Prophecy® Advance®

Preoperative Navigation Guides

Surgical Technique

MicroPort Orthopedics

Full Function, Faster®

Contents

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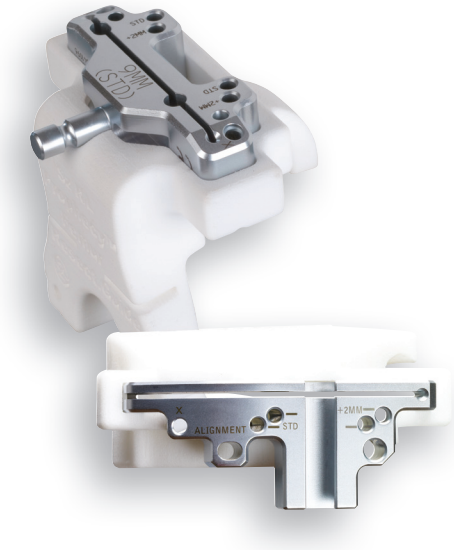
chapter 1



PROPHECY® Alignment Guides are patient specific instruments designed to improve total knee replacement results. 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.

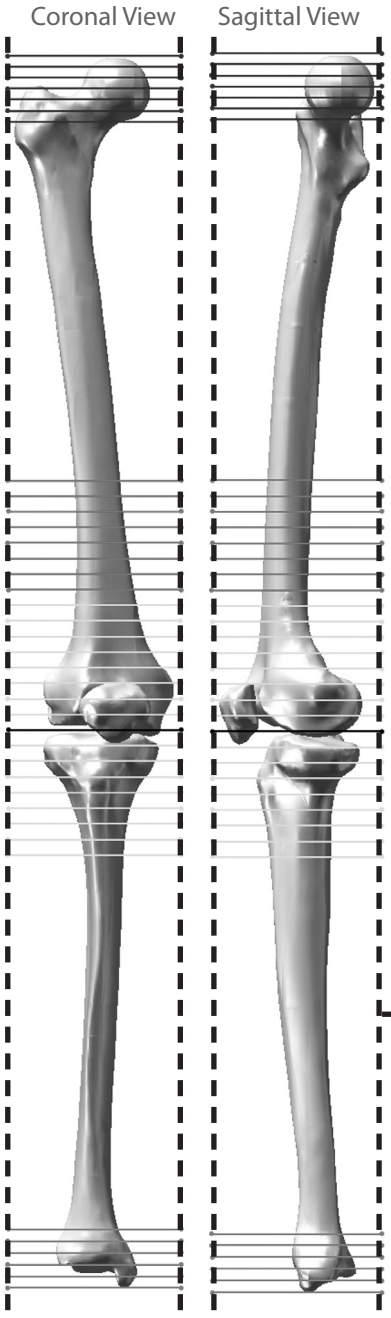
In every case, please follow these general instructions:

- **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 contra-lateral implant is present, bend contra-lateral 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
866.872.0211

CT Scan Protocol

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



SCAN LOCATIONS: HIP

- Anatomic landmarks: Femoral head
- Maximum slice thickness: 5 mm
- Scan boundaries:

- minimum of 6 slices from proximal to distal femoral head

SCAN LOCATIONS: SHAFT

- Anatomic landmarks: none
- Slice increment: maximum slice thickness: 10 mm
- Scan boundaries:

- Start at the border of the knee scan (9 cm proximal to joint line)
- End 19 cm proximal to the joint line

SCAN LOCATIONS: KNEE

- Anatomic landmarks: Patella and tibial tubercle
- Slice increment: maximum slice thickness: 1.25 mm
- Scan boundaries:

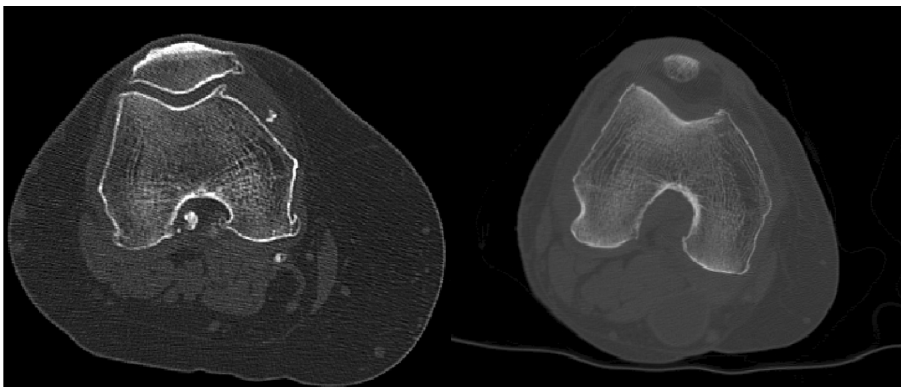
- 9 cm proximal and 9 cm distal of joint line

SCAN LOCATIONS: ANKLE

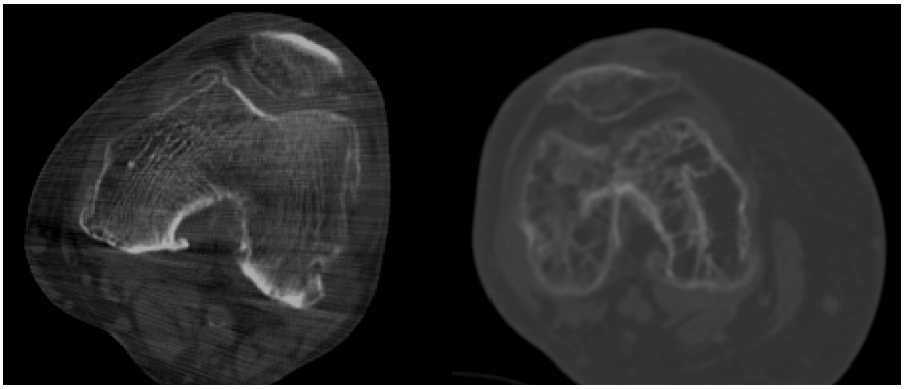
- Anatomic landmarks: Distal tibia
- Slice increment: maximum slice thickness: 2.5 mm
- Scan boundaries:

- Start 5 cm 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® Guides.

MRI Scan Protocol

PROPHECY® eMP™ and PROPHECY® aMP™ 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.*

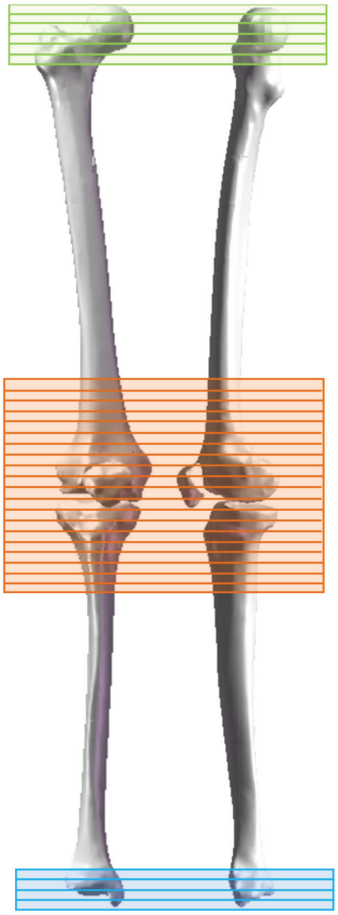
REIMBURSEMENT DISCLAIMER

The Centers for Medicare & Medicaid Services (CMS) established a National Coverage Determination (NCD) for MRIs. The NCD outlines the parameters for coverage and non-coverage. Specifically, the NCD states that "MRI is considered medically efficacious" for a number of diagnostic uses and that the descriptions (in the NCD) should be used as general guidelines or examples of what may be considered covered rather than as a restrictive list of specific covered indications. It goes on to note that CMS has determined that "imaging of cortical bone and calcifications, and procedures involving spatial resolution of bone and calcifications, are not considered reasonable and necessary indications" and are therefore "noncovered." MRIs performed prior to total joint replacement procedures for diagnostic purposes, however, may be considered medically necessary (see First Coast Service Options LCD for total joints) and billed using the CPT codes that accurately describe the imaging procedure furnished to the patient. These same images from the diagnostic MRI may, in turn, be further utilized for developing the personalized cutting or navigation guides that are used in orthopaedic procedures. However, if providers perform MRIs solely for the purpose of developing personalized cutting instruments or guides, providers should contact the payer for billing and coverage guidance and/or the American College of Radiology with billing questions.

SCAN INFORMATION

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

AP View *Sagittal View*

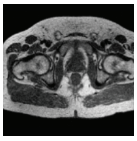


The patient cannot move between the three axial scan sequences and the machine cannot be reset between each axial scan. The coordinate system of the scans must be retained between all three axial acquisitions.

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

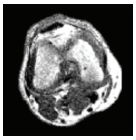
Scan Location: Hip

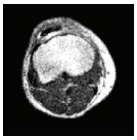
- Hip - Axial Slices
- Coil: Body
- Anatomic landmarks: Femoral head
- Slice thickness: 5mm
- Slice spacing: 3mm
- Scan boundaries: Must contain entire proximal femoral head
- Slices: Approximately 19



Scan Location: Axial Knee

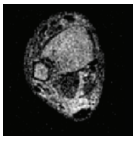
- Knee - Axial Slices
- Coil: Body
- Anatomic landmarks: Distal femur, proximal tibia
- Slice thickness: 5mm
- Slice spacing: 3mm
- Scan boundaries: Approximate field of view is 12cm proximal and 9cm distal to joint line
- Slices: Approximately 35-40



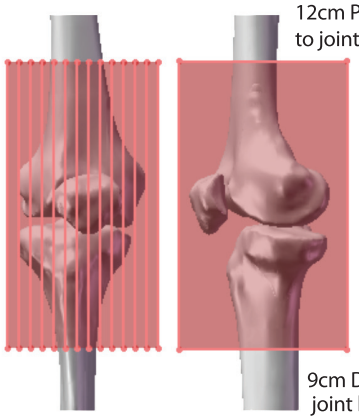


Scan Location: Ankle

- 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

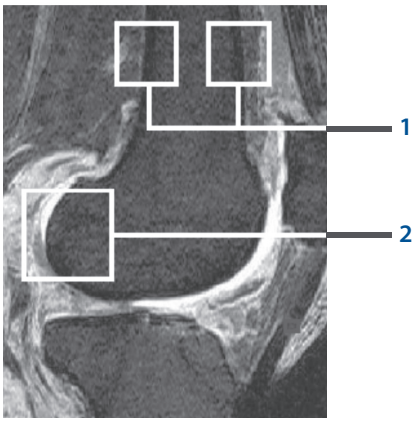


AP View *Sagittal View*



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

chapter 3

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

Rapid Electronic Scan Transfer
Pre-Operative CT and MRI scans may be sent to the PROPHECY® guides 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 to complete registration on the scan transfer site.

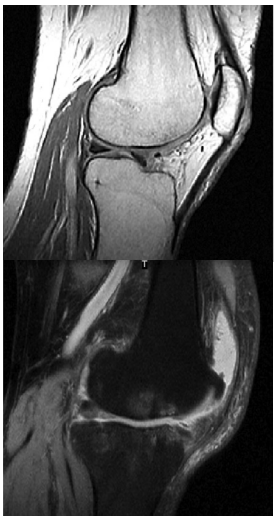
*** upload times may vary based on connection speed.*

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.

Function of the PROPHECY® Guides

chapter 3

PROPHECY® Guides are available in two versions: "**Pin Alignment**" or "**Alignment and 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.

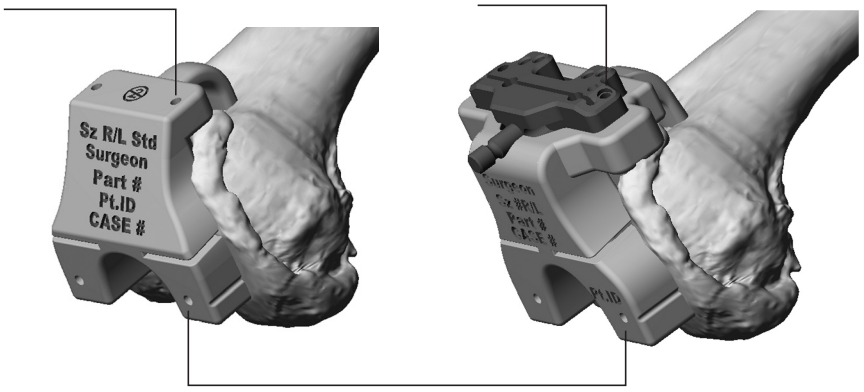
All PROPHECY® Femoral Guides are only compatible with ODYSSEY® Femoral Resection Guides (K001-2659). All PROPHECY® Tibial Guides are only compatible with ODYSSEY® tibial resection guides (K004-007L for left; K004-007R for right).

Femoral Pin Alignment Guide

Anterior holes align pins of 9mm ODYSSEY® Distal Resection Guide to set depth and valgus angle of distal resection

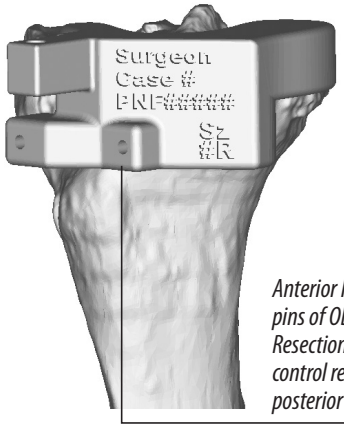
Femoral Alignment & Resection Guide

Accepts 9 mm ODYSSEY® Distal Femoral Resection Guide



Distal holes set femoral rotation of 4-in-1 resection guides

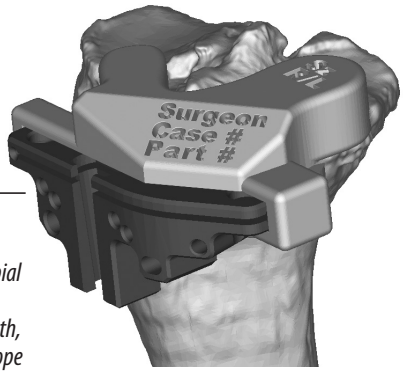
Tibial Pin Alignment Guide



Anterior holes align pins of ODYSSEY® Tibial Resection Guide to control resection depth, posterior and M/L slope

Tibial Alignment & Resection Guide

Accepts ODYSSEY® Tibial Resection Guide



Surgical Technique

chapter 4

NOTE:
In general, the PROPHECY® Guides will be 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.

FEMORAL PREPARATION

NOTE: Femoral resections should be made before tibial resections to ensure adequate joint space for the tibial alignment drill guides.

Orient the femoral pin alignment guide on the femur until the internal geometry of the guide "locks" to the topography of the femur. With the guide held securely in place, advance a 1/8" (3.2mm) drill bit through the two holes in the distal surface of the guide. (Figure 1A) The drill must protrude 15mm into the femoral bone so the drill holes will be present after the distal resection. Increased hole depth may be necessary in the event of a larger distal resection to correct a flexion contracture. When the pegs of the 4-in-1 resection guide are placed in these holes, the resection guide will be in proper rotation and anterior/posterior location. These holes are designed to correlate to the pegs of the final implant. For additional stability, fixation pins may be left in the distal holes, but must be removed prior to resection. (Figure 1C)

NOTE:
1. Insert an angel wing into the anterior slot (Figure 1B) to confirm the correct placement.

2. Utilize the pre-operative femoral guide positioning images to confirm rotation.

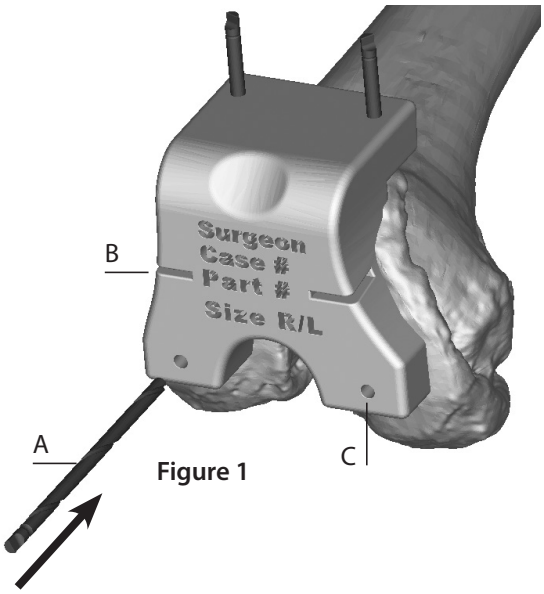


Figure 1

NOTE: Threaded pins are not recommended for PROPHECY® Pin Alignment Guide fixation. Threaded pins may be difficult to drive through the holes in the guide.

For PROPHECY® Pin Alignment Guides

Drive 1/8" (3.2mm) pins through the anterior pin holes and slide the guide off the pins. (Figure 2) and (Figure 3) If the alignment guide is difficult to remove due to conformity with the topography of the femur, temporary extraction of one pin may be necessary.

Figure 2

Figure 3

NOTE:
If left too proud, pins may interfere with the saw when completing the distal resection.

Lower the ODYSSEY® 9mm Distal Resection Guide (K001-2659) down the pins through the "STD" holes. These holes are the most proximal on the guide. (Figure 4A) 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 4B)

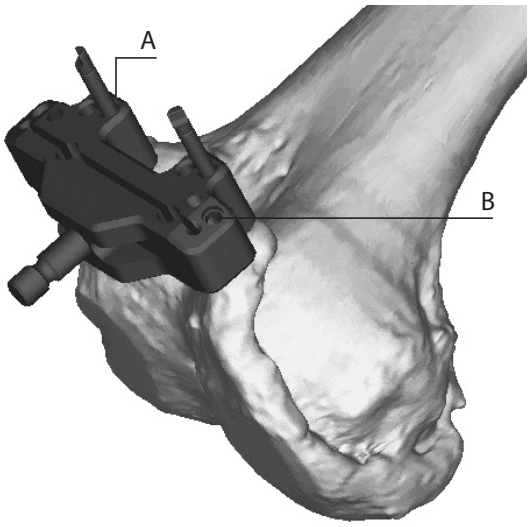


Figure 4

For PROPHECY® Alignment & Resection Guides
Place the ODYSSEY® 9mm Distal Resection Guide (K001-2659) in the anterior receptacle of the PROPHECY® Guide. Either side of the ODYSSEY® Distal Resection Guide may be facing up. (Figure 5) Drive 1/8" (3.2mm) pins through the "STD" holes. These holes are the most proximal on the guide. (Figure 6A) Place another collarless threaded pin through the convergent hole in the resection guide. (Figure 6B)

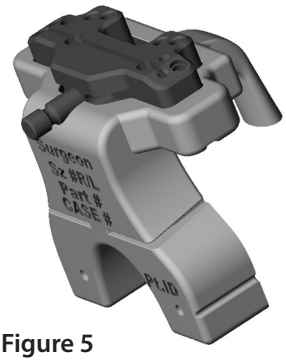


Figure 5

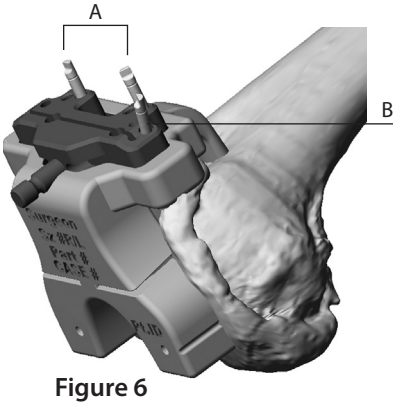


Figure 6

Anterior and Posterior Resections
After the distal resection, guide the pegs of the pre-determined 4-in-1 resection block into the distal femoral holes. (Figure 7) Ensure the 4-in-1 resection block is pressed flush against the bone prior to driving 1/8" (3.2 mm) diameter pins in the medial and lateral sides of the block. (Figure 8) The recommended order of resection is: anterior, posterior, posterior chamfer, anterior chamfer. The anterior chamfer is resected last because it removes the most bone and may leave the guide prone to tilting. (Figure 9) After resections are made, remove the block with the slaphammer and resection block extractor.

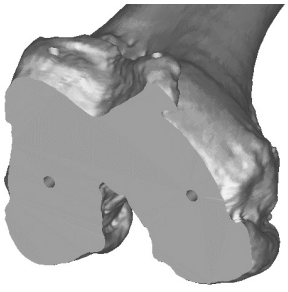


Figure 7

Trochlear Groove Resection
Place the appropriately sized sulcus resection guide on the femur. The sulcus resection guide is in the proper position when the anterior flange rests on the anterior cortex. (Figure 10) Distally the guide is the same M/L width as the femoral implant and dictates the final implant location. The lateral prominances of the guide match the lateral edge of the implant. Many surgeons place the guide along the lateral edge of the femur to reproduce the natural Q-angle. This position should correlate to the PROPHECY® guide alignment. The trochlear groove should be resected by using a 12.7mm (1/2") sawblade on the angled surface and along the sides of the central portion of the guide. (Figure 11)

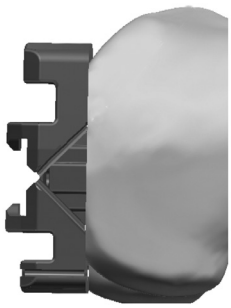


Figure 8

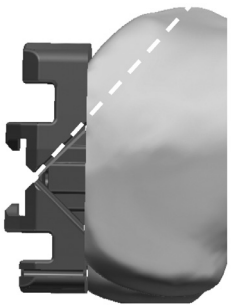


Figure 9

Figure 10

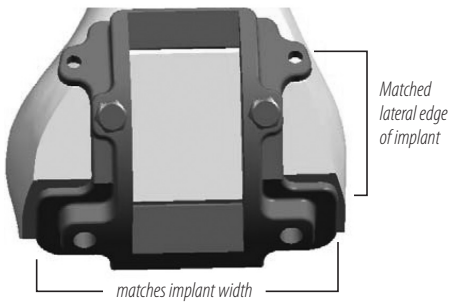


Figure 11

NOTE:
1. Utilize the alignment rod to confirm alignment.

2. Utilize the pre-operative tibial guide positioning images to confirm proper placement.

PROXIMAL TIBIAL RESECTION

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

For PROPHECY® Pin Alignment Tibial Guides:
Rotate the tibial guide on the tibial plateau until the internal geometry of the guide "locks" into the natural topography of the plateau and the medial portion of the tibial tubercle. Advance two collarless, threaded pins into the anterior holes of the tibial guide. (Figure 12A) Ensure the pins are securely fixated in the bone. Approximately 1" (2.5cm) of pin shaft should be visible from the guide.

The alignment rod can be used through the PROPHECY® Alignment Guide to check alignment to the ankle. (Figure 12B)

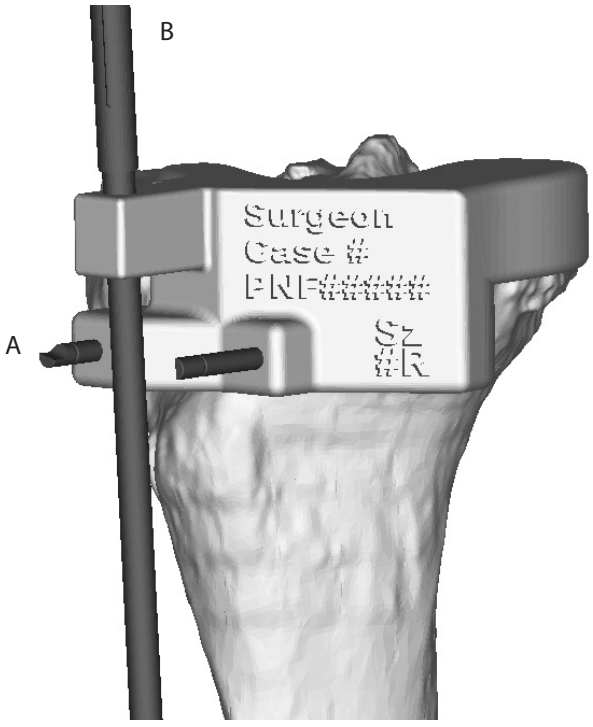


Figure 12

Gently slide the PROPHECY® Tibial Guide off the pins. If the alignment guide is difficult to remove due to conformity with the topography of the tibia, temporary extraction of one pin may be necessary.

Slide the metal tibial resection guide (K004007L for left; K004007R for right) along the pins through the "STD" holes. (Figure 13A) Ensure the guide is resting on the anterior surface and place another collarless threaded pin through the convergent hole in the resection guide. (Figure 14A) The alignment guide and rod can be used to check alignment to the ankle. (Figure 14B)

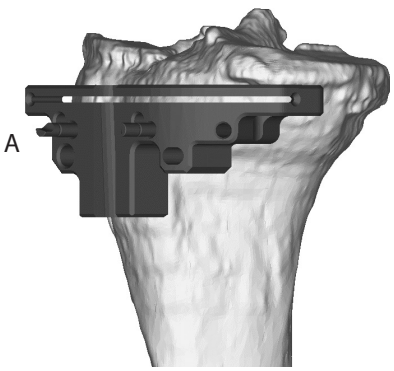


Figure 13

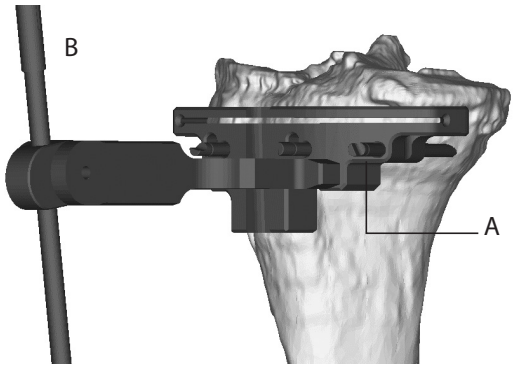


Figure 14

For PROPHECY® Alignment and Resection Guides
Load the metal ODYSSEY® Tibial Resection Guide (K004007L for left; K004007R for right) into the PROPHECY® Resection Guide. (Figure 15) Rotate the PROPHECY® Guide on the tibial plateau until the internal geometry of the guide "locks" into the natural topography of the plateau and the medial portion of the tibial tubercle. (Figure 16)

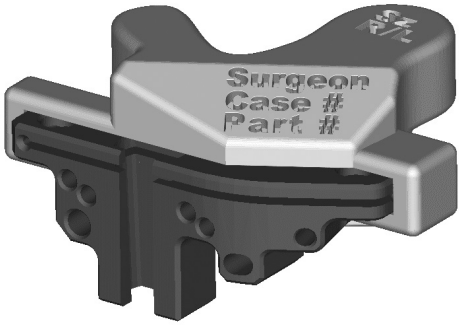


Figure 15

Figure 16

Advance two collarless pins through the "STD" holes in the ODYSSEY® Guide. Place another threaded pin through the convergent fixation hole (marked with an "X") in the resection guide. (Figure 16A) The alignment guide and rod can be used to check alignment to the ankle. (Figure 17)

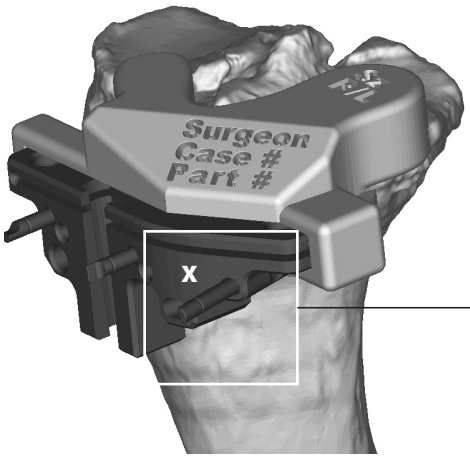


Figure 16

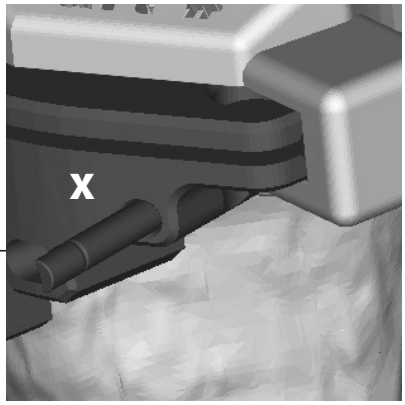


Figure 16A

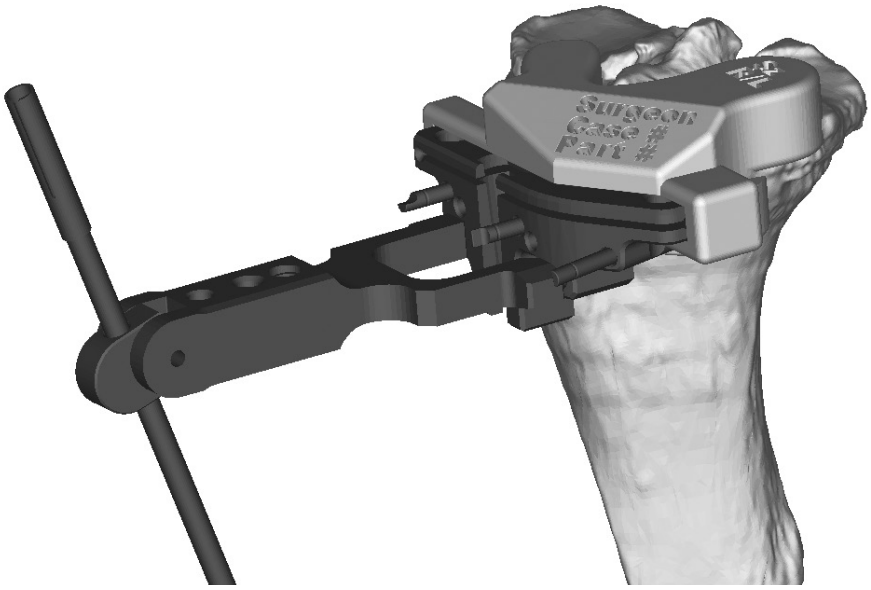
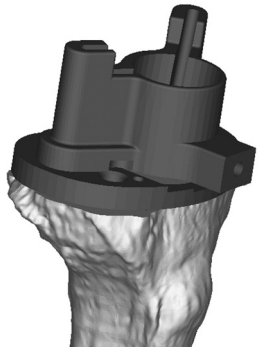


Figure 17

Tibial Preparation

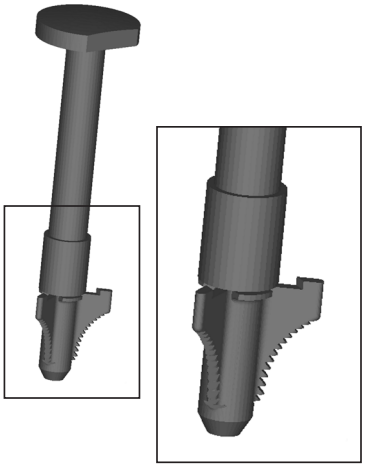
chapter 5

NOTE:
Some surgeons do not utilize the knurled handle and simply hold the keel punch guide in position.



NOTE:
The keel punches have cutting teeth and a chamfered tip so they may be used without pre-drilling.

This is contraindicated in hard bone



NOTE: In all ADVANCE® Total Knees, with the exception of the ADVANCE® Double-High Knee, the tibial insert trial size must match the femoral trial size. There are two tibial base trial sizes that can be used with any one size femoral trial. For example a size 3 femoral trial can be used with either a size 3 or 3+ tibial trial base. When using the ADVANCE® Double-High insert trial, a femoral trial one size greater than the tibial insert trial may be utilized. For example, a size 3 ADVANCE® Double-High insert trial may be used with a size 3 or 4 femoral trial and a size 3 or 3+ tibial base trial.

Tibial Sizing, Keel Preparation, and Trial Reduction

Standard Tibial Instruments
Assemble the trial tibial base that correlates to the size of the femoral implant with the trial base handle and place against the proximal tibial surface. (Figure 18) If using the ADVANCE® Double-High insert, a trial base one size smaller than the femur may be utilized. The alignment rod can be inserted through the handle to check alignment to the ankle. (Figure 18A)

Align the base and pin it to the tibia using short headed anchoring pins. (Figure18B) If the tibial size is too small, a "plus size" will provide additional tibial coverage. Attach the keel punch guide to the keel punch handle and secure it to the trial base by turning the knurled handle. (Figure 19) Prepare the entry hole for the tibial stem using the 15 mm (1/2") drill guide and reamer (press-fit or oversize). Ream to the first line on the reamer for a size 1, 1+, or 2 base, to the second line for a 2+, 3, 3+, or 4 base, and to the third line for a 4+, 5, 5+, or 6 base.

Using the threaded punch handle and appropriate keel punch, plunge through the guide until the punch is fully seated and the punch collar is level with the edge of the guide. (Figure 20A) Remove the punch and punch guide; leaving the trial base in place for a trial reduction.

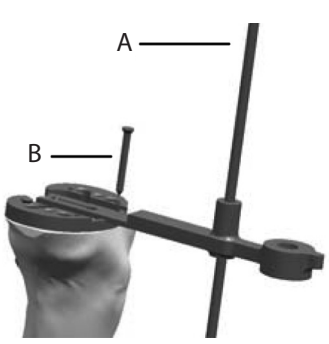


Figure 18

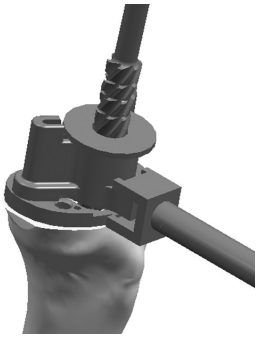


Figure 19

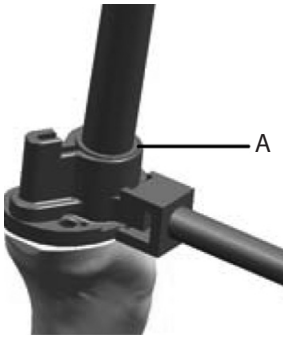


Figure 20

NOTE:
The ADVANCE® BIOFOAM® Tibial base is approximately .5mm thicker than a porous-coated base with beads. The trial tibial bases take into account this increased thickness.

BIOFOAM® Metal-Style Instruments

After the proximal tibial resection has been made, select the proper tibial base trials, keel punch guide, reamer, and keel punch. **Table 2** should be used to determine the sizing compatibility of the instrumentation.

Table 2 | Instrument Sizing Matrix

Implant Size	Base Trial	Reamer FIG 24A	Keel Punches
Size 1	Size 1	Line 1	Size 1/1+/2
Size 1+ Size 2	Size 1+/2	Line 1	Size 1/1+/2
Size 2+ Size 3	Size 2+/3	Line 2	Size 2+/3/3+/4
Size 3+ Size 4	Size 3+/4	Line 2	Size 2+/3/3+/4
Size 4+ Size 5	Size 4+/5	Line 3	Size 4+/5/5+/6
Size 5+	Size 5+/6	Line 3	Size 4+/5/5+/6

The tibial base trial handle (Figure 21A) is assembled to the appropriate size tibial base trial (Figure 21B) by aligning the tabs on each. The lever on the handle (Figure 21C) is then rotated 90° to the "LOCKED" position. The trial base is then placed onto the resected surface of the tibia and properly aligned (generally to the medial one-third of the tibial tubercle) to check the overall coverage. If the tibial trial base size is too small, a "plus size" will provide additional tibial coverage. The trial base is then pinned to the tibia using short headed anchoring pins (Figure 22A) through the anteromedial, anterolateral and posterior holes. The holes may be pre-drilled using a 3.2mm (1/8") drill bit if required. The alignment rod can be inserted through the handle to check alignment to the ankle (Figure 22B).

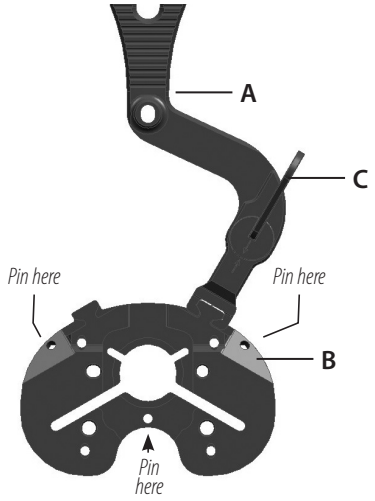


Figure 21

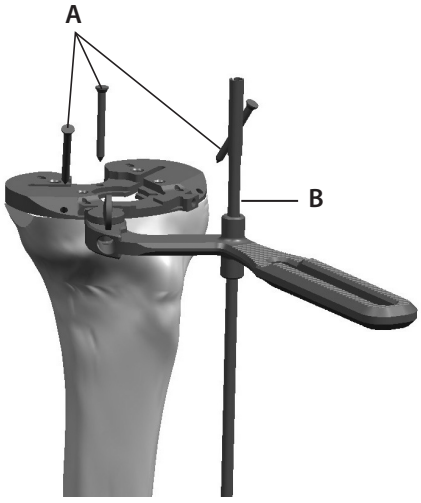


Figure 22

NOTE:
Some surgeons do not pin the base before utilizing the keel punch guide.

Align the four spikes on the keel punch guide with the corresponding holes on the trial base and impact the guide with a mallet until flush with the surface of the trial base. (Figure 23)

The reamer can be used to prepare the medullary canal if needed. Referring to **Table 2**, ream through the keel punch guide to the appropriate line indicated on the reamer. (Figure 24A) A 3.2mm drill bit may be used to prepare for the spikes on the implant as well (Figure 25) if utilizing a BIOFOAM® Tibial Base

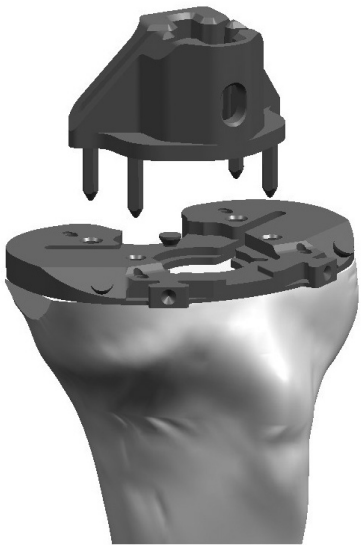


Figure 23

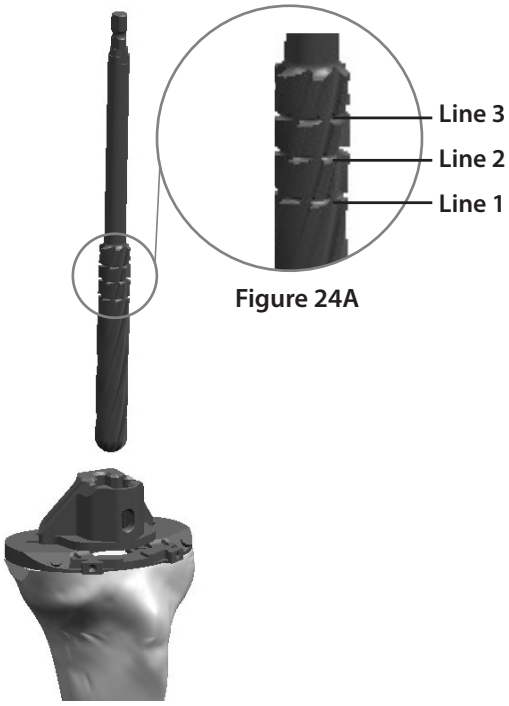
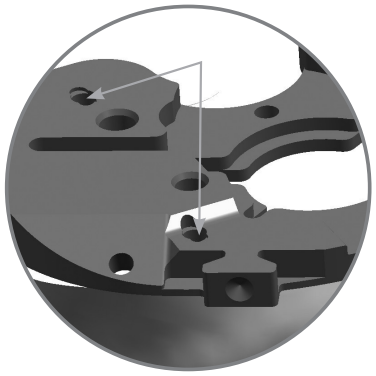


Figure 24A

Figure 24



Drill for Spikes

Figure 25

Assemble the appropriate size keel punch to the keel punch handle by pulling back on the trigger mechanism on the handle (Figure 26A) and inserting it into the opening on the punch. The keel punch handle is impacted with a mallet until fully seated and the bottom edge of the handle aligns with the top of the punch guide (Figure 27A). The handle is disassembled from the punch by pulling back on the trigger mechanism and the punch guide is removed with a slaphammer and hook (Figure 28). A trial reduction can then be performed with the femoral, tibial, and insert trial components. If desired, the lines on the anterior portion of the trial bases (Figure 29A) can be marked to aid with alignment of the tibial base component during implantation. After trialing, the punch handle is used to remove the punch and the headed pins are removed with the slaphammer.

Figure 26

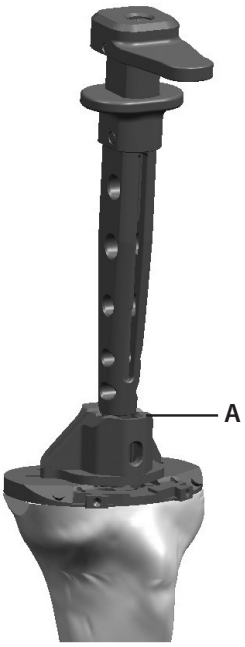


Figure 27

Figure 28

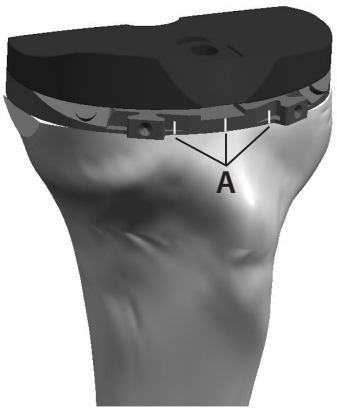


Figure 29

To prevent bony impingement in deep flexion, the posterior condyle which will not be covered by the femoral component is removed with a curved osteotome. (Figure 30)

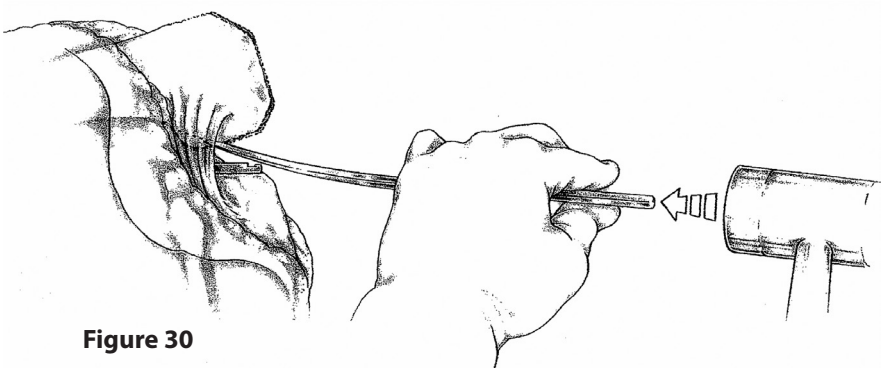


Figure 30

Patella Preparation

NOTE: Recessed patellar instrumentation is also available. To use this instrumentation, see Part B of the Additional Information Section

With the leg extended, the patella is tilted to almost a 90º angle. The 8mm resection depth gauge is attached to the top of the resection guide with the lock screw. (Figure 31) Position the resection guide jaws parallel to the articular margin and securely clamp the guide to the bone; ensuring the gauge is contacting the apex of the articular surface. (Figure 31A) Remove the gauge and locking screw and make the patellar resection. (Figure 32) Attach the appropriate drill guide to the patellar clamp (Figure 33A). The drill guides have grooves on their surfaces indicating the patellar diameter options. The appropriate tri-peg or central peg reamer is used to prepare the peg hole(s).

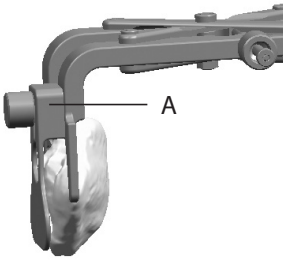


Figure 31

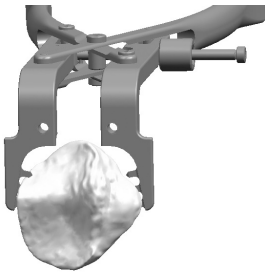


Figure 32

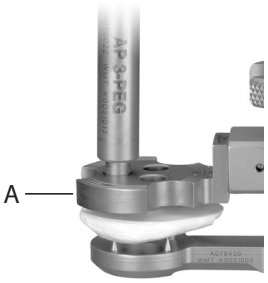


Figure 33

NOTE:
Instead of utilizing a clamp for patellar resection some surgeons prefer a non-instrumented technique.

NOTE:
The tri-peg patellae have the same peg locations between sizes and can be easily changed during trial reduction.

Trial Reduction and Implant Insertion

chapter 6

TRIAL REDUCTION/IMPLANT INSERTION

NOTE:
It is highly recommended to sacrifice the PCL when utilizing the ADVANCE® Medial-Pivot insert. For PCL-retention, the ADVANCE® Double-High Insert is available.

NOTE:
In all ADVANCE® total knees, with the exception of the ADVANCE® Double-High Knee, the tibial insert size must match the femoral implant size (see Table 3). ***There are two tibial base sizes that can be used with any one size femoral component. For example a size 3 femoral implant can be used with either a size 3 or 3+ tibial base.*** (Figure 34) ***When using the ADVANCE® Double-High insert, a femoral component one size greater than the tibial insert may be utilized. For example, a size 3 ADVANCE® Double-High insert may be used with a size 3 or 4 femur and a size 3 or 3+ tibial base*** (see Table 4)

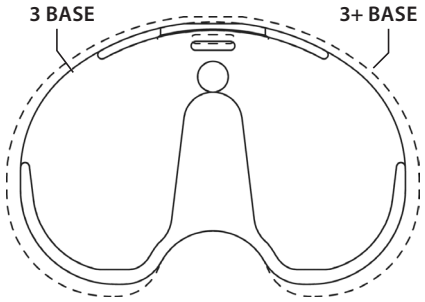


Figure 34

Table 3

Medial-Pivot		
Traditional		
PS		
Femur	Insert	Tibia
1	1	1 or 1+
2	2	2 or 2+
3	3	3 or 3+
4	4	4 or 4+
5	5	5 or 5+
6	6	6

Table 4

Double High		
Femur	Insert	Tibia
1 or 2	1	1 or 1+
2 or 3	2	2 or 2+
3 or 4	3	3 or 3+
4 or 5	4	4 or 4+
5 or 6	5	5 or 5+

Place the appropriate size femoral trial on the distal femur using the femoral impactor (Figure 35). Insert the trial insert of appropriate size and thickness onto the trial base and complete the trial reduction. If necessary, drill for the femoral implant fixation peg through the femoral trial implant using the 4.8mm (3/16") drill bit. After the trial reduction is complete, remove the femoral trial with the slaphammer by sliding the disc extractor tip between the femoral condyles (Figure 36). During removal, keep one hand on the trial to control its extraction. Remove the short headed tibial fixation pins with the pin puller or slap hammer pin extractor.

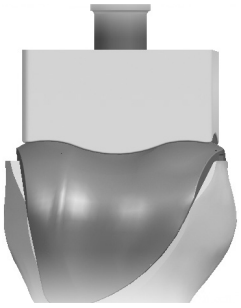


Figure 35

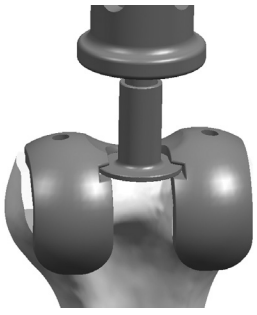


Figure 36

The recommended order for implantation is left to the discretion of the orthopaedic surgeon. Insert the femoral implant with the femoral impactor. **Care should be taken to ensure the femoral component is not forced into flexion by the divergent anterior flange.**

CEMENTED TIBIAL BASES

The tibial base implant is inserted with a tibial base impactor. (Figure 37) After the base has been inserted, the appropriate trial tibial insert can be used to recheck ligament and soft tissue balancing. (Figure 38) An additional trial insert pin may be placed through the trial insert and tibial base implant to provide a more secure construct during final assessment of joint stability. (Figure 38A)

NOTE:
The trial insert only engages the central locking detail and a gap will be present along the anterior periphery of the insert. (Figure 38B)

Figure 37

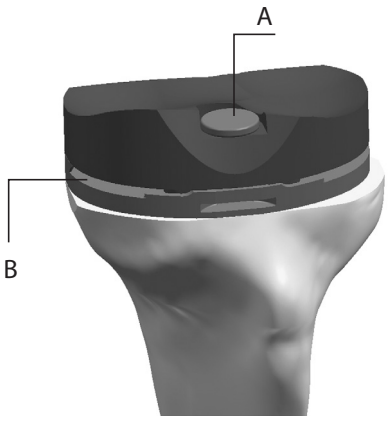


Figure 38

The patellar implant can be held in place while the cement cures using the parallel patellar recessing clamp and plastic seater. (Figure 39)

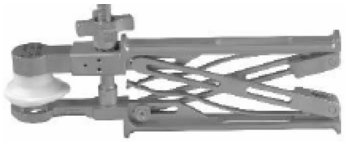


Figure 39

TIBIAL INSERT SEATING

Once the cement surrounding the tibial base has cured, the appropriate tibial insert may be locked into place. Initial seating is accomplished by pushing the insert as far posterior as possible with hand pressure, paying special attention to engage the central dovetail and posterior captures of the tibial base. For final seating of the insert, two options are available. The 45° insert impactor, may be utilized by placing the impactor tip in the anterior slot of the tibial insert. (Figure 40) The impactor handle should be at an angle slightly greater than 45º. Keeping the impactor tip in the slot, decrease the angle of the impactor handle

until the tip is felt to impinge within the slot. This should be approximately 45º. While maintaining this 45° angle relative to the tibial base, apply several strong mallet blows directing the insert posteriorly. After the anterior edge of the insert has been pushed past the anterior capture of the tibial base, it will automatically drop behind the anterior capture and the insert face will be flush against the surface of the tibial base. (Figure 41)

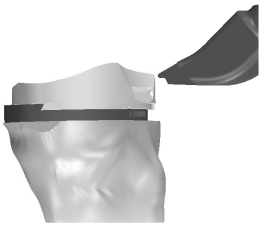
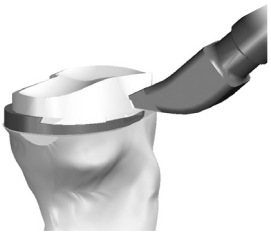


Figure 40



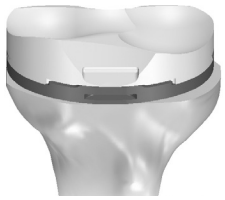


Figure 41

ODYSSEY® Tibial Insert Seater

After the tibial base has been implanted, load the appropriate insert implant onto the base, paying special attention to engage the central dovetail and posterior captures of the base with the insert. Push the insert as far posterior as possible with hand pressure. Next, connect the Tibial Insert Seater, K0027214, to the tibia base implant by connecting the bottom jaw of the Insert Seater to the anterior slot (Figure 42) of the tibia implant. To do this, pull the trigger (Figure 43A) which retracts the locking shims of the positioning platform. Insert the positioning platform into the anterior slot of the tibia base and line up the raised tip of the positioning platform with the proximal slot in the tibia base. (Figure 44) Release the trigger to engage the locking shims, securing the locking gun to the tibial base implant. (Figure 45)

Figure 42

To seat the insert, squeeze the handle (Figure 46A) until the locking piston pushes the insert fully posterior and flush against the surface of the tibial base. (Figure 47) Withdraw the locking shims to loosen the insert seater and remove from the operating field. Perform a visual check to be sure the insert is seated flush with the base before continuing the operation.

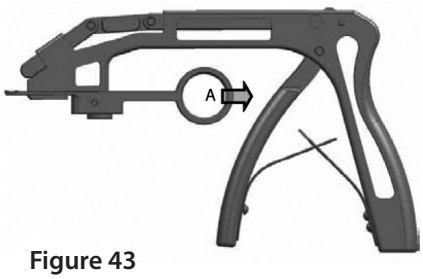


Figure 43

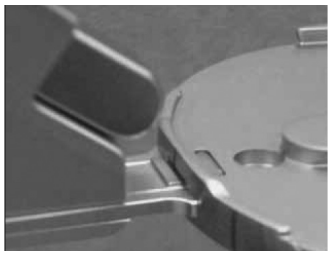


Figure 44

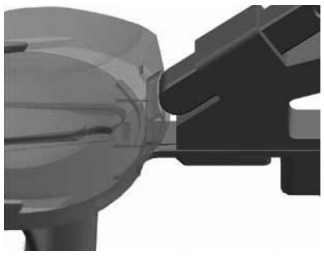


Figure 45

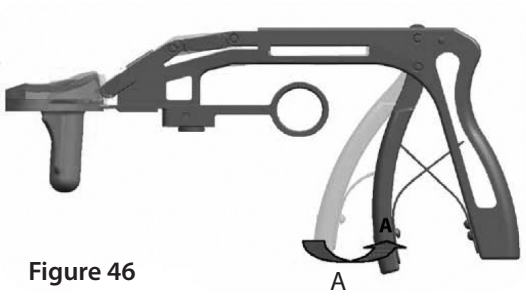


Figure 46

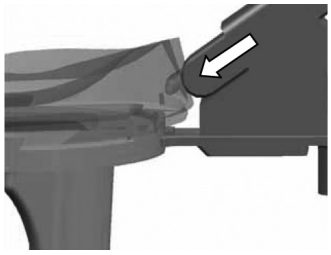
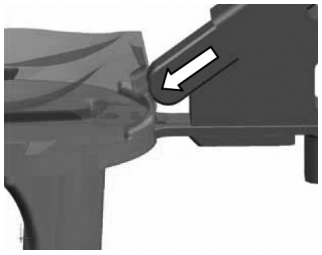


Figure 47



Additional Information

NOTE:
Care should be taken when handling the tibial bases. The locking mechanism on the proximal surface of the tibial base may contain sharp edges that could puncture surgical gloves.

NOTE:
If press-fitting the tibial base, care should be taken to ensure the tibial plateau is completely flat after the resection is made. A tibial base trial can be used to check the flatness of the surface.

PART A
BIOFOAM® TIBIAL BASES

The proper size tibial base and keel is chosen and assembled by placing the stem onto the Morse taper on the underside of the base. Care should be taken to align the anterior tab and key. The stem is impacted with three or four strong blows from a mallet, ensuring the base is placed on a rigid surface during assembly.

IMPORTANT NOTE: To assemble, do not cushion the mallet, stem or base with any materials. The base should be placed directly on a firm surface, while the end of the stem is directly struck with the head of the mallet.

The inserter/extractor is utilized to implant the base (Figure 48) by engaging the insert locking dovetail and impacting with a mallet until fully seated on the bone. The monolithic tibial impactor (Figure 49) can also be used to seat the tibial base.

To prepare for the bone screws, each hole is drilled using the fixed-angle drill guide (Figure 50A) and a 3.2mm (1/8") drill bit (Figure 50B). The recommended angulation of the screws is shown in (Figure 51). **The posterolateral screw is angled toward the midline of the tibial to avoid the peroneal nerve.** If the screws are to be angled outward, care should be taken when drilling throught the cortical bone.

To avoid damage to surrounding soft tissue, do not plunge the drill bit through the cortex. The screw depth gauge is utilized to approximate the screw lengths to be used. For bi-cortical screw fixation, the inside "hook" is used to grasp the cortical bone. Additionally, trans-cortical screws can be measured by placing the end of the gauge into the bottom of the hole. The screw length is determined by reading the increments off the end of the gauge and the appropriate length screw is chosen. A 3.5mm hex screwdriver is used to advance and fully seat the cancellous screws into the base.

Figure 48

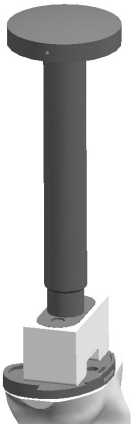


Figure 49

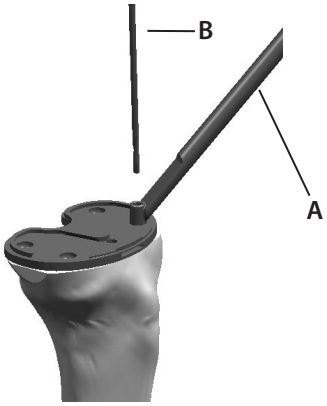


Figure 50

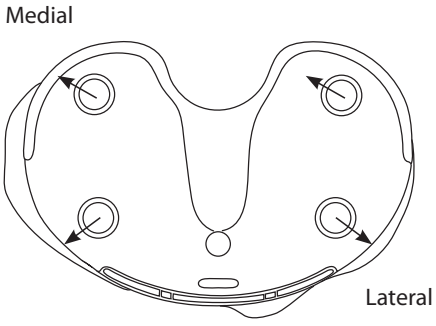


Figure 51

Additional Information

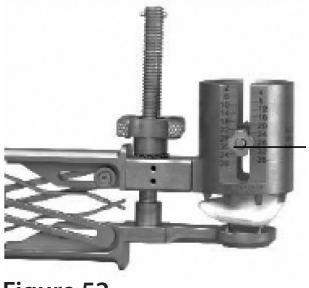


Figure 52

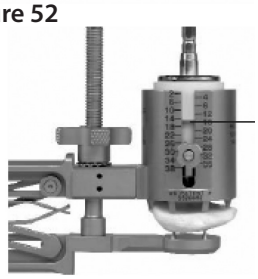


Figure 53

PART B

RECESSED PATELLA INSTRUMENTATION

Attach the patellar reamer guide to the parallel patellar clamp. Center the guide over the apex of the patellar articular surface, and clamp the patella. (Figure 52) Slightly loosen the two thumbscrews on the depth regulator until it sits at the bottom of the patellar reamer guide. (Figure 52A) Insert the appropriate patellar reamer into the guide until it rests on the apex of the patellar articular surface. Note the reamer depth by referencing the bottom of the reamer collar (Figure 53A) to the scale on the side of the reamer guide. Set the top edge of the depth regulator to 14mm below the patellar reamer collar for a high dome patellar implant, and 12mm below the reamer collar for a low dome. Ream until the depth regulator stops the patellar reamer.

NOTE:
The reamer is a "one step" instrument that resects bone for the patellar body and peg simultaneously.

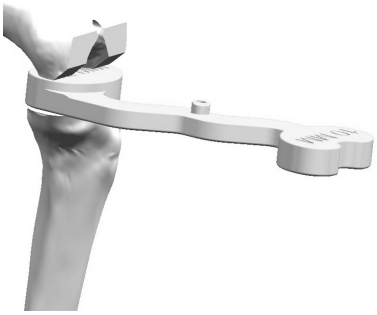


Figure 54

Part C

FLEXION/EXTENSION GAP MEASUREMENT

Two types of flexion/extension blocks are available: Modular and "Dog Bone".

USE OF FLEXION/EXTENSION BLOCKS

The flexion/extension gaps are measured following the tibial resection and femoral resections. With the knee flexed at 90º, insert the 10mm spacer block assembly into the space between the posterior femoral condyle and tibial bone surfaces. (Figure 54) If the 10mm spacer block does not fit in flexion, additional tibial resection or a smaller femoral size may be needed. Use progressively thicker spacer blocks until the appropriate tension is obtained in flexion. Slide the external alignment rod through the holes in the tibial trial base handle to check accuracy of the tibial cut to the center of the ankle.

After the flexion gap has been determined, place the leg in extension. (Figure 55) If the 10mm spacer block does not fit, additional distal resection may be required to achieve full extension.

NOTE:
If using the modular flexion/extension blocks, the minus 2mm spacer block is available in the event the 10mm block cannot fit in the joint space. If the 2mm block fits the joint space, 2mm more resection is necessary.

NOTE:
The spacer blocks indicate the thickness of the appropriate tibial insert. The thickness of the femoral condyles, tibial base, and tibial insert are built into the spacer block thickness

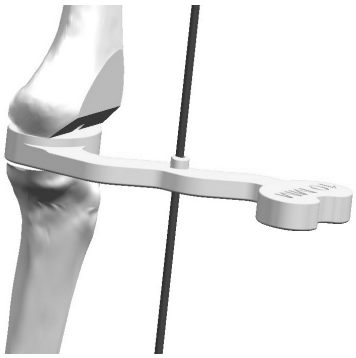


Figure 55

Additional Information

Figure 56

PART D: 2mm Resection Guide

The 2mm resection guide is generally employed for use on the proximal tibial resection. To position the guide, place the anterior wings on the resected surface with the resection slot abutting the edge of the surface. Two convergent pin holes are available for fixation. (Figure 56)

PART E: Efficient Use of Fixation Pins

NOTE:
PROPHECY® Alignment Guides and ODYSSEY® Total Knee Instruments are designed for use with 1/8" (3.2mm) fixation pins. Both threaded pins and standard impact-driven are available. Threaded pins are generally utilized for enhanced fixation.

Figure 57

General recommendations for use of pins…
A wire driver with pin collet is the most effective instrument for driving threaded pins. This is due to the high rate of rotation and tensioning handle to grip the pin during removal. (Figure 57)

The ODYSSEY® Pin Driver is most effective if loaded into a drill instead of a reamer due to the faster rotation of the drill. (Figure 58)

Figure 58

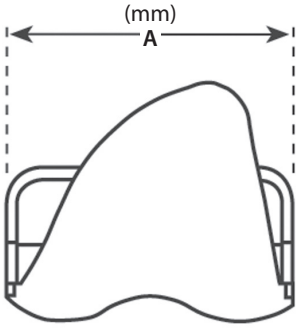
Headless pins are most commonly utilized with the distal femoral and proximal tibia resection guides. Headless pins allow the guides to be removed and repositioned through the 2mm holes. These pins should not be left overly proud (over 1-inch/25mm) to prevent interference with the saw as it is driven deep into the bone. Ensure the pins are not impacted too deeply to be retrieved with a pin extractor. If threaded pins are inserted too deeply to be engaged with a wire driver, the ODYSSEY® Pin Driver may be utilized.

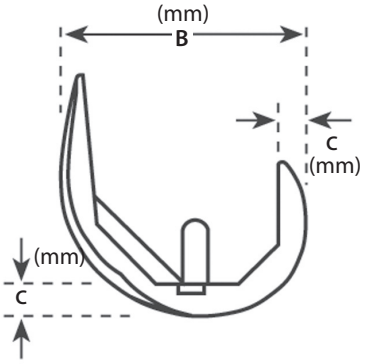
Collared threaded or headed impaction pins are generally utilized for the 4-in-1 resection guides. Ensure the collared, threaded pins are not over-driven once the collar contacts the guide outrigger. If over-driven, the threaded pins will strip the bone and lose fixation.

Component Specifications

Primary Femoral Components

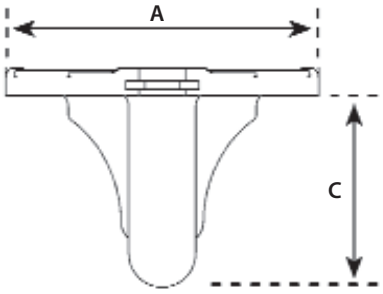
SIZE	A	B	C
1	60	52	8
2 – ADVANCE STATURE™	60	57	8
2	65	57	8
3 – ADVANCE STATURE™	65	62	8
3	70	62	8
4 – ADVANCE STATURE™	70	66	8
4	75	66	8
5	80	71	8

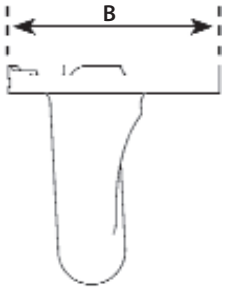




Tibial Component

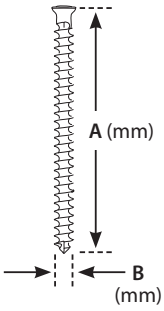
TRAY SIZE	A	B	C
1	60	41	35
1+	65	44	35
2	65	44	32
2+	70	48	43
3	70	48	43
3+	75	51	43
4	75	51	43
4+	80	54	50
5	80	54	50
5+	85	58	50
6	85	58	50

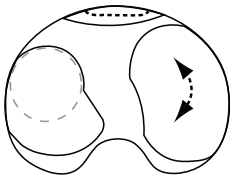




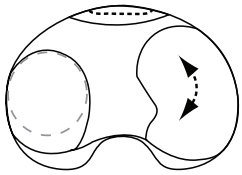
6.5mm Cancellous Bone Screws

SIZE	A	Ø B
15mm	15	6.5
20mm	20	6.5
25mm	25	6.5
30mm	30	6.5
35mm	35	6.5
40mm	40	6.5
45mm	45	6.5
50mm	50	6.5
55mm	55	6.5





ADVANCE® DOUBLE-HIGH INSERT
PCL RETAINING
Available Thicknesses
10, 12, 14, 17mm

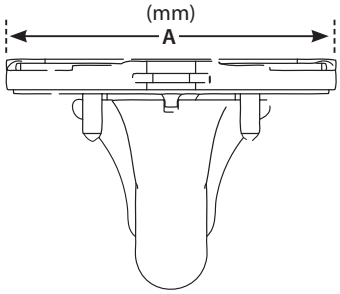


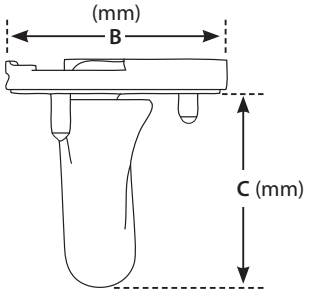
ADVANCE® MEDIAL-PIVOT INSERT
PCL SACRIFICING
Available Thicknesses
10, 12, 14, 17, 20, 25mm

Component Specifications

Primary Pressfit Keels

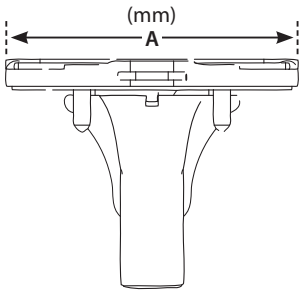
SIZE	A	B	C
1	60	41	34
1+	65	44	34
2	65	44	34
2+	70	48	41
3	70	48	41
3+	75	51	41
4	75	51	41
4+	80	54	49
5	80	54	49
5+	85	58	49

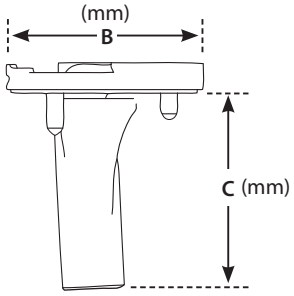


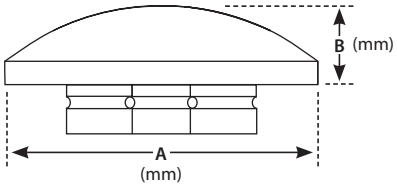


Modular Pressfit Keels

SIZE	A	B	C
1	60	41	47
1+	65	44	47
2	65	44	47
2+	70	48	47
3	70	48	47
3+	75	51	47
4	75	51	47
4+	80	54	47
5	80	54	47
5+	85	58	47

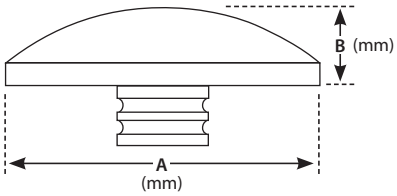






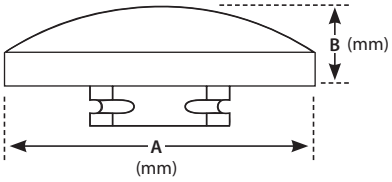
Onlay All-poly Tri Peg

A	B
26	8
29	8
32	8
35	8
38	10
41	11



Onlay All-poly Single Peg

A	B
32	8
35	8
38	10
41	11



Recessed All-poly

A	B
25 Low	7
25 High	9
28 Low	7
28 High	9

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5677 Airline Road
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866 872 0211

ortho.microport.com

EC REP
MicroPort Orthopedics BV
Hoogoorddreef 5
1101 BA Amsterdam
The Netherlands
+31 20 545 01 00

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