Prophecy® aMP™ & eMP™

Preoperative Navigation Guides

Surgical Technique

MicroPort Orthopedics

Full Function, Faster®

PROPHECY® aMP™ & **eMP™**

Preoperative Navigation Guides

SURGICAL TECHNIQUE

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience and patient condition. Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions For Use package inserts are also available by contacting the manufacturer.

Contact information can be found on the back of this Surgical Technique and the Instructions For Use package inserts are available on the website listed.

Please contact your local MicroPort Orthopedics representative/distributor for product availability.

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Product Information

GENERAL PRODUCT INFORMATION

MicroPort Orthopedic's PROPHECY® Preoperative Navigation Guides are designed for single use only. They are manufactured with certain patient-specific features, which renders them unusable in patients other than those for whom they were designed. These surgical instruments are supplied clean and non-sterile, and must be sterilized before use. After use, these instruments must be properly disposed of. The following information outlines the proper steps for processing MicroPort Orthopedics disposable surgical instruments.

A. INTENDED USE

IMPORTANT Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions for Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the Instructions for Use package insert is available on the website listed.

MicroPort Orthopedic's PROPHECY® Preoperative Navigation Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting. The PROPHECY® Preoperative Navigation Guides are intended for use with either MicroPort Orthopedic's aMP™ or eMP™ Total Knee Systems and their cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. The PROPHECY® Preoperative Navigation Guides are intended for single use only.

B. LIMITATIONS AND RESTRICTIONS OF REPROCESSING

The medical provider must match the case number provided on design paperwork with the case number on the device labeling. End of functional life is intended to be the conclusion of the case for which the device was designed. These instruments are created based on patient-specific data which may be subject to change at varying rates depending on the patient condition. It is up to the medical provider to determine if the patient's condition or anatomy may have changed sufficiently to require redesign of the device. Extreme care should be taken not to drop or contaminate the device during surgery. All unused devices must be destroyed upon the conclusion of the case for which the devices were designed.

C. PACKAGING

MicroPort Orthopedics packaging is intended to protect instrumentation during shipping. Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material, including a reusable rigid container system, is validated for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to assure that conditions essential to sterilization can be achieved. MicroPort Orthopedics does not accept responsibility or liability arising from a lack of sterility of any medical devices supplied by MicroPort Orthopedics that should have been sterilized by the end user.

D. CLEANING (European Union Only)

Additional manual cleaning instructions can be found in the Instructions For Use package inserts are available on the website listed on the back of this Surgical Technique.

E. STERILIZATION

MicroPort Orthopedics instruments manufactured from Nylon may be steam sterilized with no detrimental effects. All items to be sterilized must be packaged appropriately for the type of sterilization. The package must permit contact of the sterilant with the item, while also serving as a barrier to microorganisms, during any storage period. Users should wear non-linting gloves, i.e. Latex or Nitrile, when handling instruments, to minimize bioburden and particulates.

WARNINGS

• When handling instruments use extreme caution to avoid injury: consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.

STEAM STERILIZATION

The minimum recommended steam sterilization conditions for MicroPort Orthopedics instruments are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or a similar type non-woven medical grade wrapping material.

2. Autoclave according to the following parameters:

Steam Sterilization		
Prevacuum 270˚F (132 ˚C)	Preconditioning Pulses	3
	Exposure Temperature	270˚F (132 ˚C)
	Exposure Time	4 minutes
	Dry Time	16 minutes

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with AAMI TIR 12: 2010, Table 5, Row 1 and have been developed and validated using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

F. STORAGE

Surgical instruments that will not be utilized within a short time should be stored clean, and completely dry. The packaging that items are in may offer an effective barrier to prevent contamination of the item. The type of packaging required for steam sterilization is an FDA-cleared CSR wrap or non-woven medical grade wrapping material. This packaging type offers a level of protection from contamination, which must be consistent with the final intent of the item. The surgical instruments must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

G. REFERENCES

ISO 17664:2017(E) Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices

AAMI TIR 12:2010 Designing, testing and labeling reusable medical devices for reprocessing in healthcare facilities: A guide for device manufacturers

ANSI/AAMI/ISO17665-1:2006, Sterilization of health care products - Moist heat - Part 1 Requirements for the development, validation and routine control of a sterilization process for medical devices

Scan Protocols

CT Scan Protocol

PROPHECY® Preoperative Navigation Guides are patient specific instruments designed for total knee replacement surgery. One significant requirement for a successful case is adhering to the CT scan protocol. Engineers at MicroPort Orthopedics have determined the necessary scanning parameters which are described in this document.

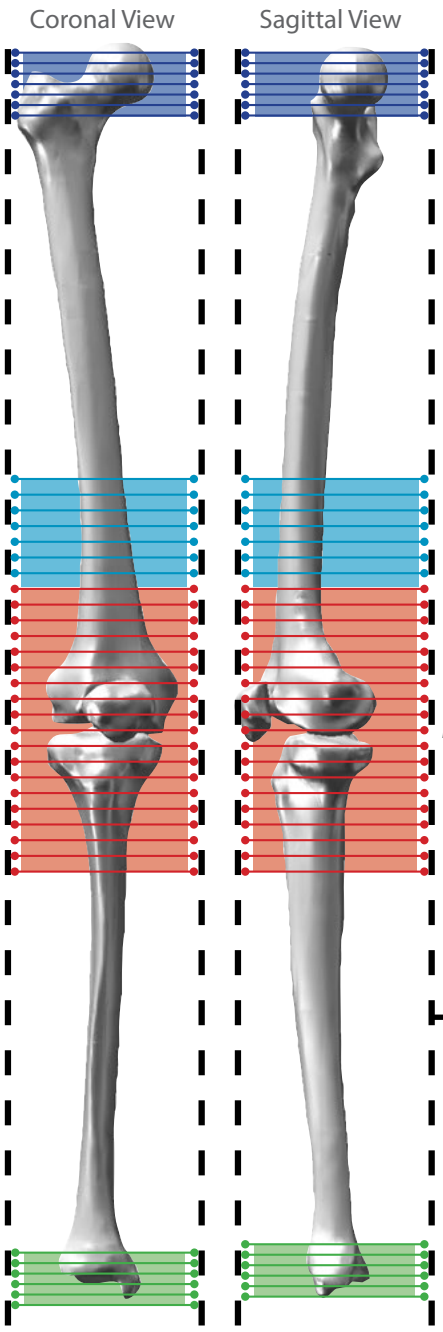
In every case, please follow these general instructions:

- **Maintain a single coordinate system for all scans**
  - **If possible, all group edges should be the same Increasing the width of some groups is acceptable to ensure the borders are aligned**
- **Maintain a consistent pixel size**
- **Use Bone Contrast, not Standard Contrast**
- **Helical and Axial reconstruction are acceptable**
- **Do not allow patient movement between or during scans**
- **Include coronal and sagittal scout images of the hip to ankle when submitting files to MicroPort Orthopedics**
- **If contralateral implant is present, bend contralateral limb out of the field of view of the knee to be scanned**

CONTACT FOR ASSISTANCE:
MicroPort Orthopedics
5677 Airline Road
Arlington TN, USA 38002
+1866.872.0211

CT Scan Protocol

NOTE: All scan locations (hip, femur, knee and ankle) are necessary.



Proximal Femoral Head

5mm or less slice increment

Distal Femoral Head

SCAN LOCATIONS: **HIP**
- o Slice increment: maximum slice thickness: **5mm or less**
- o Scan boundaries:
  - *minimum of 6 slices from proximal to distal femoral head*

19cm proximal to joint line

10mm or less slice increment

9cm Proximal to joint line

1.25mm or less slice increment

Knee joint line

1.25mm or less slice increment

9 cm Distal to joint line

SCAN LOCATIONS: **SHAFT**
- o Slice increment: maximum slice thickness: **10mm or less**
- o Scan boundaries:
  - *Start 19cm proximal to the joint line*
  - *End at the border of the knee scan (9cm proximal to joint line)*

SCAN LOCATIONS: **KNEE**
- o Slice increment: maximum slice thickness: **1.25mm or less**
- o Scan boundaries:
  - *9cm proximal and 9cm distal of joint line*

Maintain equal edges & same centers for all scan groups/windows

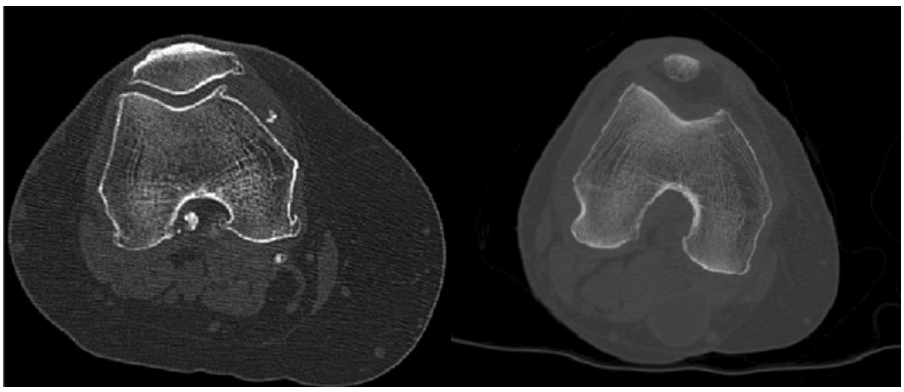
5cm Proximal to distal tibia

2.5mm or less slice increment

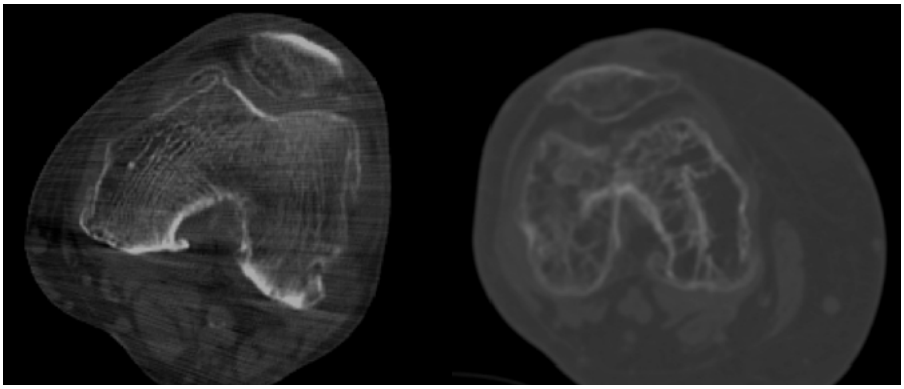
Distal most point of tibia

SCAN LOCATIONS: **ANKLE**
- o Slice increment: maximum slice thickness: **2.5mm or less**
- o Scan boundaries:
  - *Start 5cm above distal tibia*
  - *End at distal most tibial point*

CT Imaging Examples



Satisfactory CT Imaging
Quality images have clear, crisp bone dyes. Distinct boundaries between the bone and the surrounding soft tissue are apparent in these images.



Unacceptable CT imaging
Images are blurry and have poor contrast between the bone and the surrounding soft tissues. These images are difficult for the PROPHECY® guide engineers to segment out the three dimensional bone models.

NOTE: These images will not be accepted for processing by the PROPHECY® team.

Frequently Asked Questions

Q. "I can't put in a 1.25mm slice. I can only do a 1mm increment. Is that ok?"
A. Slices thinner than our specified slice thickness are acceptable.

Q. "Do we use axial or helical reconstruction?"
A. Either is acceptable.

Scan Protocols

MRI Scan Protocol

PROPHECY® aMP™ and PROPHECY® eMP™ Preoperative Navigation Guides are patient-specific instruments designed for total knee replacement surgery. One significant requirement for a successful case is adhering to the MRI scan protocol. Engineers at MicroPort Orthopedics have determined the necessary scanning parameters which are described in this document.

In every case, please follow these general instructions:

- Do not allow patient movement during all three axial scans - coordinate system must be retained.

- All three scan locations must be acquired (Hip, Knee, and Ankle).
  - Perform the three body coil scans successively prior to switching to the knee coil

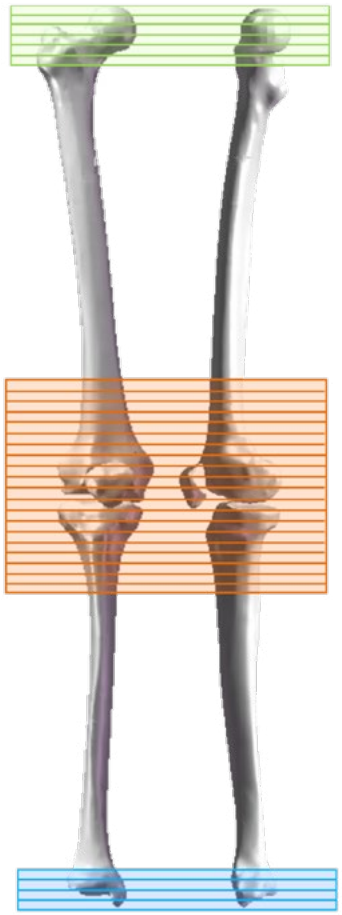
- No metal objects within 10 cm of the knee joint line.

**If the hip and ankle cannot be captured, anatomic alignment must be used.*

SCAN INFORMATION

NOTE: All scans locations (Hip, Knee and Ankle) are necessary

AP View ***Sagittal View***

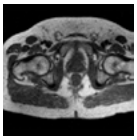


The patient cannot move between the three axial scan sequences and the machine cannot be reset between each axial scan. The coordinate system of the scans must be retained between all three axial acquisitions.

No metal objects within 10cm of the knee joint line.

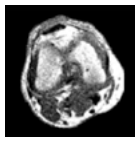
Scan Location: Hip

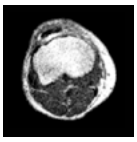
- Hip - Axial Slices
- Coil: Body
- Anatomic landmarks: Femoral head
- Slice thickness: 5mm
- Slice spacing: 3mm
- Scan boundaries: Must contain entire proximal femoral head
- Slices: Approximately 19



Scan Location: Axial Knee

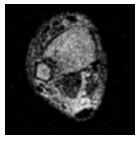
- Knee - Axial Slices
- Coil: Body
- Anatomic landmarks: Distal femur, proximal tibia
- Slice thickness: 5mm
- Slice spacing: 3mm
- Scan boundaries: Approximate field of view is 12cm proximal and 9cm distal to joint line
- Slices: Approximately 35-40



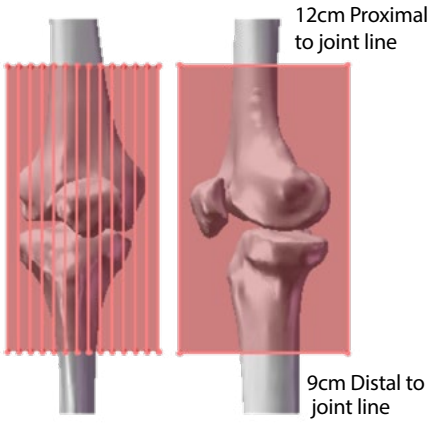


Scan Location: Ankle

- Ankle - Axial Slices
- Coil: Body
- Anatomic landmarks: Distal tibia
- Slice thickness: 5mm
- Slice spacing: 3mm
- Scan boundaries: 5cm proximal to the distal tibia through the distal most point of the tibia
- Slices: Approximately 19

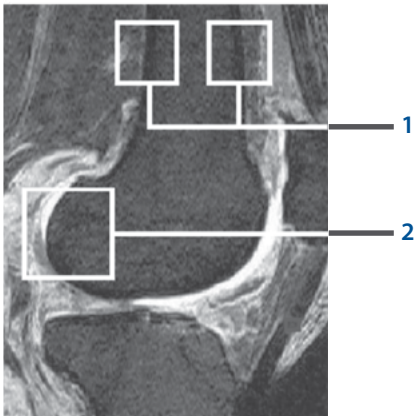


AP View ***Sagittal View***



Scan Location: Sagittal Knee

- Knee - Sagittal Slices
- Coil: Knee
- Anatomic landmarks: Patella and tibial tubercle
- Slice thickness: 2mm
- Slice spacing: 0mm
- Scan boundaries: Approximate field of view is 12cm proximal and 9 cm distal of joint line or the extent of the knee coil



NOTE: Distinguishable contrast between cartilage and bone

NOTE: T2 – weighted, fat- suppressed image with bright cartilage, dark bone (1) and with sufficient contrast between the bone and surrounding soft tissue in the regions specified (2).

MRI SCAN PROTOCOL

NOTE: Parameters listed in Table 1 & 2 are recommended for a 1.5 Tesla Magnet. Different magnetic field strength or scanner settings require variation of parameters to achieve quality images.

Table 1. MRI Scanner Settings

Scan ID	Knee Sagittal	Hip	Knee	Ankle
Coil	HD TR knee (RO coil preferred)	Body	Body	Body
Pulse Sequence	See Table 2 Below	See Table 2 Below	See Table 2 Below	See Table 2 Below
TR	15-500 ms	600 - 2700 (2 Acq)	600 - 2700 (2 Acq)	600 - 2700 (2 Acq)
TE	2-50 ms	min full	min full	min full
Plane	Sagittal	Axial	Axial	Axial
Slice Thickness	2	5	5	5
Slice Spacing	0	3	3	3
Matrix	512 x 256	256x256	256x256	256x256
Pixel Size	< 0.5 mm	< 2 mm	< 2 mm	< 2 mm
Acquisition time (min)	~ 9:00	< 6:00	< 6:00	< 6:00
Phase Encoding	AP	RL	RL	RL

Table 2. Pulse Sequence

Manufacturer	Knee Sagittal	Hip	Knee	Ankle
GE	3D SPGR FATSAT	2D FSE-XL (PD)	2D FSE-XL (PD)	2D FSE-XL (PD)
Siemens	3D FATSAT FLASH	TSE (PD)	TSE (PD)	TSE (PD)
Philips	3D-SPIR-FFE	TSE (PD)	TSE (PD)	TSE (PD)
Toshiba	RF Spoiled FE	FSE (PD)	FSE (PD)	FSE (PD)
Hitachi	GE/GFE	FSE (PD)	FSE (PD)	FSE (PD)

Submitting the Scan

NOTE: There are two options to choose from when submitting preoperative scans to MicroPort Orthopedics; either electronic transfer or standard mail. Either is acceptable.

Rapid Electronic Scan Transfer**
Preoperative CT and MRI scans may be sent to the PROPHECY® engineering team through our rapid electronic transfer system.
https://prophecyscans.ortho.microport.com

Please follow these steps to request an account and transfer scans:

1. E-mail *prophecyscans@ortho.microport.com* with the e-mail address of the person who needs access to the system (No other information is needed)

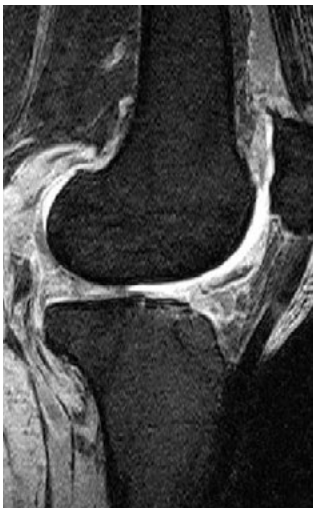
2. Within a few hours, an invitation message will be sent to that address with instructions on how to complete registration on the scan transfer site.

*** upload times may vary based on connection speed.*

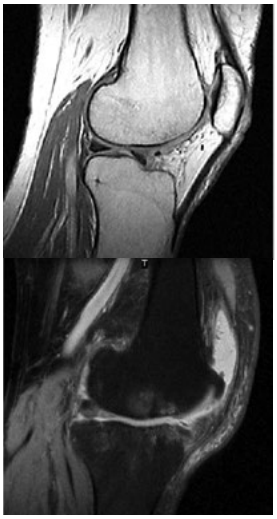
Mail CD

- Ensure the dicom files are located on the CT Scan CD
- Mail the CD to:
  MicroPort Orthopedics
  5677 Airline Road
  Arlington TN, USA 38002
  Attention: Prophecy Lab

MRI Imaging Example



Satisfactory MRI Imaging
Quality images have bright cartilage and dark bone. There are clear, distinct boundaries between the bone, cartilage and the and the surrounding tissue.



Unacceptable MRI Imaging
There are numerous examples of bad MRI images. These can include using an incorrect sequence, blurry boundaries or unclear cartilage.

Preoperative Report

chapter 2

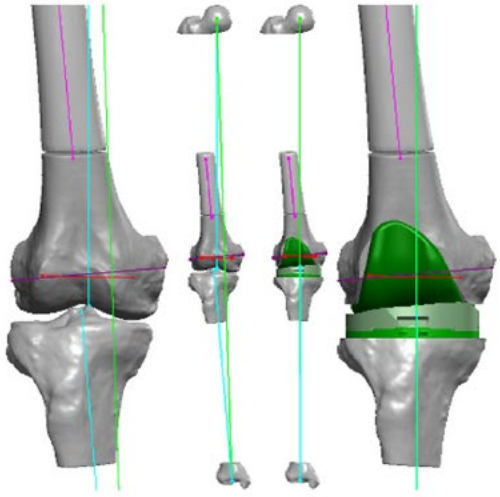
The PROPHECY® Preoperative Report is made for each individual PROPHECY® case and contains information specific to each patient. The information contained in the preoperative report should be used as a reference for preoperative and post-operative alignment and the images may be used to assist with intraoperative PROPHECY® guide placement.

PROPHECY® EVOLUTION®
Preoperative Navigation Guides

CASE##### - Dr. John Doe
Jane Smith - MM/DD/YYYY

Size 5 Right EVOLUTION® CR/CS, Size 5 Right Base 10mm Medial-Pivot (CS) Insert

Recommended implants for surgery

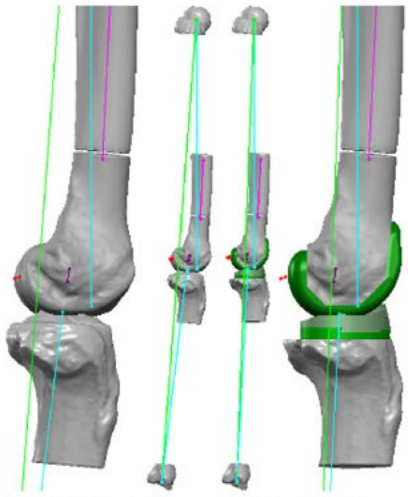


AP Pre-Op AP Post-Op

Varus-Valgus Angle
(measured from the femoral anatomic axis)
Pre-op: 0.5° valgus
Post-op: 5.3° valgus

Mech. axis to Anatomic axis angle (in coronal plane): **5.3°**
Hip-Ankle Line
Pre-op: 760.3 mm
Post-op: 762.7 mm

Fem. Anat. Axis
Fem. Mech. Axis
TEA
Hip/Ankle Line



Lat. Pre-Op Lat. Post-Op

Sagittal Mech Axis Angle
(femoral anatomic axis to tibial anatomic axis)
Pre-op: 4.0° flexion
Post-op: 0.2° flexion

Distal Cuts
Medial: 10.0 mm
Lateral: 6.5 mm

Implant distal thickness is 10mm

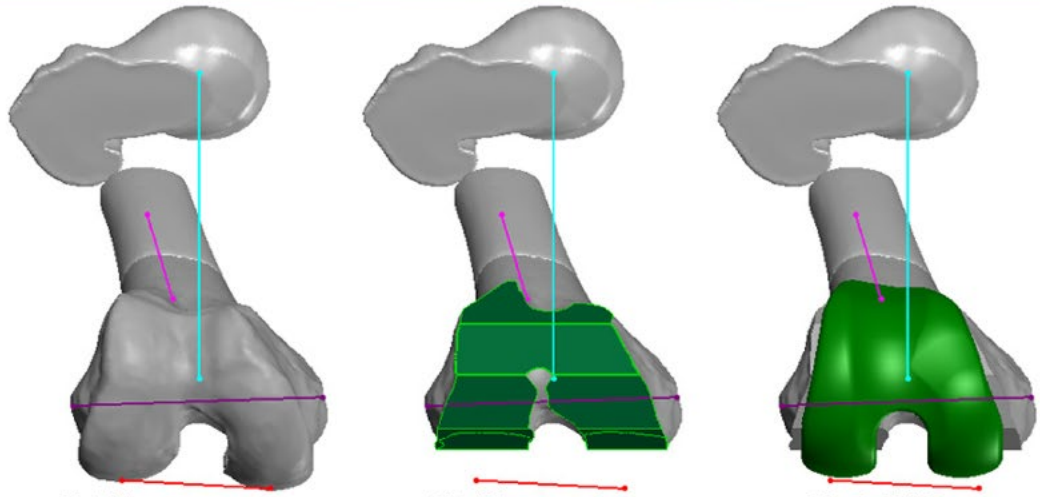
Posterior Cuts
Medial: 13.6 mm
Lateral: 11.2 mm

Implant posterior thickness is 10 or 11mm depending on size

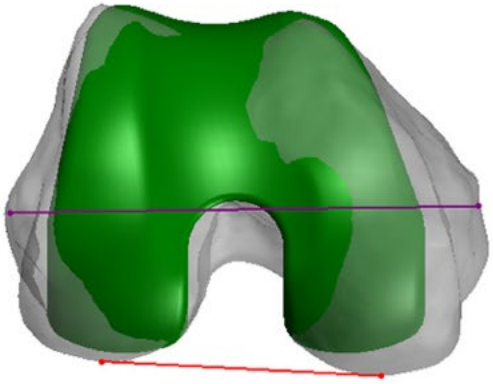
Mech. axis to Anatomic axis angle (in sagittal plane): **2.8°**

Fem. Anat. Axis
Fem. Mech. Axis
TEA
Hip/Ankle Line

Size 5R EVOLUTION® CR/CS



Distal femur - no cuts | Distal femur - cuts | Size 5 CR/CS



Lateral | Medial

TEA is 3.8° external from the posterior condyles

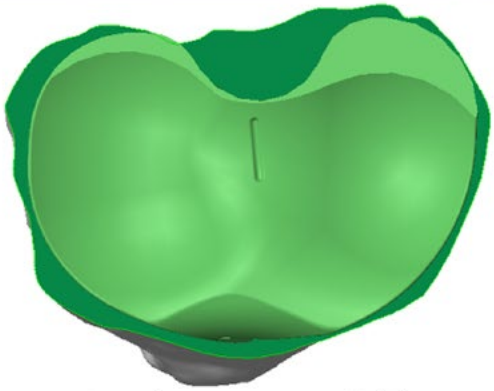
No stuffing of the patella

Similar trochlear groove profiles

TEA

Post. Cond. Line

Size 5R EVOLUTION®, Medial-Pivot (CS)



Lateral Medial

- Tibial Cut 3.0° posterior slope
- Resection side: 2 mm from lowest side
- Insert AP orientation: Medial tubercle
- Medial resection: 2.0 mm
- Lateral resection: 7.1 mm

Set by Surgeon Preference

Femoral Alignment Method

Surgeon Preference

- Distal cut is referenced to Mechanical Axis - 0 degree
- Femoral rotation set by the 3 degree external to posterior condyles
- Distal resection level set to 10 mm
- AP component position set by Anterior flange placed to prevent notch/overhang
- Femoral component perpendicular to the mechanical axis in order to obtain optimal posterior resections
- Size 5R EVOLUTION® CR/CS Femur

Tibial Alignment Method

Surgeon Preference

- Proximal cut 3° posterior slope to anatomic axis
- Component rotation set by Medial tubercle
- Resection level from 2 mm from lowest side
- EVOLUTION® Tibia Base Size 5R
- Size 5 Right 10mm EVOLUTION® Medial Pivot (CS) Insert

PROPHECY® Engineer Comments

Additional comments concerning the case will be placed here - information about alignment, hardware, or special instructions from the surgeon will be listed in detail.

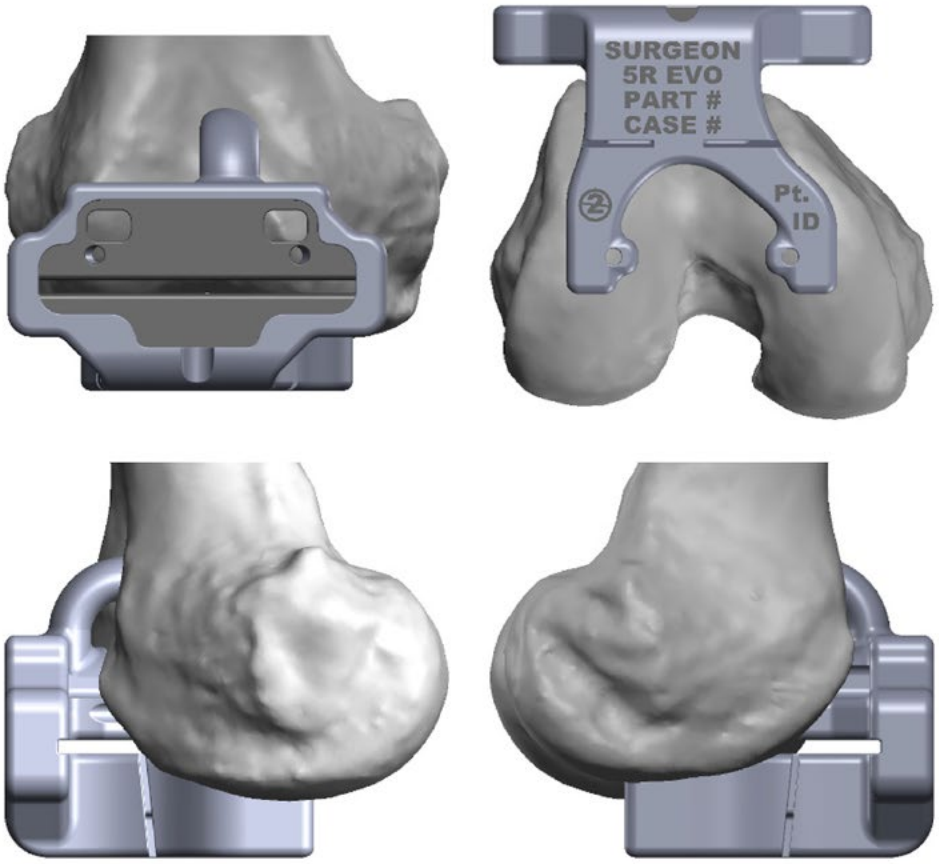
Recommended Implants

PROPHECY® Guide Part Number

- Femoral component: EFSRN5PR
- Tibial base: ETPKN5SR
- Insert: EIC5S10R
- Part Number: PNF#####
- Order Kit: E200KT10, E200KIT1, E200KIT7, and E200KT29

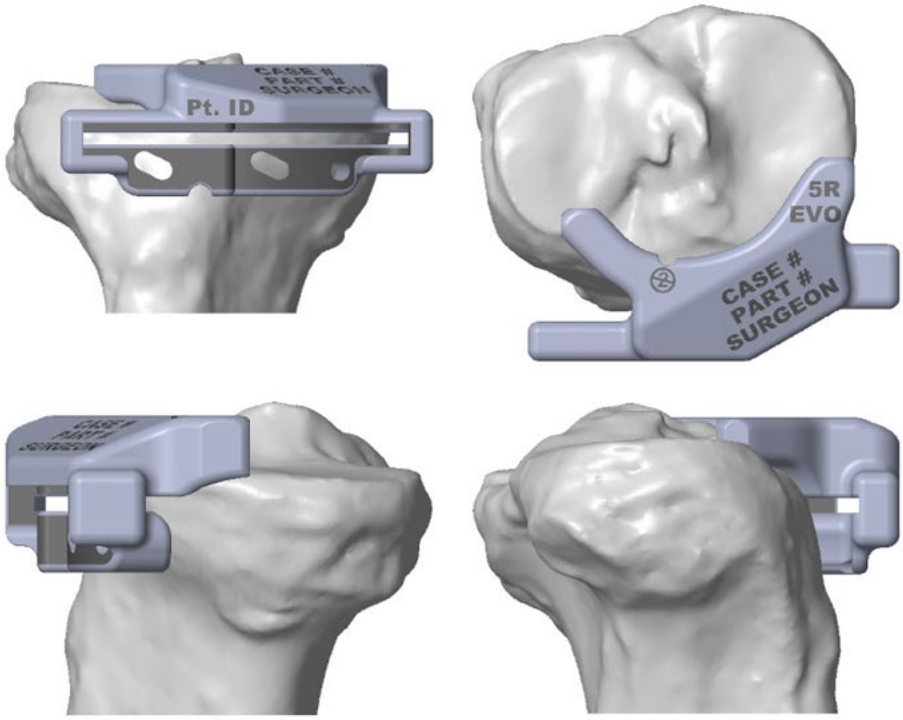
Images may be used as a reference during surgery.

Femoral Guide Placement



Images may be used as a reference during surgery.

Tibial Guide Placement



Function of the PROPHECY® Preoperative Navigation Guides

chapter 3

PROPHECY® Preoperative Navigation Guides are designed to interface with standard ODYSSEY® or EVOLUTION® instrumentation. If necessary, the surgeon may choose to switch to traditional instrumentation at any point during the surgery.

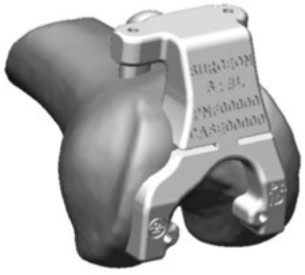
PROPHECY® Preoperative Navigation Guides are available in two versions: "Pin Alignment" or "Resection." The pin alignment guides are designed for use in minimally-invasive exposures. The alignment and resection guides are designed to further reduce the steps of the surgical procedure.

Femoral Pin Alignment Guide

Anterior holes align pins of the 9mm ODYSSEY® (K0012659) or the EVOLUTION® 10mm distal resection guide (E1000010) to set depth and valgus angle of distal resection. Distal holes set femoral rotation of 4-in-1 resection guides.

Femoral Resection Guide

9mm ODYSSEY® (K0012659) or the EVOLUTION® 10mm distal resection guide. (E1000010) . Distal holes set femoral rotation of 4-in-1 resection guides.

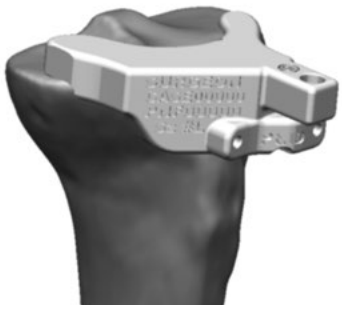


Tibial Pin Alignment Guide

Anterior holes align pins of ODYSSEY® Tibial Resection Guide to control resection depth and posterior slope.

Tibial Resection Guide

Accepts ODYSSEY® Tibial Resection Crosshead (K004007L for left or K004007R for right).



Surgical Technique

chapter 4

Option 1: PROPHECY® Preoperative Navigation Pin Alignment Guides

Femoral Preparation

PROPHECY® Preoperative Navigation Guides are designed to incorporate osteophytes on or near the articulating surfaces. However, osteophytes may be removed if they interfere with the seating of the PROPHECY® guides. Ensure the area of the anterior cortex where the PROPHECY® guide will surface match is free of soft tissue.

Femoral resections should be made before tibial resections to ensure adequate joint space for the PROPHECY® guides.

Orient the PROPHECY® femoral pin alignment guide on the femur until the internal geometry of the guide "locks" onto the topography of the femur. The guide should be applied to the bone with moderate pressure ensuring that the anterior stylus is touching the anterior cortex. | **FIGURE 1** Refer to the images from the preoperative navigation report for assistance in placing the guide onto patient anatomy. Drive 1/8" (3.2mm) pins through the anterior pin holes in the guide. Insert the dual reference "angel wing" gauge eMP™ (E5001006) or aMP™ (K0014407) into the anterior slot to confirm the correct placement of the guide. | **FIGURE 2** Advance the 1/8 "3.2mm" drill bit (K0001015) through the two holes in the distal surface of the guide. | **FIGURE 3** The drill bit (K0001015) must advance 16mm past the distal resection for drill holes to be present after the distal resection.

NOTE: ***When the pegs of the 4-in-1 resection block are placed in these holes, the resection block will be in proper rotation and anterior/posterior location. These holes are designed to correlate to the pegs of the final implant.***

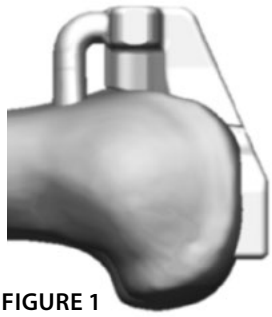


FIGURE 1

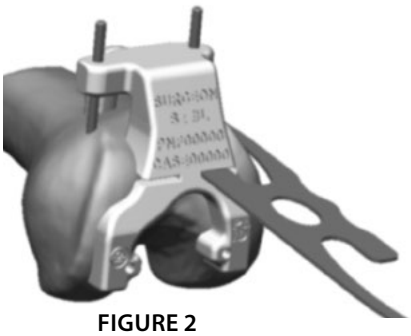


FIGURE 2

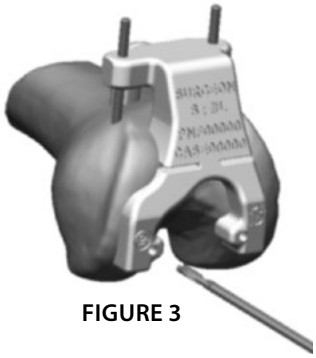


FIGURE 3

K0014407

E5001006

K0001015

Slide the PROPHECY® guide off the pins and lower the aMP™ 9mm ODYSSEY® (K0012659) or eMP™ 10mm femoral resection guide (E1000010) down the pins through the "STD" holes. | **FIGURE 4** and | **FIGURE 5** These holes are the most proximal on the femoral resection guide. Ensure the distal resection guide is resting on the anterior cortex and place another headless pin through the convergent hole in the resection guide. | **FIGURE 6**

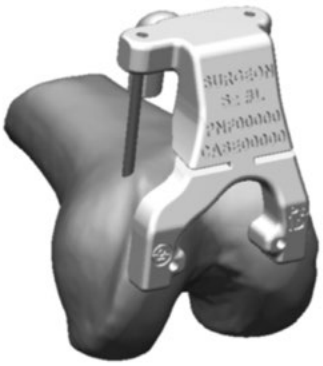


FIGURE 4

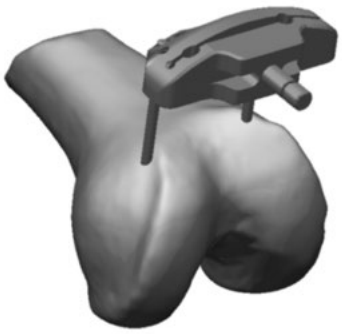


FIGURE 5

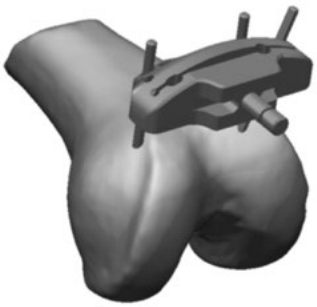


FIGURE 6

Distal Resection
Using a 1" wide, .050" (1.3 mm) thick saw blade, cut through the metal femoral resection guide to make the distal resection. | **FIGURE 12** and | **FIGURE 7.**

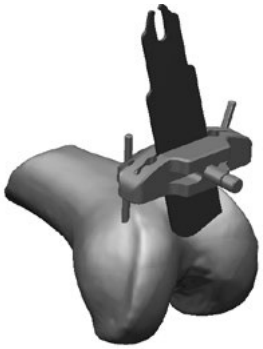


FIGURE 7

K0012659

E1000010

Option 2: PROPHECY® Preoperative Navigation Resection Guides

Place the aMP™ 9mm femoral resection guide (K0012659) or the eMP™ 10mm femoral resection guide (E1000010) in the anterior receptacle of the PROPHECY® guide. Ensure that the rounded side of the eMP™ 10mm femoral resection guide is facing up. Either side of the ODYSSEY® distal guide may be facing up. Orient the PROPHECY® alignment and resection guide on the femur until the internal geometry of the guide "locks" onto the topography of the femur. The guide should be applied to the bone with moderate pressure ensuring that the anterior stylus is touching the anterior cortex. | **FIGURE 8** and **9** Refer to the images from the preoperative navigation report for assistance in placing the guide onto patient anatomy. Insert the dual reference "angel wing" gauge (K0014407) or (E5001006) into the anterior slot to confirm the correct placement of the guide. | **FIGURE 9** Drive 1/8" (3.2mm) pins through the anterior pin holes in the guide. Advance the 1/8" (3.2mm) drill bit (K0001015) through the two holes in the distal surface of the guide. | **FIGURE 10** The drill (K0001015) must advance 16mm past the distal resection for drill holes to be present after the distal resection. When the pegs of the 4-in-1 resection block are placed in these holes, the resection block will be in proper rotation and anterior/posterior location.
These holes are designed to correlate to the pegs of the final implant. Place another collarless pin through the convergent hole in the resection guide. | **FIGURE 12**

Distal Resection
Using a 1" wide, .050" (1.3 mm) thick saw blade, cut through the metal femoral resection guide to make the distal resection. | **FIGURE 13**

FIGURE 8

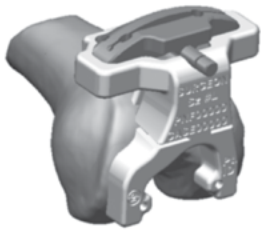


FIGURE 9

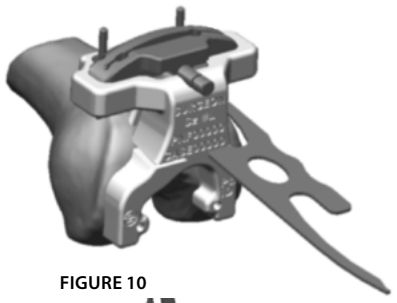


FIGURE 10

FIGURE 11

FIGURE 12

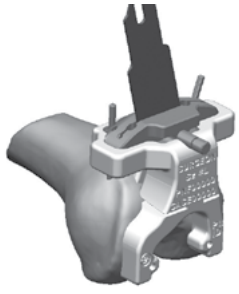


FIGURE 13

K0001015

Anterior and Posterior Resections
After the distal resection, select the 4-in-1 resection block: aMP™ (K001438X) or eMP™ (E12041XX) that corresponds to the pre-determined size indicated on the preoperative plan and place the pegs into the pre-drilled holes. | **FIGURE 14** If the holes for the 4-in-1 resection block are difficult to find, the dual reference gauge (K0014407) or (E5001006) may be used to remove debris from the femur. | **FIGURE 15**

Continue to make all anterior and posterior resections.

Note: The remainder of the surgical technique continues as described in the following surgical techniques: aMP™ 008016 and eMP™ 015263.

FIGURE 14

FIGURE 15

K001438X

E12041XX

Tibial Preparation

The ODYSSEY® Tibial Resection Guides are designed for use with a .050" (1.3 mm) thick saw blade.

PROPHECY® Preoperative navigation guides are designed to incorporate osteophytes on or near the articulating surfaces. However, osteophytes may be removed if they interfere with the seating of the PROPHECY® guides. Ensure that the anterior medial surface of the tibia is clear of soft tissue. This will improve surface matching of the tibial guide. Remove the meniscus and meniscal attachments.

Option 1: PROPHECY® Preoperative Navigation Pin Alignment Guide

Rotate the tibial guide on the tibial plateau until the internal geometry of the guide "locks" into the natural topography of the tibia. | **FIGURE 16** Refer to the images from the preoperative navigation report for assistance in placing the guide onto patient anatomy. The tibial rotation marker is located on the anterior portion of the guide. | **A IN FIGURE 16** Marking and aligning the tibial base to this line will replicate placement in the preoperative surgical plan.

Advance two collarless pins into the anterior holes of the tibial guide. | **A IN FIGURE 17** Ensure the pins are securely fixated in the bone. Approximately 1" (2.5cm) of pin shaft should be visible from the guide. The aMP™ (K0000901) or eMP™ (E5101001) alignment rod can be used through the PROPHECY® alignment guide to check alignment to the ankle. | **B IN FIGURE 17**

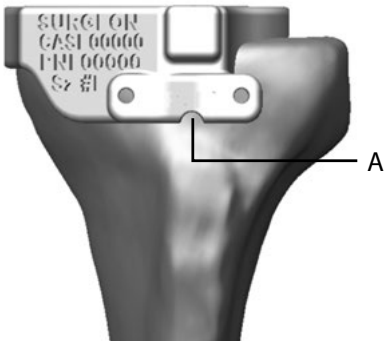


FIGURE 16

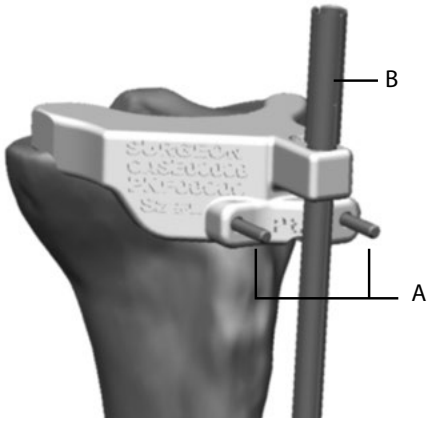


FIGURE 17

K0000901

E5101001

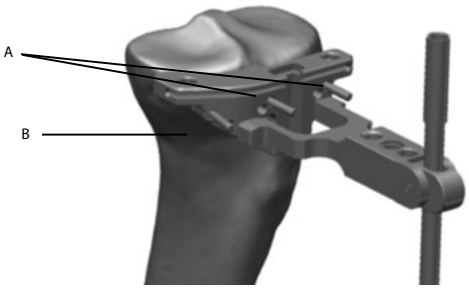


FIGURE 18

Gently slide the PROPHECY® tibial guide off the pins. Slide the metal tibial resection crosshead (K004007L for left; K004007R for right) along the pins through the "STD" holes. | **A IN FIGURE 18** The alignment guide (K0040052) or (E51010002) and the alignment rod can be used to check alignment to the ankle. | **FIGURE 18** Ensure the crosshead is resting on the anterior surface and place another collarless pin through the convergent hole in the resection crosshead. | **B IN FIGURE 18**

Option 2: PROPHECY® Preoperative Navigation Resection Guide

Load the metal ODYSSEY® tibial resection crosshead (K004007L for left; K004007R for right) into the PROPHECY® resection guide. Rotate the PROPHECY® guide on the tibial plateau until the internal geometry of the guide "locks" into the natural topography of the tibia. | **FIGURE 19** The preoperative tibial guide images may be used to confirm proper placement. Advance two collarless pins into the STD holes in the tibial resection crosshead. | **A IN FIGURE 20** Ensure the pins are securely fixated in the bone. Approximately 1" (2.5cm) of pin shaft should be visible. The alignment guide (K0040052 or E5101002) and the external alignment rod (K0000901 or E5101001) can be used to check alignment to the ankle. | **B IN FIGURE 20** Place another pin through the convergent fixation hole in the resection guide. | **C IN FIGURE 20**

Note: The remainder of the surgical technique continues as described in the following surgical techniques: aMP™ 008016 and eMP™ 015263.

FIGURE 19

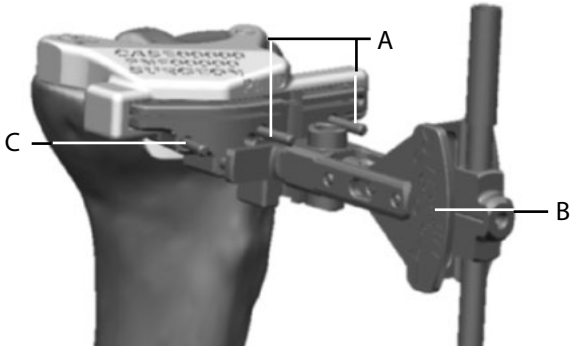
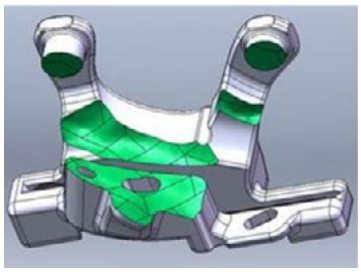


FIGURE 20

K004007L *K004007R* *E5101002* *K0040052*



Note:

When you or your surgeon submit a request for PROPHECY® tibia guide using the CT scan protocol, the cartilage is not imaged and therefore it cannot be modeled on the tibia bone models. The guide reference area which is built is then typically limited to the anterior ridge of the tibia and not in the compartments where the cartilage is thicker. For MRI-based guides, the cartilage can be seen within the tibia compartments, and our guides extend into that.

Please be aware that, upon request to the PROPHECY® team, it is possible to receive tibia guides (designed based on the CT imaging protocol) which have circular touch-off points within the tibia compartments (see picture). It is important to note that those guides are designed to be referencing bone, so if the guide does not fit well due to cartilage, some cartilage removal may be necessary.

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