Signature™ Personalized Patient Care*

Surgical Technique Addendum

Vanguard® Complete Knee 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.
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Non-sterile Signature™ bone models** may be used for surgeon evaluation of anatomical guide positioning preoperatively. Intraoperatively, Signature™ bone models may assist in confirming anatomical guide position, when sterilized.

MRI bone models provide the following reference information:

A. Landmarks and resection values
B. Rotational axes
C. Resection levels
D. Tibial guide registration area represented by crosshatching
Exposure

Expose the bony anatomy of the femur and tibia. Prepare the anatomy in the usual fashion by removing as much soft tissue around the femur and tibia as needed to allow for good exposure and optimal Signature™ MRI-based femoral and tibial positioning guide registration (Figure 1).

Note: The Signature™ MRI-based femoral and tibial positioning guides were designed to register on the osteophytes. Therefore, do not remove the osteophytes at this stage.

Note: The Signature™ MRI-based femoral and tibial positioning guides are designed and manufactured to replicate the approved preoperative surgeon plan. Final component position should be validated intraoperatively when the capsular soft tissues may be appropriately assessed.

Femoral Preparation

Register the Signature™ MRI-based femoral positioning guide on the femur. The Signature™ MRI-based femoral guide is designed to register in one unique location on cartilage, where present, and on bone where cartilage is absent (Figure 2).
Once the optimal position of the Signature™ MRI-based femoral positioning guide has been located, hold the guide firmly in place on the femur while inserting $\frac{1}{8}$ inch pins in the distal aspect of guide (Figure 3). Malpositioning of the Signature™ MRI-based femoral positioning guide during pinning may lead to malposition of the femoral component.

**Note:** Spring pins (Part No. 42-422401) or $\frac{1}{8}$ inch trochar pins (Part No. 32-486255) may be used to secure the distal portion of the Signature™ MRI-based femoral positioning guide to the femur. A wire/pin driver attached to a power drill is recommended when using spring pins. Do not fully compress springs to maintain fixation.
Figure 4

Place the distal femoral drill guide into the anterior holes of the Signature™ MRI-based femoral positioning guide and drill two \( \frac{1}{8} \) inch trochar pins though the guide (Figure 4).

**Note:** \( \frac{1}{8} \) inch drill pins or \( \frac{1}{8} \) inch trochar pins (Part No. 32-486255) may be used to secure the anterior portion of the Signature™ femoral positioning guide to the femur.
Femoral Preparation, continued

Remove the distal pins and slide the Signature™ MRI-based femoral positioning guide and drill guide off of the anterior trochar pins. Mark the distal pin holes with methylene blue so as to easily locate the holes after the distal femoral resection is made (Figure 5).

Slide the distal cut block onto the anterior pins using the middle hole location. The zero slot (most distal) and middle hole location represent the resection from the approved preoperative plan.

**Note:** To confirm resection orientation for anteromedial pin placement, visualize cut orientation through the zero cut slot on the distal cut block. To confirm resection orientation for direct anterior pin placement, use standard Vanguard® distal femoral resection assembly, incorporating the femoral valgus angle from the preoperative plan.

Before making the distal cut, ensure orientation and bone resection level. If more or less bone removal is desired, simply move the cut block to the appropriate cut level. Make the distal cut (Figure 6).
Remove the anterior pins and locate the previously drilled distal holes marked with methylene blue (Figure 7). In addition, pulsatile lavage and/or bulb syringe may be used to clear debris from the distal holes in preparation for the four-in-one pins.

Figure 7
Femoral Preparation, continued

To validate femoral rotation, A/P position and size, the A/P sizing guide may be utilized. Reference the patient-specific femoral rotation angle from the approved preoperative plan (posterior condylar axis to transepicondylar axis) and incorporate this angle into the A/P sizer dial feet (Figure 8).

If there is a discrepancy between two sizes, resect anterior bone with the larger size first. If it is possible to downsize without risk of notching, then downsize to the next smaller size.
Place the four-in-one block in the distal holes and make the corresponding cuts (Figure 9).

**Note:** The Premier™ four-in-one block may serve as a reference to the medial/lateral width of the corresponding femoral component size.

**Note:** Review the femoral images from the approved preoperative plan with the femoral component in place to ensure removal of all osteophytes under the collateral ligaments and in the posterior recesses.
Tibial Preparation

Signature™ MRI-based Tibial Positioning Guides

Ensure that soft tissue is removed from the anterior tibia to allow for optimal Signature™ tibial positioning guide registration on the anterior bone (Figure 10).

Once the optimal position for the Signature™ MRI-based tibial positioning guide has been located, place the drill guide into the anterior Signature™ tibial positioning guide holes. Drill the ¼ inch pins through the corresponding holes and leave the drill guide in place (Figure 11).

Note: Spring pins (Part No. 42-422401) or ⅜ inch trochar pins (Part No. 32-486255) may be used to secure the distal portion of the Signature™ MRI-based femoral positioning guide to the femur. A wire/pin driver attached to a power drill is recommended when using spring pins. Do not fully compress springs to maintain fixation.
Place the drill guide into the Signature™ tibial rotation positioning guide holes located on the tibial plateaus. Drill the ⅛ inch pins through the corresponding holes (Figure 12), then remove rotation pins, tibial drill guides and Signature™ MRI-based tibial positioning guide, leaving anterior pins in place (Figure 13).

**Note:** One-eighth inch drill pins or ⅛ inch pins may be used to secure the tibial plateau portion of the Signature™ MRI-based tibial positioning guide to the tibia.

Locate the previously drilled rotation holes on the tibial plateaus and mark with methylene blue so that they will be easily located after the tibial resection has been made (Figure 13).
Tibial Preparation, continued

Slide the tibial cut block onto the pins, using the middle hole location, and make the corresponding resection (Figure 14).

Note: To confirm varus/valgus and slope alignment, an extramedullary guide may be used.

Note: Before making the tibial cut, ensure orientation and bone resection level. If more or less bone removal is desired, simply move the cut block to the appropriate cut level and make the tibial cut.
To carry out planned tibial rotation, locate the previously drilled tibial rotation holes marked with methylene blue and insert the ¼ inch pins. Slide the anterior holes of the previously determined size punch-through trial plate over the pins. To ensure accuracy of rotation, place an alignment rod through the corresponding hole (Figure 15).

Prepare for the tibial stem in the usual fashion.

Whether using Microplasty® or Premier™ tibial stem preparation instruments, the tibial rotation pin position corresponds to the anterior hole locations on the tibial template.

Trial Reduction

Trial and balance the knee (Figure 16). Reference the Vanguard® Complete Knee System surgical techniques for implantation and cementing processes as follows:

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOI0428.0</td>
<td>Microplasty® Elite Total Knee Instrumentation Surgical Technique</td>
</tr>
<tr>
<td>BOI0427.0</td>
<td>Premier™ Total Knee Instrumentation Surgical Technique</td>
</tr>
<tr>
<td>BOI0429.0</td>
<td>Microplasty® Total Knee Instrumentation Surgical Technique</td>
</tr>
</tbody>
</table>
Non-sterile Signature™ bone models** may be used for surgeon evaluation of anatomical guide positioning preoperatively. Intraoperatively, Signature™ bone models may assist in confirming anatomical guide position, when sterilized.

CT bone models provide the following reference information:

A. Landmarks and values
B. Rotational axes
C. Resection levels
D. Femoral and tibial guide registration is represented by crosshatching
Exposure

Expose the bony anatomy of the femur and tibia. Prepare the anatomy in the usual fashion by removing as much soft tissue around the femur and tibia as needed to allow for good exposure and optimal Signature™ CT-based femoral and tibial positioning guide registration (Figure 1).

Note: The Signature™ CT-based femoral and tibial positioning guides were designed and manufactured to replicate the approved preoperative surgeon plan. Final component position should be validated intraoperatively when the capsular soft tissues may be appropriately assessed.

Note: The Signature™ CT-based femoral and tibial positioning guides were designed to register on the osteophytes. Therefore, do not remove the osteophytes at this stage.
Femoral Preparation

The Signature™ CT-based femoral positioning guide will not rest on the articular cartilage of the femur due to the absence of cartilage visualization from CT images. The surgeon should register the guide on the medial and lateral boney structure of the anterior portion of the trochlear groove and then rotate the guide posteriorly into the notch between the distal condyles. The body of the guide is designed to be offset 5 mm from the bone surface to avoid guide interference where cartilage may be present (Figures 2 and 3). In areas where cartilage is present, the gap may be less than 5 mm at the time of surgery.

Note: If guide position is questioned in the O.R., reference the bone model for planned guide contact represented by the crosshatched areas on the bone model (refer to Signature™ Bone Model section on page 14).

Note: Pressure should only be applied to the portions of the Signature™ CT-based femoral positioning guide where in contact with bone.
Once the optimal position of the Signature™ femoral positioning guide has been located, hold firmly in place on the femur while inserting ⅛ inch trochar pins in the distal aspect of the guide (Figure 4). Malpositioning of the Signature™ CT-based femoral positioning guide during pinning may lead to malposition of the femoral component.

**Note:** Spring drill pins should not be used with Signature™ CT-based femoral positioning guides.
Femoral Preparation, continued

Place the distal femoral drill guide into the anterior holes of the Signature™ CT-based femoral positioning guide and drill two 1/8 inch drill pins or 1/8 inch trochar pins though the guide (Figure 5).
Remove the distal pins and slide the Signature™ CT-based femoral positioning guide and drill guide off of the anterior trochar pins. Mark the distal pin holes with methylene blue so that they will be easily located after the distal femoral resection is made (Figure 6).

Slide the distal cut block onto the anterior pins using the middle hole location. The zero slot (most distal) and middle hole location represent the resection from the approved preoperative plan.

**Note:** To confirm resection orientation for anteromedial pin placement, visualize cut orientation through the zero cut slot on the distal cut block. To confirm resection orientation for direct anterior pin placement, use standard Vanguard® distal femoral resection assembly, incorporating the femoral valgus angle from the approved preoperative plan.

Before making the distal cut, ensure orientation and bone resection level. If more or less bone removal is desired, simply move the cut block to the appropriate cut level. Make the distal cut (Figure 7).
Femoral Preparation, continued
Remove the anterior pins and locate the previously drilled distal holes marked with methylene blue (Figure 8). In addition, pulsatile lavage and/or bulb syringe may be used to clear debris from the distal holes in preparation for four-in-one pins.
To validate femoral rotation, A/P position and size, the A/P sizing guide can be utilized. Reference the patient-specific femoral rotation angle from the preoperative plan (posterior condylar axis to transepicondylar axis) and incorporate this angle into A/P sizer dial feet (Figure 9). If there is a discrepancy between two sizes, resect anterior bone with the larger size first. If it is possible to downsize without risk of notching, then downsize to the next smaller size.
Femoral Preparation, continued

Place the four-in-one block in the distal holes and make the corresponding cuts (Figure 10).

**Note:** The Premier™ four-in-one block may serve as a reference to the medial/lateral width of the femoral component.

**Note:** Review the femoral images from the approved preoperative plan with the femoral component in place to ensure removal of all osteophytes under the collateral ligaments and in the posterior recesses.
Tibial Preparation

**Signature™ CT-based Tibial Positioning Guides**

Ensure that soft tissue is removed from the anterior tibia to allow for optimal Signature™ CT-based tibial positioning guide registration on the anterior bone (Figure 11).

**Note:** Pressure should only be applied to the pressure point indicated on the guide.

The Signature™ CT-based tibial positioning guide will not register directly on the medial and lateral plateaus (Figure 12).

**Note:** The Signature™ CT-based Tibial Positioning Guide is designed to reference bone due to the absence of cartilage visualization from CT images. The body of the guide is offset 5 mm from bone surface to avoid guide interference where cartilage may be present.
Tibial Preparation, continued

Once the optimal position of the Signature™ CT-based tibial positioning guide has been located, place the drill guide into the anterior Signature™ tibial positioning guide holes. Drill the $\frac{1}{8}$ inch pins through the corresponding holes and leave the drill guide in place (Figure 13).

**Note:** Spring drill pins should not be used with Signature™ CT-based femoral positioning guides.

Place the drill guide onto the Signature™ tibial rotation positioning guide holes located on the tibial plateaus. Drill the $\frac{1}{8}$ inch pins through the corresponding holes (Figure 14), then remove rotation pins, drill guides and Signature™ tibial positioning guide, leaving anterior pins in place.
Locate the previously drilled rotation holes on the tibial plateaus and mark with methylene blue so that they will be easily located after the tibial resection has been made (Figure 15).

Slide the tibial cut block onto the pins using the middle hole location and make the corresponding resection (Figure 16).

Note: To confirm varus/valgus and slope alignment, an extramedullary guide may be used.

Note: Before making the tibial cut, ensure orientation and bone resection level. If more or less bone removal is desired, simply move the cut block to the appropriate cut level and make the tibial cut.
Tibial Preparation, continued

To carry-out planned tibial rotation, locate the previously drilled tibial rotation holes marked with methylene blue and insert the $\frac{3}{8}$ inch pins. Slide the anterior holes of the previously determined size punch-through trial plate over the pins. To ensure accuracy of rotation, place an alignment rod through the corresponding hole (Figure 17).

Prepare for the tibial stem in the usual fashion. Whether using Microplasty® or Premier™ tibial stem preparation instruments, the tibial rotation pin position corresponds to the anterior hole locations on the tibial template.
Trial Reduction

Trial and balance the knee (Figure 18). Reference the Vanguard® Complete Knee System surgical techniques for implantation and cementing processes as follows:

<table>
<thead>
<tr>
<th>Part Number</th>
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<tbody>
<tr>
<td>BOI0428.0</td>
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</tr>
<tr>
<td>BOI0429.0</td>
<td>Microplasty® Total Knee Instrumentation Surgical Technique</td>
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</tbody>
</table>
# Instruments

## Pins

<table>
<thead>
<tr>
<th>Product</th>
<th>Part Number</th>
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</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Pins Icon" /></td>
<td>32-486265</td>
<td>1/8 inch Drill Pins, Sterile (Each)</td>
</tr>
<tr>
<td><img src="image2.png" alt="Pins Icon" /></td>
<td>32-467623</td>
<td>1/8 inch Drill Pins, Non-sterile (Pack of six)</td>
</tr>
<tr>
<td><img src="image3.png" alt="Pins Icon" /></td>
<td>32-486255</td>
<td>Trochar Pins (Pack of two)</td>
</tr>
<tr>
<td><img src="image4.png" alt="Pins Icon" /></td>
<td>42-422411</td>
<td>Collared Drill Pins (Each)</td>
</tr>
<tr>
<td><img src="image5.png" alt="Pins Icon" /></td>
<td>42-422401</td>
<td>Spring Drill Pins* (Pack of two)</td>
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</tbody>
</table>

*Optional

## Femoral Drill Guides

<table>
<thead>
<tr>
<th>Product</th>
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<th>Description</th>
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<tr>
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<td>42-422404</td>
<td>**Microplasty® Slidex® Distal Femoral Drill Guide</td>
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<tr>
<td><img src="image7.png" alt="Femoral Drill Guides Icon" /></td>
<td>42-422403</td>
<td>**Microplasty® Premier™ Drill Guide</td>
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<td><img src="image8.png" alt="Femoral Drill Guides Icon" /></td>
<td>42-422406</td>
<td>**Microplasty® Elite AMDC Drill Guide</td>
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**Pin spacing varies to match associated cut block

## Tibial Drill Guides

<table>
<thead>
<tr>
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<tbody>
<tr>
<td><img src="image9.png" alt="Tibial Drill Guides Icon" /></td>
<td>42-422405</td>
<td>**Microplasty®/Premier™ Tibial Drill Guide</td>
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<tr>
<td><img src="image10.png" alt="Tibial Drill Guides Icon" /></td>
<td>42-422402</td>
<td>**Microplasty® Elite Universal Tibial Drill Guide</td>
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<td><img src="image11.png" alt="Tibial Drill Guides Icon" /></td>
<td>42-422407</td>
<td>**Microplasty® Elite Slidex® Tibial Drill Guide</td>
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<td>42-422408</td>
<td>**Microplasty® Elite Anatomic Drill Guide</td>
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<td><img src="image13.png" alt="Tibial Drill Guides Icon" /></td>
<td>42-422409</td>
<td>Universal Drill Guide</td>
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**Pin spacing varies to match associated cut block
## Femoral Cut Block Options

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<th>Product</th>
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<tr>
<td><img src="image" alt="Slidex™ Distal Femoral Resector" /></td>
<td>32-485000</td>
<td>Slidex™ Distal Femoral Resector</td>
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<tr>
<td><img src="image" alt="Microplasty® Fixed Distal Resector" /></td>
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<td>Microplasty® Fixed Distal Resector</td>
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<td>32-487002</td>
<td>Premier™ Fixed Distal Resector</td>
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<td>32-484000</td>
<td>Microplasty® Elite Anteromedial Distal Resector</td>
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</table>
**Signature™ Personalized Patient Care**

Instruments, continued

## Tibial Cut Block Options

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<th>Product</th>
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<tr>
<td><img src="rd140512.png" alt="Image" /></td>
<td>RD140512</td>
<td>Microplasty® Tibial Resection Head (Anatomic), Right</td>
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<td><img src="rd140513.png" alt="Image" /></td>
<td>RD140513</td>
<td>Microplasty® Tibial Resection Head (Anatomic), Left</td>
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<tr>
<td><img src="32-487555.png" alt="Image" /></td>
<td>32-487555</td>
<td>Premier™ Tibial Resection Head (Anatomic), Right</td>
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<tr>
<td><img src="32-487556.png" alt="Image" /></td>
<td>32-487556</td>
<td>Premier™ Tibial Resection Head (Anatomic), Left</td>
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<tr>
<td><img src="32-484551.png" alt="Image" /></td>
<td>32-484551</td>
<td>Microplasty® Elite Tibial Resection Head (Anatomic), Right</td>
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<td><img src="32-484552.png" alt="Image" /></td>
<td>32-484552</td>
<td>Microplasty® Elite Tibial Resection Head (Anatomic), Left</td>
</tr>
<tr>
<td><img src="32-487557.png" alt="Image" /></td>
<td>32-487557</td>
<td>Premier™ Tibial Resection Head Universal</td>
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<tr>
<td><img src="32-484554.png" alt="Image" /></td>
<td>32-484554</td>
<td>Microplasty® Elite Universal Closed Resection Block</td>
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<td><img src="32-484553.png" alt="Image" /></td>
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<td>Microplasty® Elite Universal Open Resection Block</td>
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**ATTENTION OPERATING SURGEON**

**DESCRIPTION**

The Signature™ Personalized Patient Care System includes the Signature™ Patient-Specific Surgical Guides which are patient specific instruments (guides are considered custom-made per EU definition). The Signature™ Patient-Specific Surgical Guides are intended to be used as part of the Signature™ Personalized Patient Care System. It is intended to be used as a guide during the surgical procedure for total and partial knee arthroplasty.

**MATERIALS**

Polyamide

**INDICATIONS FOR USE**

Pin Placement Guides

**Signature™ Personalized Patient Care System** is intended to be used as a surgical instrument to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The Signature™ Personalized Patient Care System can be used with the following Biomet® Knee Systems and their respective components: Vanguard™ Complete Knee System, Vanguard™ SSK 360, Vanguard™ SSK Revision Knee System, Regenerex™ Primary Tibial System, Offset & Microplasty™ Tibial Systems, Maxi™ Complete Knee System, Ascent™ Total Knee System, and AGC™ Complete Knee system.

Cut-Through Guides

**Signature™ Personalized Patient Care System** is intended to be used as a surgical instrument to assist in the positioning of total and partial knee replacement components intra-operatively and in guiding the marking of bone before cutting and to guide cutting, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The Signature™ Personalized Patient Care System can be used with the following Biomet® Knee Systems and their respective components: Vanguard™ Complete Knee System, Vanguard™ Unicompartmental Knee System, Vanguard™ SSK 360, Vanguard™ SSK Revision Knee System, Regenerex™ Primary Tibial System, Offset & Microplasty™ Tibial Systems, Maxi™ Complete Knee System, Ascent™ Total Knee System, and AGC™ Complete Knee system.

The Signature™ Personalized Patient Care System is compatible for use with the Oxford® Partial Knee System as approved in P010014/S31.

The Signature™ guides are intended for single use only.

**CONTRAINDICATIONS**

Active infection is a contraindication for use of this device.

**WARNINGS**

1. The user should be aware of possible allergic reactions to materials used in the guide. The patient should be informed on this matter by the user.
2. The guide’s patient specific identifiers are to be checked for readability and confirmed by the surgeon before use.
3. Device is single use only. Do not attempt to re-clean or re-sterilize this product for other than its originally intended patient. After use, this product may be a potential biohazard.
4. Cut-through guides can only be developed using MRI scans.

5. The cutting blade used for the cut-through guide bone cuts should be placed into the slot of the guide prior to turning on the power to the cutting instrument.

**PRECAUTIONS**

1. The Signature™ Guide is for single use only. The guide is not reusable.
2. If the patient’s anatomy has changed significantly since the time of the CT/MRI-scan (CT cannot be used to make cut-through guides), the Signature™ Guide should not be used.
3. Store it in a properly cleaned and dry place.
4. The guide should be properly cleaned before sterilization.
5. Open, clean and sterilize immediately prior to surgery.
6. Do not use if the Signature™ Guide is broken, cracked, or when loose powder is present.
7. Do not alter the guide.
8. The surgeon should be familiar with the package insert and appropriate surgical technique(s) specific to the joint replacement implants utilized in conjunction with the Signature™ Guides.

9. All trial, packaging, and instrument components must be removed prior to closing the surgical site, do not implant.

**POSSIBLE ADVERSE EFFECTS**

1. Infection following the procedure.
2. Introduction of foreign materials can result in an inflammatory response or allergic reaction.
3. Wound dehiscence.
4. Nerve damage.

**STERILITY AND CLEANING**

- Guides and bone models are provided in Non-Sterile condition and must be sterilized prior to surgery.
- Guides must be cleaned until visibly clean prior to sterilization. Visible soil should be removed under running water using a mechanical aid such as a brush with rigid nylon bristles. It is recommended that the instruments be decontaminated using an automatic washer-disinfection unit utilizing thermal disinfection. This should preferably be the ultrasonic or continuous tunnel process type. The cabinet type is an acceptable alternative if a continuous process machine is not available. Compatible detergents and rinse aids may be used as recommended by the manufacturer of the washer-disinfection unit. The following table outlines a validated automated cleaning method for use.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Time (Minutes)</th>
<th>Temperature &amp; Water Quality</th>
<th>Detergent &amp; Concentration</th>
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<tr>
<td>Pre-Wash</td>
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<td>95°F (35°C)</td>
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<td>Detergent Wash</td>
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<td>Tap Water</td>
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<td>Wash</td>
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<td>Tap Water</td>
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<td>Rinse</td>
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<td>Drying</td>
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<td>239°F (115°C)</td>
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* The following tables outline sterilization parameters for use.

<table>
<thead>
<tr>
<th>U.S. PARAMETERS</th>
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</thead>
<tbody>
<tr>
<td>Dynamic-Air-Removal Sterilization</td>
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<tr>
<td>Option 1</td>
</tr>
<tr>
<td>Temperature:</td>
</tr>
<tr>
<td>Exposure Time:</td>
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<td>Drying Time:</td>
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<tr>
<td>Wrap*: Per Manufacturer’s instructions</td>
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</table>
**NON-U.S. PARAMETERS**

<table>
<thead>
<tr>
<th>Dynamic-Air-Removal Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature: 132°C – 140°C (270°F – 284°F)</td>
</tr>
<tr>
<td>Exposure Time: 3 minute minimum</td>
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<tr>
<td>Drying Time: 30 minute minimum</td>
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<tr>
<td>Wrap*: Single, Double, or Unwrapped</td>
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<table>
<thead>
<tr>
<th>Gravity Displacement Sterilizer</th>
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</thead>
<tbody>
<tr>
<td>Temperatures: 132°C – 140°C (270°F – 284°F)</td>
</tr>
<tr>
<td>Exposure Time: 10 minutes minimum</td>
</tr>
<tr>
<td>Drying Time: 30 minutes minimum</td>
</tr>
<tr>
<td>Wrap*: Single, Double, or Unwrapped</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>U.S. PARAMETERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterrad 100S - Short Cycle</td>
</tr>
<tr>
<td>Cycle Temperature: 113°F - 131°F (45°C - 55°C)</td>
</tr>
<tr>
<td>Cycle Time: ~55 minutes (short cycle)</td>
</tr>
<tr>
<td>Wrap: Single Wrap</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NON-U.S. PARAMETERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterrad 100S - Short Cycle</td>
</tr>
<tr>
<td>Cycle temperature: 45°C - 55°C (113°F - 131°F)</td>
</tr>
<tr>
<td>Cycle Time: ~55 minutes (short cycle)</td>
</tr>
<tr>
<td>Wrap: Single, Double, or Unwrapped</td>
</tr>
</tbody>
</table>

*Wraps used during the steam sterilization process are to be FDA cleared wraps (e.g., Kimguard® Sterilization Wrap; 510K #K082554). Use Manufacturer’s instructions.

Since Biomet is not familiar with individual hospital handling procedures, cleaning methods, bioburden levels, and other conditions, Biomet assumes no responsibility for sterilization of product by a hospital even if the general above guidelines are followed.

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-3968.

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Kimguard® is the trademark of Kimberly-Clark Health Care. Enzol® is a registered trademark of Johnson & Johnson Co. Renu-Klenz™ is a trademark of Steris Corporation.

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA UK

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**Symbol Legend**

- Manufacturer
- Date of manufacture
- Do not reuse
- Caution, see instructions for use
- Non-sterile
- Sterilized using ethylene oxide
- Sterilized using irradiation
- Sterile
- Sterilized using aseptic processing techniques
- Sterilized using steam or dry heat
- Use by date
- WEEE device
- Catalogue number
- Batch code
- Flammable
- Authorized representative in the European Community

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A collaborative partnership with Materialise N.V.

**Signature™** positioning guides and bone models must be sterilized prior to surgery.

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