Signature™ Personalized Patient Care

Surgical Technique
Acetabular Guide System
Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it’s meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally invasive surgical technique, advanced biomaterials or a patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.

This brochure describes the surgical technique protocol used by Adolph Lombardi, M.D.; William Long, M.D.; James Nairus, M.D.; Tamon Kabata, M.D. and Stephen Jones, F.R.C.S. Biomet does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate implants and techniques for implanting the prosthesis in each individual patient. It is recommended that standard hip instrumentation be sterilized and available in the event that the Signature™ surgical technique and/or Signature™ Acetabular Guides are not used during surgery.

INDICATIONS FOR USE

The Signature Personalized Patient Care System - Acetabular Guide System is intended to be used as a surgical instrument to assist in the positioning of acetabular cup components intra-operatively using anatomical landmarks of the pelvis that are clearly identifiable on preoperative MRI imaging scans.

The Signature Personalized Patient Care System - Acetabular Guide System can be used with all Biomet 510(k) cleared, legally marketed, primary acetabular systems and their respective components.

The Signature Guides are intended for single-use only.

CONTRAINDICATIONS

The Signature Guides are contraindicated for patients with significant anatomical disruption or distortion of the pelvis. This may include patients with pelvic and/or acetabular fractures and/or dislocations, osteoporosis or other diseases that affect pelvic anatomy and bony landmark recognition.

Active infection is a contraindication for use of this device.

The Signature Guides are contraindicated for use with flanged acetabular components.
Soft Tissue Removal

The Signature™ acetabular guides have been designed for exposure obtained through a posterior or lateral approach.

Prepare the anatomy in the usual routine by removing as much soft tissue in and around the acetabulum as needed to allow for good exposure and optimal Signature™ guide fit. Specifically, remove the Labrum and soft tissue from the rim of the acetabulum at the twelve o’clock position in areas of guide registration. Additionally, remove the fatty tissue in and around the Acetabular Fossa, making sure not to remove osteophytes (Figure 1).

Note: The Signature™ guides are designed to reference off of bone and cartilage. Therefore, do not remove the osteophytes in the areas where the guides will be placed.

Note: When available, electrocautery should be used to aid in removal of the labrum and soft tissues. This will help to preserve boney landmarks needed for proper guide registration.

Note: The Signature™ guides are designed and produced to replicate the preoperative surgical plan. Final component position should be validated intraoperatively when the capsular soft tissues may be appropriately assessed.

Signature™ Primary Acetabular Guide – Positioning and Pin Placement

Place the first guide, the Signature™ Primary Acetabular Guide, in the acetabulum. When available, reference the patient-matched bone model and guides for confirmation of accurate fit (Figure 2).

Note: The following guide design features may be used for intraoperative confirmation of proper alignment:

A. The line scribed on the inferior side of the guide should be parallel to the transverse acetabular ligament.

B. The posterior edge of the guide should be flush with the rim of the acetabulum.

C. The “hook” on the inferior side of the guide should lock into the posterior side of the acetabular notch, beneath the transverse acetabular ligament.

Additionally, the windows of the guide may be used to visually confirm the guide is fully seated in the acetabulum (Figure 3).
Signature™ Primary Acetabular Guide – Positioning and Pin Placement (cont.)

**Note**: To aid with guide placement, assemble the guide inserter handle to the central post of the primary acetabular guide. Internally rotate the guide handle while applying light downward pressure with the handle to achieve proper guide registration (Figure 4).

Place the drill sleeve into the tapered holes of the Signature™ Primary Acetabular Guide (Figure 5). Ensure the drill sleeve is engaged properly with the Primary Acetabular Guide (Figure 5a).

If available, attach a pin driver to the surgical drill. While firmly holding the guide in place, insert 1/8 in (3.2 mm) drill pins through the drill sleeve and two guide holes. Drill the pins into the rim of the acetabulum (Figure 6), seated to a depth as indicated by the two etched lines on the drill pins (Figure 6a). The most anterior pin should be inserted first to secure the guide in place and aid with insertion of the second pin. Malpositioning of the guide during pinning may lead to malpositioning of the final acetabular component.

Leaving the drill pins in place, remove the drill sleeve then slide the Signature™ Primary Acetabular Guide off of the pins (Figure 7). The guide is designed with open-back drill holes to aid in removal.

**Note**: Caution must be used when placing the drill pins to prevent soft tissue injury that may occur from penetrating the medial cortex of the pelvis. Each pin is designed to provide the surgeon with tactile feedback when the pin shoulder contacts the outer, lateral cortex of the pelvis. Excessive downward pressure should be avoided when drilling to prevent advancing the pin beyond this shoulder stop.

The tactile feedback provided by the pin shoulder should be used in combination with the visual feedback provided by the etched lines, as described above, to obtain proper placement of the Signature™ acetabular drill pins.
Reaming

The surgeon’s preferred technique should be used during reaming of the acetabulum. The Signature™ Alignment Pin may be used as a visual reference during reaming. However, reaming in alignment with the pin is not required as this should not affect final implant positioning (Figure 11).

Note: If necessary, the Signature™ Secondary Acetabular Guide may be repositioned at any point along the length of the drill pins or removed entirely during reaming.

Cup Insertion

Before impacting the cup, align the long axis of the cup inserter parallel to the Signature™ Alignment Pin (Figures 11 and 11a). Strike the cup inserter handle with a mallet keeping the inserter steadily aligned with the Signature™ Alignment Pin until the cup is fully seated. Remove the cup inserter.

Signature™ Secondary Acetabular Guide - Positioning and Pin Placement (Cont.)

Slide the second guide, the Signature™ Secondary Acetabular Guide, over the drill pins into a position such that the guide does not obstruct reaming (Figure 8). It is not necessary for the guide to be seated against bone (i.e. pushed down all the way) (Figure 8a). The guide should be positioned so the alignment pin cylinder protrudes away from the acetabulum.

Note: The bottom surface of the Signature™ Secondary Acetabular Guide may not fully engage the patient’s unique anatomical features. However, this will not affect component positioning provided the guide is correctly positioned on the two drill pins.

Insert the Signature™ Alignment Pin, by hand, into the alignment pin cylinder. This pin does not need to be drilled into bone, as it is for alignment purposes only (Figure 9).

Note: The Signature™ Alignment Pin is oriented parallel to the preoperatively planned cup insertion axis.

Signature™ Personalized Patient Care
Cup Insertion (Cont.)

**Note:** The Signature™ acetabular guides are designed and produced to replicate the preoperative surgical plan. Final component position and orientation (i.e. anteversion and inclination) should be validated intraoperatively. If the orientation of the alignment pin is determined to be unacceptable, the pins and guide may be removed and traditional version guides may be used for final cup orientation.

After the cup is properly positioned, remove the Signature™ Secondary Acetabular Guide by sliding it off of the drill pins. Remove the drill pins from the rim of the acetabulum (Figure 12).

Cup Insertion – Optional Alignment Pin Adaptor

To assist with alignment during cup insertion, utilize the optional alignment pin adaptor (Figure 13). The pin adaptor is compatible with Biomet® RingLoc®/RingLoc®+ acetabular cup inserter handles and works in conjunction with the Signature™ Alignment Pin.

Attach the alignment pin adaptor to the version guide holder on the cup inserter. Starting with the Signature™ Secondary Acetabular Guide and Signature™ Alignment Pin positioned near the top of the drill pins, align the cup inserter parallel to the alignment pin (Figure 14).
Slide the Signature™ guide down the drill pins until the alignment pin contacts the groove in the alignment pin adaptor (Figure 15). Verify that the alignment pin contacts the entire length of the groove in the alignment pin adaptor and that the long axis of the cup inserter is parallel to the alignment pin.

Strike the cup inserter handle with a mallet keeping the inserter steadily aligned with the alignment pin until the cup is fully seated. Remove the cup inserter.

Note: The alignment pin adaptor will not securely hold the cup inserter in the preoperatively planned position. While the pin adaptor will assist with alignment, it is important to keep the cup inserter steady and parallel with the Signature™ Alignment Pin.

After the cup is properly positioned, remove the Signature™ Alignment Guide by sliding it off of the drill pins. Remove the drill pins from the rim of the acetabulum (Figure 16).

Instruments

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## Signature™ Personalized Patient Care

Instruments (Cont.)

### Signature™ Cup Placement Instruments

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