid face should be congruent with the medial side of the glenoid trial and implant. In cases of excessive glenoid wear, ream eccentrically to neutralize the glenoid and prevent instability.

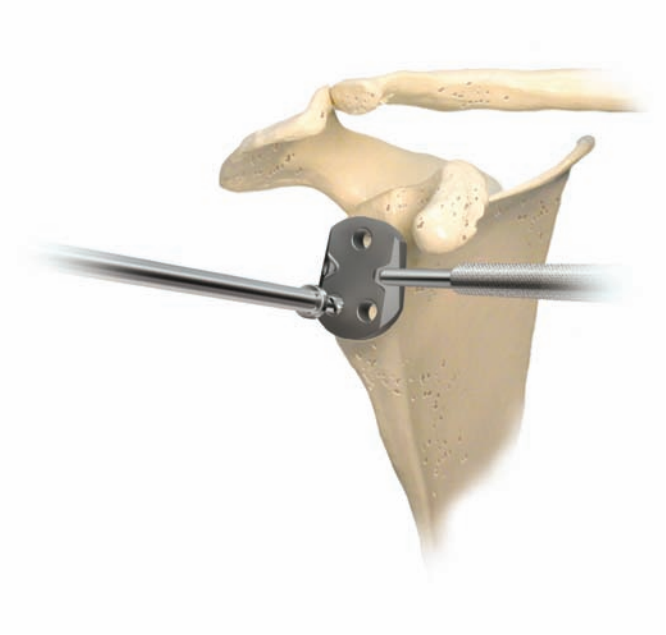


Figure 33

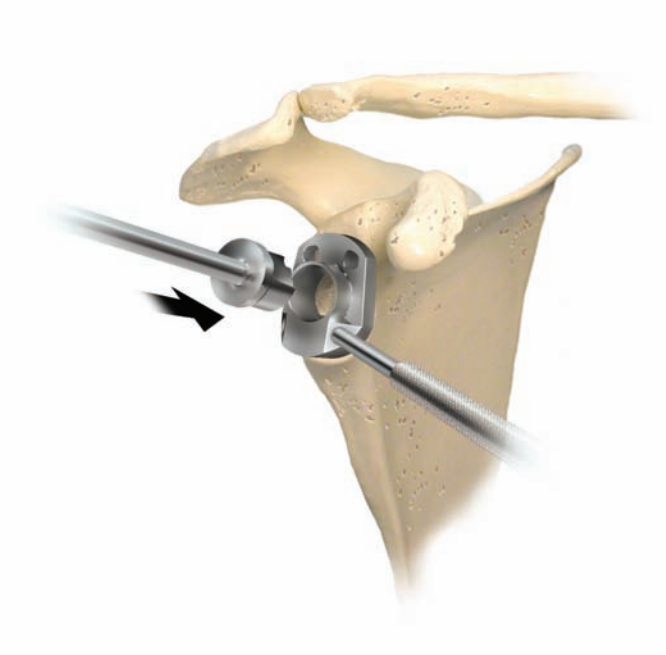


Figure 34

OUTER PEG DRILLING

Choose the appropriate anatomic drill guide and attach to the threaded guide handle. Place the centering peg in the center hole drilled in the prior step. Ensure the pegged glenoid drill guide is firmly seated on the face of the glenoid. Drill the posterior-inferior hole until the stop is engaged (Figure 33).

Use the alignment pin forceps to place an alignment pin through the guide and into the posterior-inferior hole. Move to the anterior-inferior hole and drill until the stop is engaged. Move an alignment pin to this hole following drilling. Move to the superior hole and drill until the stop is engaged, thereby creating the three outer peg holes.

Regardless of whether a central peg will be utilized, attach the threaded handle to the center peg drill guide. Firmly seat the alignment pegs on the medial side of the boss cutting guide in the outer peg holes just created. Use the boss cutter and drill until the stop is engaged (Figure 34).

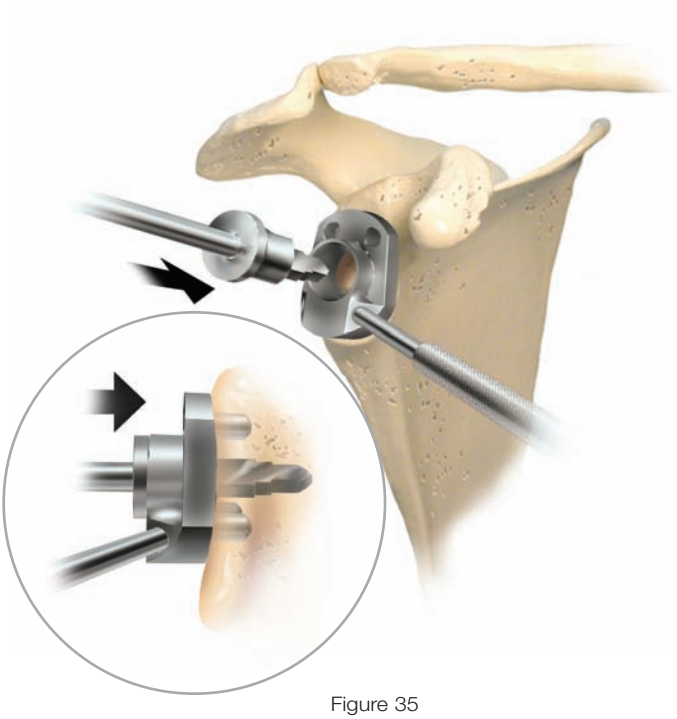


Figure 35

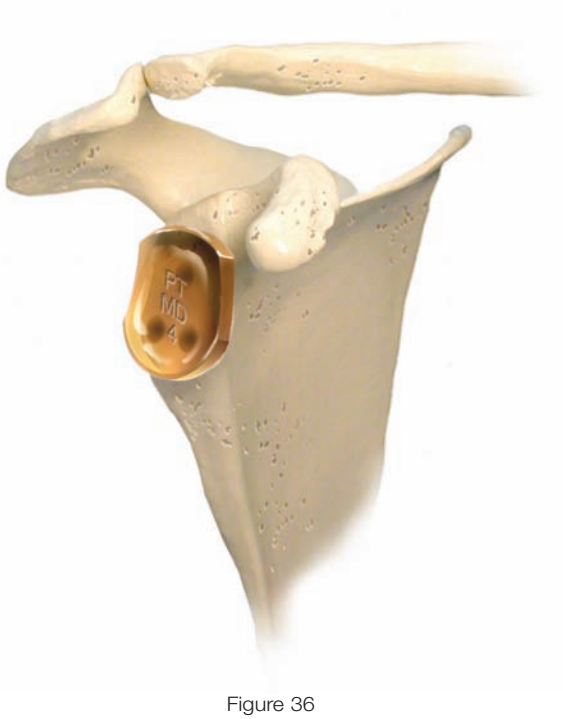


Figure 36

OPTIONAL– REGENEREX™ POROUS TITANIUM OR POLYETHYLENE CENTRAL PEG

Using the threaded handle attached to the center peg drill guide, place the guide on the face of the glenoid. Firmly seat the drill guide with the three pegs inserted into the outer holes. Based on the chosen central peg, use the appropriate post cutter (Figure 35–Regenerex™ post cutter shown). Drill until the stop is engaged (Figure 35 inset).

Seat the appropriate size glenoid trial firmly on the face of the glenoid (Figure 36). Ensure the trial is congruent with the reamed surface.

Reassemble the humeral head trial on the humeral broach/trial and evaluate range of motion. Make any necessary adjustments to the humeral head height and diameter to properly tension the joint.

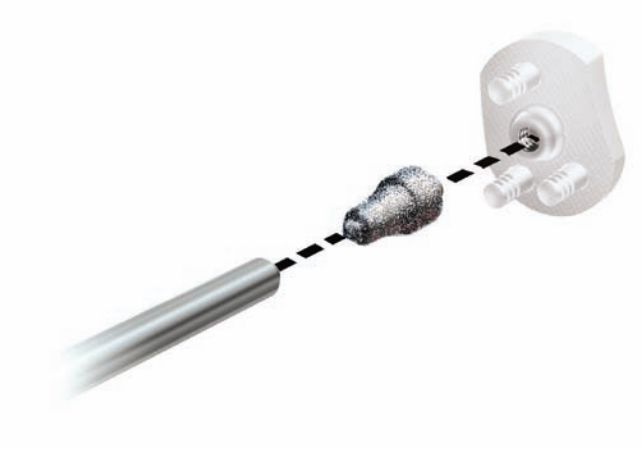


Figure 37

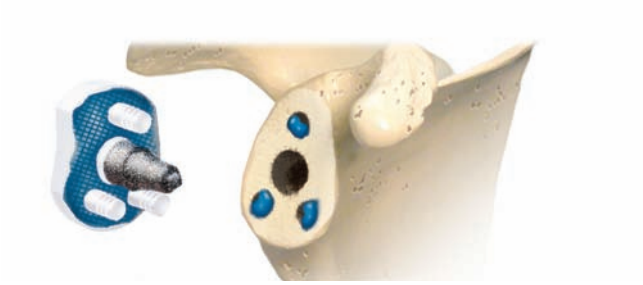


Figure 38A

Figure 38B

GLENOID FIXATION

Remove the glenoid trial. Using a high-speed irrigation lavage system, cleanse the cortical cancellous surface. If used, thread the appropriate central peg into the modular hybrid glenoid with the central post driver (Figure 37). Digitally pressurize bone cement into the three peripheral holes.

Based on the chosen central peg, use cement as follows: if using the polyethylene central peg, place a small amount of bone cement between the fins and the base of the central peg; if using the Regenerex™ Porous Titanium central peg, bone cement should not be used.

Place a thin layer of cement on the medial side of the glenoid component (Figure 38A–Regenerex™ Porous Titanium central peg; Figure 38B–polyethylene central peg). Insert the glenoid and carefully remove any excess cement.

Comprehensive®
SHOULDER SYSTEM

KEELED GLENOID TECHNIQUE

KEELED GLENOID TECHNIQUE

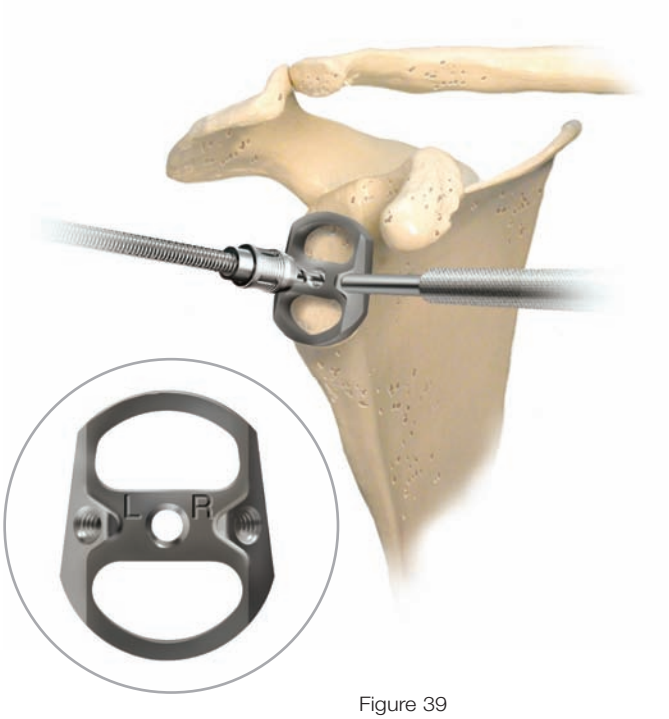


Figure 39

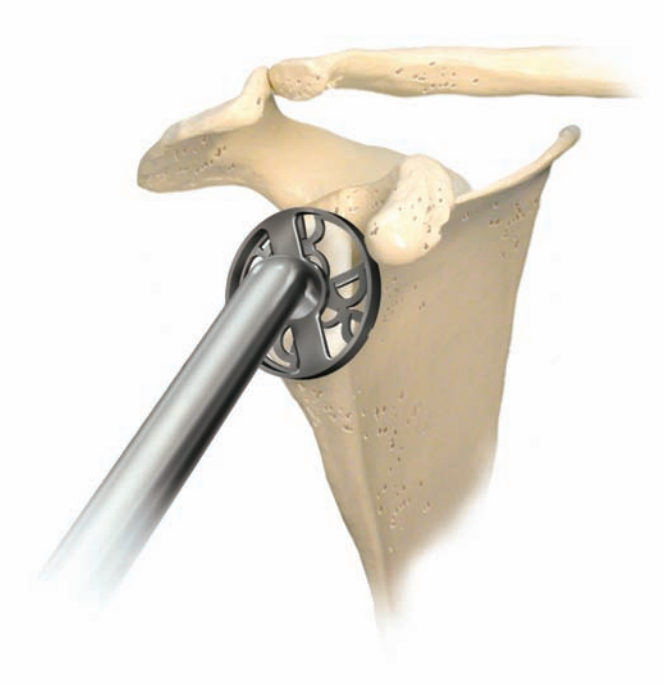


Figure 40

SIZING AND REAMING

Based on the operative shoulder, attach the threaded guide handle to the appropriate anatomic glenoid sizer. Place the sizer in the center of the glenoid with the wide side inferior and firmly seated against the face of the glenoid to give the appropriate position for the centering hole to be drilled. Drill the hole for the centering peg until the stop is engaged (Figure 39).

Attach the appropriate size glenoid reamer to the angled or straight reamer shaft. Position the reamer's center peg in the center hole on the glenoid. Ream the face of the glenoid until concentric reshaping is achieved (Figure 40). When finished, the glenoid face should be congruent with the medial side of the glenoid trial and implant. In cases of excessive glenoid wear, ream eccentrically to neutralize the glenoid and prevent instability.

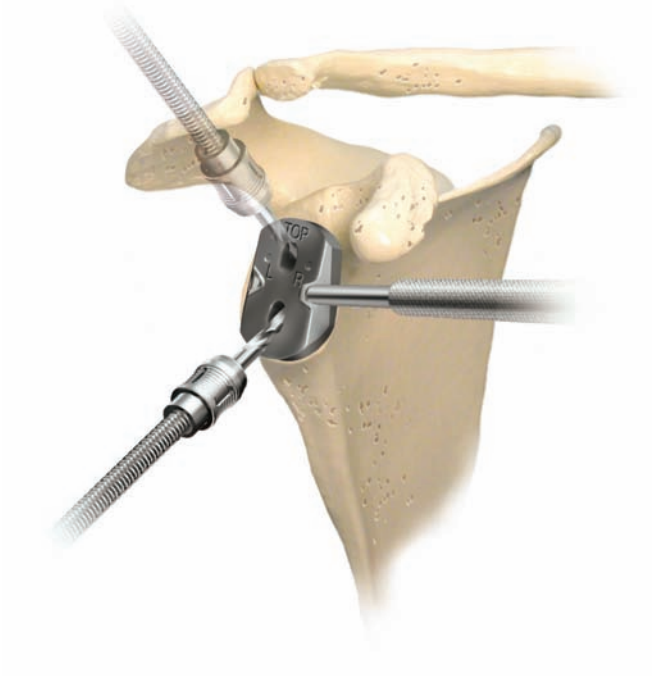


Figure 41

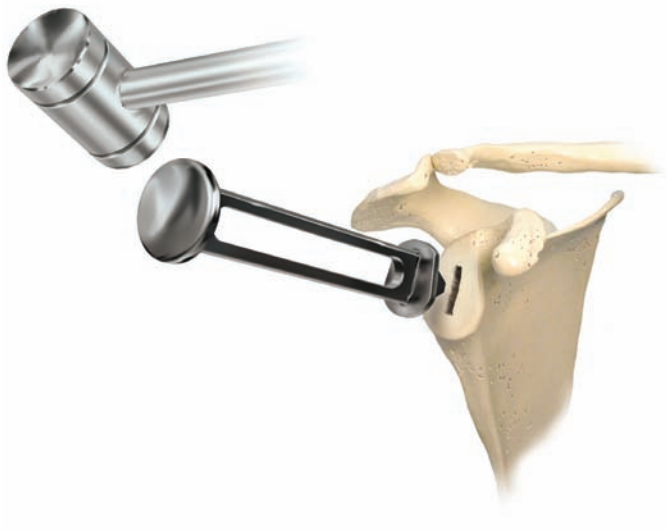


Figure 42

DRILLING

Attach the threaded guide handle to the keeled glenoid drill guide. Ensuring that the center peg is in the 4mm center hole and the wide side is inferior, place the drill guide firmly against the glenoid.

Using the 4mm drill bit, drill holes angling toward the center of the guide in each of the two slots (Figure 41).

Remove the guide and connect the angled holes with a high speed burr. Use the glenoid broach to complete the keel slot (Figure 42). Insert the appropriate size keeled glenoid trial. Reassemble the humeral head trial on the humeral broach/trial and evaluate range of motion. Make any necessary adjustments to the humeral head height or glenoid thickness to properly tension the joint.

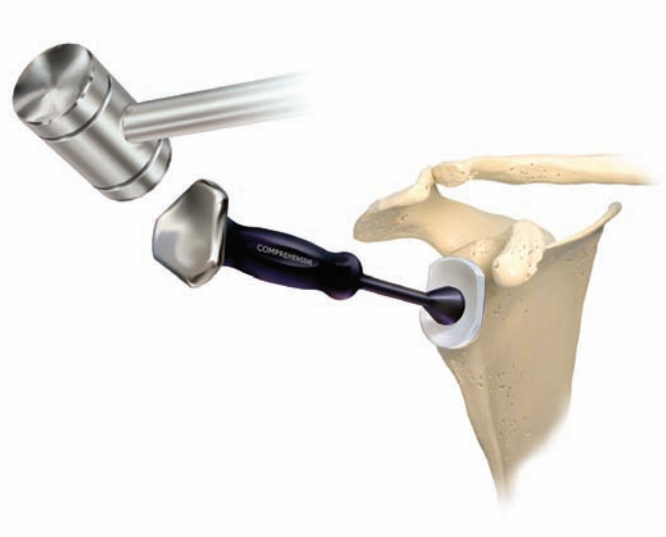


Figure 43

GLENOID FIXATION

Remove the glenoid trial. Using a high-speed irrigation lavage system, cleanse the cortical cancellous surface. Introduce the appropriately sized component into bone cement with digital pressure to ensure proper component fixation. The glenoid impactor may be used to seat the component (Figure 43). Carefully remove any excess cement, particularly posterior to the component where visualization may be impaired.

Comprehensive®
SHOULDER SYSTEM

POSTOPERATIVE CARE

POSTOPERATIVE CARE

POSTOPERATIVE CARE

Evaluate the limits of external rotation at the time of the subscapularis tendon repair to determine the maximum amount of external rotation during the rehabilitation period. Immobilize the patient in a sling and swathe for 24 hours; use the sling intermittently for up to three weeks to protect the subscapularis repair. Encourage early active motion of the hand and elbow. Begin gentle passive range of motion two days postoperatively. Initiate active assisted elevation three to four days after surgery, based on surgeon preference. Begin strengthening exercises two to three months postoperatively. Continue therapy for many months, with improvement in range of motion and function expected for up to one year.

APPENDIX–HUMERAL STEM SIZING

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.*

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

ORDERING INFORMATION

Mini Length Humeral Stems

Implant Image	Implant Part Number	Broach/Trial Part Number	Description	Size
	**113624**	**407304**	Humeral Stem—Mini	4mm
	113625	**407305**	Humeral Stem—Mini	5mm
	113626	**407306**	Humeral Stem—Mini	6mm
	113627	**407307**	Humeral Stem—Mini	7mm
	113628	**407308**	Humeral Stem—Mini	8mm
	113629	**407309**	Humeral Stem—Mini	9mm
	113630	**407310**	Humeral Stem—Mini	10mm
	113631	**407311**	Humeral Stem—Mini	11mm
	113632	**407312**	Humeral Stem—Mini	12mm
	113633	**407313**	Humeral Stem—Mini	13mm
	113634	**407314**	Humeral Stem—Mini	14mm
	113635	**407315**	Humeral Stem—Mini	15mm
	113636	**407316**	Humeral Stem—Mini	16mm
	113637	**407317**	Humeral Stem—Mini	17mm
	113638	**407318**	Humeral Stem—Mini	18mm
	113639	**407319**	Humeral Stem—Mini	19mm
	113640	**407320**	Humeral Stem—Mini	20mm

Standard Length Humeral Stems

Implant Image	Implant Part Number	Broach/Trial Part Number	Description	Size
	113644	407304	Humeral Stem — Standard	4mm
	113645	407305	Humeral Stem — Standard	5mm
	113646	407306	Humeral Stem — Standard	6mm
	113647	407307	Humeral Stem — Standard	7mm
	113648	407308	Humeral Stem — Standard	8mm
	113649	407309	Humeral Stem — Standard	9mm
	113650	407310	Humeral Stem — Standard	10mm
	113651	407311	Humeral Stem — Standard	11mm
	113652	407312	Humeral Stem — Standard	12mm
	113653	407313	Humeral Stem — Standard	13mm
	113654	407314	Humeral Stem — Standard	14mm
	113655	407315	Humeral Stem — Standard	15mm
	113656	407316	Humeral Stem — Standard	16mm
	113657	407317	Humeral Stem — Standard	17mm
	113658	407318	Humeral Stem — Standard	18mm
	113659	407319	Humeral Stem — Standard	19mm
	113660	407320	Humeral Stem — Standard	20mm

Revision Length Humeral Stems

Implant Image	Implant Part Number	Broach/Trial Part Number	Description	Size
	**113664**	**407304**	Humeral Stem — Revision	4mm
	113665	**407305**	Humeral Stem — Revision	5mm
	113666	**407306**	Humeral Stem — Revision	6mm
	113667	**407307**	Humeral Stem — Revision	7mm
	113668	**407308**	Humeral Stem — Revision	8mm
	113669	**407309**	Humeral Stem — Revision	9mm
	113670	**407310**	Humeral Stem — Revision	10mm
	113671	**407311**	Humeral Stem — Revision	11mm
	113672	**407312**	Humeral Stem — Revision	12mm
	113673	**407313**	Humeral Stem — Revision	13mm
	113674	**407314**	Humeral Stem — Revision	14mm
	113675	**407315**	Humeral Stem — Revision	15mm

Versa-Dial™ Humeral Heads

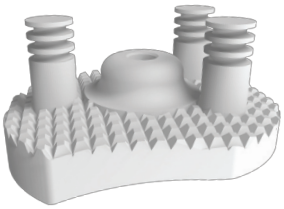
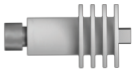
Implant Image	Implant Part Number	Trial Part Number	Description	Size
	**113022**	**407222**	Versa-Dial™ Humeral Head	38 X 19 X 39
	113024	**407224**	Versa-Dial™ Humeral Head	38 X 21 X 38
	113032	**407232**	Versa-Dial™ Humeral Head	42 X 18 X 46
	113034	**407234**	Versa-Dial™ Humeral Head	42 X 21 X 43
	113036	**407236**	Versa-Dial™ Humeral Head	42 X 24 X 42
	113042	**407242**	Versa-Dial™ Humeral Head	46 X 18 X 53
	113044	**407244**	Versa-Dial™ Humeral Head	46 X 21 X 50
	113046	**407246**	Versa-Dial™ Humeral Head	46 X 24 X 47
	113048	**407248**	Versa-Dial™ Humeral Head	46 X 27 X 46
	113053	**407254**	Versa-Dial™ Humeral Head	50 X 21 X 57
	113055	**407256**	Versa-Dial™ Humeral Head	50 X 24 X 52
	113057	**407258**	Versa-Dial™ Humeral Head	50 X 27 X 50
	113063	**407264**	Versa-Dial™ Humeral Head	54 X 21 X 64
	113065	**407266**	Versa-Dial™ Humeral Head	54 X 24 X 58
	113067	**407268**	Versa-Dial™ Humeral Head	54 X 27 X 55
	113075	**407276**	Versa-Dial™ Humeral Head	58 X 24 X 64
	113077	**407278**	Versa-Dial™ Humeral Head	58 X 37 X 61

Humeral Head Taper Adaptors

Implant Image	Implant Part Number	Trial Part Number	Description	Size
	**118001**	**407201**	Comprehensive® Standard Taper Adaptor	
	**118006**	**407206**	Bio-Modular® Standard Taper Adaptor	

ORDERING INFORMATION—IMPLANTS AND TRIALS

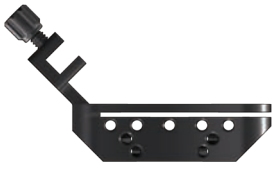
Modular Hybrid Glenoids

Implant Image	Implant Part Number	Trial Part Number	Description	Size
	113952	-	SM Modular Hybrid Glenoid Base	4mm
	113954	-	MD Modular Hybrid Glenoid Base	4mm
	113956	-	LG Modular Hybrid Glenoid Base	4mm
	PT-113950	-	Modular Hybrid Glenoid Post—Regenerex™	
	113951	-	Modular Hybrid Glenoid Post—Polyethylene	
	-	406172	SM Modular Hybrid Glenoid Base & Polyethylene Post	4mm
	-	406173	MD Modular Hybrid Glenoid Base & Polyethylene Post	4mm
	-	406174	LG Modular Hybrid Glenoid Base & Polyethylene Post	4mm
	-	406192	SM Modular Hybrid Glenoid Base & Regenerex™ Post	4mm
	-	406193	MD Modular Hybrid Glenoid Base & Regenerex™ Post	4mm
	-	406194	LG Modular Hybrid Glenoid Base & Regenerex™ Post	4mm
	-	406112	SM Modular Hybrid Glenoid Base	4mm
	-	406113	MD Modular Hybrid Glenoid Base	4mm
	-	406114	LG Modular Hybrid Glenoid Base	4mm

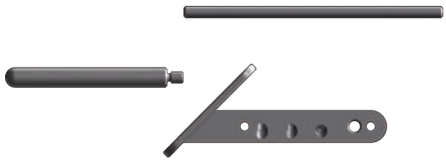
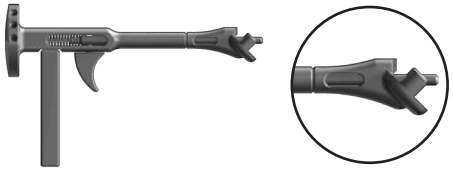
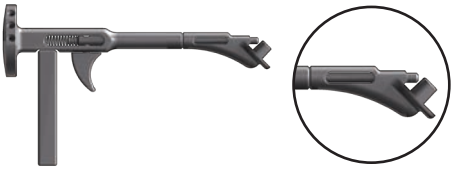
Keeled Glenoids

Implant Image	Implant Part Number	Trial Part Number	Description	Size
	113849	406574	SM Keeled Glenoid	4mm
	113851	406575	MD Keeled Glenoid	4mm
	113853	406576	LG Keeled Glenoid	4mm
	113850	406577	SM Keeled Glenoid	7mm
	113852	406578	MD Keeled Glenoid	7mm
	113854	406579	LG Keeled Glenoid	7mm

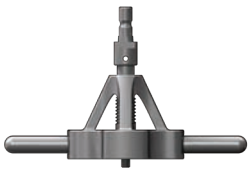
Humeral Stems

Image	Part Number	Description	Size
	41-406804	Humeral Reamer	4mm
	41-406805	Humeral Reamer	5mm
	41-406806	Humeral Reamer	6mm
	41-406807	Humeral Reamer	7mm
	41-406808	Humeral Reamer	8mm
	41-406809	Humeral Reamer	9mm
	41-406810	Humeral Reamer	10mm
	41-406811	Humeral Reamer	11mm
	41-406812	Humeral Reamer	12mm
	41-406813	Humeral Reamer	13mm
	41-406814	Humeral Reamer	14mm
	41-406815	Humeral Reamer	15mm
	41-406816	Humeral Reamer	16mm
	41-406817	Humeral Reamer	17mm
	41-406818	Humeral Reamer	18mm
	41-406819	Humeral Reamer	19mm
	41-406820	Humeral Reamer	20mm
	407393	Comprehensive® Broach Extractor Tool	
	407397	Comprehensive® Intramedullary Resection Guide Boom with Version Rod	
	407396	Comprehensive® Intramedullary Resection Guide Block	

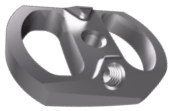
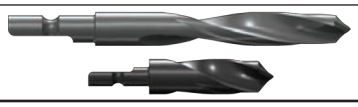
Humeral Stems (continued)

Image	Part Number	Description	Size
	**407392**	Comprehensive® Extramedullary Resection Guidewith Version Rod	
	**407395**	Comprehensive® Screw-in Version Rod	
	**407391**	Comprehensive® Broach Protector Plate Set	
	**406669**	Threaded Steinmann Pins	
	**32-486259**	Pin Driver	
	**406801**	Ratcheting T-handle	
	**407399**	Comprehensive® Broach Handle with Version Rod	
	**407398**	Comprehensive® Stem Inserter with Version Rod	
	**406997**	Comprehensive® Stem Extractor	
	**31-473621**	Slide Hammer	
	407394	Comprehensive® Stem X-ray Templates	

Versa-Dial™ Humeral Heads

Product	Part Number	Description	
	**407298**	Versa-Dial™ Taper Extractor	
	**407297**	Versa-Dial™ Head Impactor	
	**407296**	Versa-Dial™ Trial Head Screw Driver	
	**407280**	Versa-Dial™ Taper Impactor Tool	
	**407281**	Versa-Dial™ Taper Impactor Base	
	**406515**	Humeral Head Removal Fork	
	**406660**	Choice Calcar Planer with Six Blades	
	407294	Versa-Dial™ Humeral Head X-ray Templates	
	595261	Comprehensive® Primary Shoulder Total Instrument Case	
	595260	Comprehensive® Primary Shoulder Instrument Case Shell (with Lid)	
	595259	Comprehensive® Primary Versa-Dial™ Humeral Head Instrument Case	
	595258	Comprehensive® Primary Reamer Instrument Case	
	595257	Comprehensive® Primary Broach Instrument Case	

Modular Hybrid and Keeled Glenoids

Image	Part Number	Description	Size
	406831	Glenoid Sizer	SM
	406832	Glenoid Sizer	MD
	406833	Glenoid Sizer	LG
	406160	Hybrid Glenoid Outer Peg Drill Guide	SM
	406162	Hybrid Glenoid Outer Peg Drill Guide	MD
	406164	Hybrid Glenoid Outer Peg Drill Guide	LG
	406161	Hybrid Glenoid Central Peg Drill Guide	SM
	406163	Hybrid Glenoid Central Peg Drill Guide	MD
	406165	Hybrid Glenoid Central Peg Drill Guide	LG
	406180	Hybrid Glenoid Drill Guide Alignment Pin	
	406849	Glenoid Guide Handle	
	406837	Keeled Glenoid Drill Guide	SM
	406838	Keeled Glenoid Drill Guide	MD
	406839	Keeled Glenoid Drill Guide	LG
	406632	Glenoid Reamer	SM
	406633	Glenoid Reamer	MD
	406634	Glenoid Reamer	LG
	406151	Hybrid Glenoid Regenerex™ Post Cutter (PT)	
	406152	Hybrid Glenoid Polyethylene Post Cutter (PC)	
	406150	Hybrid Glenoid Boss Cutter	
	406181	Hybrid Glenoid Straight Shank Drill	4mm
	406182	Hybrid Glenoid Straight Shank Drill	15/64”
	31-406181	Hybrid Glenoid Quick Connect Drill	4mm
	31-406182	Hybrid Glenoid Quick Connect Drill	15/64”

Modular Hybrid and Keeled Glenoids (continued)

Image	Part Number	Description	Size
	**31-111115**	Comprehensive® Flexible Drill Shaft	
	**31-111116**	Comprehensive® Straight Drill Handle	
	**31-406636**	Comprehensive® Universal Drill	
	**RD481137**	Angled Glenoid Reamer Shaft–Small	1/2”
	**406521**	Angled Glenoid Reamer Shaft	3/4”
	**406587**	Keel Broach	
	**406183**	Hybrid Glenoid Central Post Driver	
	**406156**	Hybrid Glenoid Impactor	
	**424417**	Screw Forceps	
	**402648**	Straight Reamer Shaft	
	**406596**	Reamer T-handle	3/4”
	**406525**	Glenoid Surface Wrench	

Modular Hybrid and Keeled Glenoids (continued)

Image	Part Number	Description	Size
	**406699**	Ring Retractor with Handle	
	**994500850**	Bent Ring Retractor with Angled Tip	
	595267	Comprehensive® Hybrid Glenoid Total Instrument Case	
	595266	Comprehensive® Hybrid Glenoid Instrument Case Shell (with Lid)	
	595264	Comprehensive® Hybrid Glenoid Preparation Instrument Case	
	595263	Comprehensive® Hybrid Glenoid General Instrument Case	
	595265	Keeled Glenoid Instrument Case	
	406199	Hybrid Glenoid X-ray Template	

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

01-50-0944
Date: 12/06

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 and the glenoid components of the Bio-Modular® Shoulder System.

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

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.

STERILITY

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

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

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

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

CE 0086

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.

NOTES

NOTES

ORTHOPEDICS, INC.

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

Form No. BOI0049.0 • REV093007