Signature* Personalized Patient Care

Surgical Technique Addendum
Vanguard Complete Knee System

MRI-based Positioning Guides
CT-based Positioning Guides
MRI-based Cut-through Guides
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.
Signature Personalized Patient Care

Table of Contents

Signature MRI-based Positioning Guides

Bone Models ........................................................................................................................................................................... 2
Exposure................................................................................................................................................................................... 3
Femoral Preparation ............................................................................................................................................................ 3
Tibial Preparation ............................................................................................................................................................... 10
Trial Reduction .................................................................................................................................................................... 13

Signature CT-based Positioning Guides

Bone Models ........................................................................................................................................................................ 14
Exposure................................................................................................................................................................................ 15
Femoral Preparation ......................................................................................................................................................... 16
Tibial Preparation ............................................................................................................................................................... 23
Trial Reduction .................................................................................................................................................................... 27

Signature MRI-based Cut-through Guides

Bone Models ........................................................................................................................................................................ 28
Exposure................................................................................................................................................................................ 29
Femoral Preparation ......................................................................................................................................................... 29
Tibial Preparation ............................................................................................................................................................... 33
Trial Reduction .................................................................................................................................................................... 35

Ordering Information .......................................................................................................................................................... 36

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, Maxim 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 M Unicompartmental Knee System, Vanguard SSK 360, Vanguard SSK Revision Knee System, Regenerex Primary Tibial System, Offset & Microplasty Tibial Systems, Maxim 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.
**Signature MRI-based Positioning Guides**

**Signature Bone Models**

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).

This surgical technique is utilized by Roger Emerson Jr., M.D., Adolph Lombardi Jr., M.D. Biomet as manufacturer of medical devices, does not practice medicine and does not recommend this device. Each surgeon is responsible for determining the appropriate to utilize on each individual patient.
**Femoral Preparation (cont.)**

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 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 or ¹⁄₈ inch trochar pins 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.
Femoral Preparation (cont.)

Place the drill guide into the anterior holes of the Signature MRI-based femoral positioning guide and drill two ⅛ inch trochar pins through the guide (Figure 4).

Note: ⅛ inch drill pins or ⅛ inch trochar pins may be used to secure the anterior portion of the Signature femoral positioning guide to the femur.
Femoral Preparation (cont.)

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).
Femoral Preparation (cont.)

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.
Femoral Preparation (cont.)

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.
Femoral Preparation (cont.)

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 corresponding alignment drill guide into the anterior Signature tibial positioning guide holes. Drill the 1/8 inch pins through the corresponding holes and leave the drill guide in place (Figure 11). To confirm desired alignment and placement of the tibial guide, insert the Vanguard 1/4 inch alignment rod in the alignment guide hole.

**Note:** Spring pins or 1/4 inch trochar pins may be used to secure the anterior portion of the Signature MRI-based tibial positioning guide to the tibia. A wire/pin driver attached to a power drill is recommended when using spring pins. Do not fully compress springs to maintain fixation.

**Note:** The Universal Drill guide may also be used in the anterior tibial positioning guide holes if so desired.
Tibial Preparation (cont.)

Place the drill guide into the Signature tibial rotation positioning guide holes located on the tibial plateau. Drill the $\frac{1}{8}$ 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 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 (cont.)

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.
Tibial Preparation (cont.)

To carry out planned tibial rotation, locate the previously drilled tibial rotation holes marked with methylene blue and insert the 1/8 inch pins. Slide the anterior holes of the previously determined size punch-through trial plate over the pins. To determine 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.

Note: Tibial rotation pin location is size, rotation and position specific based upon planned parameters. Intraoperative change of size may result in a different pin location compared to plan.

Trial Reduction

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

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<tr>
<th>Part Number</th>
<th>Description</th>
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</thead>
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<tr>
<td>BOI0428.1</td>
<td>Microplasty Elite Total Knee Instrumentation Surgical Technique</td>
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<td>BOI0427.1</td>
<td>Premier Total Knee Instrumentation Surgical Technique</td>
</tr>
<tr>
<td>BOI0429.1</td>
<td>Microplasty Total Knee Instrumentation Surgical Technique</td>
</tr>
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Signature CT-based Positioning Guides

Signature Bone Models

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 17).

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 18 and 19). 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.
Femoral Preparation (cont.)

Once the optimal position of the Signature femoral positioning guide has been located, hold firmly in place on the femur while inserting 1⁄8 inch trochar pins in the distal aspect of the guide (Figure 20). 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 use with Signature CT-based femoral positioning guides.
Femoral Preparation (cont.)

Place the drill guide into the anterior holes of the Signature CT-based femoral positioning guide and drill two \( \frac{3}{8} \) inch drill pins or \( \frac{1}{4} \) inch trochar pins through the guide (Figure 21).
Femoral Preparation (cont.)

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 22).

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 23).
Femoral Preparation (cont.)

Remove the anterior pins and locate the previously drilled distal holes marked with methylene blue (Figure 24). 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.
Femoral Preparation (cont.)

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 25). 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 (cont.)

Place the four-in-one block in the distal holes and make the corresponding cuts (Figure 26).

**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 27).

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

The Signature CT-based tibial positioning guide will not register directly on the medial and lateral plateaus (Figure 28).

**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 (cont.)

Once the optimal position for the Signature CT-based tibial positioning guide has been located, place the corresponding alignment drill guide into the anterior Signature tibial positioning guide holes. Drill the 1/8 inch pins through the corresponding holes and leave the drill guide in place (Figure 29). To confirm desired alignment and placement of the tibial guide, insert the Vanguard 1/4 inch alignment rod in the alignment guide hole.

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

**Note:** The Universal Drill guide may also be used in the anterior tibial positioning guide holes if so desired.

Place the drill guide onto the Signature tibial rotation positioning guide holes located on the tibial plateaus. Drill the ⅛ inch pins through the corresponding holes (Figure 30), then remove rotation pins, drill guides and Signature tibial positioning guide, leaving anterior pins in place.
Tibial Preparation (cont.)

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 31).

Slide the tibial cut block onto the pins using the middle hole location and make the corresponding resection (Figure 32).

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 (cont.)

To carry-out planned tibial rotation, locate the previously drilled tibial rotation holes marked with methylene blue and insert the 3/8 inch pins. Slide the anterior holes of the previously determined size punch-through trial plate over the pins. To determine accuracy of rotation, place an alignment rod through the corresponding hole (Figure 33).

Note: Tibial rotation pin location is size, rotation and position specific based upon planned parameters. Intraoperative change of size may result in a different pin location compared to plan.

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 34). 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>BOI0428.1</td>
<td>Microplasty Elite Total Knee Instrumentation Surgical Technique</td>
</tr>
<tr>
<td>BOI0427.1</td>
<td>Premier Total Knee Instrumentation Surgical Technique</td>
</tr>
<tr>
<td>BOI0429.1</td>
<td>Microplasty Total Knee Instrumentation Surgical Technique</td>
</tr>
</tbody>
</table>
**Signature MRI-based Cut-through Guides**

**Signature Bone Models**

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 cut-through femoral and tibial guide registration (Figure 35).

**Note:** The Signature cut-through femoral and tibial guides were designed to register on the osteophytes. Therefore, do not remove the osteophytes at this stage.

**Note:** The Signature cut-through femoral and tibial 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

**MRI-based Femoral Cut-through Guides**

Register the Signature MRI-based cut-through femoral guide on the femur. The Signature femoral cut-through guide is designed to register in one unique location on cartilage, where present, and on bone where cartilage is absent.
Femoral Preparation (cont.)

Once the optimal position of the Signature cut-through femoral 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 37). Malpositioning of the Signature cut-through femoral guide during pinning may lead to malposition of the femoral component.

**Note:** Spring pins or \( \frac{1}{8} \) inch trochar pins may be used to secure the distal portion of the Signature cut-through femoral 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 anterior holes of the Signature cut-through femoral guide and drill two \( \frac{3}{8} \) inch trochar pins through the guide (Figure 38).

**Note:** \( \frac{3}{8} \) inch drill pins or \( \frac{1}{8} \) inch trochar pins may be used to secure the anterior portion of the Signature cut-through femoral guide to the femur.
Femoral Preparation (cont.)

Remove the distal pins. Insert the saw blade into the cut slot before engaging power. Execute the distal cut through the cut slot in the Signature cut-through femoral guide. (Figure 39).

**Note:** Before making the distal cut, ensure orientation and bone resection level. If more or less bone removal is desired, simply remove the Signature cut-through femoral guide and attach the corresponding distal cut block based on the surgeon’s preference. The Signature cut-through femoral resection approved in the pre-op plan corresponds with the zero slot (most distal) and middle hole locations on the distal femoral cut block. Move the femoral cut block to the top or bottom holes to remove more or less bone respectively.

Remove the Signature cut-through guide and anterior pins. Locate the previously drilled distal holes (Figure 40). Pulsatile lavage and/or bulb syringe may be used to clear debris from the distal holes in preparation for the four-in-one pins.

**Note:** If additional distal resection is necessary, attach the corresponding distal cut block based on the surgeon’s preference onto the anterior pin, using the most distal hole locations on the cut block.
Place the four-in-one block in the distal holes and make the corresponding cuts (Figure 42).

**Note:** The Premier four-in-one block may also 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.

**Femoral Preparation (cont.)**

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 41). 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.
Once the optimal position for the Signature cut-through tibial guide has been established, drill ⅛ inch trochar pins through the parallel anterior holes in the Signature cut-through tibial guide. The most distal pin hole may also be utilized for additional guide stability during tibial plateau resection (Figure 44).

Tibial Preparation

MRI-based Tibial Cut-through Guides

Ensure that soft tissue is removed from the anterior tibia to allow for optimal Signature cut-through tibial guide registration on the anterior bone (Figure 43).

Once the optimal position for the Signature cut-through tibial guide has been established, drill ⅛ inch trochar pins through the parallel anterior holes in the Signature cut-through tibial guide. The most distal pin hole may also be utilized for additional guide stability during tibial plateau resection (Figure 44).
Tibial Preparation (cont.)

Place the drill guide into the Signature cut-through tibial rotation guide holes located on the tibial plateaus. Drill the $\frac{1}{8}$ inch pins through the corresponding holes, then remove the drill guide and rotation pins (Figure 45).

Insert the saw blade into the cut slot before engaging power. Execute the proximal tibial resection through the cut slot in the Signature cut-through tibial guide (Figure 46).

**Note:** Before making the tibial cut, ensure orientation and bone resection level. If more or less bone removal is desired, simply remove the Signature cut-through tibial guide and slide the tibial cut block onto the pins. The approved Signature cut-through tibial resection corresponds with the middle hole location on the tibia cut block. Move the tibial cut block to the top or bottom holes to remove more or less bone respectively.

Remove the Signature cut-through tibial guide.
**Tibial Preparation (cont.)**

To carry out planned tibial rotation, locate the previously drilled tibial rotation holes and insert the ¼ inch pins. Slide the anterior holes, of the previously determined size punch-through trial plate over the pins. For rotation positioning, place an alignment rod through the corresponding hole (Figure 47). 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.

**Note:** Tibial rotation pin location is size, rotation and position specific based upon planned parameters. Intraoperative change of size may result in a different pin location compared to plan.

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**Trial Reduction**

Trial and balance the knee (Figure 48). Reference the Vanguard Complete Knee System surgical techniques for implantation and cementing process as follows:

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<th>Part Number</th>
<th>Description</th>
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<tr>
<td>BOI0428.1</td>
<td>Microplasty Elite Total Knee Instrumentation Surgical Technique</td>
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<td>BOI0427.1</td>
<td>Premier Total Knee Instrumentation Surgical Technique</td>
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## Ordering Information

### Instruments

#### Pins

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<td>1/8 inch Drill Pins, Sterile (Each)</td>
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<tr>
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<td>1/8 inch Drill Pins, Non-sterile (Pack of six)</td>
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<td>Trochar Pins (Pack of two)</td>
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<td>Collared Drill Pins (Each)</td>
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*Optional

#### Femoral/Tibial Drill Guide

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<td>Microplasty Elite Anatomic Drill Guide</td>
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Instruments (cont.)

Femoral Cut Block Options

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<td>Slidex Distal Femoral Resector</td>
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<td>Microplasty Fixed Distal Resector</td>
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<td>32-484000</td>
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## Signature MRI-based Cut-through Guides

### Instruments (cont.)

### Tibial Cut Block Options

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<td>Microplasty Tibial Resection Head (Anatomic), Left</td>
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<td>32-484554</td>
<td>Microplasty Elite Universal Closed Resection Block</td>
</tr>
<tr>
<td><img src="image9.png" alt="Image" /></td>
<td>32-484553</td>
<td>Microplasty Elite Universal Open Resection Block</td>
</tr>
</tbody>
</table>