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Introduction

The following surgical technique is an addendum to either the Zimmer® Trabecular Metal™ Reverse Shoulder System surgical technique (97-4309-203-00) or the Anatomical Shoulder™ Inverse/Reverse surgical technique (97-4223-102-00), depending upon which humeral stem has been chosen for implantation.

Indications / Contraindications

INDICATIONS

The Zimmer PSI Shoulder is indicated, based on patient-specific radiological images with identifiable placement anatomical landmarks, to assist in pre-operative planning and/or intra-operative guiding of surgical instruments for shoulder replacement surgical procedures on patients not otherwise precluded from being radiologically scanned. The Zimmer PSI Shoulder is to be used with the Zimmer Trabecular Metal Reverse Shoulder Baseplate in accordance with the implant system’s indications and contraindications. The Zimmer PSI Shoulder hardware components (instrument guides and bone model) are intended for single use only.

CONTRAINDICATIONS

The Zimmer PSI Shoulder should not be used when the patient already has metallic devices implanted that could interfere with the CT scan quality. Additionally, the Zimmer PSI Shoulder should not be used in cases of revision surgery where native bone is absent on surfaces intended to mate with the Zimmer PSI Shoulder instrument guides or in cases where a custom bone augment/graft will be used on surfaces intended to mate with the PSI Shoulder instrument guides.

COMPATIBILITY

The Zimmer PSI Shoulder is compatible for use with Zimmer Trabecular Metal Reverse Shoulder Baseplate. See the applicable package inserts and surgical technique for implantation instructions, indications and contraindications specific to the implant system.
Overview

Pre-Operative Planning
The first step in PSI Shoulder surgical technique and a precursor to using the PSI guides is to undergo a Pre-Operative Planning process using the PSI Shoulder Planner software. See the Zimmer PSI Shoulder Planner software User Guide (803.122) for usage instructions to the Zimmer PSI Shoulder Planner software. The surgeon must conduct, review and approve the plan in order to initiate the manufacture of PSI instrument guides. The output of this process will be the Pre-Operative Report and the manufacturing specifications of the PSI Guides and Bone Model.

Pre-Operative Report
A copy of the Pre-Operative Report (20-8015-016-00) is provided in the PSI Shoulder Instrument Guides and Bone Model packaging. This report includes general case information and the planned position and orientation of the glenoid implant components with related images. This document is to help the surgeon assess whether the PSI Shoulder Instrument Guides and Bone Model follow the pre-operative plan.

Notes
• Federal (U.S.) law restricts this device to sale by or on the order of a physician.
• Zimmer strongly recommends formal PSI Shoulder training prior to use of the system. Contact your local Zimmer representative or the Zimmer Institute (1-855-ZSurgeon, or 1-855-978-7436) for more information.
• The PSI Shoulder Instrument Guides and Bone Model are provided non-sterile and must be cleaned and sterilized before use per instructions provided in this Surgical Technique.
• Given the potential for patient morphological changes, the PSI Shoulder Instrument Guides and Bone Model have a limited shelf life of 6 months. The PSI Shoulder Instrument Guides and Bone Model must not be used after the expiration date indicated on the package label.
• If you experience difficulties with the PSI Shoulder Instrument Guides during surgery, stop using the instrument guides and revert to the standard (non-PSI) Zimmer Trabecular Metal Reverse Shoulder System surgical technique (Zimmer Item Number 97-4309-203-00).
• The PSI Shoulder Instrument Guides and Bone Model are patient specific and single use and should be discarded after surgery.
**WARNING:** Ensure that the delivered PSI Shoulder Instrument Guides and Bone Model correspond to the intended patient. The copy of the Pre-Operative Report is provided in the PSI Shoulder Instrument Guides and Bone Model packaging. Use the PSI Shoulder Instrument Guides and Bone Model only if the Zimmer Case ID markings are both legible on the PSI Shoulder Instrument Guides and Bone Model and match the Zimmer Case ID specific to the intended patient.

If the Zimmer Case ID markings (Fig. 1) on the PSI Shoulder Instrument Guides and Bone Model do not match the Zimmer Case ID specific to the intended patient, DO NOT USE the PSI Shoulder Instrument Guides and Bone Model on that patient and notify your Zimmer representative.

**Glenoid Preparation**

**Exposure**

Straight-on exposure of the glenoid is necessary for proper reaming and component insertion (Fig. 2).

It is recommended to use the deltopectoral approach since the superior-lateral approach may not provide adequate exposure. If the deltopectoral approach is chosen, the proximal humerus is retracted posteriorly and inferiorly.

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<tbody>
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<td><strong>S</strong></td>
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<tr>
<td>First Character of First Name</td>
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**Fig. 1**

Zimmer Case Identifier.

**Fig. 2**

Straight-on exposure of the glenoid.
If exposure is limited, re-check the humeral osteotomy level and ensure inferior capsular releases were thorough.

This approach requires circumferential exposure of the glenoid with labral excision. The long head of the biceps tendon must be excised completely. Inferiorly, the glenoid must be exposed to allow palpation of the inferior glenoid pillar and inferior positioning of the glenoid base plate. The use of needle tip cautery will allow safe incision of the inferior capsule while maintaining contact with the glenoid bone. Palpation of the axillary nerve will allow safe capsulotomy.

**NOTE:** While preparing the glenoid, the retraction 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. Consider use of the Zimmer Shoulder Shoehorn Retractor as it has been designed to aid in retracting the humeral head and other soft tissue when placed on the posterior side of the glenoid.

Use Glenoid Scraper to clean the glenoid face of any remaining articular cartilage or scar tissue (Fig. 3). Take care not to deform the cortical surface. Use caution with the sharp edges of the scraper to prevent subchondral gouges, which may prevent proper use of the PSI Pin Guide by precluding proper seating.

**NOTE:** It is important to compare the native glenoid bone with the PSI Bone Model provided to ensure that all of the soft tissue has been removed and that the PSI Pin Guide will have a good fit on the glenoid. This may be done with direct finger palpation along the entire glenoid surface and coracoid base. This area must be free of interfering soft tissue to allow seating of the PSI Pin Guide.
Position Guide Pins

Insert the two metal bushings into the PSI Pin Guide ensuring they are stable within the Guide.

Place the PSI Pin Guide on the surface of the glenoid.

**OPTIONAL:** The Threaded Alignment Rod may be used to aid in the placement of the PSI Pin Guide. Thread the Alignment Rod into the PSI Pin Guide containing the two bushings and use it as a handle to position it on the surface of the glenoid (Fig. 4). By gently pushing medially and posteriorly, the guide should “lock” onto the face of the glenoid without toggling. Common errors in placement may cause the guide pins to be placed aiming anteriorly.

The PSI Pin Guide fit must be assessed by holding the instrument guide by hand (Fig. 5). It should sit tightly on the glenoid surface and lock in place once positioned correctly. The hook should be on the anterior-superior quadrant of the glenoid, and the opening along the bushing should face the posterior side of the glenoid (Fig. 6).

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**Fig. 4**
Threaded Alignment Rod assists in positioning PSI Pin Guide on glenoid surface.

**Fig. 5**
Assess fit by holding PSI Pin Guide by hand.

**Fig. 6**
PSI Pin Guide sits tightly on glenoid surface, with hook on the anterior superior quadrant.
Confirm Pin Guide placement by comparing with the engraved outline of the Guide and Pins on the PSI Bone Model (Fig. 7). Remove additional soft tissue if necessary and verify Pin Guide placement again.

**NOTE:** It is contraindicated to use electrocautery to outline the contour of the PSI Pin Guide on the glenoid face.

Before inserting the Pins, ensure that the bushings are stable and completely inserted into the PSI Pin Guide.

Load the first 2.5mm Pin into a K-wire driver or Jacobs chuck. The 2.5mm Pin is marked for the appropriate insertion depth. Consult the preoperative plan to identify the correct insertion depth mark for each 2.5mm Pin. Insert the Pins to identified laser etch mark.

**WARNING:** Insert superior guide pin to the planned marking to avoid risk of neurovascular injury.

Holding the PSI Pin Guide tight with your fingers with medial pressure, insert the superior 2.5mm Pin through the superior hole of the PSI Pin Guide until the desired depth mark on the Pin meets the top of the metal bushing. Palpation and/or visualization along the anterior scapular neck may identify early scapular violation and thus improper PSI Pin Guide placement (i.e. penetration of the anterior glenoid vault less than 5-10mm deep).

**WARNING:** Do not use excessive force when driving the 2.5mm Pin into bone as this may cause it to bend or fracture.

A common error is to drop the hand while drilling due to the weight of the drill. Therefore, it is preferred to use K-wire drivers over Jacobs chuck drills. Release the Pin from the K-wire driver or Jacobs chuck, and insert the inferior 2.5mm Pin through the center hole of the PSI Pin Guide until the desired depth mark indicated on the Pin meets the top of the metal bushing (Fig. 9). Check again that the PSI Pin Guide has not rotated off the glenoid from its proper initial placement.

Remove the metal bushings by sliding them laterally along the 2.5mm Pins and out of the sleeves on the PSI Pin Guide.
Lift the PSI Pin Guide from the glenoid leaving the two 2.5mm Pins in place (Fig. 10). The Pins should be parallel and stable. The next visual check is to once again make sure the Pins remain parallel.

Compare the positioning of the Pins to the PSI Bone Model provided. **Assure accurate placement of the two Pins before proceeding.**

**Drill Base Plate Pilot Hole**

**NOTE:** The Trabecular Metal Reverse Shoulder instrument set contains size-specific 6mm Cannulated Drills and 7.5mm 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.

**NOTE:** No PSI Guide is required for this step. Use the appropriate 6mm Cannulated Drill.

The 6mm Cannulated Drill is now used to create a pilot hole for the glenoid reamers. It is attached to the Cannulated Straight Driver by sliding the Driver tabs into the rounded slots of the 6mm Cannulated Drill. Turn the Cannulated Straight Driver to retain the 6mm Cannulated Drill. Place the Cannulated Drill assembly over the inferior 2.5mm Pin and drill until the housing collar is flush to the glenoid face. Do not over penetrate the glenoid face, and be careful to keep Pins parallel when drilling. Try to drill to the necessary depth and remove the drill without stopping the drill. This will usually leave the 2.5mm inferior pin in place. If the inferior pin is loose after drilling, remove it.

**WARNING:** In the event of a steep inclination and version angle, the 6mm Cannulated Drill may not contact the glenoid surface (Fig 11). If such a situation is suspected, redrill with the 6mm Cannulated Drill after complete surface reaming to ensure drilling is complete.

Remove the 6mm Cannulated Drill from the glenoid leaving the 2.5mm Pins in place.
Ream Glenoid

Slide the PSI Ream Guide over the superior 2.5mm Pin. The smaller channel is intended for the Guide Pin and should be superior to the larger open channel of the Cannulated Straight Driver.

Attach Base Plate Reamer 1 to the Cannulated Straight Driver by sliding the Driver tabs into the rounded slots of Base Plate Reamer 1. Slide the Cannulated Reamer 1 assembly over the inferior 2.5mm Pin. Rotate the PSI Ream Guide such that it engages and clips over the shaft of the Cannulated Straight Driver. Ensure that it clips onto the two locations of the Cannulated Straight Driver (Fig 12).

**NOTE:** It is important to ensure direct contact between the PSI Ream Guide and the superior glenoid bone. There should not be excessive force to attach Reamer 1 to the guide required.

Hand ream until the subchondral bone is exposed inferiorly matching the preoperative plan (Fig. 13) and until the PSI Ream Guide reaches the lateral end of the Cannulated Straight Driver (Fig. 14), ensuring that the medial end of the PSI Ream Guide contacts the glenoid bone surface (Fig. 15).

**WARNING:** This is a sharp reamer 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.
Lift the Cannulated Reamer 1 assembly from the glenoid leaving the 2.5mm Pins in place taking care not to change the angle of the Pins. The PSI Ream Guide is still attached to the Cannulated Straight Driver. Unclip the PSI Ream Guide from the shaft of the Cannulated Straight Driver by pushing on the two tabs on the shaft to unsnap the Guide (Fig. 16a).

**NOTE:** Do not use the shaft of the PSI Ream Guide to unclip it from the Cannulated Straight Driver, as this may cause the guide to snap. (Fig. 16b).

Compare reamed glenoid surface with image provided in the pre-operative plan. It should correspond with the surgical steps.

If the inferior pin is loose, it may be removed at this point.

**NOTE:** If necessary, remove any remaining prominent glenoid bone with a small motorized burr or rongeur.

Depending on which size glenosphere will be implanted, select the appropriately sized Cannulated Base Plate Reamer 2. Attach either the 36mm or the 40mm bow-tie shaped Cannulated Base Plate Reamer 2 to the Cannulated Straight Driver by sliding the Driver tabs into the rounded slots of Base Plate Reamer 2. Set the Ratchet T-Handle on the LOCKED position. Place the Cannulated Reamer 2 assembly over the inferior 2.5mm Pin and ream by hand, using an oscillating motion, until the spokes are flush to the previously reamed face (Fig. 17). The outer cutting teeth of 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 without potentially damaging the base plate which may occur when using a hand burr.

**NOTE:** This step is necessary to help 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 of base plate reamer corresponds to the glenosphere head to be used.

Lift the Cannulated Reamer 2 assembly from the glenoid leaving the 2.5mm Pins in place taking care not to change the angle of the superior Pin.

Remove the inferior 2.5mm Pin from the glenoid bone.
Drill Base Plate Post Hole

**NOTE:** No PSI Guide is required for this step. Use the appropriate length of the 7.5mm Drill determined by the pre-operative plan. Do not use the PSI Ream Guide.

The base plate post hole must now be prepared. The system provides three tools for a 15mm long post base plate, a 7.5mm Drill, a 7.5mm Cortex Drill and a 7.5mm Compression Plug, to aid in post hole preparation based on bone quality and surgeon preference (Fig. 18). All three are used through the Base Plate Drill Guide 2 which is placed in the cavity created by the last Base Plate Reamer used.

**NOTE:** For the 25mm and 30mm base plates, a 7.5mm Drill is the only available option for bone preparation.

### Poor Bone Stock

When poor bone stock exists, use the 7.5mm Cortex Drill to remove only the first 3 to 4mm 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 7.5mm Compression Plug to compress the cancellous bone in the vault prior to implant insertion.

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

### Good Bone Stock

Only if there is good hard bone, use the 7.5mm Drill to ream bone for the full depth of the post of the base plate.

Attach the 7.5mm Drill to the Cannulated Straight Driver by sliding the Driver tabs into the rounded slots of the 7.5mm Drill.

Introduce the Base Plate Drill Guide 2 to the 7.5mm Drill assembly and drill until the drill housing collar is flush to the top of the Base Plate Drill Guide 2 (Fig. 19).
Insert Base Plate

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

Prior to implantation, confirm the base plate post size. The base plate center post length comes in three sizes (15, 25 and 30mm), and the final implant size must match the length of 6mm Cannulated Drill and 7.5mm Drill used to prepare the glenoid vault.

Clip the PSI Roll Guide to the shaft of the Base Plate Inserter. Attach the definitive Base Plate implant to the Base Plate Inserter. Verify the side marked “A” is positioned anterior and the side marked “P” is positioned posterior, then insert the Base Plate/Base Plate Inserter assembly into the prepared glenoid and achieve the intended baseplate rotation (roll) orientation by engaging the superior guide pin into the hole of the PSI Roll Guide (Figs. 20 & 21).

The PSI Roll Guide should be slid down on the Base Plate Inserter up to the level illustrated in Fig. 21. Ensure not to slide it lower than this level.

The Base Plate is implanted by striking the Base Plate Inserter with a mallet until the back of the component is completely flush with the prepared surface. Once again take care to slide the PSI Roll Guide in line with the reference Pin. A tendency to drop the hand will not allow the PSI Roll Guide to properly place the Base Plate at its proper position with respect to tilt and version.

Disengage the Base Plate Inserter and PSI Roll Guide from the fully seated Base Plate implant. Make sure to visualize full seating thru the screw holes of the Base Plate and reengage the Impactor if necessary for further seating.

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**Instruments**

- **6mm Cannulated Drill**
  15mm, 25mm, Or 30mm
  - 47-4309-061-15/25/30
- **7.5mm Base Plate Drill**
  15mm, 25mm Or 30mm
  - 00-4309-045-15/25/30
- **Base Plate Inserter**
  - 00-4309-044-01
- **PSI Roll Guide L/R**
  - 20-8015-003/004-00
Drill Screw Holes and Insert Screws and Locking Caps

**NOTE:** If the Base Plate post size used differs from the preoperative plan, the PSI Screw Guide should not be used and the Trabecular Metal Reverse Drill Guide should be used instead in the standard non-PSI fashion.

Insert the PSI Screw Guide into the cavity of the base plate making sure to mate the protrusions of the PSI Screw Guide with the screw holes at the bottom of the cavity of the base plate. Ensure that the arrow on the PSI Screw Guide is positioned superiorly (Fig. 22) and points to the superior pin (Fig. 23). This confirms the base plate screw holes are oriented according to the pre-operative plan.

**NOTE:** If the arrow does not point to the superior Pin, the PSI Screw Guide should not be used and the Trabecular Metal Reverse Drill Guide should be used instead in the standard non-PSI fashion.

Remove the Superior Pin from the glenoid. Attach the 2.5mm Drill to power. Hold the PSI Screw Guide by hand using your index finger while inserting the Drill. Drill the screw pilot holes bi-cortically through the PSI Screw Guide and Base Plate (Fig. 24). A drill push technique is useful to palpate for the second cortex in this relatively thin walled area of the scapula. Lines on the 2.5mm Drill should not be used to measure the screw length as the height of the PSI Screw Guide will affect the reading.
**WARNING:** When drilling the screw holes, care should be taken to avoid bending the 2.5mm Drill when it is inside the Drill Guide. This creates resistance between the Drill and Drill Guide which may cause the drill to break. Ensure that the Drill is engaged in the orientation planned by the Guide to avoid bending the 2.5mm Drill.

Remove the 2.5mm Drill and PSI Screw Guide. Assemble the Depth Gauge (Fig. 25) and insert into the screw holes to aid in validating the proper screw length. The planned screw length appears on the pre-operative plan. Note that the depth gauge reading may not be the identical value as the planned screw length, due to planned screw tip perforation. Screws are available in 18-48mm lengths. Remove the superior 2.5mm Guide Pin from the base of the coracoid process. Insert the Inverse/Reverse screws in the inferior and superior screw holes with the Hexagonal Screw Driver. The screws should be inserted and then tightened back and forth from superior to inferior screw to aid in proper compression of the Base Plate (as one would tighten lug nuts on a tire). To rigidly lock the screw in place, affix a locking cap to the Reverse Torque Wrench with rounded surface facing lateral, and gently slide the Locking Screw Holder over the locking cap (Fig. 26). The locking cap and Reverse Torque Wrench should be orientated perpendicular to the base plate surface. Slide back the Locking Screw Holder and turn the locking cap in place until the Torque Wrench slips or an audible click is heard.
NOTE: The locking screws only engage in one orientation. The flat surface must be pointing toward the screw (Fig. 27). 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.

Follow Appropriate Reverse Shoulder Surgical Technique

Following the insertion of the base plate, screws and locking caps, proceed with the insertion of the glenosphere as explained in the Zimmer Trabecular Metal Reverse Shoulder System surgical technique (97-4309-203-00). Depending on which humeral stem has been chosen for implantation, refer to the aforementioned technique, or the Anatomical Shoulder Inverse/Reverse surgical technique (97-4223-102-00).

Fig. 27
The flat surface of locking cap must point towards the screw.
Cleaning/Sterilization Methods

*Zimmer* PSI System Instrument Guides (including the Bone Model) are provided non-sterile and are single use. They must be cleaned and sterilized by the end-user before the surgery.

If, after end-user cleaning and sterilization, the sterility has been compromised (without introduction of blood, protein or any other bio-contaminants), the *Zimmer* PSI System Instrument Guides can only be re-cleaned and re-sterilized once.

**WARNING:** Before every surgery, the user must verify that all instrument guides have been cleaned and sterilized.

**Cleaning**

1. Disassemble the Bushings from the Main Component of the PSI Ream Guide (see top right image).
2. Pre-soak all Instrument Guide Components (including the Bone Model) in an enzyme solution.
3. Scrub all Instrument Guide Components (including the Bone Model) with a soft bristle brush to remove all visible soil.
4. Use a water jet to flush difficult to access areas and closely mated surfaces (see areas labeled “B” in the images in the next column).
5. Ultrasound clean (Sonication) all Instrument Guides (including the Bone Model) in an enzyme solution with a minimum cycle time of five minutes.
6. Thoroughly rinse and dry all Instrument Guides (including the Bone Model).

**Sterilization Parameters**

All *Zimmer* PSI Shoulder Instrument Guides components (including the Bone Model) required Steam Sterilization before use per the Sterilization (Autoclave) method provided below.

All PSI Shoulder components should not be sterilized in the packaging supplied with them. All sterilizations should be performed using standard and regularly maintained equipment.

### Sterilization (Autoclave)

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¹ Both the given cycle temperature and time can be increased to 134°C + 3°C (273.2°F + 5.4°F) and 18 minutes according to local requirements outside of the United States such as in the European Union.

² Drying times vary according to load size and should be increased for larger loads.

³ Cooling times vary according to the type of sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used. Cooling process should comply with ANSI/AAMI ST79.
## Instruments Required

### PSI Components

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<td>PSI Bone Model</td>
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<td>PSI Roll Guide L/R</td>
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### Required Instruments

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

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