Multiple Targets. Same Results.

Signature™ Personalized Patient Care
for **Comprehensive Total**
and **Reverse Shoulder Systems**

Surgical Technique

BIOMET

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Introduction

The Signature™ Glenoid system provides an image-based approach to preoperative planning, visualization and the creation of patient-specific surgical positioning guides. Based on each patient's unique anatomy, integrated with proprietary algorithms, and known anatomical landmarks, the Signature™ Glenoid guide offers a tailored approach to shoulder arthroplasty.

Signature™ patient-specific glenoid guides are created from 3D CT imaging to offer an individualized approach to both anatomic and reverse shoulder arthroplasty. When used in conjunction with Comprehensive® cannulated total and reverse shoulder instrumentation, this personalized patient care system provides an efficient solution for glenoid component positioning.

The Signature™ Personalized Patient Care system includes:

- Seamless integration into existing scanning platform
- Interactive and user-friendly pre-operative planning system
- Bone model that replicates patient anatomy
- Multiple preoperative views of the implant components placed within the glenoid vault
- Patient specific glenoid guide planned for anatomic and reverse shoulder procedures
- Full access to the Signature™ technical support team and dedicated help line

Signature™ Help Line

574.371.3710 Signature@biomet.com

Surgical Technique

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INDICATIONS

The Signature™ Personalized Patient Care System – Glenoid Guide System is intended to be used as a surgical instrument to assist in the positioning of glenoid components intraoperatively using anatomical landmarks of the shoulder that are identifiable on preoperative imaging scans.

The Signature™ Personalized Patient Care System – Glenoid Guide System can be used in conjunction with the Comprehensive® Total and Reverse Shoulder Systems (including the Modular Hybrid Glenoid, Bio-Modular Heads and Stems), and their respective components, which require placement of an initial center pin or hole to guide the associated system instruments.

The Signature™ Glenoid Guide is intended for single use only.

This surgical technique is utilized by John Sperling, M.D.; Professor Simon Frostick; Jason Hurst, M.D. and Thomas Throckmorton, M.D. Biomet, as a manufacturer of this device, does not practice medicine and does not recommend this device or technique. Each surgeon is responsible for determining the appropriate device and technique to utilize on each individual patient.

Specifically Created for Your Patient

Landmarks and Scapular Planes

The Signature™ Glenoid system pairs well established surgical planning methodology with an enhanced focus on preoperative planning. Referencing the 3D CT reconstruction, primary landmarks are first located in order to identify the scapular plane. These three points include the center of the glenoid, the intersection of the scapular spine and medial border, and the inferior angle of the scapula (Figure 1).

Calculated Glenoid Center

To determine the Steinmann pin entry point for the anatomic implant, the center of the glenoid is found by taking the perpendicular measurement at the midpoint of the inferior/superior measurement. The entry point for the reverse baseplate is found by referencing the inferior rim of the glenoid and then measuring superiorly to the center of the mini or standard baseplate measurements. (Figure 2).

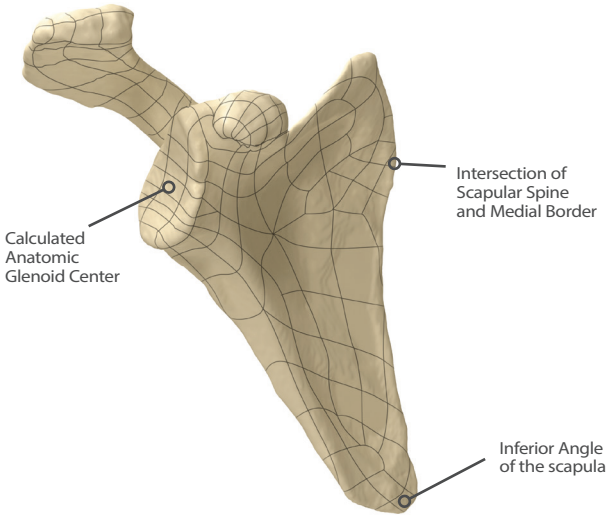


Figure 1

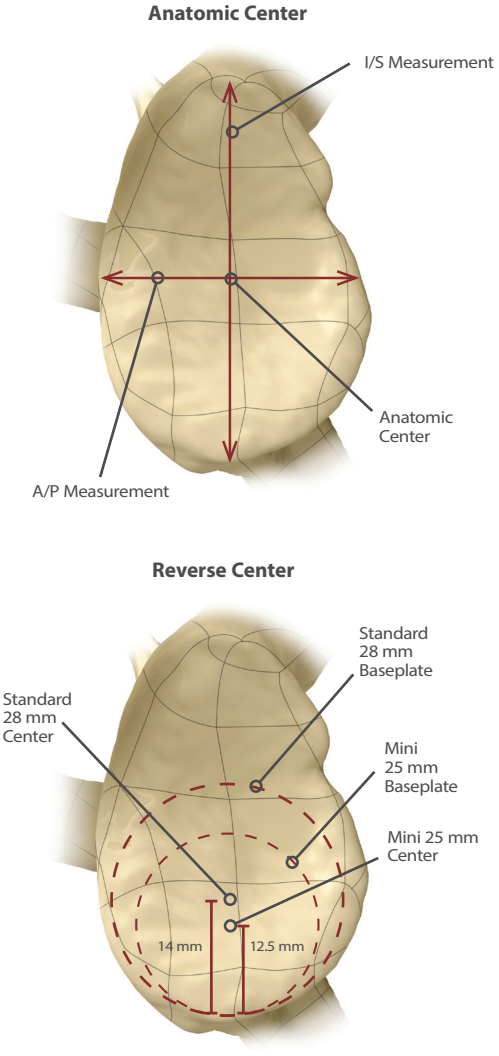


Figure 2

Inclination and Version

The scapular plane is used to create a 3D coordinate system that is then used to create the inclination plane. Once the inclination plane has been established, the medial border point is identified and used to discover the patient's neutral version. An axis is created between the glenoid center point and the medial border point to create the patient-specific anatomic trajectory.

The anatomic trajectory defaults to a population-based average of 8° of glenoid inclination (referenced from patient-specific landmarks), while the reverse trajectory defaults to 10° of inferior tilt (in relation to the anatomic axis) (Figure 3).

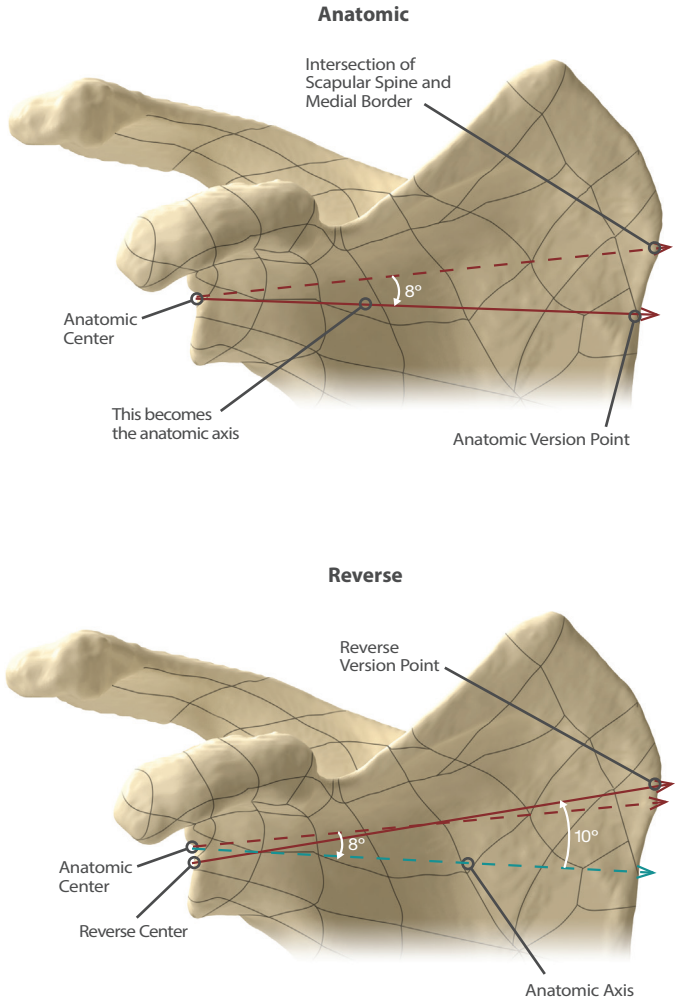


Figure 3

Specifically Created for Your Patient

Surgeon Review Tools

Utilizing a web-based portal, surgeons will be able to view the pre-operative plan from any computer. The planning suite features patient specific images for an anatomic and reverse procedure, detailing the default position, orientation, and size of each implant (Figures 4–5).

Upon review of the plan, the surgeon will be able to change the position and orientation of each implant and send back to the Biomet Signature™ team to update the plan. The surgeon is required to approve the final design specifications before the Signature™ team will create the guide.

Anatomic Plan

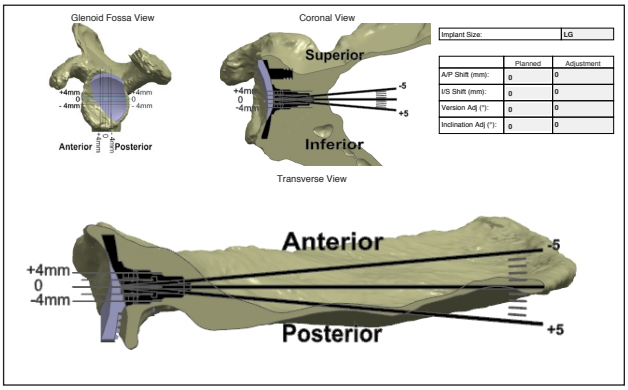


Figure 4

Glenoid Guide and Bone Model

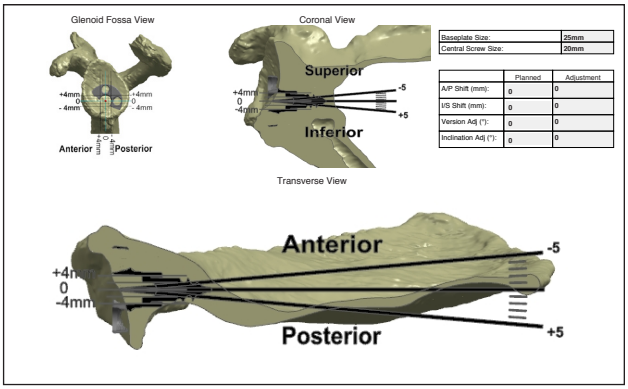
Standard markings are incorporated into each guide and bone model that will help match the guide to the correct patient.

The thumb rest was specifically designed to act as a pressure point that will help position each guide in the correct registration on the glenoid face. A viewing window was designed into the guide to act as a visual aid to help ensure the guide is correctly registered against the glenoid.

With each Signature™ guide, the surgeon will receive a patient-specific bone model. Both the guide and the model are constructed from a sterilizable material, intended as a single use, disposable instrument.

The "REVERSE" designation is built into the inferior-tilted pin guide to help identify the correct trajectory for a reverse procedure, while a portion of the patient ID is incorporated into the superior pin hole for an anatomic procedure (Figures 6–9).

Reverse Plan



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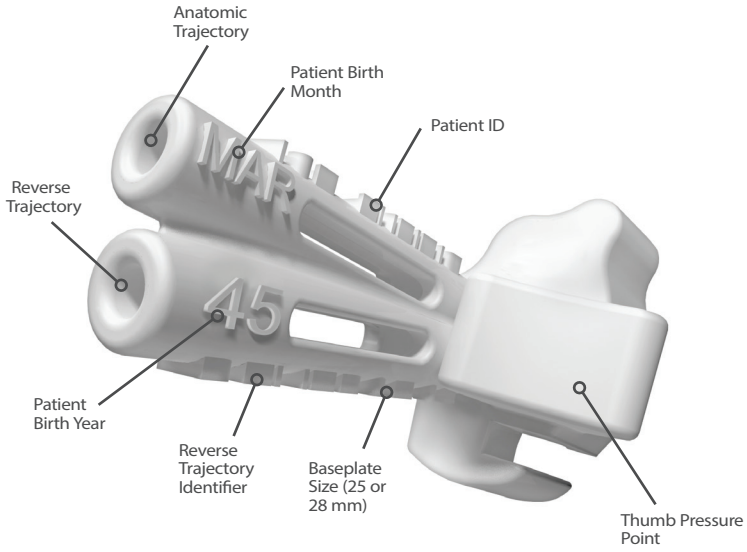

Figure 6

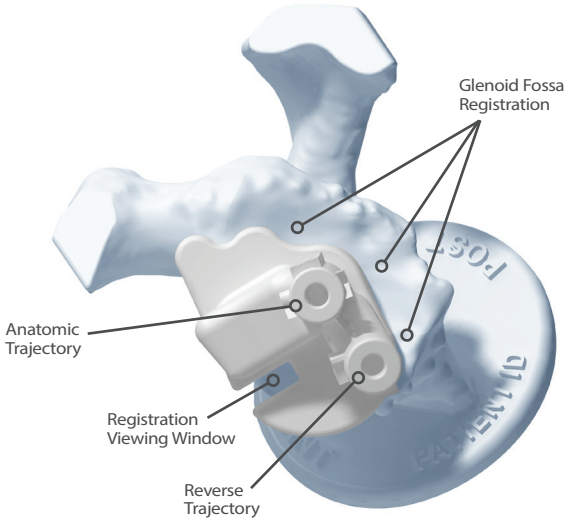

Figure 7

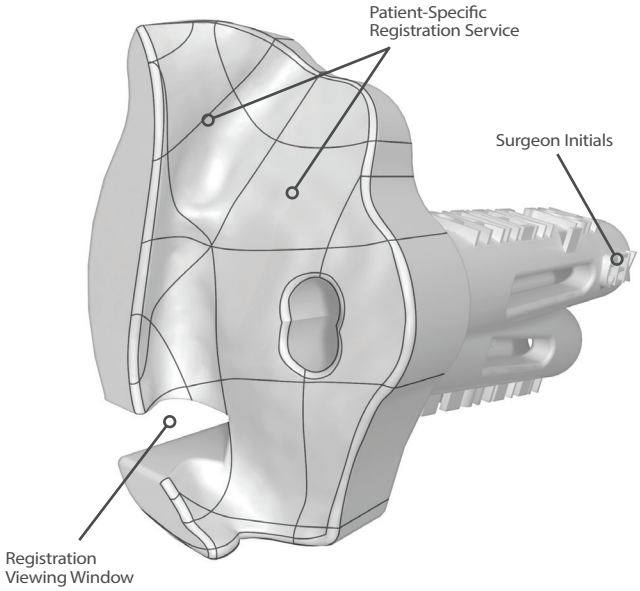

Figure 8

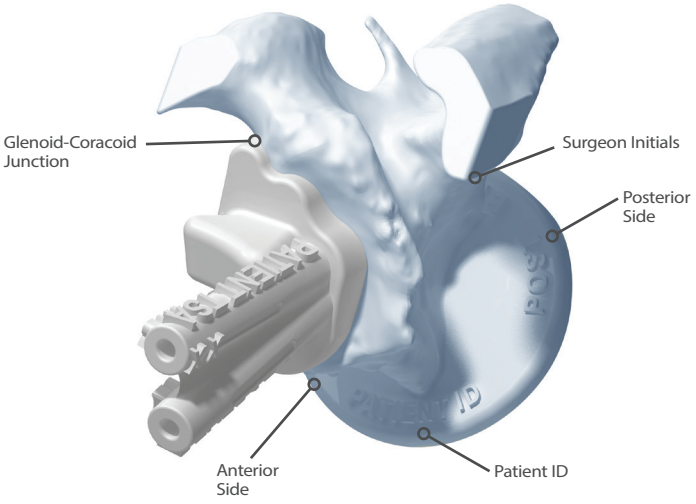

Figure 9

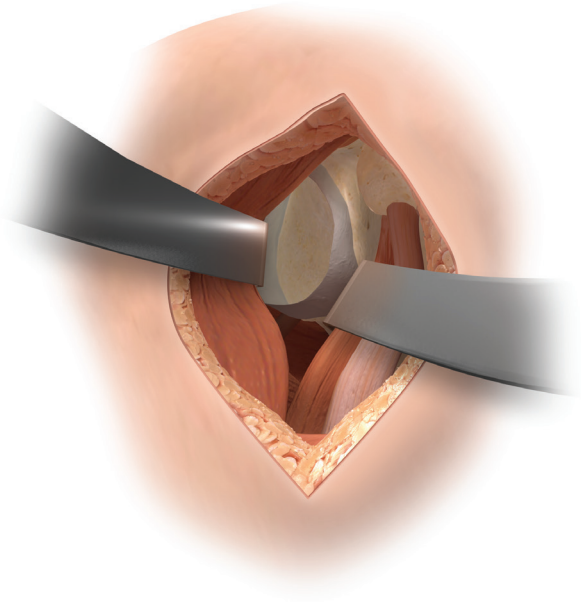

Figure 10

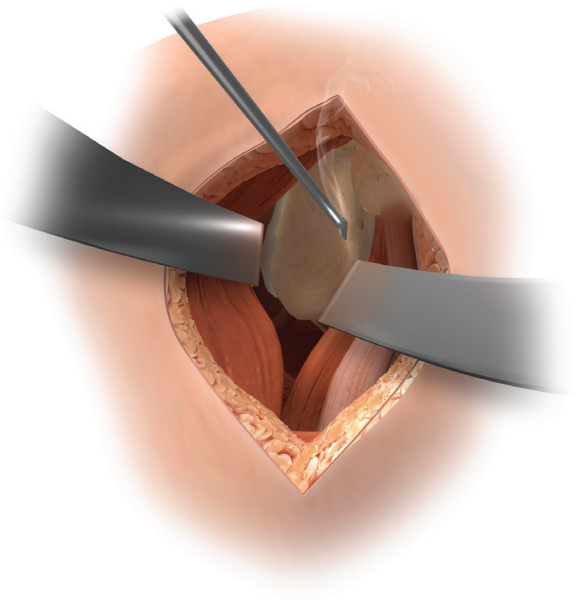

Figure 11

Glenoid Exposure and Soft Tissue Removal

The Signature™ Glenoid Guide was designed to reference the glenoid fossa, the anterior glenoid rim, and the glenoid-coracoid junction utilizing the deltopectoral approach (Figure 10). Once visualization of the glenoid is achieved it is important to remove the appropriate amount of soft tissue to ensure proper guide placement and alignment.

Prepare the anatomy and remove as much soft tissue in and around the glenoid as needed to allow for optimal Signature™ Guide fit and placement. Specifically, remove the entire capsulolabral complex on the anterior and inferior rim of the glenoid, approximately 1 to 6 o'clock on a right shoulder (Figure 11). Proceed with additional capsule releases surrounding the anterior and inferior rim of the glenoid as necessary. When placed correctly, the guide will fit snug against the face and the anterior rim of the glenoid.

NOTE

Electrocautery can be used to aid in the removal of the labrum. This will help to preserve bony landmarks needed for proper registration.

NOTE

Signature™ Glenoid 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 (Figure 12). The guide will fit firmly on the glenoid and will not toggle once correct placement is found (Figure 13).

NOTE

The provided patient specific bone model can serve as an excellent reference for adequate soft tissue removal.

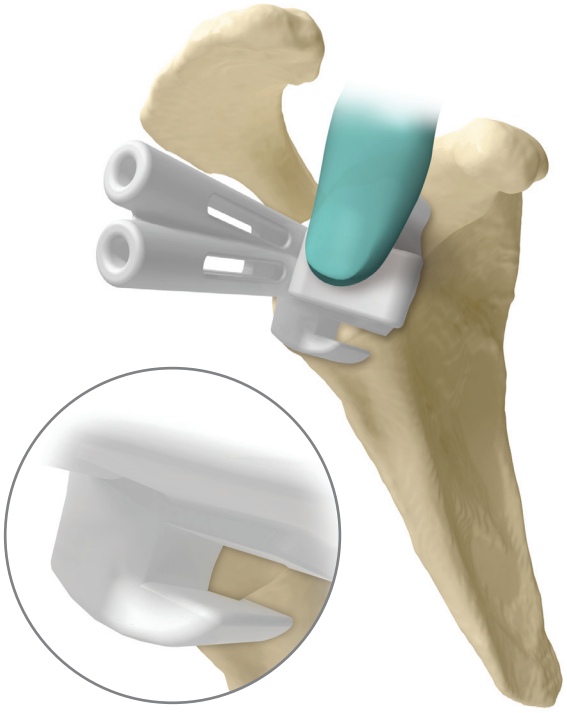

Figure 12

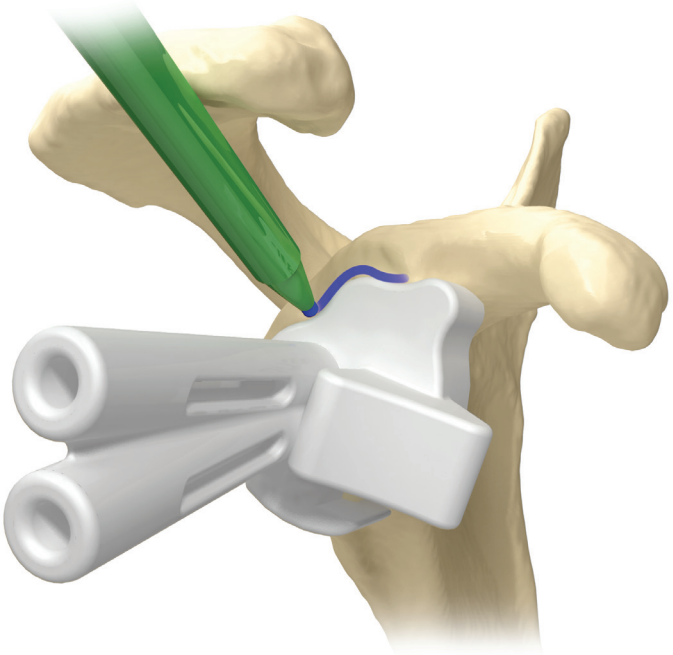

Figure 13

Guide Positioning

The Pressure Point was designed to help align the guide when direct thumb pressure is applied to this point on the guide (Figure12). Be sure to provide sufficient superior/posterior directed pressure when securing the guide to the bone and inserting the Steinmann pin.

The anterior viewing window allows a visual check to assure the guide is fully seated (Figure 12 inset).

NOTE

Signature™ Glenoid Guides are designed and produced to replicate the preoperative surgical plan. Final component position should be evaluated intraoperatively when the capsular soft tissues may be appropriately assessed.

A sterile marking pen can be used to outline the glenoid guide intraoperatively and then reference the provided bone model to compare the placement of the guide (Figure 13).

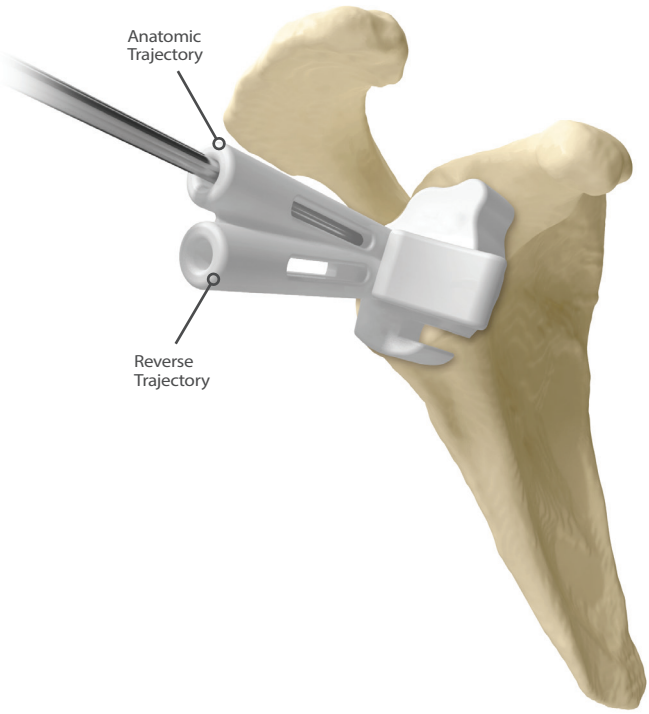

Figure 14

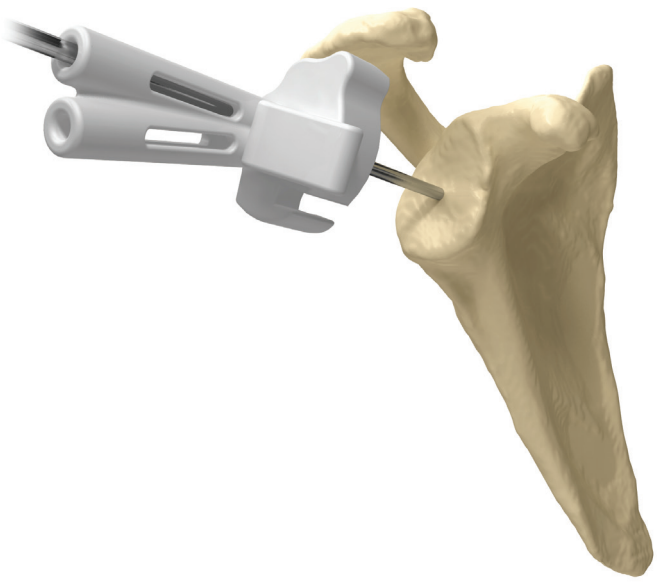

Figure 15

Pin Placement

Once desired guide placement is found, identify the correct pin hole. Use the superior hole (Figure 14) for anatomic shoulder arthroplasty and use the inferior hole for reverse shoulder arthroplasty. Insert the 3.2 mm Steinmann pin.

Proceed at minimal power until the threaded tip of the Steinmann pin engages the medial cortical wall. Remove the pin from the drill, leaving the pin in the bone.

NOTE

When inserting the Steinmann pin, careful attention should be paid so that levering pressure does not cause the guide to misalign.

Remove the Signature™ Guide from the joint by disengaging it from the glenoid rim and sliding it back over the Steinmann pin (Figure 15).

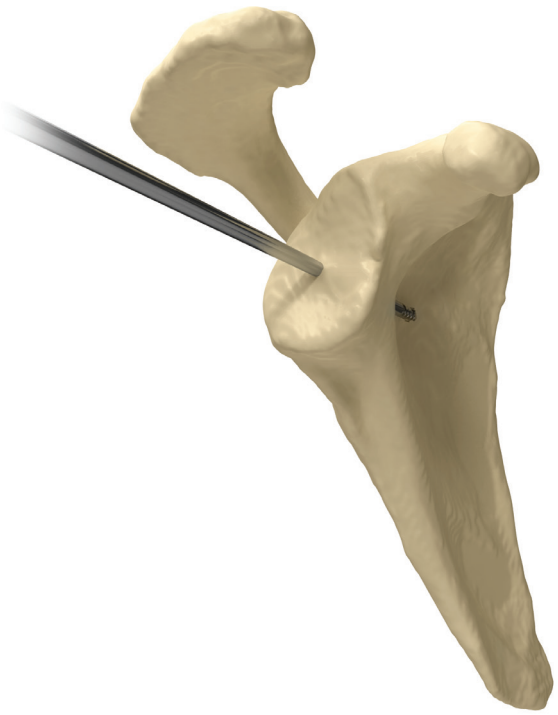

Figure 16

Proceed to the appropriate Comprehensive® Total or Reverse shoulder Surgical Technique for glenoid preparation guidance.

BMET0206.0	Comprehensive® Total Shoulder Technique
BOI0383.5	Comprehensive® Reverse Shoulder Technique

Ordering Information	
110004347	Signature™ Glenoid CT Guide and Bone Model
110017143S	Signature™ Glenoid Guide and Scapula (Sample)
110017144S	Signature™ Glenoid Guide and Target (Sample)
110017145S	Signature™ Glenoid Guide and Sawbone 1021 (Sample)

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

BIOMET

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