



BKS® Total PSI

Surgical Technique



The following surgical technique is an addendum to the BKS[®] and BKS TriMax[®] Surgical Techniques designed for use with the BKS[®] Total PSI instrumentation as indicated in the preoperative plan provided by Ortho Development.

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Device Description

The BKS Total PSI Guide Set is a patient-matched device designed to fit the patient's anatomy and transfer a patient-specific preoperative plan to the operating room. It is intended for surgical interventions in orthopedic procedures for total knee arthroplasty in skeletally mature patients. The guide set includes patient-specific femoral and tibial bone models.

Indications for Use

The device is intended to be used as a surgical instrument to assist in the intraoperative positioning of total knee replacement components and in guiding the marking of bone before cutting.

The device must be used in conjunction with the compatible Ortho Development prostheses families only: BKS® CR and BKS® PS, BKS TriMax® CR and BKS TriMax® PS. The device is single use only.

Contraindications

Do not use if the anatomic landmarks necessary for alignment and positioning of the implant and pin guides are not identifiable on the MRI preoperative scan.

Do not use in case of active infection of the knee joint area.

For a detailed list of contraindications pertaining to the knee system itself, please refer to the Balanced Knee System Instructions for Use.

General Considerations

This document describes the surgical technique for the BKS Total PSI Guides for Total Knee Arthroplasty (TKA).

The figures contained in this surgical technique describe the procedure using standard pin positions.

The same surgical technique is applicable for all pin guides.



Figure 1: BKS Total PSI Femur and Tibia Guides

A conventional incision is made for exposure of the knee joint following the conventional technique of the implant used.

BKS Total PSI Guides are designed and produced to transfer the preoperative TKA surgical plan to the patient (Figure 1). Final component orientation and position are evaluated intraoperatively.

The BKS Total PSI Guides are used in conjunction with a femur first surgical technique.

The BKS Total PSI Guides are developed to be compatible with the neutral (0°) Cut Guides and neutral (0mm) pin locations on the Cut Guides. All orientations and resections are planned in the planning software and incorporated into the BKS Total PSI Guides. Intraoperative changes to the approved plan can be made by using other Cutting Blocks or pin locations.

The surgeon is able to revert to conventional instrumentation and procedure at all times.

Prior to exposure, verify that the patient ID on the BKS Total PSI Guides match the patient ID on the surgical report and the patient on the table.

Following exposure of the femur and tibia according to the applicable surgical technique, proceed to remove soft tissues on the bone that may prevent sufficient contact with the PSI Guide such as fat tissue and meniscus. Avoid removing any osteophytes or cartilage to keep in place bony anatomy used in planning and creating the guides.

Technical Tip: If the bone model is significantly different from the anatomy of the bone intraoperatively, it is not recommended to use the BKS Total PSI Guides. The standard instrumentation for the applicable surgical technique should be used.

Femoral Preparation

The anatomy is prepared by removing tissue, excluding cartilage and osteophytes, in the BKS Total PSI Femur Guide support regions.

Position BKS Total PSI Femur Guide

Seat the BKS Total PSI Femur Guide on the distal femur until the most stable position is achieved. The Femur Guide will be captured by the anterior ridge of the femur (Figure 2). Apply pressure to the pressure point of the BKS Total PSI Femur Guide to verify a secure fit (Figure 3).

Technical Tip: Whiteside's line and the EPI axis on the Femur Guide may be used to assess alignment. Reference axes may be colored prior to positioning using a surgical marker to increase visibility while positioning intraoperatively (Figure 4).

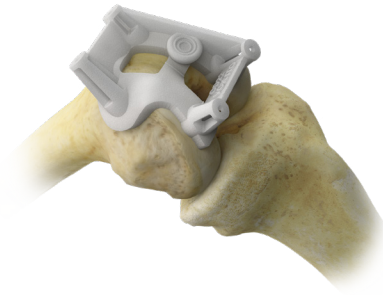


Figure 2: Contact Surface of the Femur Guide on the Bone

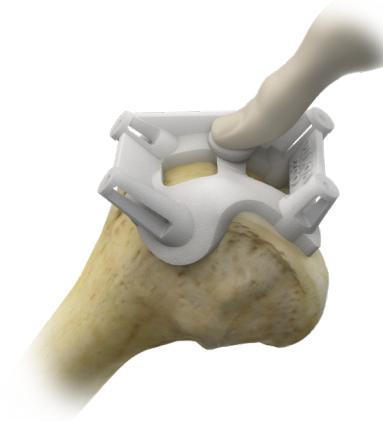


Figure 3: Pressure on the Femur Guide

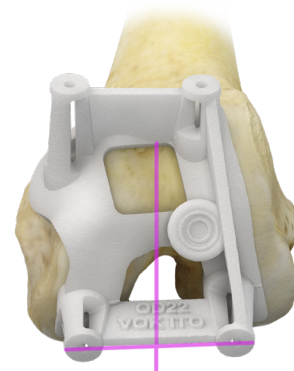


Figure 4: Mark of Whiteside's Line and EPI Axis Colored on the Femur Guide

Drill and Pin Anterior Pinholes

Holding the Femur Guide securely in position, drill the first anterior pinhole leaving the pin in place (Figure 5). If a pinhole is on top of osteophytes, drill the other anterior pinhole first.

While still holding the Femur Guide in place, drill the second anterior pinhole and leave the pin in place.

Note: The recommended depth of drilling for the distal pinholes is approximately 35 mm.

Technical Tip: Irrigation may be used during drilling to clear debris and reduce heat from the drill.

Drill Distal Pinholes

Following the drilling and placement of the anterior pins, drill both of the distal pinholes one after the other without leaving any pins in place.

Note: The recommended depth of drilling for the distal pinholes is approximately 35 mm. No pinning is required for the distal pinholes.

After drilling both anterior and distal pinholes, slide the guide off the anterior pins.

Technical Tip: Due to patient anatomy and instrument parameters, sliding the guide off may be difficult. In this event, remove the anterior pins before removing the Femur Guide, then reinsert the anterior pins into the drilled pinholes.

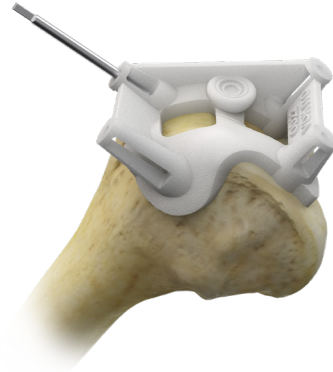


Figure 5: Drilling and Placement of One of the Anterior Pins Through the Femur Guide

Place Distal Cut Block and Cut Femur

Place the Distal Cut Block over the anterior pins, evaluate orientation and resection level and perform the distal cut (Figure 6). Remove the Distal Cut Block. Remove the anterior pins.

Place 4-in-1 Cutting Block and Cut Femur

Select the appropriate size 4-in-1 Cutting Block as determined during planning. Choose either a pinned or pegged style Cutting Block. Find the distal pinholes on the distal cut surface of the femur.

If using the pinned 4-in-1 Cutting Block, place one pin in each of the previously drilled distal pinholes. Place the 4-in-1 Cutting Block over the pins and onto the cut surface.

If using the pegged 4-in-1 Cutting Blocks, line up the pegs with the existing pinholes and press the pegs into the holes.

Technical Tip: Clean the area if the pinholes are covered following the distal cut. Drilled holes may be colored with a surgical marker to increase visibility.

Evaluate sizing and resection levels by checking notching with a Cut Feeler Gage. Make the remaining cuts using the selected 4-in-1 Cutting Block. Proceed with the conventional femur surgical technique as defined in the preoperative plan.

Technical Tip: If unsure about sizing, revert to conventional instrumentation.



Figure 6: Distal Cut Using Distal Cut Block

Tibia Preparation

To prepare the tibia, make sure any soft tissue has been removed, including the anterior cruciate ligament, the menisci and soft tissue on the anterior shaft at the medial side of the tuberosity. Avoid removing any osteophytes and cartilage.

Position BKS Total PSI Tibia Guide

Position the BKS Total PSI Tibia Guide on the tibia until the most stable position is achieved (Figure 7). Apply pressure to the pressure point of the BKS Total PSI Tibia Guide to verify a secure fit (Figure 8).

Technical Tip: The AP axis and proximal resection line on the Tibia Guide may be used to assess alignment. Reference axes may be colored prior to positioning using a surgical marker to increase the visibility while positioning intraoperatively (Figure 9).



Figure 7: Contact Surface of the Tibia Guide on the Bone



Figure 8: Pressure on the Tibia Guide

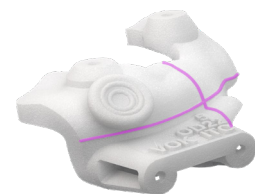


Figure 9: Colored Mark of AP Axis and Proximal Cut on the Guide

Drill and Pin Lateral and Medial Pinholes

While holding the BKS Total PSI Tibia Guide in position, drill the lateral pinhole on the anterior of the Tibia Guide leaving the pin in place (Figure 10). Follow by drilling the medial pinhole leaving the pin in place.

Technical Tip: Irrigation may be used during drilling to clear debris and reduce heat from the drill.

Establish Tibia Rotation

Drill the rotational pinholes for Tibial Tray placement if desired without leaving the pins in place.

Note: The recommended depth of drilling is approximately 35 mm.



Figure 10: Insert the Lateral Pin Before Drilling the Medial Pin

Remove BKS Total PSI Tibia Guide

After placing and drilling pins, slide the Tibia Guide off of the anterior tibia pins.

Technical Tip: Due to the combination of patient anatomy and instrument parameters, some Tibia Guides may be more difficult to slide off the pins. In this event, remove the anterior tibia pins before removing the Tibia Guide. Following the removal of the Tibia Guide, find the anterior tibial pinholes and reinsert the pins in the pinholes. Avoid bending pins to maintain accuracy of the guide pins.



Figure 11: Proximal Tibial Cut

Secure Cut Guide and Cut Tibia

Slide the Proximal Tibial Cut Guide over the anterior tibial pins to be flush with the anterior of the proximal tibia. Evaluate orientation and resection level using a cut feeler gauge if desired. Proceed to make the proximal tibial cut using the appropriate resection level on the Proximal Tibia Cut Guide (Figure 11).

Proceed with conventional tibial surgical procedure as indicated in the preoperative plan.

Position Tibial Tray Trial

After removing the Proximal Tibial Cut Guide and anterior tibial pins, place the planned Tibial Tray Trial and secure using Headed Pins placed in the previously prepared rotational pinholes. Proceed with conventional tibial surgical procedure as indicated in the preoperative plan.



Ortho Development® Corporation designs, manufactures, and distributes orthopedic implants and related surgical instrumentation—with a specialty focus on hip and knee joint replacement, trauma fracture repair, and basic spinal fixation. Ortho was founded in 1994 and is located at the base of the Wasatch Mountains in the Salt Lake City suburb of Draper, Utah. The company has established distribution throughout the United States and Japan, along with other select international markets.



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