

Trabecular Metal Reverse PlusTM (TMR+TM) Shoulder System

Base Plate and Glenosphere

Version 1.0

Surgical Technique



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Implant System

The Trabecular Metal Reverse Plus System focuses on the glenoid construct for the Reverse Shoulder Arthroplasty. It is compatible with the humeral construct of the Trabecular Metal™ Reverse Shoulder System, Anatomical Shoulder™ System and Comprehensive® Shoulder System. The complete compatibility matrix is available at the website <http://www.zimmerbiomet.com/medical-professionals/support/product-compatibility.html>

Patient Positioning

Patient positioning is especially important in shoulder surgery. Place the patient in a semi beach-chair position with the knees flexed (Figure 1). Raise the head of the table approximately 25-30 degrees to reduce the venous pressure. Use a head rest that allows for the superior part of the table to be removed. Place two towels under the spine and the medial border of the scapula to raise the affected side. The torso should be at the edge of the table. The shoulder will be off the edge of the table. Attach a short arm board to the table, or use another arm support method that will allow the arm to be raised or lowered as necessary throughout the procedure.

Incision and Exposure

There are two possible surgical approaches to the shoulder for reverse arthroplasty. The superior-lateral approach relies on a deltoid split similar to a rotator cuff procedure. It allows a more direct view and instrumentation of the glenoid. However, inferior positioning of the glenoid base plate may be more difficult and care to avoid excessive deltoid splitting is essential to minimize risk to the axillary nerve. The delto-pectoral approach will allow easier access to the proximal humerus if there are post-traumatic changes or prior arthroplasty. Additionally, it will allow easier access to the inferior portion of the glenoid.

The choice of approach is the surgeon's preference, but the delto-pectoral approach is typically preferred for revision surgery.

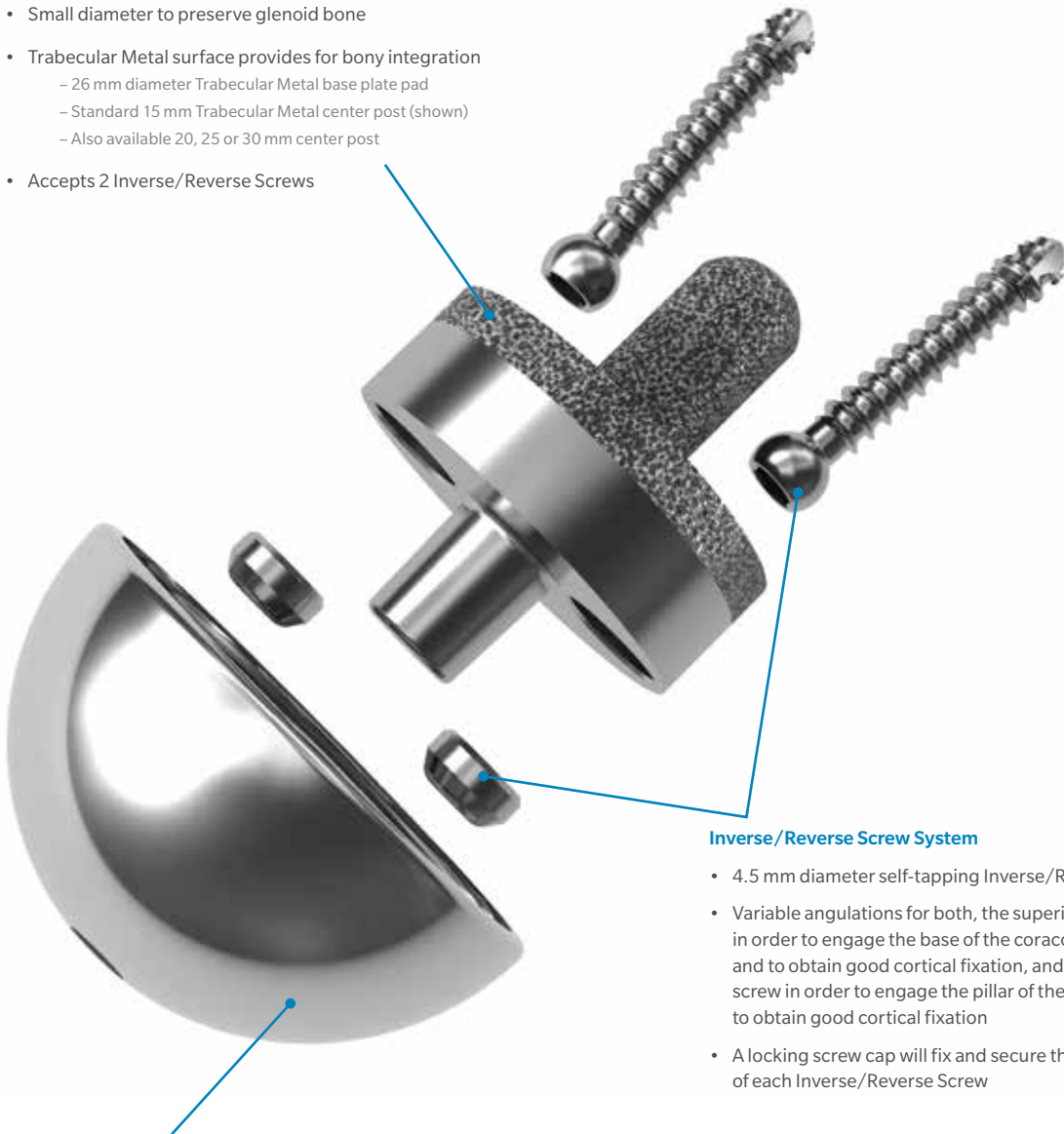


Figure 1

Description of the Implants

Trabecular Metal Base Plate

- Small diameter to preserve glenoid bone
- Trabecular Metal surface provides for bony integration
 - 26 mm diameter Trabecular Metal base plate pad
 - Standard 15 mm Trabecular Metal center post (shown)
 - Also available 20, 25 or 30 mm center post
- Accepts 2 Inverse/Reverse Screws



Inverse/Reverse Screw System

- 4.5 mm diameter self-tapping Inverse/Reverse Screws
- Variable angulations for both, the superior screw in order to engage the base of the coracoid process and to obtain good cortical fixation, and also the inferior screw in order to engage the pillar of the scapula to obtain good cortical fixation
- A locking screw cap will fix and secure the desired angle of each Inverse/Reverse Screw

Trabecular Metal Reverse Glenoid Heads

- Eccentricity: 0 or 2 mm for 36 mm glenosphere; 0 or 2.5 mm for 40 mm glenosphere
- Lateral Offset: 0, 3 or 5 mm lateral offset
- 2 diameters: 36 mm and 40 mm
- Morse taper for secure fixation

Component Implantation

Glenoid Preparation

Before implanting the base plate, it is essential to thoroughly evaluate the bony architecture of the glenoid vault. CT scan or MRI is optimal pre-operative imagery to assess glenoid vault depth, presence and amount of glenoid fossa erosion, and existence of defects. X-ray templates can be used to potentially preoperatively identify the baseplate and glenosphere implants to be used. X-ray templates are available digitally. If hard copy x-ray templates are used, then ensure that the x-rays are 15% magnified to match with the 15% magnification of x-ray templates. Superimpose the baseplate template on the AP x-ray for optimal positioning for the patient's glenoid. Evaluate various post length options to arrive at the desired post length. Superimpose glenosphere template on baseplate template. For centric glenosphere, the marker hole on the baseplate image should coincide with the marker hole on the glenosphere image. For eccentric glenosphere, the marker hole on the baseplate image should fall on or between the two marker holes on the eccentric glenosphere image. Evaluate various options of glenosphere with respect to size, lateralization and eccentricity to arrive at the optimal glenosphere option for the patient.

Straight-on exposure of the glenoid is necessary for proper reaming and component insertion. If exposure is limited, re-evaluate the level of the humeral cut.

If a delto-pectoral approach is utilized, the proximal humerus is retracted posteriorly and inferiorly. If exposure is limited, re-check the humeral osteotomy level and ensure inferior and posterior capsular releases were thorough. Both approaches require circumferential exposure of the glenoid with labral excision.

Inferiorly, the glenoid must be exposed to allow palpation of the inferior glenoid pillar and inferior positioning of the glenoid base plate.

Note: While preparing the glenoid, the placement of the proximal humerus and provisional along with retractors should be carefully considered. Their positions may allow for interference with glenosphere seating.

Exposure should allow for straight on engagement of the glenosphere on the base plate taper.

Note: The Anatomical Shoulder Inverse/Reverse System and Comprehensive Shoulder System glenoid component assembly (i.e. base plate and glenosphere) are compatible with the Zimmer Trabecular Metal Reverse Shoulder System humeral stem poly liner. Conversely, the Anatomical Shoulder System and Comprehensive Shoulder System humeral stem poly liners are compatible with the Zimmer Trabecular Metal Reverse Shoulder System glenoid component assembly. The complete compatibility matrix is available at the website <http://www.zimmerbiomet.com/medical-professionals/support/product-compatibility.html>.

If the complete surgical technique is desired, please refer to the following documents and/or websites:

Paper Copy: Comprehensive Shoulder System (item number: 1271.1-GLBL-en-REV0818); Anatomical Shoulder Inverse/Reverse System (item number: 97-4223-102-00)

Online Copy: <https://www.zimmerbiomet.com/> – Please select Medical Professional and then select surgical techniques.



Figure 2



Figure 3

Base Plate Placement Planning

If desired, the Glenoid Scraper can be used to clean the glenoid face of any remaining articular cartilage or scar tissue. Assemble the Base Plate Pin Guide 1 by placing the face into the handle so that the two pieces mate and rotate into position (Figure 2). Evaluate positioning of the base plate by placing the Base Plate Pin Guide 1 on the glenoid face. The outer rim of Pin Guide 1 is the same diameter as the base plate. The outer rim can be rotated relative to the handle to check coverage of the anterior, inferior and posterior edges of the glenoid. The Pin Guide should be placed so that the outer rim aligns with the inferior rim of the glenoid and is centered in the anterior/posterior direction (Figure 3). This will place the glenosphere at the edge of the inferior glenoid bone.

Note: In case of poor or less bone stock on the inferior rim of the glenoid, the pin guide should be placed slightly superior to ensure that the guide pin, and subsequently the baseplate, is placed in the best possible bone stock.

Note: An alternate pin guide, Base Plate Pin Guide 2, is also available, which references the anterior medial area of the glenoid. Surgical steps to assemble and place this pin guide are available in Appendix A. Either of the Base Plate Pin Guides (1 or 2) can be used.

Note: Guide pin placement is critical as it determines base plate/glenosphere position on the face of the glenoid and orientation in the sagittal plane. The Pin Guide should be centered anteriorly/posteriorly, and align to inferior border of the glenoid. Avoid placing the Guide Pin with superior tilt, as this may result in a superiorly-tilted base plate/glenosphere and increase the risk of scapular notching.

Note: The Base Plate Pin Guide's base has L & R etch marks. When operating on left shoulder, assemble the Guide's handle to its base towards the L etch mark. Follow same steps for right shoulder and the R etch mark.

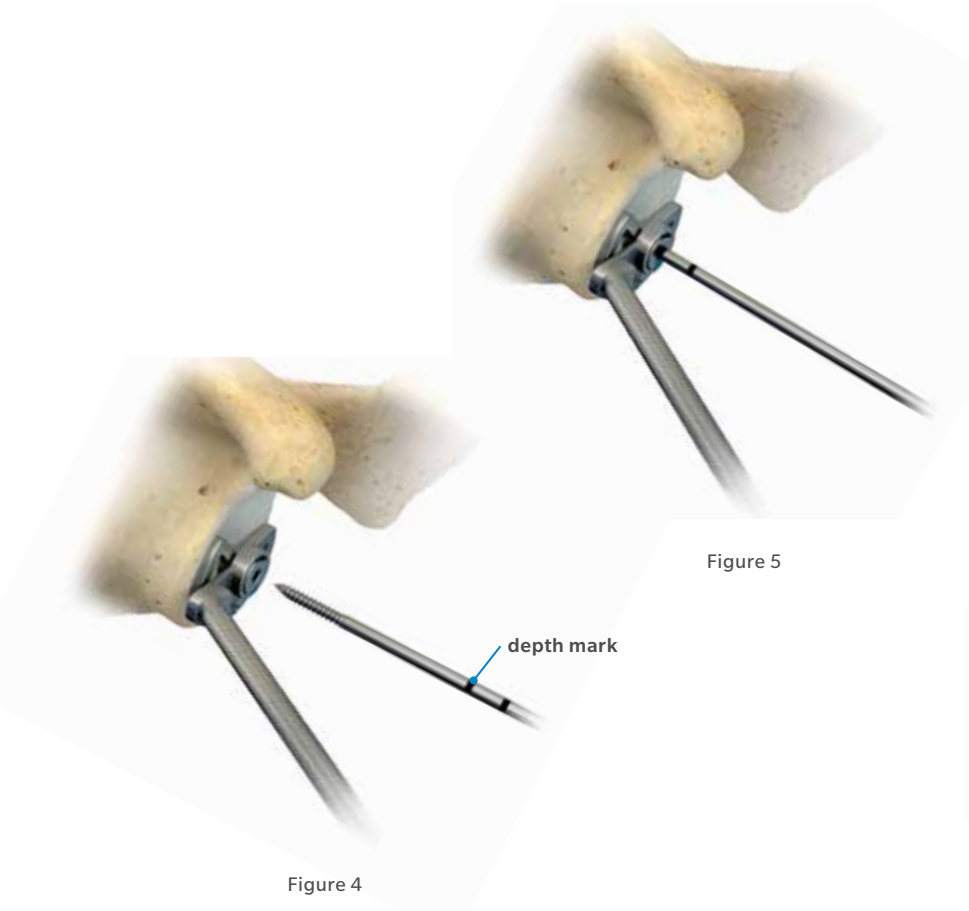


Figure 5

Figure 4



Figure 6

Base Plate Placement Planning (cont.)

Load the 2.5 mm Pin into a K-wire driver or Jacobs chuck. The 2.5 mm Pin is marked for the appropriate insertion depth (Figure 4). Insert the 2.5 mm Pin through Pin Guide 1 until the first etch depth mark indicated on the pin meets the top of Pin Guide 1 (Figure 5). Release the Pin from the K-wire driver or Jacobs chuck, and lift Pin Guide 1 from the glenoid leaving the 2.5 mm Pin in place.

Note: When inserting the 2.5 mm Guide Pin, care should be taken to avoid bending or fracturing the pin. Bending may create resistance between the Pin and cannulated 6 mm and 7.5 mm Cannulated Drills that will be used in the later steps. This may cause the pin to get caught with the drills and perforate the scapular vault. If unsatisfied with the pin placement or orientation, remove the pin entirely from the glenoid bone, use a new pin, and then slowly reintroduce the pin into the glenoid bone ensuring a more optimal pin placement.

Note: The instrumentation includes size-specific 6 mm and 7.5 mm Cannulated Drills. Care must be taken to maintain size consistency between these drills and the final implant center post length to ensure proper medial vault preparation.

Drill Pilot Hole for Center Post

To create a pilot hole for the glenoid reamers, a 6 mm Cannulated Drill is needed. The 6 mm Cannulated Drill comes in 15 mm, 20 mm, 25 mm and 30 mm lengths. Use the 6 mm Cannulated Drill with length that corresponds to the center post length of the intended base plate. The length is etched on the Drill collar to distinguish size. The 6 mm Cannulated Drill attaches to the Cannulated Straight Driver by sliding the Driver tabs into rounded slots of the 6 mm Cannulated Drill. Turn the Cannulated Straight Driver 90° clockwise to retain the 6 mm Cannulated Drill. Place the Cannulated Drill assembly over the 2.5 mm Pin and drill until the housing collar is flush to the glenoid face (Figure 6).

At this point, you can choose to either remove the 2.5 mm Pin or leave it in.

Note: While using the 6 mm Drill for 20 mm/25 mm/30 mm lengths, the guide pin may become loose. In such situation, remove the pin by hand or chuck.

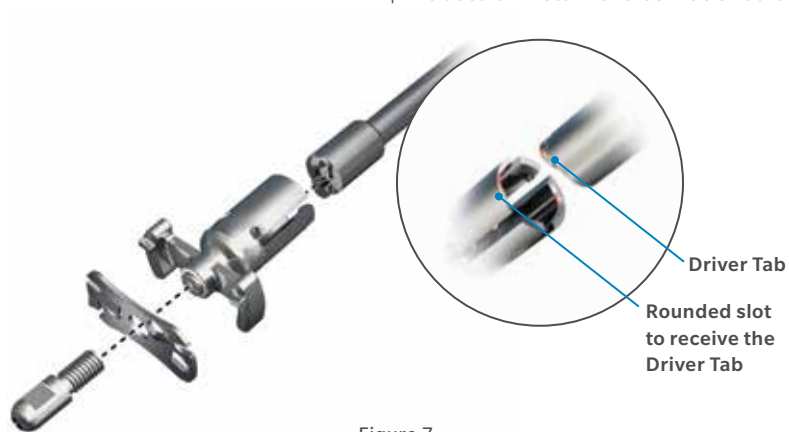


Figure 7

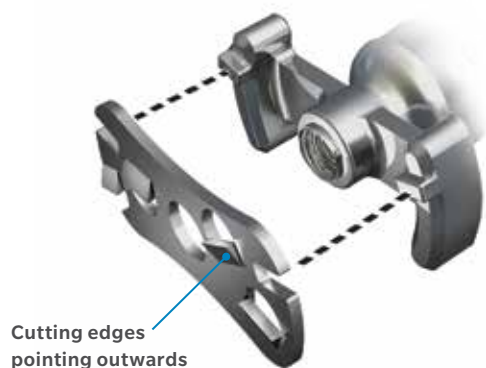


Figure 8



Figure 9



Figure 10

Ream Glenoid Bone and Prepare Center Hole

There are two options to ream glenoid bone and drill center hole. First option allows reaming the glenoid bone and drilling the center hole in discreet steps. The second option, presented in Appendix B, allows reaming the glenoid bone and drilling for center hole in a single step.

Ream Glenoid Bone and Prepare Center Hole in Discreet Steps

Construct the Base Plate Tecomet Reamer assembly (Figure 7) that utilizes the disposable Tecomet Reamer Blade by first attaching the Cannulated Straight Driver to a T-handle. Attach Tecomet Reamer Adapter to the Cannulated Straight Driver by sliding the Driver tabs into rounded slots of the Tecomet Reamer Adapter. Place the disposable bow-tie shaped Tecomet Reamer Blade on the Tecomet Adapter by aligning the slots on blade to the nubs on adapter and ensuring that the reamer's cutting edges are facing outwards and not towards the adapter (Figure 8). The Tecomet Reamer Pilot Tip should then be threaded to the adapter and tightened by the Tecomet Reamer Wrench to complete the assembly (Figure 9). Do not over-tighten the pilot tip to avoid bending the blade.

While tightening the pilot tip, the T-Handle can be held on to for support. Care should be taken to not tip the construct before the pilot tip is secured to the adapter.

- ⓘ **Note:** Slots on blade and nubs on adapter should not be misaligned (Figure 10) to avoid improper seating of blade and uneven reaming of glenoid surface.
- ⓘ **Note:** If it is desired to ream the glenoid bone and drill for center hole in a single step, a 'disposable blade with center post drill' option is available. Please refer to Appendix B for the related surgical steps.
- ⓘ **Note:** If a reusable reamer blade option is preferred, a reusable Base Plate Reamer 1 is available in the instrument set. Please refer to Appendix C for the related surgical steps.



Figure 12



Figure 11



Figure 13

Ream Glenoid Bone and Prepare Center Hole in Discreet Steps (cont.)

Place the Reamer assembly into the pilot hole created by the 6 mm Cannulated Drill. Hand reaming is recommended to prepare the glenoid surface for the back of the base plate. Do not use excessive force when reaming the bone as this may cause the instrument to bend or fracture. Ream until the reamer face is completely flush with the prepared surface. Care should be taken to preserve the subchondral bone while reaming (Figures 11 and 12). If necessary, remove any remaining prominent glenoid bone.

- ⚠ **Warning:** Caution must be observed while power reaming to avoid excessive bone removal.
- ⓘ **Note:** When reaming, care should be taken to avoid interference of retractors with the reamer blade, especially if the reamer is used on power. Interference can cause damage to the blade and result in uneven reamed surface on the glenoid face. Start rotation of reamer head before engaging the bone.
- ⓘ **Note:** The reamer's clearance from all retractors should be assessed by rotating the reamer in full circle before engaging bone, to ensure no retractor is in its motion path.

Depending on the size (36 mm or 40 mm) and eccentricity option (centric or eccentric) of glenosphere that will be implanted, select the corresponding Cannulated Base Plate Reamer 2. Rotate the Ratchet T Handle collar to the centered, locked position. Attach the chosen bow-tie shaped Cannulated Base Plate Reamer 2 to the Cannulated Straight Driver assembly. Ream by hand, using an oscillating motion (Figure 13), until the spokes are flush to the previously reamed face. The outer cutting teeth of Cannulated Base Plate Reamer 2 will ream the surrounding bone to provide clearance for the glenosphere head. Once the base plate implant is in place, surface reaming is not possible. In the event that Cannulated Base Plate Reamer 2 will not fit through the tissue envelope, the alternatives include use of a rongeur or burr to clear any peripheral bone which may inhibit full seating of the glenosphere.

- ⓘ **Note:** This step is necessary to ensure the glenosphere head will lock on the Base Plate properly. All reasonable efforts should be made to use the appropriate Base Plate Reamer 2. The size and eccentricity of base plate reamer 2 corresponds to the glenosphere head to be used.



Figure 14



Figure 15

Ream Glenoid Bone and Prepare Center Hole in Discreet Steps (cont.)

Note: On Base Plate Reamer 2 for eccentric glenosphere, one side of the cutting blade is longer than the other to accommodate for the eccentricity. It is important to orient the longer blade (marked on the instrument by “Offset”) toward the intended glenosphere offset direction. Oscillating motion during reaming is advised to minimize the extent of bone reamed.

The final glenoid preparation step is to enlarge the center post hole using a 7.5 mm Cannulated drill, which is available in lengths of 15 mm, 20 mm, 25 mm and 30 mm. Choose the appropriate drill length based on bone quality and surgeon preference. The drill length used will regulate the center post length of the base plate implant. These drills must be used with the Base Plate Drill Guide 2 to avoid drilling too far medially and to position straight on to the glenoid reamed surface (Figure 14).

Poor Bone Stock:

When implanting a 15 mm Base Plate into poor bone stock, the instrument set provides three drill types: A 7.5 mm Drill, a 7.5 mm Cortex Drill, or a 7.5 mm Compression Plug. Use the 7.5 mm Cortex Drill with Drill Guide 2 (Figure 15) to remove only the first 3 to 4 mm of glenoid cortex. If a press fit of the distal end of the Base Plate post is desired, then the preparation is complete. If it is deemed appropriate to compress more bone, use the 7.5 mm Compression Plug with Drill Guide 2 to compress the cancellous bone in the vault prior to implant insertion. There are no 20 mm, 25 mm and 30 mm versions of the Cortex Drill or Compression Plug.

Note: The Compression Plug should not be used unless the 7.5 mm Cortex Drill is used first. Otherwise there may be a risk of glenoid fracture.

Note: A small drill can be used to sound for confirming good bone quality. Drill Guide 2 has two reference marks to help aid in the superior/ inferior placement of the Inverse/Reverse Screws. You may choose to make anatomical marks for the placement of the Inverse/Reverse Screws.

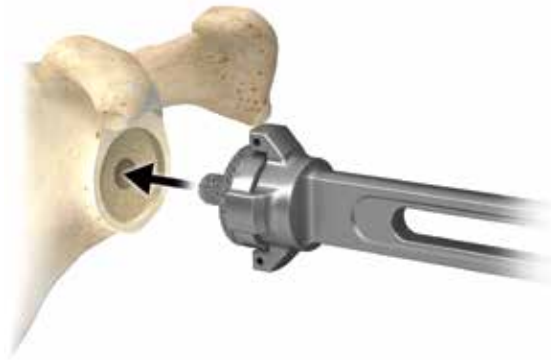


Figure 17



Figure 16



Figure 18

Base Plate Insertion

Note: Bone cement should not be used to secure the base plate to the glenoid bone. Initial base plate fixation will come from 0.5 mm interference fit along the center post and superior/inferior compression screw fixation.

Prior to base plate insertion, carefully note and mark the inferior glenoid pillar. Attach the final Base Plate implant to the Base Plate Inserter (Figure 16) and insert it into the prepared glenoid. Prior to implantation, confirm the base plate size. The base plate center post length comes in four sizes (15, 20, 25 and 30 mm) and the final implant size must match the length of 6 mm and 7.5 mm Cannulated Drills used to prepare the glenoid vault. Orientation of the base plate can be established either by aligning the inferior screw hole to the inferior scapular pillar or by aligning the superior screw hole to the base of the coracoid (Figure 17). The Base Plate is implanted by striking the Base Plate Inserter with a mallet until the component is completely flush with the prepared surface (Figure 18).

Care should be taken to avoid tipping the Base Plate during insertion, as this may prevent circumferential contact. Once the base plate is fully seated on the glenoid bone, avoid rotating the base plate or levering the Base Plate Inserter during disengagement as this may disrupt circumferential bony contact around center post. Disengage the Base Plate Inserter from the fully seated Base Plate implant.

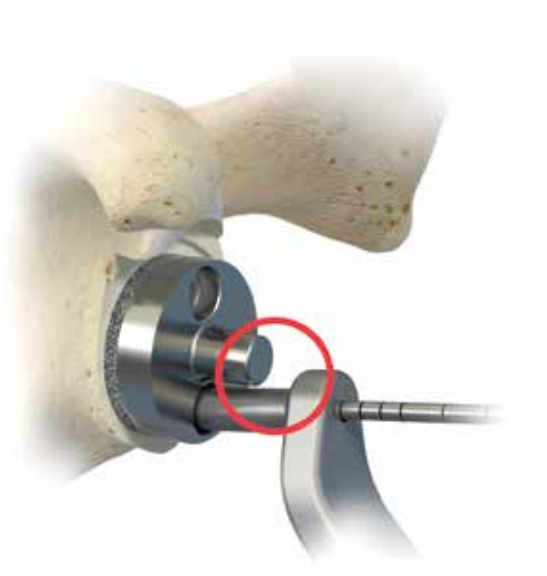


Figure 19

Screw Insertion

The Base Plate and 2.5 mm Screw Drill Guide are designed to enable polyaxial screw placement flexibility. Insert the 2.5 mm Screw Drill Guide into the inferior screw hole. The inferior screw should be oriented medially towards the scapula, either parallel to center post or with a slight inferior divergence to maximize screw length. The superior screw should be oriented towards the base of the coracoid.

ⓘ **Note:** Do not aim the drill towards the Trabecular Metal center post.

ⓘ **Note:** Tip of the drill guide should be in full contact with the bottom of the baseplate screw hole. This will ensure that the drill guide does not tip beyond the allowed screw angulation of 8 degrees.

Attach the 2.5 mm Drill to power and drill the screw holes through the 2.5 mm Drill Guide and Base Plate at the desired orientation (Figure 19). The 2.5 mm Drill has lines corresponding to the screw lengths available.

ⓘ **Warning:** When drilling the screw holes, care should be taken to avoid bending the 2.5 mm Drill when it is inside the Drill Guide. This creates resistance between the Drill and Drill Guide which may cause the drill to fracture. If unsatisfied with the resulting screw trajectory or length, then remove the drill entirely from the glenoid bone, reorient the drill guide, and then slowly reintroduce the drill into the glenoid bone ensuring a more desirable screw placement.



Figure 20



Figure 21



Figure 22a



Figure 22b



Figure 22c

Screw Insertion (cont.)

Remove the drill and the drill guide. Assemble the Screw Depth Guide and insert into the screw holes to confirm screw length (Figures. 20 and 21). Screws are available in 18–48 mm lengths. Inverse/Reverse Screws are adjustable within a possible 16° arc (Figures 22a, 22b and 22c) and thus can readily be angled to achieve good bone purchase.

Note: To avoid rotation of the baseplate while torquing the screw, thread the first screw without torquing it down completely. Engage the other screw and fully torque it, before returning to the first screw and torquing it down completely as well.



Figure 23



Figure 25



Figure 24

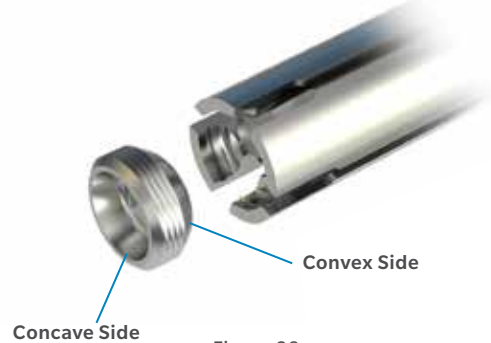


Figure 26

Screw Insertion (cont.)

Attach the screw to the Hexagonal Screw Driver, making sure good bone purchase is achieved (Figure 23). If good bone purchase is not achieved, the screw should be removed and prepared at a new angle. To rigidly lock the screw in place, affix the Locking Cap to the Reverse Torque Screwdriver with convex side facing lateral, and gently slide the Locking Screw Holder over the locking cap (Figure 24). The locking cap and Reverse Torque Screwdriver should be orientated perpendicular to the base plate surface (Figure 25). Turn the Locking Cap in place until the Torque Screwdriver slips or an audible click is heard.

Note: The locking cap only engages in one orientation. The concave surface must be pointing toward the screw (Figure 26). To avoid mis-threading, the screwdriver shaft should be perpendicular to the base plate to properly seat the locking screw. Failure to slide back the Locking Screw Holder can impede locking cap insertion.

Note: While engaging the locking cap on the baseplate with the Locking Screw Holder, orient one of the slots on the Locking Screw Holder towards the baseplate taper. This will avoid interference with the baseplate taper, in case the Locking Screw Holder expands during locking cap tightening.



Figure 27



Figure 28

Component Selection and Trial Reduction

Utilize the Liner and Glenosphere Trials to evaluate range of motion and joint retention. Based on the system used for humeral component – Trabecular Metal Reverse System or Comprehensive Shoulder System, choose the trial liner and glenosphere based on the component compatibility. The compatibility information is provided at the website <http://www.zimmerbiomet.com/medical-professionals/support/product-compatibility.html>

Refer to following surgical techniques for the humeral side of the following systems for trial reduction:

Trabecular Metal Reverse System - Humeral-side
Comprehensive Shoulder System

ⓘ **Note:** The TM Reverse Trial Liners can also be used on the actual stem if you prefer to make this determination off of the final stem position and with the actual glenosphere head.

ⓘ **Note:** The TM Reverse Proximal Trials have suture holes to help visualize their position during final implantation. If desired, these locations can be marked to facilitate trial placement.

If not placed previously, attach a Glenosphere Trial to the Base Plate by hand (Figure 27) or with the Glenosphere Helmet attached to the Dual Taper/Spacer Impactor (Figure 28). Ensure the Glenosphere Trial matches the size and eccentricity of the Base Plate Reamer 2 used to prepare the glenoid surface.



Figure 29

Component Selection and Trial Reduction (cont.)

Note: Glenosphere Trial should not be impacted. Pressure can be put by hand on the trial to get a snug fit on the base plate.

Reduce the joint and perform a range of motion assessment. The joint should be stable throughout the range of motion. If the construct dislocates, Glenosphere Trials with varying lateral offset and/ or eccentricity and varying thickness Trial Liners and/or Trial Spacers should be used to obtain the proper joint stability.

The eccentric Glenosphere Trial has two alignment marks 180 degrees apart and a max offset indicator to show the offset alignment. These alignment marks can be used to determine the optimal inferior overhang of the glenosphere. Once the inferior overhang position is determined, an 'offset positioning mark' can be put on the bone against the superior alignment mark of the Glenosphere Trial. This 'offset positioning mark' will help align the final implants offset orientation and positioning (Figure 29).

Over-tensioning the joint may cause increased shear force at the base plate/glenoid bone interface. This may lead to implant micromotion and long-term loosening of the glenoid components. Care should be taken when selecting Liner and/or Spacer thicknesses to avoid excessive joint tension. Glenosphere Trials are available in 36 mm or 40 mm diameters with lateral offsets of +0 mm, +3 mm, +5 mm.

Note: The 36 mm is used typically, while the 40 mm is used in larger patients to provide additional stability if needed, or to avoid bone impingement due to bone overhang.

Note: If there is bone impingement on the Glenosphere Trial, the excess bone should be removed. If not removed, the impinging bone will interfere with the glenosphere implant as well, and compromise glenosphere and base plate attachment.



Figure 30



Figure 31

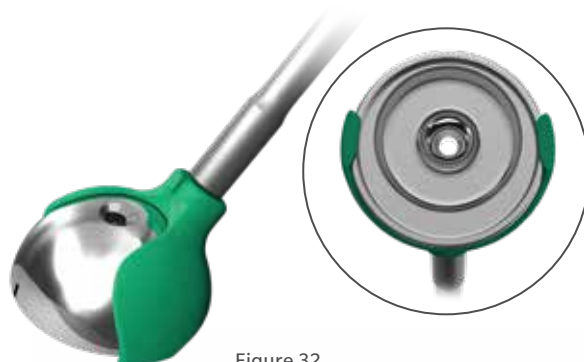


Figure 32

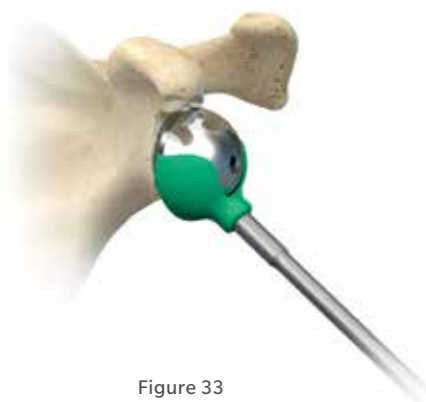


Figure 33

Provisional Removal

Remove the Glenosphere Trial, Poly Liner Trial and Spacer Trial (if used). Glenosphere Trial can be removed using the Glenosphere Removal bolt by screwing it to the hole on Glenosphere Trial surface. Removing Glenosphere Trial using other methods such as pulling by hand may compromise base plate fixation.

Implant Insertion

Glenosphere Assembly

The Glenosphere is typically inserted prior to humeral component final seating to maximize exposure of the glenoid and ease of insertion. Ensure all soft tissue is removed around the Base Plate to allow the Glenosphere to seat completely.

Assemble the Glenosphere Helmet Inserter by threading the Dual Taper/Spacer Impactor into either the 36 mm (green) or the 40 mm (yellow) Glenosphere Helmet (Figure 30). Insert the Glenosphere with the appropriate diameter, eccentricity and lateral offset into the helmet by sliding it into the helmet so that the Glenosphere is held in place by the body of the helmet and the tabs rest securely underneath the Glenosphere (Figures 31 and 32).

Clean and dry the Base Plate taper of all fluids and inspect the taper to ensure it is free of scratches or damage. Place the Zimmer Shoulder Shoehorn Retractor on the posterior side of the glenoid to aid in retracting the humerus and other soft tissue. When approaching the Base Plate, a finger can be placed on top of the Glenosphere to help guide and feel the Glenosphere slide over the taper into position. Figure 33 shows a glenosphere position when correctly placed over the baseplate taper.

Note: While engaging the Glenosphere, it is important to monitor the position of the proximal humerus and provisional along with retractors since they could interfere with Glenosphere placement. Alternatively, a bone hook can be placed on the humeral provisional to draw the humerus laterally to provide clearance for the glenosphere. It's important to feel the mechanical resistance of taper engagement before proceeding to impaction.

Note: For the eccentric glenosphere, previously put 'offset positioning mark' on the glenoid bone can be utilized to align the offset indicator on the glenosphere implant.

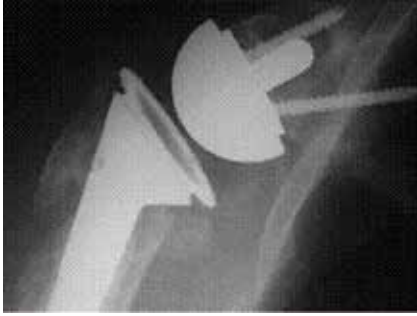


Figure 34



Figure 35

Implant Insertion (cont.)

Note: For eccentric glenosphere, care should be taken to avoid glenosphere rotation while removing the glenosphere helmet. Upon removal of the glenosphere helmet, offset of glenosphere implant should be confirmed.

Once the Glenosphere is seated evenly, use your free hand to press firmly on the Glenosphere to secure it to the Base Plate. Keeping a finger on the Glenosphere, remove the Glenosphere Helmet pulling the instrument away in the SAME DIRECTION used to insert the Glenosphere (i.e. if an anterior approach was used to insert the Glenosphere, remove the instrument by pulling it from the anterior direction). This will help minimize changes to the Glenosphere placement on the Base Plate and damage to the Glenosphere Helmet itself.

Note: If unable to visually confirm an even engagement of the Glenosphere to the Base Plate, consider the use of a fluoroscope to aid in the confirmation. Seating of the Glenosphere to the Base Plate can be examined in the axillary view or in a view parallel to glenoid version. The medial rim of the glenosphere should be parallel to the face of the Base Plate (Figure 34).

Assemble Glenosphere Impactor Head to the Impactor Handle and place the Glenosphere Impactor Head centrally on the Glenosphere. Strike the Glenosphere Impactor Head with 3 firm mallet strikes to engage the Glenosphere on the Base Plate (Figure 35). Pull on the Glenosphere to verify the taper is locked. Reconfirm uniform engagement between the Base Plate and Glenosphere by using a small angled or 90 degree clamp to assess for malalignment gaps anterior to posterior, as well as inferior to superior.

Component Removal

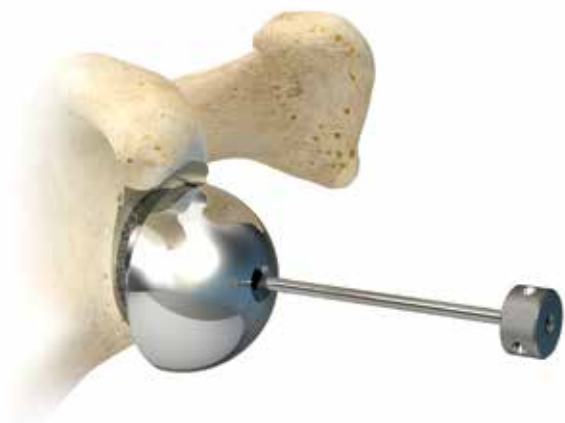


Figure 36



Figure 37

Glenosphere Removal

Attach the Glenosphere Removal Bolt to the Dual Taper/Spacer Impactor. Connect the bolt threads to the hole on the glenosphere surface and thread down bolt into the glenosphere (Figure 36). Passing through the female taper of glenosphere, the bolt will push against the head of the male taper of the base plate, thus pushing the baseplate down while pulling the glenosphere out. This will result in disengaging the glenosphere from the baseplate.

Note: The Glenosphere Removal Bolt should be inserted axially along the taper axis of the Glenosphere Trial or implant. When the Glenosphere Removal Bolt is inserted axially, there should be minimal resistance from the threads on the Glenosphere Trial or implant, until the Glenosphere Removal Bolt contacts the baseplate male taper. Contrastingly, in case the Glenosphere Removal Bolt taper bolt is not engaged axially, then resistance will be realized because of cross-threading of the Glenosphere Removal Bolt and the Glenosphere Trial or implant threads.

Note: Glenosphere that has been impacted and engaged on the baseplate may have altered the baseplate male taper's geometry while achieving a strong association with the baseplate taper.

Note: For old Base Plates that had the peripheral taper, the Glenosphere Distractor can be used. Assemble the Glenosphere Distractor. Wedge the fin tip between the superior glenoid bone and the underside of the Glenosphere (Figure 37). There must be good contact on these two surfaces for disengagement to occur. Pull the Glenosphere Distractor trigger until it fires. The Glenosphere head should be loose enough to gently remove by hand. If not, repeat the step making sure there is contact between the distractor tip, the glenoid bone surface and the Glenosphere head.



Figure 38



Figure 40

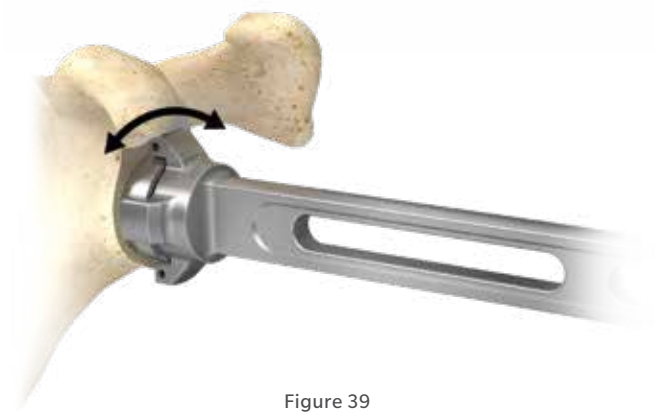


Figure 39



Figure 41

Base Plate Removal

Should the Base Plate ever need to be removed, the Locking Screws and Inverse/Reverse Screws are removed by utilizing the Hexagonal Screwdriver (Figure 38).

☰ **Tip:** Engaging the baseplate inserter with the baseplate and twisting in slight oscillating motion can also help disassociate bone in-growth from implant (Figure 39).

If removal is performed during the index procedure the Base Plate can be removed by levering with osteotome. If removal is performed during revision procedure standard osteotomes are first used to disassociate as much of the bone in-growth area as possible from the implant. Each bolt of the Base Plate Remover is threaded into the Base Plate using the Hexagonal Screwdriver. This is done by moving the barrel over to one side, threading one bolt into a screw hole in the base plate, then moving the barrel to the other side and inserting the second bolt into the other screw hole (Figure 40). Thread down the bolts until the instrument is securely attached.

A Standard Slaphammer, such as the Nexel® Slaphammer (00-8401-009-00), should be screwed into the body of the Base Plate Remover (Figure 41). Repeatedly impact until the Base Plate has been removed.

Appendix A

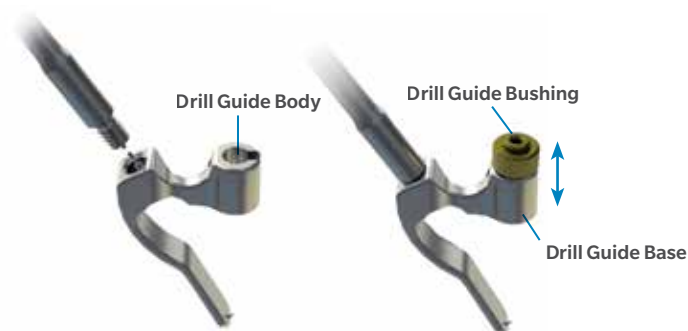


Figure 42

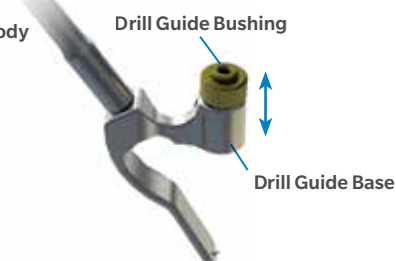


Figure 43

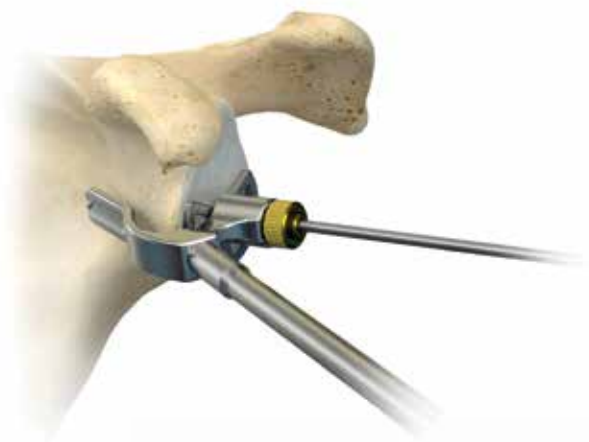


Figure 45

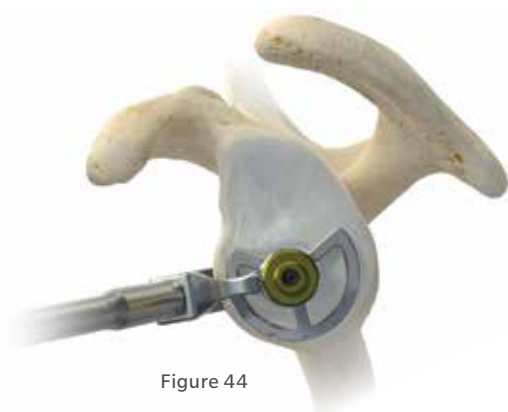


Figure 44

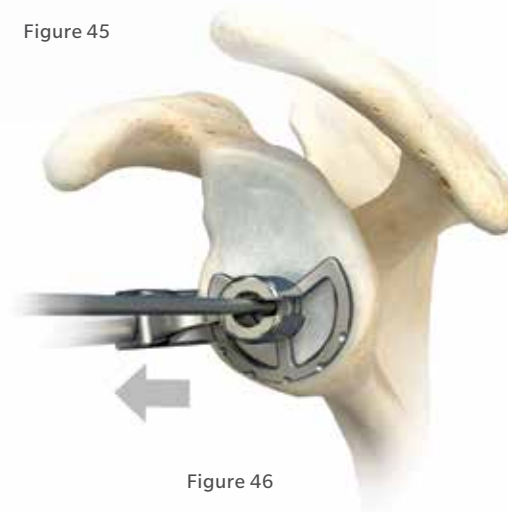


Figure 46

Alternate Pin Guide Placement Assembly: Drill Guide Assembly 2

Thread the Dual Taper Spacer Impactor into the Drill Guide Body (Figure 42). Snap the rotating Drill Guide Base onto the Drill Guide (Figure 43). The Base has several tines which will snap into the Drill Guide and allow the Base to rotate freely around the Drill Guide. Place the Drill Guide Bushing into the superior hole of the Drill Guide.

Position the assembled Cannulated Drill Guide along the anterior surface of the scapula so that the arm is at 3 o'clock (right shoulder)/9 o'clock (left shoulder) and the Bushing is centered on the glenoid articular surface (Figure 44). If, due to large size of the glenoid bone, the Bushing cannot reach the center of the articular surface, then an XL version of the Drill Guide Arm is available.

The Cannulated Drill Guide should be centered anteriorly/posteriorly, and align to inferior border of the glenoid. Insert a 2.5 mm Pin into a wire driver or Jacobs chuck. The 2.5 mm Pin is marked for the appropriate insertion depth. Insert the 2.5 mm Pin through the Cannulated Drill Guide until the second etch mark indicated on the Pin meets the top of Cannulated Drill Guide (Figure 45). Do not use excessive force when driving the 2.5 mm Pin in the bone as this may cause it to bend or fracture. Release the Pin from the wire driver or Jacobs chuck, and use a kocher or small clamp to grip the Bushing and slide it over the Guide Pin. To disengage the remaining Cannulated Drill Guide, rotate the Base so that cut-out is positioned posteriorly and aligned with the posterior cut-out in the Drill Guide Arm (Figure 46). Move the Assembled Drill Guide anteriorly to release it from the Guide Pin. After completing these surgical steps, go to 'Drill Pilot Hole for Center Post' section for the next series of surgical steps.

Appendix B

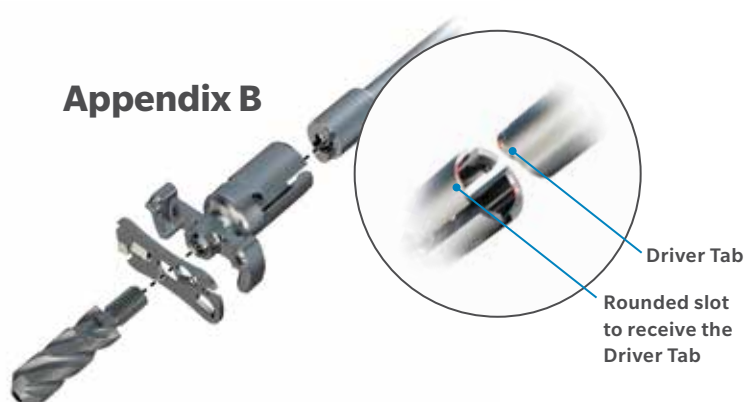


Figure 47

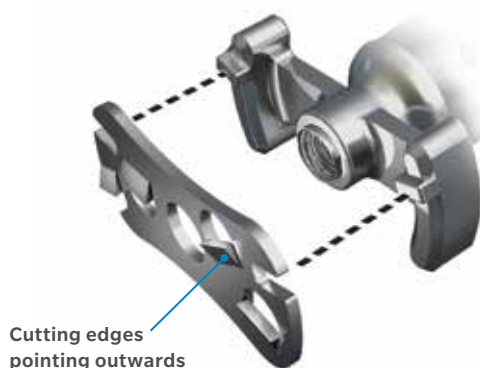


Figure 48

Alternate Reamer (Disposable): Ream Glenoid Bone and Drill Center Hole in Single Step

Note: A 6 mm cannulated drill must be used prior to this step; otherwise the 2.5 mm guide pin may get caught with the drill and get pushed beyond the scapula vault.

Optional instrumentation can be provided on demand to ream glenoid bone and drill center hole in one step.

Construct the Base Plate Tecomet Reamer assembly (Figure 47) that utilizes the disposable Tecomet Reamer Blade and the 7.5 mm Cannulated Drill simultaneously by attaching the Cannulated Straight Driver to a T-handle. Attach Tecomet Reamer Adapter to the Cannulated Straight Driver by sliding the Driver tabs into rounded slots of the Tecomet Reamer Adapter. Place the disposable bow-tie shaped Tecomet Reamer Blade on the Tecomet Adapter by aligning the slots on blade to the nubs on adapter and ensuring that the reamer's cutting edges are facing outwards and not towards the adapter (Figure 48). The 7.5 mm Cannulated Tecomet Drill should then be threaded to the adapter and tightened by the Tecomet Reamer Wrench to complete the assembly (Figure 49). Do not over-tighten the drill to avoid bending the blade. While tightening the 7.5 mm Cannulated Tecomet Drill, the T-Handle can be held on to for support.

The 7.5 mm cannulated drill length should be chosen corresponding to the center post length of the base plate implant.



Figure 49



Figure 50

Care should be taken to not tip the construct before the drill is secured to the adapter.

Note: Slots on blade and nubs on adapter should not be misaligned (Figure 50) to avoid improper seating of blade and uneven reaming of glenoid surface.

Note: While reaming and drilling in one step, special care should be taken to not drop the hand in order to follow the previously prepared pilot hole. This will ensure the optimal press-fit and circumferential contact of the baseplate.

Warning: Caution must be observed while power reaming to avoid excessive bone removal.

Note: When reaming, care should be taken to avoid interference of retractors with the reamer blade. Interference can cause damage to the blade and result in uneven reamed surface on the glenoid face. The reamer's clearance from all retractors should be assessed by rotating the reamer in full circle before engaging bone, to ensure no retractor is in its motion path. If reaming on power, start rotation of reamer head before engaging the bone.

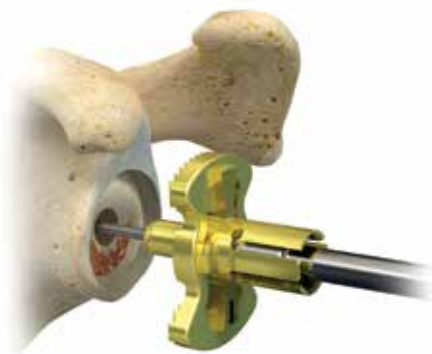


Figure 51

Alternate Reamer (Disposable): Ream Glenoid Bone and Drill Center Hole in Single Step (cont.)

Depending on the size (36 mm or 40 mm) and eccentricity option (centric or eccentric) of glenosphere that will be implanted, select the corresponding Cannulated Base Plate Reamer 2. Rotate the Ratchet T Handle collar to the centered, locked position. Attach the chosen bow-tie shaped Cannulated Base Plate Reamer 2 to the Cannulated Straight Driver assembly. Ream by hand, using an oscillating motion (Figure 51), until the spokes are flush to the previously reamed face. The outer cutting teeth of Cannulated Base Plate Reamer 2 will ream the surrounding bone to provide clearance for the glenosphere head. Once the base plate implant is in place, surface reaming is not possible. In the event that Cannulated Base Plate Reamer 2 will not fit through the tissue envelope, the alternatives include use of a Rongeur or Burr to clear any peripheral bone which may inhibit full seating of the Glenosphere.

ⓘ **Note:** This step is necessary to ensure the glenosphere head will lock on the Base Plate properly. All reasonable efforts should be made to use the appropriate Base Plate Reamer 2. The size and eccentricity of base plate reamer 2 corresponds to the glenosphere head to be used.

ⓘ **Note:** On Base Plate Reamer 2 for eccentric glenosphere, one side of the cutting blade is longer than the other to accommodate for the eccentricity. It is important to orient the longer blade (marked on the instrument by "Offset") toward the intended glenosphere offset direction. Oscillating motion during reaming is advised to minimize the extent of bone reamed.

After completing these surgical steps, go to 'Baseplate Insertion' section for the next series of surgical steps.

Appendix C



Figure 52



Figure 53

Alternate Reamer (Reusable): Ream Glenoid Bone and Drill Center Hole in Discrete Steps

Attach the Ratchet T Handle to the Cannulated Straight Driver. Then attach the Cannulated Base Plate Reamer 1 to the Cannulated Straight Driver assembly. This Cannulated Base Plate Reamer 1 has a piloted tip which includes a cannulation hole, so it can be used with or without cannulation, based on whether the 2.5 mm pin was removed or not. Turn the Cannulated Straight Driver 90° clockwise to retain Reamer 1.

Place the Reamer assembly into the pilot hole created by the 6 mm Cannulated Drill. Hand reaming is recommended to prepare the glenoid surface for the back of the base plate. The reamers are sharp and power reaming may remove excessive bone. Do not use excessive force when reaming the bone as this may cause the instrument to bend or fracture. Ream until the reamer face is completely flush with the prepared surface. Care should be taken to preserve the subchondral bone while reaming (Figures 52 and 53).

Warning: Caution must be observed while power reaming to avoid excessive bone removal.

Note: When reaming, care should be taken to avoid interference of retractors with the reamer blade. Interference can cause damage to the blade and result in uneven reamed surface on the glenoid face.

The reamer's clearance from all retractors should be assessed by rotating the reamer in full circle before engaging bone, to ensure no retractor is in its motion path.

Note: If necessary, remove any remaining prominent glenoid bone. Start rotation of reamer head before engaging the bone.

Depending on which the size (36 mm or 40 mm) and eccentricity option (centric or eccentric) of glenosphere that will be implanted, select the appropriately sized corresponding Cannulated Base Plate Reamer 2. Rotate the Ratchet T Handle collar to the centered, locked position. Attach either the 36 mm or the 40 mm chosen bow-tie shaped Cannulated Base Plate Reamer 2 to the Cannulated Straight Driver assembly. Ream by hand, using an oscillating motion (Figure 53), until the spokes are flush to the previously reamed face. The outer cutting teeth of Cannulated Base Plate Reamer 2 will ream the surrounding bone to provide clearance for the glenosphere head. Once the base plate implant is in place, surface reaming is not possible. In the event that Cannulated Base Plate Reamer 2 will not fit through the tissue envelope, the alternatives include use of a Rongeur or Burr to clear any peripheral bone which may inhibit full seating of the Glenosphere.



Figure 54



Figure 55

Alternate Reamer (Reusable): Ream Glenoid Bone and Drill Center Hole in Discrete Steps (cont.)

Note: This step is necessary to ensure the glenosphere head will lock on the Base Plate properly. All reasonable efforts should be made to use the appropriate Base Plate Reamer 2. The size and eccentricity of base plate reamer 2 corresponds to the glenosphere head to be used.

Note: On Base Plate Reamer 2 for eccentric glenosphere, one side of the cutting blade is longer than the other to accommodate for the eccentricity. It is important to orient the longer blade (marked on the instrument by “Offset”) toward the intended glenosphere offset direction. Oscillating motion during reaming is advised to minimize the extent of bone reamed.

The final glenoid preparation step is to enlarge the center post hole using a 7.5 mm Cannulated drill, which are available in lengths of 15 mm, 20 mm, 25 mm and 30 mm. Choose the appropriate drill length based on bone quality and surgeon preference. The drill length used will regulate the center post length of the base plate implant. These drills must be used with the Base Plate Drill Guide 2 to avoid drilling too far medially and to position straight on to the glenoid reamed surface (Figure 54).

Poor Bone Stock:

When implanting a 15 mm Base Plate into poor bone stock, the instrument set provides three drill types: A 7.5 mm Drill, a 7.5 mm Cortex Drill, or a 7.5 mm Compression Plug. Use the 7.5 mm Cortex Drill with Drill Guide 2 (Figure 55) to remove only the first 3 to 4 mm of glenoid cortex. If a press fit of the distal end of the Glenosphere Base Plate post is desired, then the preparation is complete. If it is deemed appropriate to compress more bone, use the 7.5 mm Compression Plug with Drill Guide 2 to compress the cancellous bone in the vault prior to implant insertion. There are no 20 mm, 25 mm and 30 mm versions of the Cortex Drill or Compression Plug

Note: The Compression Plug should not be used unless the 7.5 mm Cortex Drill is used first. Otherwise there may be a risk of glenoid fracture.

Note: A small drill can be used to sound for confirming good bone quality. Drill Guide 2 has two reference marks to help aid in the superior/inferior placement of the Inverse/Reverse Screws. You may choose to make anatomical marks for the placement of the Inverse/Reverse Screws.

After completing these surgical steps, go to ‘Baseplate Insertion’ section for the next series of surgical steps.

Appendix D

Indications and Contraindications

The Zimmer Trabecular Metal Reverse Shoulder System is a treatment option for patients with severe rotator cuff (RC) deficiency. The stem is designed so that its bearing surfaces, as compared to a traditional humeral stem, is such that the humeral component contains a concave ultra-high molecular weight polyethylene (UHMWPE) liner that articulates with a hemispheric metallic glenoid component.

Indications

- The treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint;
- Ununited humeral head fractures of long duration;
- Irreducible 3-and 4-part proximal humeral fractures;
- Avascular necrosis of the humeral head, or other difficult clinical management problems (such as a failed total shoulder arthroplasty or grossly rotator cuff deficient joint) where arthrodesis or resectional arthroplasty is not acceptable.
- The reverse base plate is intended for uncemented use, and requires two screws for fixation.

Contraindications

Reverse Applications:

- Local/systemic infection
- Presence of significant injury to the upper brachial plexus
- Paralysis of the axillary nerve
- Marked bone loss
- Nonfunctional deltoid
- Any neuromuscular disease compromising the affected limb that would render the procedure unjustifiable

For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information. Check for country product clearances and reference product specific instructions for use.

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