

Smith
Nephew

VISIONAIRE[¢] Adaptive Guides

Surgical Technique

For Total Knee Systems:

GENESIS^{\$} II Total Knee System LEGION^{\$} Total Knee System JOURNEY^{\$} II Total Knee System ANTHEM^{\$} Total Knee Systems

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Smith+Nephew VISIONAIRE[◊] Adaptive Guides are used as a patient-specific surgical instrument to assist in the positioning of total knee replacement components intraoperatively 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 VISIONAIRE Adaptive Guides are indicated for use with the following existing Smith+Nephew knee systems and their cleared indications for use: GENESIS[¢] II Total Knee System, LEGION[¢] Total Knee System, and JOURNEY[¢] II Total Knee Systems. VISIONAIRE Adaptive Guides are available for use with ANTHEM[¢] Total Knee System in select markets outside the United States.

The VISIONAIRE sample guides and bone models are intended to inform the surgeon of the expected fit of the VISIONAIRE guide on the patient's anatomy. The bone models represent the intended contact areas of the VISIONAIRE guide and are not intended to inform clinical investigation of the knee anatomy.

Nota Bene

The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the VISIONAIRE Adaptive Guides, including its indications for use, contraindications, and product safety information, please refer to the product's label and the Instructions for Use.

Note: Please verify the case information and labeling matches the information inscribed on the part.

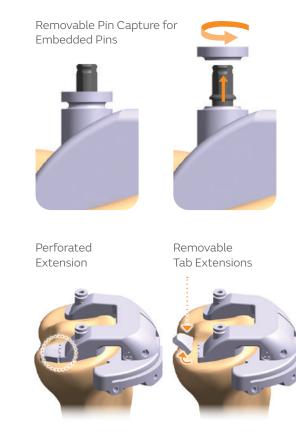
Note: It is recommended that a sterile back-up instrument set be made available nearby in the event that an Adaptive Guide is intraoperatively determined to be unsuitable for intended use.

Tip: Do not remove osteophytes before evaluating guide fit. If an osteophyte prevents proper fit, remove only the interfering osteophyte before reevaluating fit.

Tip: Avoid over-driving rimmed speed pins. If over-driven into the guide, rimmed speed pins can be extracted by removing the pin capture using a rongeur and backing them out with the driver.

Tip: Paddle extensions are perforated to allow optional removal prior to placement.

For a full list of guide preferences available refer to Appendix A.



Positioning and Exposure

1. Flex the knee.

2. Carefully remove only soft tissue from the anterior femur cortex which may prevent proper guide fit.

Pinning and Drilling

3. Place the femur guide on the distal femur by pushing the guide into the trochlear groove and down on the distal condyles.

Note: The proximal contact area of the femur guide should contact the anterior cortex to prevent unintended flexion.

Tip: The alignment rod may be used to verify alignment before pinning the femur guide (see Step 6).

4. While the femur guide is firmly held in place, secure the femur guide distally by inserting pins into the distal holes.

Note: The distal pin holes of the femur guide correspond to the spikes of the femur A/P cutting guide associated with the implant. Insert pins deeper than the resection plane.

Tip: It is best for the surgeon to hold the femur guide while an assistant pins.



Step 3



Step 4



Tip: Use of the anterior oblique pin is optional for additional security if desired.



Step 5

Resection

pin fixation.

6. Use the external alignment rod to verify proper alignment prior to making the distal resection.

Note: The A/P etch line points to the Rod when assembled correctly and is oriented neutral to the planned alignment of the femur implant. The M/L etch line length is equal to the M/L width of the planned femur implant. The rotation of the M/L etch line is parallel to the preoperatively determined transepicondylar axis.

Note: If interference occurs between soft tissue and the alignment rod, the Quick Connect Handle (71440044) can be mated with the VISIONAIRE⁽⁾ alignment connector for additional clearance.

Alignment Rod Assembly



Insert alignment guide



Use light pressure when inserting connector into guide

Step 6



Step 7

8. After completing the resection, remove the femur guide and complete the procedure per the surgical technique recommended for the implant, taking care to ensure resection alignment is acceptable.

7. Remove one distal pin prior to beginning the distal resection. To complete the resection, move the remaining distal pin to the opposite side of the femur guide to preserve three

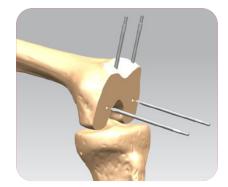
Note: The anterior parallel pin holes created through the femur guide correspond to the standard distal cutting block associated with the implant. See Appendix A for the list of available standard guides.



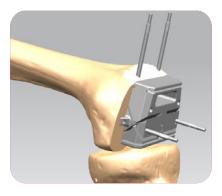
Step 8

Additional ANTHEM^{\$} Total Knee System Instructions for Femur Guide

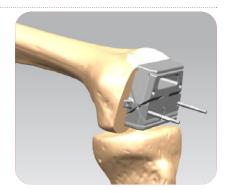
9. For ANTHEM Total Knee System, first re-insert non-headed pins into the pre-drilled distal pin holes, then slide the Orthomatch 4-in-1 cut block on to the distal femur.



Step 9a



Step 9b



Step 10

10. Remove the anterior pins and complete the procedure per the recommended ANTHEM Total Knee System Surgical Technique.

See Appendix B for a pin placement guide.

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Positioning and Exposure

- 1. Sublux the tibia.
- 2. Remove the meniscus, including the posterior medial meniscus.
- 3. Carefully remove only soft tissue from the anterior tibia cortex which may prevent proper guide fit.

Placement and Pinning

4. Place the tibia guide on the proximal tibia. The primary key contact area for the tibia guide is the anterior medial tibial cortex, the secondary contact area are the medial and lateral plateau.

Note: The key contact areas of the tibia guide should be mated flush to the corresponding anatomy. If not, remove only osteophytes or soft tissue which may be preventing proper fit.

Tip: The alignment rod may be used to verify alignment before pinning the tibia guide (see Step 7).

5. While the tibia guide is firmly held in place, secure the guide proximally by inserting pins into the proximal holes.

Note: With the exception of the TCF Guide, the proximal pin holes correspond to the pin holes of the tibial baseplate trial associated with the implant. Insert pins deeper than the resection plane.

Tip: It is best for the surgeon to hold the tibia guide while an assistant pins.

6. Secure the tibia guide anteriorly by inserting headless pins into the appropriate anterior parallel pin holes.

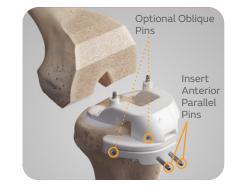
Tip: Use of one or more oblique anterior pin holes with short headed pins is optional for added security if desired.



Step 5

DCF Approach

Step 4







TCF Approach

Tibia Guide (continued)

7. Use the external alignment rod to verify proper alignment prior to making the proximal resection.

Note: The anterior line corresponds to the sagittal mid-plane of the tibial implant and the intended M/L position of the alignment rod.

Tip: The medial side of the guide includes a symbol which indicates that the Alignment Rod will align either Parallel \parallel to the tibia mechanical axis or Perpendicular \perp to the cutting slot.





Resection for Cruciate-Retaining (CR), Posterior-Stabilized (PS) or Bi-Cruciate-Stabilized (BCS) Tibia

 Remove one distal pin prior to beginning the distal resection. To complete the resection, move the remaining distal pin to the opposite side of the femur guide to preserve three pin fixation.



Step 8

9. After completing the resection, remove the tibia guide and complete the procedure per the surgical technique recommended for the implant, taking care to ensure resection alignment is acceptable.

Note: For ANTHEM[¢] CR or PS, the proximal pin holes align with the anterior pin hole location on the Orthomatch Stemless Tibia Trials.

Tip: The anterior parallel pin holes created through the tibia guide correspond to the standard proximal tibia cutting guide specified for the case. See Appendix A for the list of available standard guides.



Step 9

Pin Positioning for Bi-Cruciate Retaining (XR) Tibia

10. Mark the tibia with the M/L and A/P position of the tibial eminence to be preserved using the 'goal post' feature of the guide. Mark the internal/external rotation of the tibia eminence to be preserved using the straight inside edge of the proximal medial paddle. Pin through the XR anterior parallel pin holes labelled 'XR'.

Note: Verify that the ACL is viable before proceeding. If not, continue with the JOURNEY⁶ II Cruciate Retaining Knee System or JOURNEY II Bi-Cruciate Stabilized Knee System technique using the non-XR anterior parallel pin holes.



Step 10a



Step 10b

Drill

Step 11a

Potential damage: Verify guide placement does not interfere with ACL.



Step 11b

Incorrect Position and Rotation – Do NOT Drill

11. If satisfied with the position and rotation of the tibia eminence to be preserved relative to the ACL footprint, predrill through the pin hole lateral to the cut slot using a 1/8" (3.2mm) drill or 110mm Headless Speed Pin.

Note: The ACL may be obscured in the MRI, therefore the VISIONAIRE[¢] Engineer sets the rotation and placement as a result of best fit for the asymmetric base plate.

Tibia Guide (continued)

12. Remove the guide and mate the 3° Datum Block to the anterior parallel pins. Center the XR Orientation Stylus on the 'goal post' mark and orientate the arms parallel with the medial line. Complete the procedure using the JOURNEY^o II XR^o Bi-Cruciate Retaining Knee System surgical technique taking care to ensure resection alignment is acceptable.

Note: The Adaptive Guide XR pin guide is designed to match the 3° XR Datum Block. If additional slope is needed, the 5° XR Datum Block should be used as a recut guide.

Tip: If predrilled, the pin hole in-line with the cut slot can be used to position and rotate the Orientation Stylus.

Tip: Later in the XR Technique, use the 'goal post' marking to position the XR Anterior Eminence Chisel.



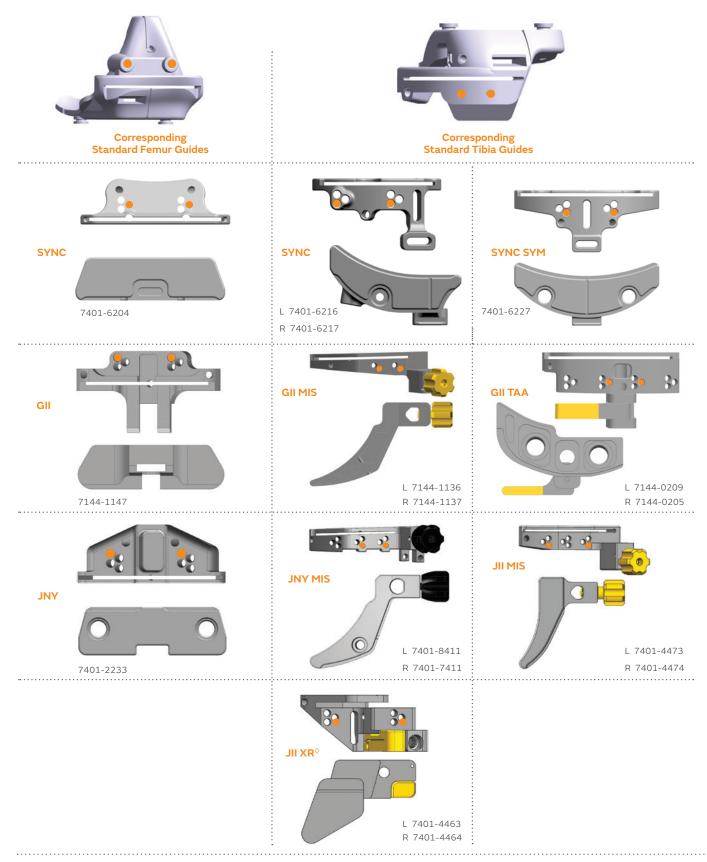
Step 12a



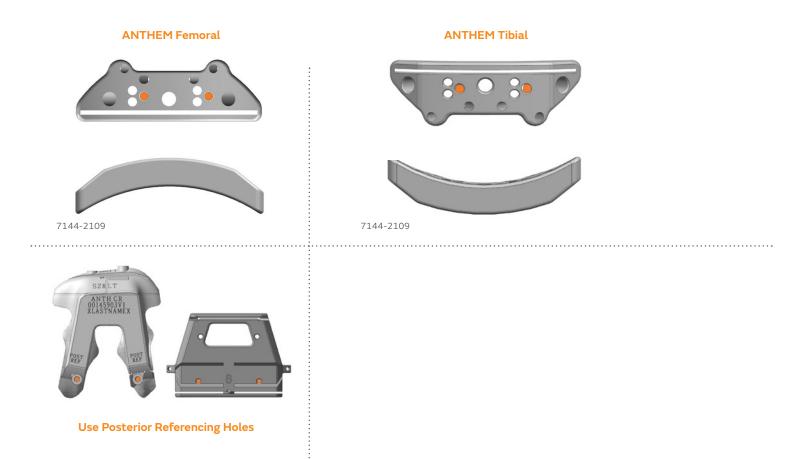
Step 12b

Appendix A: Standard Distal Femur and Proximal Tibia Resection Guides

VISIONAIRE⁶ Adaptive Guides provide anterior parallel pin holes which correspond to Smith+Nephew conventional distal femur and proximal tibia resection guides. On the anterior face of each Adaptive Guide, the conventional resection guide intended for use is labeled. Below are pictured the standard resection guides which correspond to each text label.



Appendix B: ANTHEM^{\$} Standard Distal Femur and Proximal Tibia Resection Guides



Appendix C: Adaptive Femur and Tibia Guide Surgeon Design Preferences



Catalog Items

71440302	VISIONAIRE Lightweight Alignment Rod
71440303	VISIONAIRE Alignment Connector
VISIONAIRE Adaptive G	uide Case Specific Samples
V0100103	VISIONAIRE Adaptive Guide Sample Bone And Cutting Guide
VISIONAIRE Adaptive G	uide Sterile Part Numbers
V0100104	VISIONAIRE Adaptive Guide Distal Femur GENESIS ⁰ II
V0100105	VISIONAIRE Adaptive Guide Proximal Tibia GENESIS II
V0100106	VISIONAIRE Adaptive Guide Kit GENESIS II
V0100107	VISIONAIRE Adaptive Guide Distal Femur LEGION ^o Primary
V0100108	VISIONAIREz Adaptive Guide Proximal Tibia LEGION Primary
V0100109	VISIONAIRE Adaptive Guide Kit LEGION Primary
V0100110	VISIONAIRE Adaptive Guide Distal Femur JOURNEY [©] II
V0100111	VISIONAIRE Adaptive Guide Proximal Tibial JOURNEY II
V0100112	VISIONAIRE Adaptive Guide Kit JOURNEY II
V0100125	VISIONAIRE Adaptive Guide Distal Femur ANTHEM ⁶
V0100126	VISIONAIRE Adaptive Guide Proximal Tibia ANTHEM
V0100127	VISIONAIRE Adaptive Guide Kit ANTHEM

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V0200104	Nonsterile VISIONAIRE Adaptive Guide Distal Femur GENESIS [®] II
V0200105	Nonsterile VISIONAIRE Adaptive Guide Proximal Tibia GENESIS II
V0200106	Nonsterile VISIONAIRE Adaptive Guide Kit GENESIS II
V0200107	Nonsterile VISIONAIRE Adaptive Guide Distal Femur LEGION ^o Primary
V0200108	Nonsterile VISIONAIRE Adaptive Guide Proximal Tibia LEGION Primary
V0200109	Nonsterile VISIONAIRE Adaptive Guide Kit LEGION Primary
V0200110	Nonsterile VISIONAIRE Adaptive Guide Distal Femur JOURNEY [©] II
V0200111	Nonsterile VISIONAIRE Adaptive Guide Proximal Tibial JOURNEY II
V0200112	Nonsterile VISIONAIRE Adaptive Guide Kit JOURNEY II
V0200125	Nonsterile VISIONAIRE Adaptive Guide Distal Femur ANTHEM ^o
V0200126	Nonsterile VISIONAIRE Adaptive Guide Proximal Tibia ANTHEM
V0200127	Nonsterile VISIONAIRE Adaptive Guide Kit ANTHEM
SPEED PIN Adaptors	
74013489	SPEED PIN Quick Connect
74016461	SPEED PIN Quick Connect
Headed SPEED PIN	
74013471	45mm
74013472	65mm
74016465	MIS 45mm
74016466	MIS 65mm
Non-Headed SPEED PIN	
74013480	65mm
Drill Bit	
114969	3.2mm X 76mm
Trocar Pin	
71210002	GEN TROCAR Pin 1/8 X 3
74016461	3.2mm X 75mm

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