ZIMMER BIOMET
Moving You Forward.™

Signature™ ONE Guides

Surgical Technique

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Overview

The first step in the Signature™ ONE surgical technique and a precursor to using the Signature™ ONE Patient-specific guides is to conduct a Pre-Operative Planning process using the Signature™ ONE Planner. Refer to the Signature™ ONE Planner software User Guide (807.001) for usage instructions on the application. The surgeon must conduct, review and approve the plan in order to initiate the manufacturing of the Signature™ ONE instrument guides. The output of this process will be the Surgical Planning Report and the manufacturing specifications of the Signature™ ONE Guides and Bone Model.

In addition, the surgeon can preoperatively plan a surgical case within the Signature™ ONE Planner without initiating guides by using the Pure Planning option. The output of this process is a digital plan that the surgeon can reference prior to surgery. A summary PDF of the planning report is provided as well.

The Signature™ ONE Planner uses established pre-operative imaging technology to provide 3D bone representation to the surgeon, which they use to review, modify and approve a pre-operative size and positioning plan of shoulder implants. The guides' patient-specific geometries are then generated based on the approved pre-operative plan, and perform by replicating the planned glenoid implant position and orientation intraoperatively in terms of version, inclination and reaming depth. For TMR+® and Comprehensive® Reverse Augment procedures, the guides also allow the surgeon to replicate the baseplate rotation intraoperatively.

Please refer to the Instructions for Use and the package label for the products to be used with this Surgical Technique.

Indications for Use

The Signature™ ONE System 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 precluded from being radiologically scanned.

The Signature™ ONE System is designed for use on a skeletally mature patient population. The targeted population has the same characteristics as the population that is suitable for the implants compatible with the Signature™ ONE System.

The Signature™ ONE System is to be used with the glenoid components of the following shoulder implant systems in accordance with their indications and contraindications: Zimmer® Trabecular Metal Reverse Plus® Shoulder, Comprehensive® Total Shoulder System, Comprehensive® Reverse Shoulder System, Comprehensive® Reverse Augmented Baseplates and Alliance® Glenoid System.

The Signature™ ONE System pre-operative planning is also compatible with the humeral components of the following shoulder implant systems in accordance with their indications and contraindications: Comprehensive® Total Shoulder System, Comprehensive® Reverse Shoulder System, and Identity™ Shoulder System.

The Signature™ ONE System Guides and bone models are intended for single use only.

Contraindications

The Signature™ ONE System should not be used when the patient has metallic devices implanted that could interfere with the CT scan quality. Additionally, the Signature™ ONE System should not be used in cases where native bone is absent, or where a custom bone augment/graft will be used on surfaces intended to mate with the Signature™ ONE Guides.

Surgical Planning Report

A copy of the Surgical Planning Report (20-8018-020-00) and patient bone model is provided with the Signature™ ONE Guides packaging. A hardcopy of the Surgical Planning Report will not be included for Pure Planning. The 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 Signature™ ONE Guides and Bone Model represent the pre-operative plan. In addition, the report includes information on the implant sizes, implant systems, and instrumentation options the surgeon selected in the pre-operative planning.

WARNING: Ensure to use the guides with the implant system and the implant size that was planned in order to reproduce the plan accurately. If a different procedure (Anatomic vs. Reverse) or implant size was selected intra-operatively, the Signature™ ONE guide must not be used and must be discarded.

Notes:

- Federal (U.S.) law restricts this device for sale by or on the order of a physician.
- Zimmer Biomet strongly recommends formal Signature™ ONE Guide training prior to use of the system. Contact your local Zimmer Biomet representative or the Zimmer Institute (1-855-ZSurgeon, or 1-855-978-7436) for more information.
- Signature™ ONE guides are designed to register on the bony surface of the anterior glenoid. Therefore do not remove any osteophytes or bony landmarks that were used to create the guide until the guide has been used.
- Given the potential for patient morphological changes, the surgeon must assess the changes between the time of manufacturing and the date of surgery. In case of any doubt the Signature™ ONE Guides and Bone Model must not be used. The Signature™ ONE Guides and Bone Model have a limited shelf life of 6 months after the manufacturing date, as indicated on the package label. Signature™ ONE Guides and Bone Models should not be used after the expiration date.
- If you experience difficulties with the Signature™ ONE Guides during surgery, stop using the guides and revert to one of the following standard non-patient-specific surgical technique: Zimmer® Trabecular Metal Reverse Plus® (TMR+) Shoulder System surgical technique (Zimmer Biomet Item Number 1423.1-US); Comprehensive® Reverse Shoulder Technique (0173.1); Comprehensive® Augmented Baseplate Shoulder Technique (0468.1); Comprehensive® Modular Hybrid Glenoid Technique (1271.1); or Alliance® Glenoid Technique (2872.2)
- The Surgeon must refer to conventional surgical approach in gauging final implant placement and orientation.
- The Signature™ ONE Guides and Bone Model are single use, patient-specific instrumentation that should be discarded as biohazardous material after surgery.
- The Signature™ ONE Guides and Bone Model can be used for the glenoid component, however standard surgery should be used for the humeral component.
- If any serious incident occurs with regards to the guides themselves, please report the issue to the manufacturing and competent authority of the Member State in which the user and/or patient is established.

Example:	SAM123L77DD13UO
Printed on Pin Guide / Impactor Guide / Screw Guide / Rotational Guide:	123
Printed on Reamer Guide:	SAM123L
Printed on Bone Model:	SAM123L77DD13UO

S	AM	123	L	77	DD	13	U	O
First letter of patient first name	First two letters of patient last name	Unique index assigned by Zimmer Biomet	Operated side (left/right)	Patient's birth year	Surgeon initals	Year when the case was created	Region where the case ID originated	Identifier for Signature™ ONE product code assigned on the technology

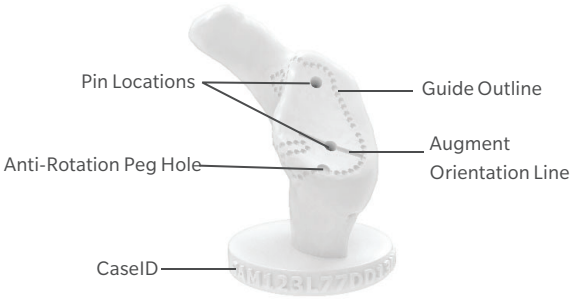
Figure 1
Signature™ ONE Case Identifier

WARNING: Ensure that the delivered Signature™ ONE Guides and Bone Model correspond to the intended patient. The Surgical Planning Report is provided with the Signature™ ONE Guides and Bone Model as well as in the Signature™ ONE Planner. Only use the Signature™ ONE Guides and Bone Model if the Zimmer Biomet Case ID markings are legible and match the Signature™ ONE Case ID for the intended patient.

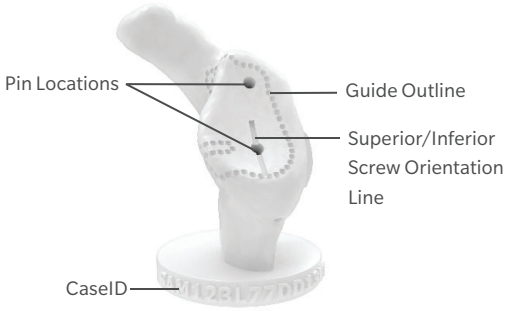
If the Zimmer Biomet Shoulder Case ID markings (Figure 1) on the Signature™ ONE Guides and Bone Model do not match the Zimmer Biomet Case ID specific to the intended patient, DO NOT USE the Signature™ ONE Guides and Bone Model and notify your Zimmer Biomet representative. The Case ID is 15 characters and is automatically assigned. The Case ID nomenclature and marking on the instrument guides and bone model are described in Figure 1.

Bone Model Features and Text

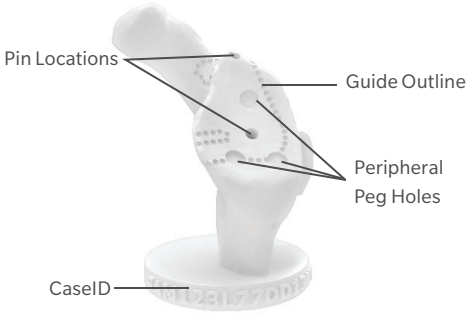
Comprehensive Augmented Baseplate Bone Model



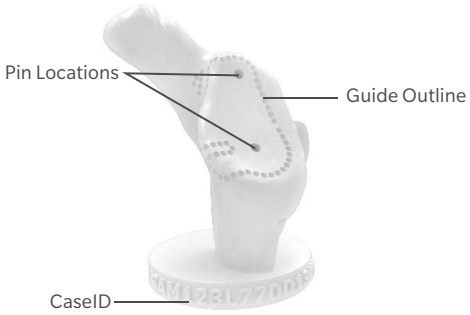
Comprehensive Mini Baseplate Bone Model



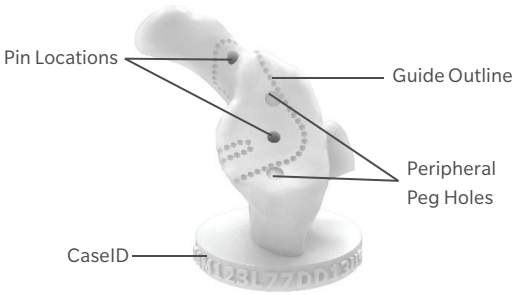
Comprehensive Modular Hybrid Glenoid Bone Model



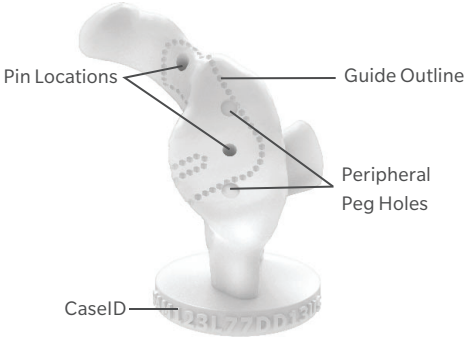
TMR+® Bone Model



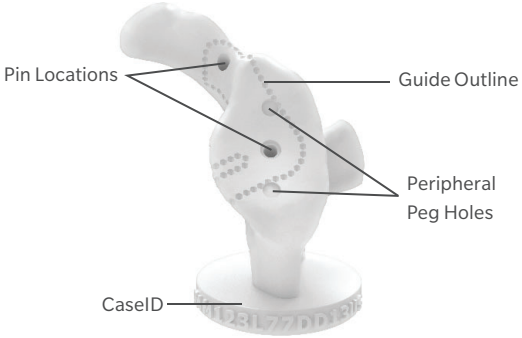
Alliance® Glenoid - 2 Peg Monoblock



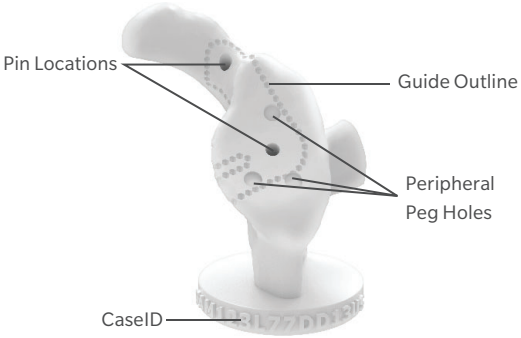
Alliance® Glenoid - 3 Peg Modular



Alliance® Glenoid - 3 Peg Monoblock



Alliance® Glenoid - 4 Peg Modular



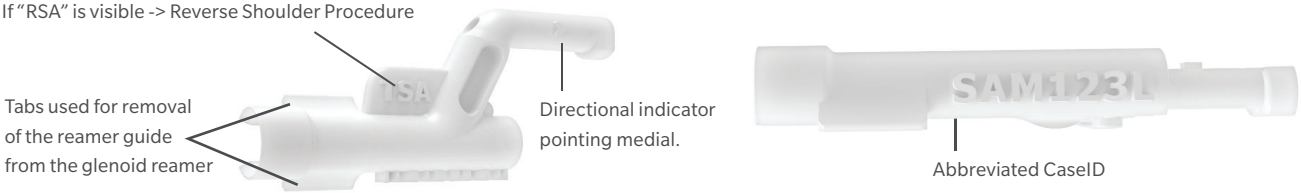
Signature™ ONE Guides Features and Text

Signature™ ONE Reverse Pin Guides

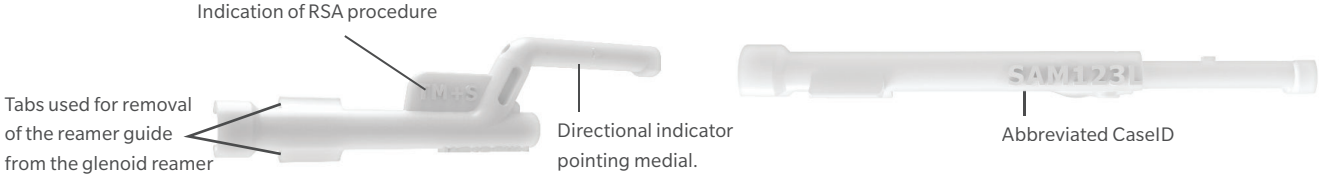
Signature™ ONE Modular Hybrid Glenoid & Alliance® Glenoid Pin Guides

Signature™ ONE Reamer Guides – Alliance® Glenoid, Comprehensive Modular Hybrid Glenoid & Comprehensive Reverse Shoulder

Indication of TSA or RSA procedure:
If "TSA" is visible -> Comprehensive Modular Hybrid Glenoid Procedure
If "AGL" is visible -> Alliance® Glenoid Procedure
If "RSA" is visible -> Reverse Shoulder Procedure

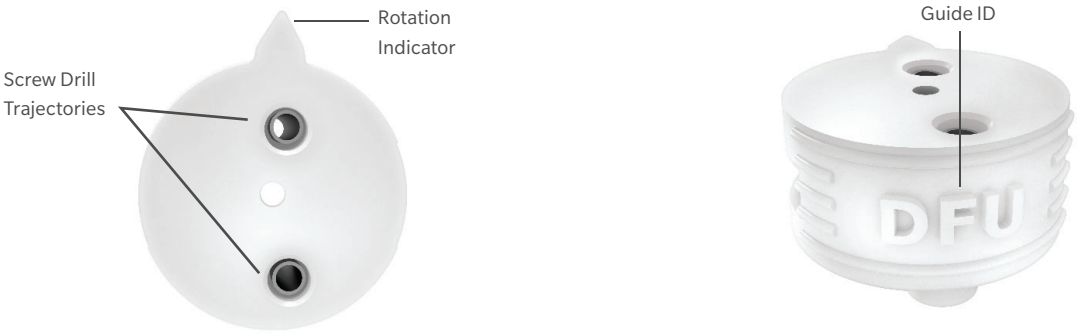


Signature™ ONE Reamer Guides – TMR+®

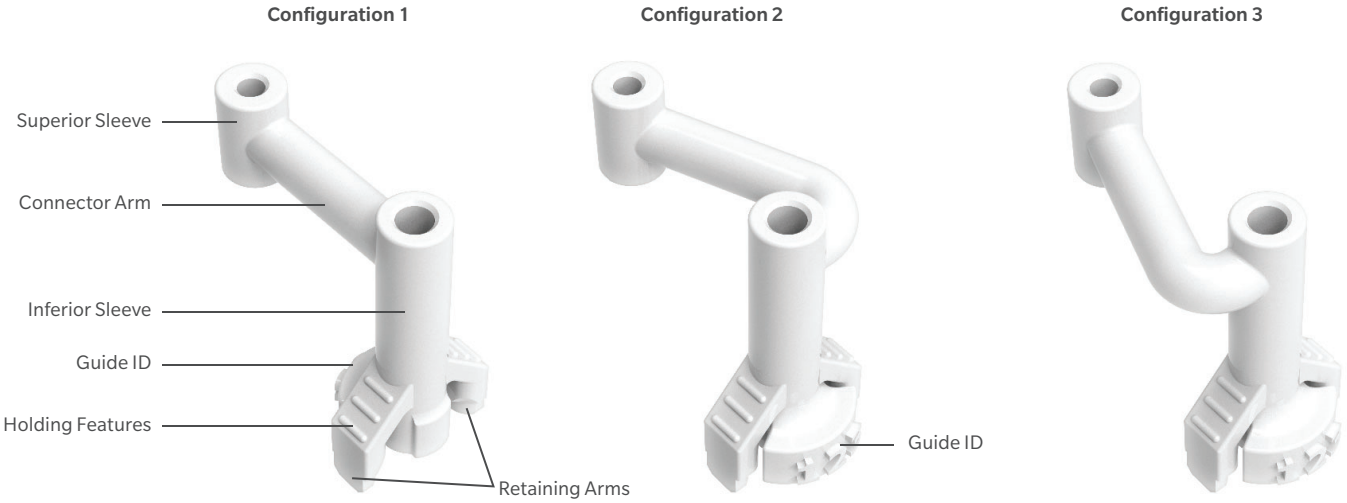


Signature™ ONE Impactor Guide – TMR+®

Signature™ ONE Screw Guide – TMR+®



Signature™ ONE Rotational Guide - Comprehensive Reverse Augmented Baseplate



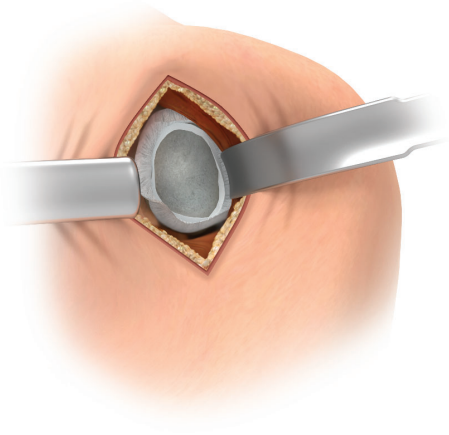


Figure 2
Straight on exposure is necessary.

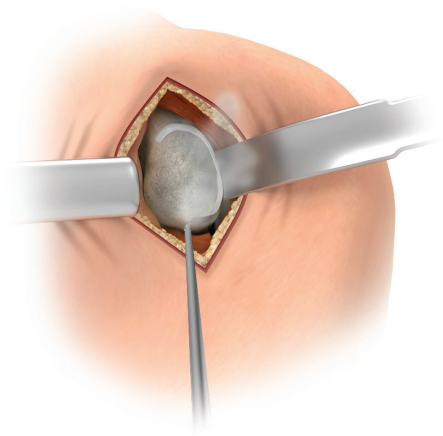


Figure 3
Remove the entire capsulolabral complex from 11 to 6 o'clock.

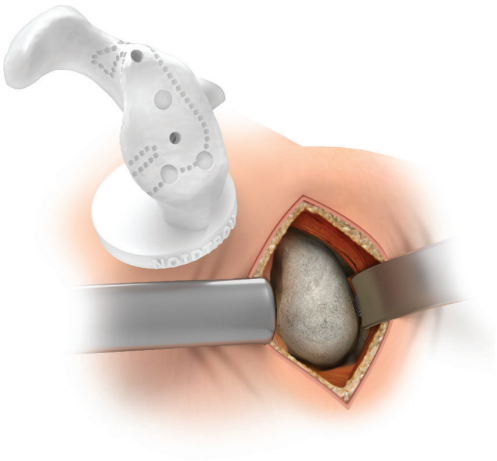


Figure 4
Compare the registration surface of the guide (imprinted on the bone model) to the soft tissue dissection. Ensure that sufficient soft tissue has been removed to allow for complete guide seating.

Glenoid Preparation

Exposure

- **Note:** While preparing the glenoid, the retraction of the proximal humerus and humeral head provisional along with retractors should be carefully considered. Their positions may interfere with glenosphere seating. Exposure should allow for straight on engagement of the glenosphere on the base plate taper. Consider use of the Zimmer Biomet 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.

- **Note:** The Signature™ ONE Pin Guide was designed to reference the glenoid fossa, the anterior glenoid rim, and the glenoid-coracoid junction. It is important to compare the native glenoid bone with the provided patient-specific bone model to ensure that all of the soft tissue has been removed from the area where the guide registers (Figure 4). 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 pin guide.

- **Note:** Signature™ ONE Guides are designed to register on the bony surface of the anterior glenoid. Therefore, do not remove any osteophytes or bony landmarks that were previously referenced to build the guide until the guide has been used.

Straight-on exposure of the glenoid is necessary for proper reaming and component insertion (Figure 2). It is recommended to use the delto-pectoral approach since the superio-lateral approach may not provide adequate exposure. If the delto-pectoral approach is chosen, the proximal humerus is retracted posteriorly and inferiorly allowing straight on access to the glenoid.

Tips: If exposure is limited, re-check the humeral osteotomy level and ensure inferior capsular releases were thorough. The long head of the biceps tendon must be excised completely. Also, ensure full deltoid mobilization and removal of humeral osteophytes.

Ensure to preserve glenoid osteophytes since the Signature™ ONE Guide is designed to mate with them. Prepare the anatomy and remove as much soft tissue in and around the glenoid as needed to allow for optimal Signature™ ONE Guide fit and placement. Specifically, remove the entire capsulolabral complex on the anterior and inferior rim of the glenoid, approximately 11 to 6 o'clock on a left shoulder (Figure 3). Proceed with additional capsule releases surrounding the anterior and inferior rim of the glenoid as necessary. When placed correctly, the guide will fit snuggly against the face and the anterior rim of the glenoid.

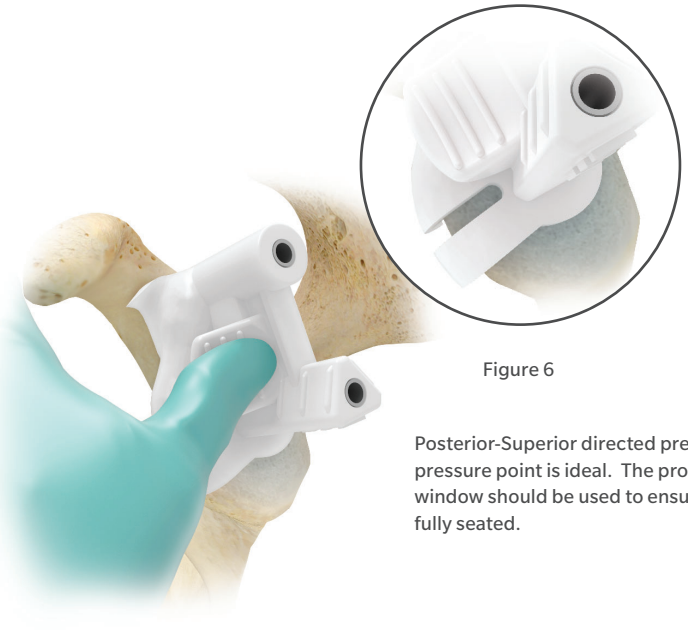


Figure 5

Figure 6

Posterior-Superior directed pressure on the pressure point is ideal. The provided viewing window should be used to ensure the guide is fully seated.

Figure 7
A sterile marking pen can be used to outline the guide on the patient's glenoid.

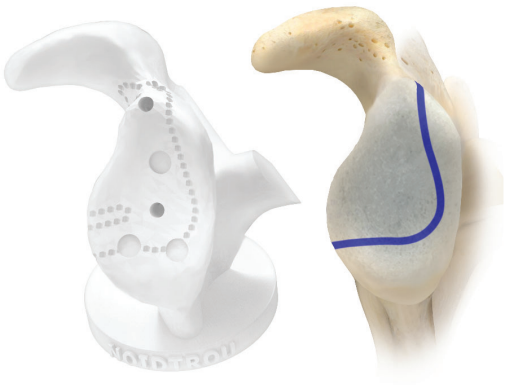


Figure 8
The outline can be compared to the bone model registration outline.

Figure 9

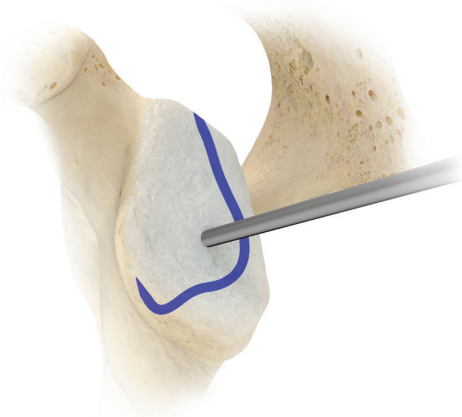


Figure 10
The guide pin must be secure and in the correct location.

Placing the Signature™ ONE Pin Guide

The pressure point was designed to help align the guide when direct thumb pressure is applied to this point on the guide (Figure 5). Be sure to provide sufficient superior/posterior directed pressure when securing the guide to the bone. The anterior viewing window allows a visual check to ensure the guide is fully seated (Figure 6 inset).

A sterile marking pen can be used intraoperatively to trace the outline of the pin guide on the glenoid. The outline can be visually compared to the engraving on the bone model (Figure 7 and 8).

When placed correctly, the pin guide will fit snuggly against the face and the anterior rim of the glenoid.

Inserting Guide Pins

While securing the guide to the bone, insert the inferior guide pin through the guide and into bone. Ensure the guide pin engages and perforates the medial cortical wall and is stable within bone (Figure 9 and 10). It is imperative that the guide pin be evaluated for accurate placement and orientation. Compare the inserted pin with the pin location on the Bone Model. If the guide pin is not correctly oriented, please remove and repeat with the guide again ensuring complete registration on the patient's glenoid.

Figure 11
Insert the superior pin if depth, rotational*, and screw orientation* control is desired

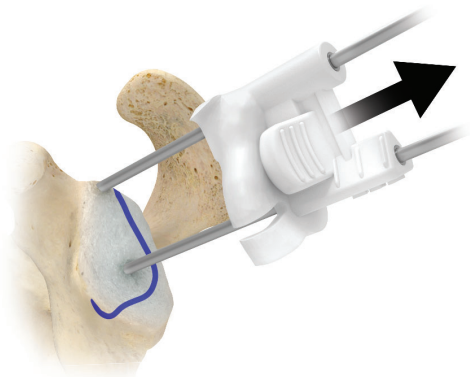


Figure 12
While removing the guide, ensure to remove parallel to the guide pin(s).

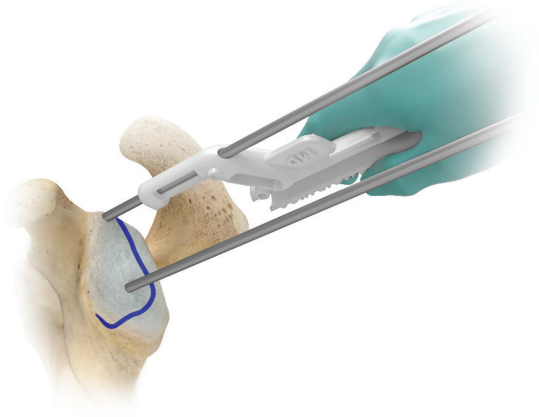


Figure 13
First, slide the Signature™ ONE Reamer guide over the superior pin.

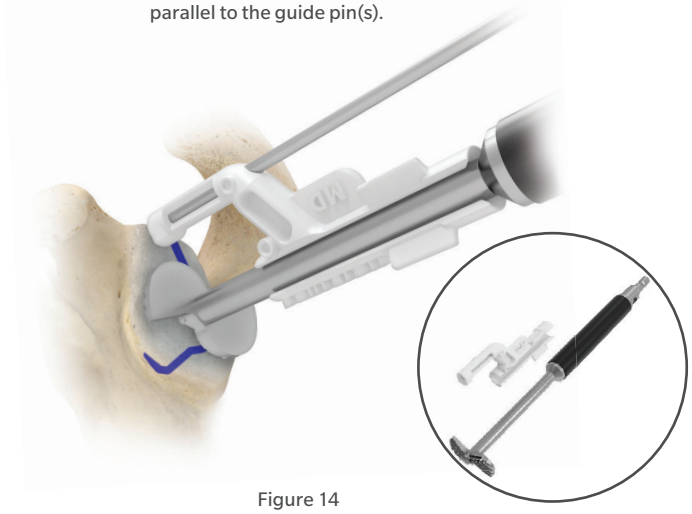


Figure 14
After inserting the reamer over the inferior pin, assemble the Signature™ ONE reamer guide to the reamer shaft. The guide will snap into place

If depth control, rotational* control, and screw orientation* control are desired, insert the superior guide pin as well (Figure 11). Compare the superior pin placement with the pin location on the bone model.

Remove the guide from the bone ensuring the direction of travel is parallel with the pins (Figure 12). The pins should be parallel and stable.

*Rotation and screw orientation is only available on certain ZimmerBiomet implant systems.

Note: The Signature™ ONE Pin Guides use a 3.2 mm Steinman pin when used with a Comprehensive Implant System and use 2.5 mm pins when used with the TMR+® system.

Glenoid Preparation

For depth control and screw orientation, refer to the subsequent steps in this surgical technique. If only position, version and inclination control are desired, please refer to one of the following surgical techniques for glenoid preparation and implant insertion:

- Comprehensive Reverse Technique 0173.1
- Comprehensive Augmented Baseplate Technique 0468.1
- Comprehensive Modular Hybrid Glenoid Technique 1271.1
- TMR+® Shoulder System 1423.1

Glenoid Preparation – Comprehensive Anatomic, Reverse, and Augmented Baseplate Procedures

(for Zimmer Biomet TMR+®, skip to page 14)

Slide the Signature™ ONE Reamer Guide over the superior pin (Figure 13). While the Signature™ ONE Reamer Guide is captured by the superior pin, slide the Comprehensive anatomic fossa reamer or glenoid mini baseplate reamer over the inferior pin depending on the procedure being performed. With the reamer captured by the inferior pin, rotate the Signature™ ONE Reamer Guide such that it engages and clips over the shaft of the reamer (Figure 14).

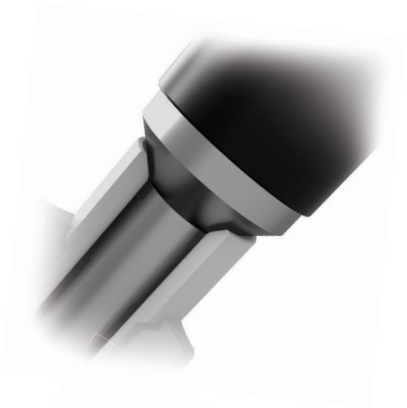


Figure 15
Ream until the lateral portion of the Signature™ ONE reamer guide contacts the reamer collar.

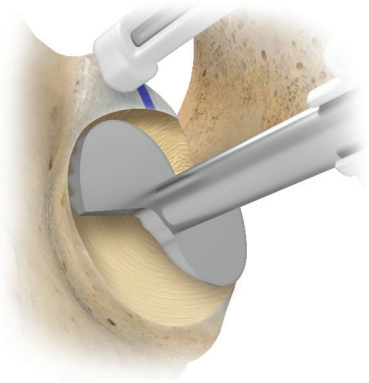
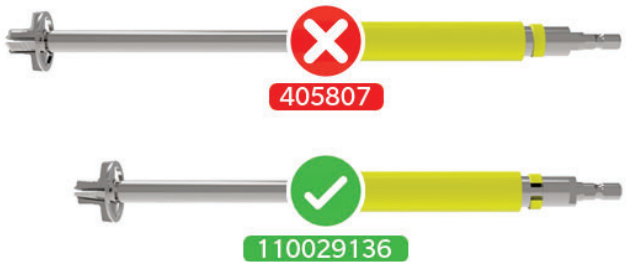


Figure 16
Ensure that the Signature™ ONE Reamer guide has completely contacted bone and not soft tissue.

Figure 17
Remove the guide by pushing on the two tabs

Warning: When using the Signature™ ONE Reamer Guide with the Comprehensive Reverse Mini baseplate, the system is only compatible with item 110029136 (9.0 inches). The system is not compatible with item 405807 (10.4 inches).



Hold the reamer assembly parallel to the superior pin and ream until the Signature™ ONE Reamer Guide reaches the lateral end of the reamer shaft (Figure 15), ensuring that the medial end of the Signature™ ONE Reamer Guide contacts the bone surface (Figure 16) and there is no soft tissue between the guide and the bony surface.

Slide the reamer assembly away from the glenoid leaving pins in place and taking care not to change the angle of the pins. With the Signature™ ONE Reamer Guide is still attached to the reamer shaft, confirm that the reamed surface matches the preoperative plan (see picture in the Surgical Planning report for reference). Then unclip the Signature™ ONE Reamer Guide from the shaft of the reamer by pushing on the two tabs to unsnap the Guide (Figure 17).

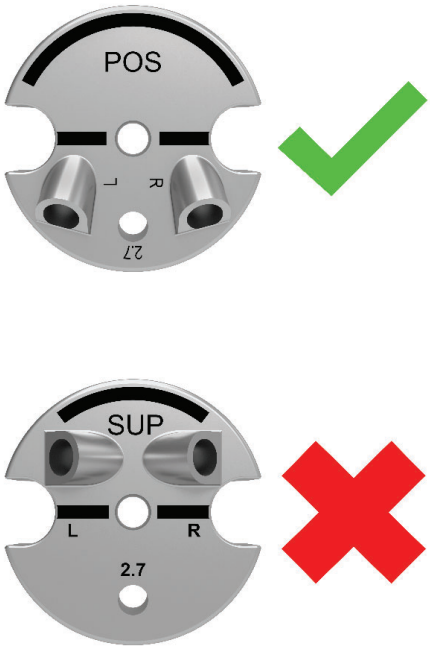


Figure 18

Use only the Anterior/Posterior (POS) 2.7 mm peg Drill Guide with the Rotational Guide and NOT the Superior/Inferior (SUP) 2.7 mm peg Drill Guide as it will not be compatible.

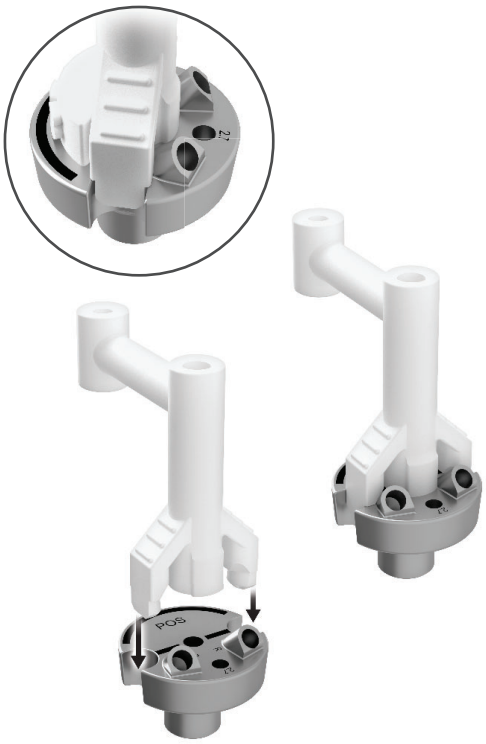


Figure 19

Clip the Signature™ ONE Rotational Guide onto the 2.7 mm POS Drill Guide. The inferior sleeve of the Rotational Guide should be fully seated onto the Drill Guide, and oriented such that the Guide ID on the Rotational Guide faces away from the Drill Guide's 2.7 mm drill hole.

Reference Peg Preparation with the Signature™ ONE Rotational Guide– Comprehensive Reverse Augmented Baseplate Procedure

The Signature™ ONE Rotational Guide is to be used only in conjunction with the Anterior/Posterior (marked "POS") 2.7 mm peg Drill Guide of the standard surgical instrumentation. Note that the Signature™ ONE Rotational Guide is designed to be incompatible with the Superior/Inferior (marked "SUP") 2.7 mm peg Drill Guide (Figure 18).

Assemble the Signature™ ONE Rotational Guide onto the POS Drill Guide by clipping the Rotational Guide retaining arms into the Drill Guide windows (Figure 19). The inferior sleeve of the Rotational Guide should be fully seated on the top surface of the Drill Guide. The Guide ID feature on the Rotational Guide should be oriented away from the 2.7 mm drill hole.

Figure 20
Slide the assembled Signature™ ONE Rotational Guide and 2.7 mm POS Drill Guide onto the pins, ensuring that the inferior pin passes through the Drill Guide and Inferior Sleeve of the Rotational Guide while the superior pin passes through the superior sleeve of the Rotational Guide.

Figure 21
Drill the 2.7 mm hole ensuring the drill has bottomed out on the POS Drill Guide surface.

Once the Signature™ ONE Rotational Guide and POS Drill Guide are securely clipped together, slide the assembled parts together along the superior and inferior pins (Figure 20).

Insert the POS Drill Guide into the reamed cavity of the glenoid. Care should be taken to ensure this cavity is clear of all soft tissue to allow for proper seating of the Drill Guide before use. Use the Rotational Guide holding features to stabilize the guides, and drill through the 2.7 mm hole ensuring the drill has bottomed out on the Drill Guide (Figure 21). Remove the 2.7 mm drill, and slide the assembled Rotational Guide and Drill Guide carefully off the pins. See the **Comprehensive Reverse Shoulder Augmented Baseplate Surgical Technique** for steps on Augment Reamer Guide Placement to continue the procedure.

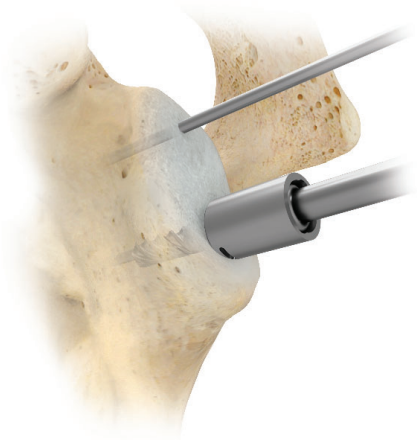


Figure 22

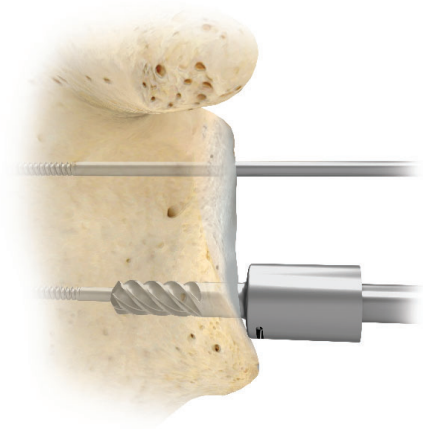


Figure 23
In case of steep inclination and version angle, drill shoulder may not fully contact glenoid surface. In such cases, redrill after reaming.

Glenoid Preparation – Zimmer Biomet TMR+® Shoulder System

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 the length that corresponds to the center post length of the intended base plate (see Surgical Planning Report for planned post length). The length is indicated on the Drill collar. The 6 mm Cannulated Drill attaches to the Cannulated Straight Driver by sliding the Driver tabs onto the 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 with the glenoid face (Figure 22). Do not over-penetrate the glenoid face and ensure that the pins remain parallel when drilling.

Once the necessary drilling depth has been reached, keep the drill in motion as the Cannulated Drill is retracted along the inferior pin as this will prevent the pin from coming loose.

Note: In the event of a steep inclination and version angle, the 6 mm Cannulated Drill may not contact the glenoid surface (Figure 23). If such a situation is suspected, redrill with the 6 mm Cannulated Drill after complete surface reaming to ensure drilling is complete.

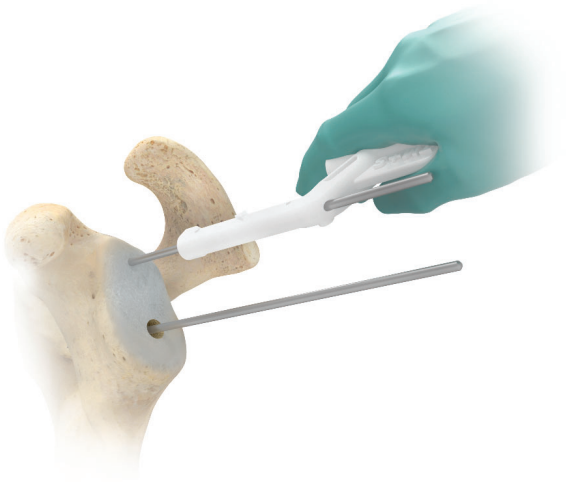


Figure 24
First, slide the Signature™ ONE Reamer Guide over the superior pin.

Optional: Use of single use; Tecomet reamer

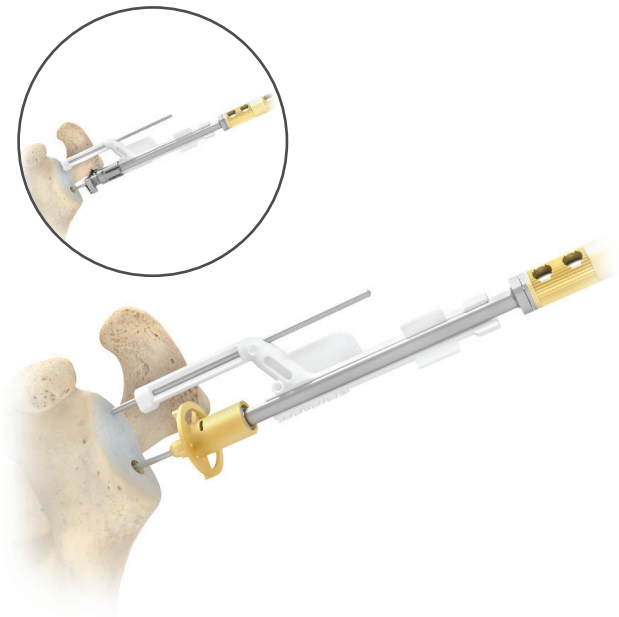


Figure 25
After inserting the reamer over the inferior pin, assemble the Signature™ ONE Reamer Guide to the reamer shaft.
The guide will snap into place

Slide the Signature™ ONE Reamer Guide over the superior pin (Figure 24). While the Signature™ ONE Reamer Guide is captured by the superior pin, slide the *TMR+® baseplate reamer over the inferior pin. With the reamer captured by the inferior pin, rotate the Signature™ ONE Reamer Guide such that it engages and clips over the shaft of the reamer (Figure 25).

***Note:** Please see the TMR+® Shoulder System Baseplate and Glenosphere surgical technique (1423.1-US) for additional details on the reamer options and usage. Refer to the "Ream Glenoid Bone and Prepare Center Hole" section.

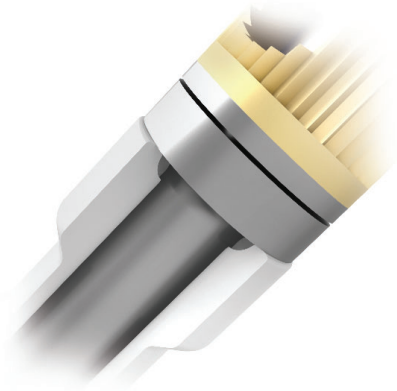


Figure 26

Ream until the lateral portion of the Signature™ ONE Reamer Guide contacts the reamer collar.

Optional: Use of single use; Tecomet reamer

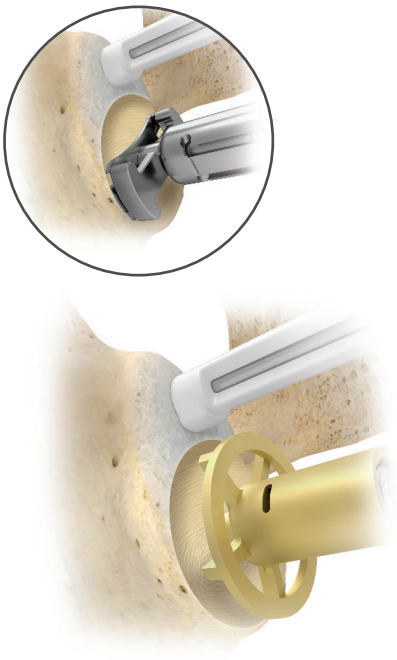


Figure 27

Ensure that the Signature™ ONE Reamer Guide has completely contacted bone and not soft tissue.

Warning: The reamer option specified in the pre-operative planning must be used (Tecomet reamer or reusable gold-coated reamer). This could either be the single-use reamers (Tecomet reamer) or the reusable reamers (gold-coated). The selected option is marked on the reamer guide (TM+S for single use and TM+R for reusable) and is shown in the Surgical Planning Report.

Hand ream until the Signature™ ONE Reamer Guide reaches the lateral end of the reamer shaft (Figure 26), ensuring that the medial end of the Signature™ ONE reamer guide contacts the bone surface (Figure 23).

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.

Figure 28
Remove the guide by pushing on the two tabs

Lift the reamer assembly from the glenoid leaving pins in place taking care not to change the angle of the pins, with the Signature™ ONE Reamer Guide is still attached to the reamer shaft. Confirm that the reamed surface matches the preoperative plan (See picture provided in the Surgical Planning Report). Unclip the Signature™ ONE Reamer Guide from the shaft of the reamer by pushing on the two tabs to unsnap the Guide (Figure 28).

Depending on the size (36 mm or 40 mm) and eccentricity option (centric or eccentric) of the glenosphere implant, select the corresponding Cannulated Base Plate Reamer 2. Refer to the Surgical Planning Report to see the option selected during the pre-operative plan. 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, until the spokes are flush with 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 does not fit through the tissue envelope, a rongeur or burr may be used to clear any peripheral bone that prevents a 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 of base plate reamer corresponds to the glenosphere head to be used.

Lift the Cannulated Reamer 2 assembly from the glenoid leaving the pins in place while taking care not to change the angle of the superior Pin. Remove the inferior pin from the glenoid bone.

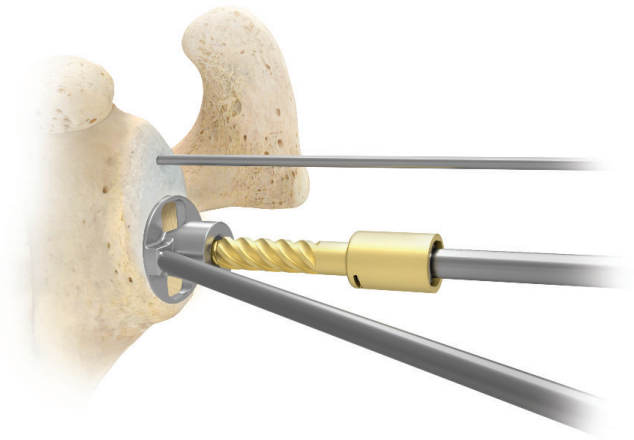


Figure 29
Use of the Base Plate Drill Guide 2

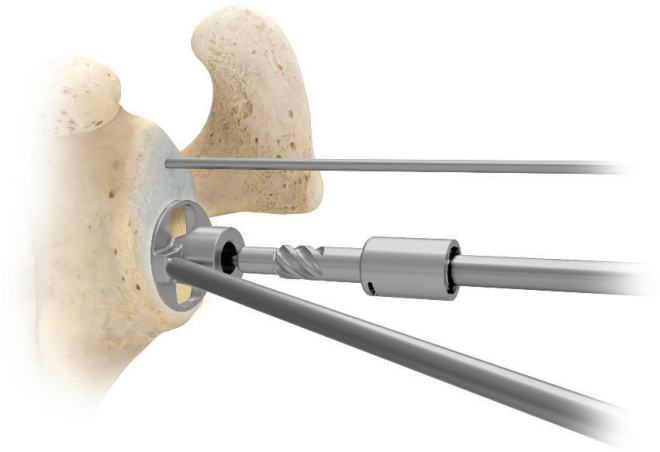


Figure 30
Use of Cortex Drill

Drill Base Plate Post Hole for TMR+® Shoulder System

Note: No Signature™ ONE Guide is required for this step. Use the 7.5 mm Drill length specified in the pre-operative plan. Do not use the Signature™ ONE Reamer Guide.

Note: When using the Base Plate Reamer 2 for eccentric Glenospheres, 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, 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 ensure a straight position on the glenoid reamed surface (Figure 29).

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 and a 7.5 mm Compression Plug. Use the 7.5 mm Cortex Drill with Drill Guide 2 (Figure 30) 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 more bone compression is desired, 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. Marked bone loss is contraindicated.

Note: The Compression Plug should not be used unless the 7.5 mm Cortex Drill is used first to prevent the risk of glenoid fracture.

Note: A small drill can be used to test the bone quality. If the Signature™ ONE screw guide is not used, the drill guide 2 has two reference marks to aid in the superior/inferior placement of the Inverse/Reverse Screws. Anatomical marks may be used for the placement of the Inverse/Reverse Screws.

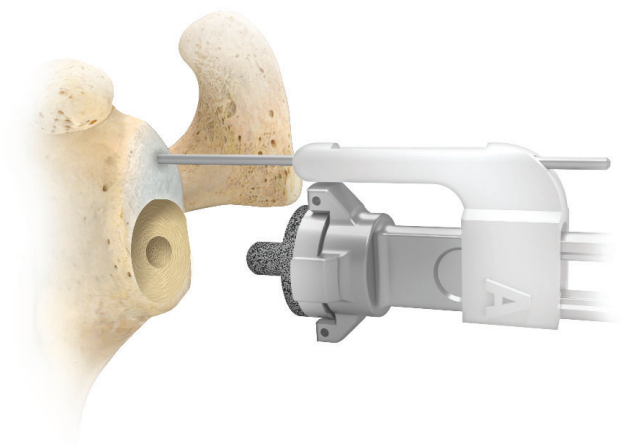


Figure 31
Clip the Signature™ ONE Impactor Guide to shaft of the Base Plate Inserter assembly and engage the superior guide pin into the hole of the Signature™ ONE Impactor Guide.

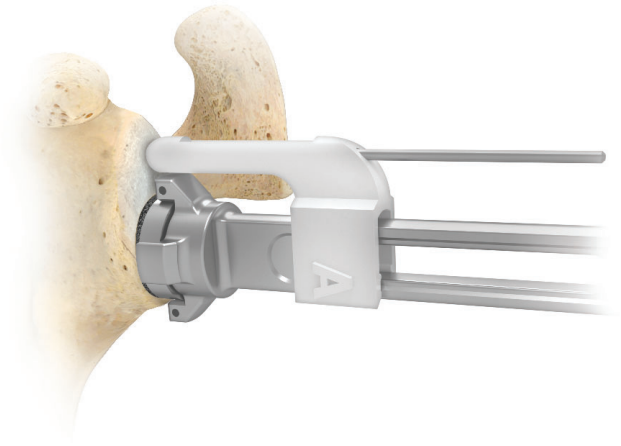


Figure 32
Insert the Base Plate/Base Plate Inserter assembly into the prepared glenoid. The Impactor Guide should contact the bone over the superior pin.

Base Plate Insertion TMR+® Shoulder System

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 implantation, confirm the base plate post size. The base plate center post length comes in four sizes (15, 20, 25 and 30 mm). The final implant size must match the length of 6 mm Cannulated Drill and 7.5 mm Drill used to prepare the glenoid vault.

Clip the Impactor Guide to the shaft of the Base Plate Inserter. Attach the definitive Base Plate implant to the Base Plate Inserter. Confirm 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 perform the intended baseplate rotation (roll) orientation by engaging the superior guide pin into the hole of the Impactor Guide (Figures 31 and 32).

The Impactor Guide must be positioned on the Base Plate Inserter as shown in Figure 31. Ensure the Impactor Guide is fully advanced along the Base Plate Inserter shaft in the direction of the implant.

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 glenoid surface. When the Impactor Guide is engaged on the reference pins, the weight of the instrument must be carried by the surgeon to ensure that the pins maintain their position. Failure to support the Impactor Guide may result in improper Base Pate tilt and version.

Disengage the Base Plate Inserter and Impactor Guide from the fully seated Base Plate implant. Visually confirm proper seating of the Base Plate via the screw holes in the Base Plate. Re-engage the Impactor Guide if necessary for proper seating.

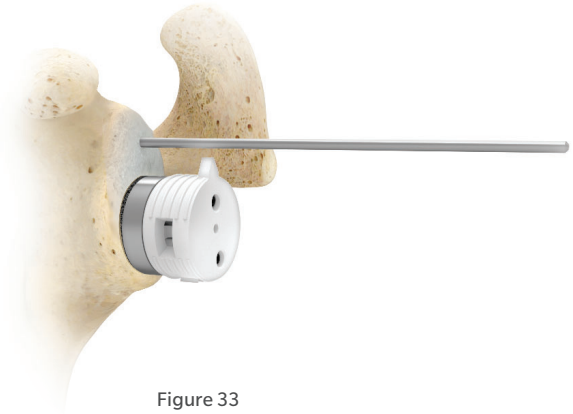


Figure 33
Insert the Signature™ ONE Screw Guide into the cavity of the base plate. Ensure guide protrusions mate with screw holes on the base plate and guide arrow is positioned superiorly.

Figure 34
Visually verify that the arrow on the Signature™ ONE Screw Guide points to the superior pin

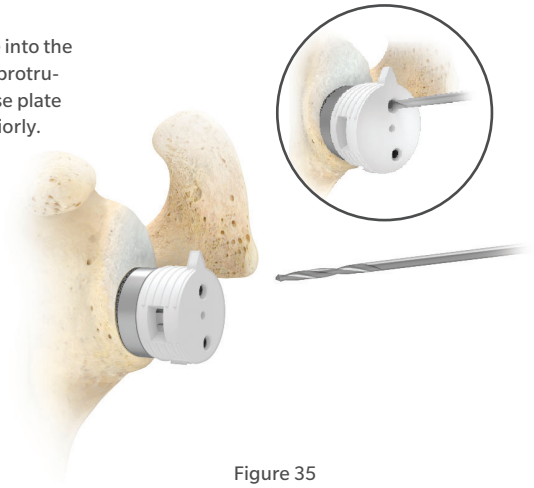


Figure 35
Drill the screw pilot holes bi-cortically through the Signature™ ONE Screw Guide and Base Plate.

Drill Screw Holes and Insert Screws and Locking Caps for TMR+® Shoulder System

Insert the Screw Guide onto the base plate making sure to mate the hole of the Screw Guide with the male taper of the base plate. Ensure that the arrow on the Screw Guide is positioned superiorly (Figure 33) and points to the superior pin (Figure 34). 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 Screw Guide should not be used and the Trabecular Metal™ Reverse Drill Guide should be used instead in the standard non-patient-specific instrument fashion.

Remove the Superior Pin from the glenoid. Attach the 2.5 mm Drill to power. Hold the Screw Guide by hand using your index finger while inserting the Drill. Drill the screw pilot holes bi-cortically through the Screw Guide and Base Plate (Figure 35). A drill push technique is useful to palpate for the second cortex in this relatively thin walled area of the scapula. Lines on the 2.5 mm Drill should not be used to measure the screw length as the height of the Screw Guide will affect the reading.

WARNING: When drilling the screw holes, care should be taken to avoid bending the 2.5 mm Drill when it is inside the Screw Guide. This creates resistance between the Drill and screw Guide which may cause the drill to fracture. Ensure that the Drill is engaged in the orientation planned by the Guide to avoid bending the 2.5 mm Drill.

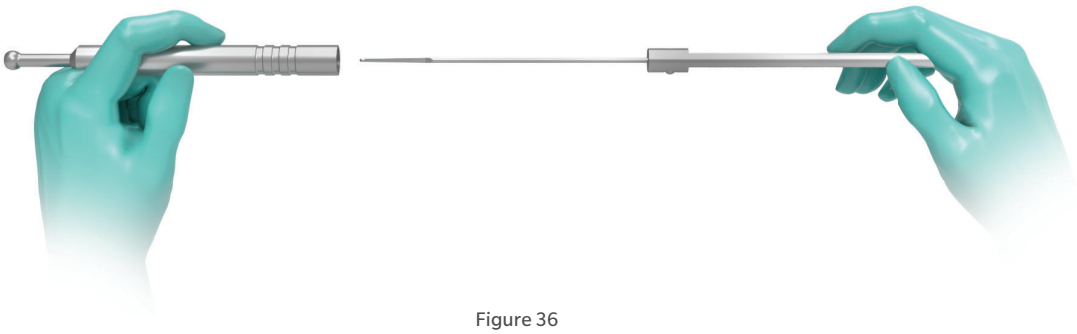


Figure 36
Assemble the Depth Gauge and insert into screw holes to validate proper screw length.

Figure 37
Affix Locking Cap to the Reverse Torque Wrench and gently slide the Locking Screw Holder over the Locking Cap. The flat surface of the Locking Cap must point towards the screw.

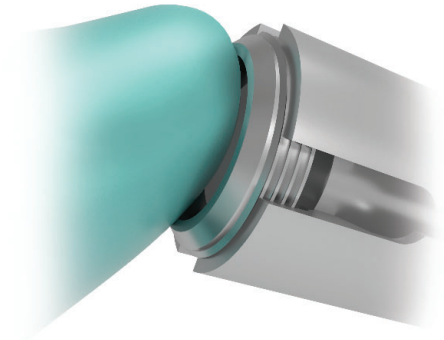


Figure 38
The flat surface of Locking Cap must point towards the screw.

Remove the 2.5 mm Drill and Signature™ ONE Screw Guide. Assemble the Screw Depth Guide (Figure 36) and insert into the screw holes to confirm screw length. The planned screw length appears on the pre-operative plan. Note that the depth gauge reading may not be identical to the value as the planned screw length due to planned screw tip perforation. Screws are available in 18-48 mm lengths. Remove the superior 2.5 mm Guide Pin from the base of the coracoid process. Attach the screw to the Hexagonal Screw Driver, making sure good bone purchase is achieved.

Note: To avoid rotation of the baseplate while torquing the screw, thread the first screw without torquing it down completely. Engage the second screw and fully torque it, then tighten the first screw completely.

To rigidly lock the screw in place, affix a Locking Cap to the Reverse Torque Wrench with convex side facing lateral and gently slide the Locking Screw Holder over the Locking Cap (Figure 37). The Locking Cap and Reverse Torque Screwdriver should be oriented perpendicular to the base plate surface. 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 38). 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 may 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.

There are no additional Signature™ ONE Guide steps and the remainder of the procedure will follow the TMR+® Glenoid Surgical Technique 1423.1.

For indications, contraindications, warnings, precautions, potential adverse effects and patient counselling 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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