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Vanguard[®] 360 Revision Knee System

Surgical Technique

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Product Selection

The status of the ligamentous structures and the extent of the bony deficiencies help guide in the implant selection. Minimally deformed knees with intact ligamentous structures may be addressed with posterior cruciate retaining or posterior stabilized condylar devices. Stemmed systems not only assist in fixation, but also facilitate proper alignment of both components and minimize the interface stresses on the implant-bone interface. When collateral ligament stability cannot be balanced and restored, consider a rotating-hinge arthroplasty.^{1–4}

Technique Summary

This technique is based on intramedullary instrumentation which uses the patient's anatomy to aid in determining implant positioning. Because Vanguard 360 offers tibial and femoral stem offsets, the IM canal does not limit final implant positioning.

Approach

The approach is typically made through the previous incision. Perform intra-articular scar excision in the medial and lateral gutters to mobilize the extensor mechanism. Patellar eversion may not be necessary and may be avoided until the failed implants are removed. Care should be taken to avoid avulsion of the patellar tendon. Various extensile exposures may be utilized including extensor mechanism tenolysis,¹ quadriceps snip, quadriceps turndown and tibial tubercle osteotomy.

The Vanguard 360 Revision System was designed in conjunction with Adolph Lombardi, Jr., M.D., Christopher Peters, M.D., Thomas Donaldson, M.D., James Scott, M.D., Keith Berend, M.D., and Mike Berend, M.D.

This brochure is presented to demonstrate the surgical technique utilized by Adolph Lombardi, Jr., M.D., Christopher Peters, M.D., Thomas Donaldson, M.D., James Scott, M.D., Keith Berend, M.D., and Mike Berend, M.D. Biomet, as the manufacturer of this device, does not practice medicine and does not recommend this device or technique. Each surgeon is responsible for determining the appropriate device and technique to be utilized on each individual patient.



Component Removal

Flex the knee and remove the tibial polyethylene, allowing greater access to the prosthesis/cement interface of both the femur and tibia. Disrupt the femoral implant/bone interface with flexible osteotomes or thin saw blades with an oscillating saw. Utilize the ultrasonic knee osteotome with the Ultra-Drive cement removal system to disrupt this interface with minimal damage to the underlying bone (Figure 1). If the ultrasonic tools are used, generous irrigation is required.

Note: In the case of a porous component, disrupt the bone/implant interface by using a gigli saw, the thin blade of a reciprocating saw or flexible osteotomes. Disrupt cement along the tibial plateau with a thin blade reciprocating saw or the Ultra-Drive knee osteotomes and manual osteotomes prior to utilizing a mallet and extraction device. In the case of stemmed components, remove screws and disengage the morse tapers. This allows for direct access to the stems. When access to the stem is achieved, disrupt the cement interface around the stem with either the Ultra-Drive System, osteotomes or a pencil-tipped high-speed burr.



Film Har 1000. Total

Figure 2

Figure 3

Early Trialing Philosophy

Bone loss is a significant concern in many revision knee procedures, and it is important to have good options available to help preserve bone.

The early trialing steps outlined in this section allow for the use of trial components before committing to any bone resections. This approach can help to:

- Preserve bone by eliminating the use of 4-in-1 cut blocks
- Save O.R. time by reducing the number of surgical steps and instrumentation needed
- Focus on balancing the knee and reestablishing the proper joint line (vs. removing more bone)

Gap Spacers

Once the knee implant components have been removed, gap spacers can measure flexion and extension gaps to help balance the knee and restore the proper joint line. The joint line should be approximately 3 cm distal to the medial femoral epicondyle, 2.5 cm distal to the lateral epicondyle and 1 cm proximal to the fibular head.⁵ Tibial spacer sizes range from 10 mm up to 26 mm in 2 mm increments (Figure 3). Tibial bearing sizes range from 10 mm up to 24 mm in 2 mm increments.



Gap Spacers (cont.)

The femoral spacer is 9 mm, which represents the distal and posterior thickness of the femoral implant. The 5 mm, 10 mm and 15 mm shim spacers represent augment thicknesses (Figure 4).

Vanguard 360 instruments are designed to allow for gap checks during the procedure. For example, the femoral

4-in-1 cutting block is 9 mm thick and has a 9 mm extension posteriorly to replicate the implant thickness. The tibial sled is 10 mm thick to match the smallest thickness for tibial replacement.

Note: The 15 mm femoral augment is only available distally.

	Loose in Extension	Tight in Extension	Stable in Extension
Loose in Flexion	 Increase poly bearing thickness Add/increase tibial augments Augment distal femur and upsize femur with posterior augments Augment distal femur and offset femur posteriorly 	 Resect distal femur and use thicker poly bearing Resect distal femur and upsize femur with posterior augments Resect distal femur and offset femur posteriorly 	 Upsize femur with posterior augments Offset femur posteriorly
Tight in Flexion	 Downsize femur and add distal augments Offset femur anteriorly to be flush with anterior cortex and add distal augments 	Decrease tibial poly thicknessResect tibia	 Downsize femur Offset femur anteriorly to be flush with anterior cortex
Stable in Flexion	Augment distal femur	Resect distal femur	Trialing adequate

Revision Knee Trialing Stability Matrix*

*To ensure proper patella tracking, joint line should be 3 cm distal to medial epicondyle

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Reaming



Tibial and Femoral Intramedullary (IM) Reamers

Vanguard 360 reamers are available in 1 mm increment diameters from 10 mm to 24 mm. Reamers include depth markings showing stem lengths for the femur on one side (dark - Figure 5 inset), and stem length depth markings for the tibia on the other designated "T" (Figure 5 inset).

Numbers followed by a small "o" indicate the stem length used with an offset adapter. Ream line-to-line for smooth, grit-blasted and splined stems.



Figure 7

Tibial and Femoral Intramedullary (IM) Reamers (cont.)

Figure 6 shows the reamer depth at $120/80^{\circ}$ for the femur. A 120 mm long stem may be used without an offset adapter. An 80 mm long stem may be used with either a 2.5, 5.0 or 7.5 mm offset stem adapter.

ONDE: See construct length matrix (Appendix B).

Figure 6 shows the reamer depth at $120/80^{\circ}$ T for the tibia. A 120 mm long stem may be used without an offset stem adapter. An 80 mm long stem may be used with either a 2.5, 5.0 or 7.5 mm offset stem adapter.

Tibial Preparation

TIBIAL PREPARATION





Figure 9

Intramedullary Proximal Tibial Resection

It is important to understand that when stemming the tibial component, a canal-filling straight stem is designed to control the mediolateral and anterior/ posterior position of the proximal tibial component. 2.5, 5 and 7.5 mm offset stem adapters allow adjustments to the A/P and M/L tibial tray position to achieve better tibial coverage.

Fully flex the knee and locate the center of the tibial plateau. Center the drill and create an entry hole with the 9 mm drill, if necessary. Most revision cases will already have a plateau opening (Figure 8).

Progressively ream the tibial medullary canal with the fluted cylindrical reamers to the proper depth until cortical chatter is obtained (Figure 9). When reaming is finished, engage the fins of the reamer into the bone several millimeters by tapping the end of the reamer with a mallet.

Note the diameter and the tibial trial stem lengths shown at the selected reaming depth.

Note: Silvermarkings, followed by an engraved "T", are for tibial reaming.



Figure 11

Proximal Tibial Resection, Anatomic Specific Block - Option 1

Attach the appropriate side specific tibial resection block to the IM tibial resection guide by the screw attachment (Figure 10).

Attach the stylus by pushing the silver button and sliding the stylus into the housing. To adjust the tibial resection level, press the dial and rotate it to the desired resection level. The dial may be adjusted in 1 mm increments. Place the IM tibial resection guide over the proximal end of the reamer and lower it until the stylus contacts the least affected tibial condyle (Figure 11). Position the stylus at a point where a clean-up cut will provide a smooth, flat surface for the tibial implant. Typically 1 or 2 mm is a sufficient clean-up cut. If a bone defect is present on one side, do not position the stylus on the defect since it will remove the additional bone stock on the other side.

Move the cutting block against the anterior tibia by pushing in the silver button on the resector body.



Anatomic Specific Block – Option 1

To confirm alignment, insert a mini alignment handle into the cut block and a $\frac{1}{4}$ " alignment rod into the handle. The distal tibial crest or medial $\frac{1}{3}$ of the tibial tubercle may be referenced.

Note: Attach the mini handle upside down when using the alignment rod with an anatomic cut block. Once the correct position is established, ¹/₈" drill bits are used to secure the cutting block to the tibia through the most distal pin holes of the cut block (Figure 12). This will allow additional resection of +2 or +4 mm of the proximal tibial plateau by moving the block distally if additional resection is necessary.

Remove the tibial resection guide, alignment tower and rod, leaving the tibial resection block in place. Resect the plateau using a .054" saw blade.





Figure 14

Proximal Tibial Resection, Universal Block with Augment Cut Slots - Option 2

Attach the Universal Block with augment cut slots to the IM tibial resection guide with the integral screw attachment using a 3.5 mm hex driver (Figure 13). The Universal Block has a clean-up slot and tibial augment resection slots (5, 10, and 15 mm).

To adjust the tibial resection level, press the dial in and rotate it to the desired resection level. The dial may be adjusted in 1 mm increments.

Note: Tibial augment resections can also be made in a later step using anatomic tibial augment resection blocks with the tibial sled or trial tibial tray and mini-alignment handle. Place the IM Tibial Resection Block over the proximal end of the reamer and lower it until the stylus contacts the least affected tibial condyle (Figure 14). Position the stylus at a point where a clean-up cut will provide a smooth, flat surface for the tibial implant. Typically 1 or 2 mm is a sufficient clean-up cut. If a bone defect is present on one side, do not position the stylus on the defect since it will remove the good bone on the other side.

Move the cutting block against the anterior tibia by pushing in the silver button on the resector body.

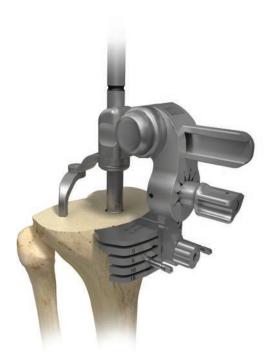




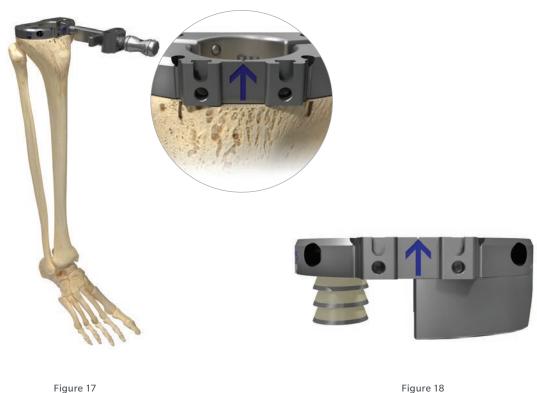
Figure 16

Proximal Tibial Resection, Universal Block with Augment Cut Slots - Option 2 (cont.)

Pin the tibial revision resection block to the anterior tibia with $\frac{1}{8}$ " drill bits through holes on the face of the tibial resection block (Figure 15). If augment slots are going to be used, make sure to not place the pin in the cutting slot needed for augmentation.

Remove the tibial resection guide, leaving the tibial resection head in place (Figure 16). Make sure to note the diameter and depth of reaming (using the silver markings) that achieved cortical chatter, since that will determine the size of tibial stem used, then remove the reamer.

Resect the tibial plateau through the slot with a .054" saw blade. Tibial augment resections can be made at 5 mm, 10 mm, or 15 mm.

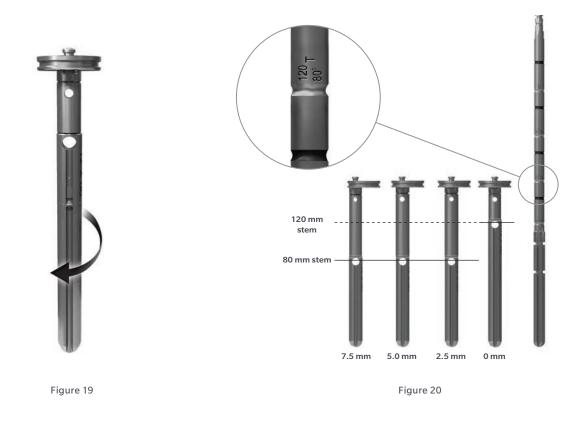


Tibial Sizing and Positioning

Select a tibial sled size that provides the best tibial plateau coverage (Figure 17). Available tibial sled sizes include: 59, 63, 67, 71, 75, 79, 83, 87 and 91 mm. The tibial sled thickness is 10 mm to correspond to the tibial tray implant combined with the thinnest available tibial bearing. The 10 mm thickness can be used for gap analysis and joint line determination.

The mini-alignment handle should be attached to the sled in the medial position.

- **ONDE:** If augment cuts have been made, either 5 mm magnetic spacers or trial tibial augments can be used to fill the augment space (Figure 18).
- **ONDE:** 10 mm or 15 mm heights can be achieved by stacking the 5 mm magnetic spacers.



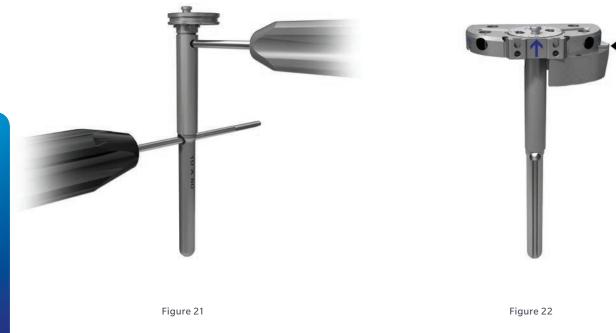
Tibial Preparation

In some cases, in order to achieve optimal tibial plateau coverage, a tibial stem offset may be beneficial. The Vanguard 360 utilizes universal offset stem adapters that are used with both the tibial tray and femoral implants. The stem offset can be rotated 360 degrees for exact tibial placement and is available in 2.5 mm, 5 mm and 7.5 mm offset magnitudes.

Offset Specific Coin

Tibial sled coins allow trial stem attachments to evaluate sled position with a stem. Starting with a 0 mm coin (no stem offset), thread a trial stem corresponding to the tibial reaming diameter and depth to the tibial sled coin by rotating the stem clockwise (Figure 19).

Note: Use the 40 mm longer stem length noted on the reamer with the non-offset (0 mm) coin. Use the stem length marked with a small "o" with the 2.5 mm, 5 mm, and 7.5 mm offset modular boss. The 40 mm shorter stem length accounts for the length of the offset adapter (Figure 20).



Offset Specific Coin (cont.)

A 3.5 mm hex driver can be placed through the hole in the trial stems to aid in tightening the stem to the coin (Figure 21). Snap the tibial coin and trial stem assembly into the top of the tibial sled (Figure 22).

Note: If a tibial augment resection was made, either 5 mm stackable magnetic spacers or trial tibial augments can be attached to the sled.



Figure 24

Offset Specific Coin (cont.)

The coin can be secured to the sled with the 2.5 mm hex screwdriver, turning the screw clockwise on the medial side (Figure 23).

Insert the tibial sled, with trial stem assembly, into the tibia.

After insertion, loosen the coin locking feature by turning the 2.5 mm hex screwdriver counterclockwise.

● Note: Be careful not to back the screw out completely. Only 2-3 turns are required.

Evaluate tibial plateau coverage. If an acceptable position is not found with the 0 mm coin, remove the coin and trial stem assembly from the sled and continue trialing with a 2.5 mm, 5 mm or 7.5 mm offset coin until the best possible coverage is determined.

To adjust the offset direction, insert the two prongs on the coin driver into the two holes in the top of the coin (Figure 24). Rotate the coin driver to adjust the sled position on the tibial plateau.

- Note: Rotating the 0 mm coin has no effect on the sled position.
- Note: The sled/trial tray remover can be used to remove the sled, coin and trial stem assembly. Pull back on the top lever, slide the handle down into the anterior attachment points. Release lever and then impact the strike plate upward to remove the sled.





Figure 26

Offset Specific Coin (cont.)

Once an appropriate position is found, secure the sled to the tibia with long headed bone nails (Figure 25).

Be sure to note the offset magnitude (2.5 mm, 5 mm and 7.5 mm) and offset direction reference number (0 through 19). The offset magnitude is on the coin and the offset rotation reference on the coin is read at the blue arrow on the anterior portion of the sled (Figure 25 inset).

- Note: If the coin was screwed to the sled using the locking ports, be sure to use a 2.5 mm hex screwdriver counterclockwise before removing the coin.
- Note: Be careful not to back the screw out completely. Only 2-3 turns are required.

Note: If trial tibial augments are attached to the sled, the two central sled holes cannot be used to secure the sled to the tibia. Use either the two anterior holes or the two posterior holes (Figure 26).





Offset Specific Coin (cont.)

Use the slap hammer to remove the coin and trial stem (Figure 27).

Note: If used, remember to loosen the 2.5 mm hex screw on the tibial sled prior to removing the coin.

Boss and Offset Adapter Preparation

Select either a neutral, 2.5 mm, 5 mm or 7.5 mm tibial reamer bushing based on the offset magnitude determined using the coin. Place the tibial reamer bushing into the sled and align the rotational reference mark with the position that was determined with the coin (Figure 28). Once the proper orientation is selected, press down on the bushing to snap it into place. To adjust the rotation, pull up on the bushing, rotate and then press down to snap back into place.

Figure 28

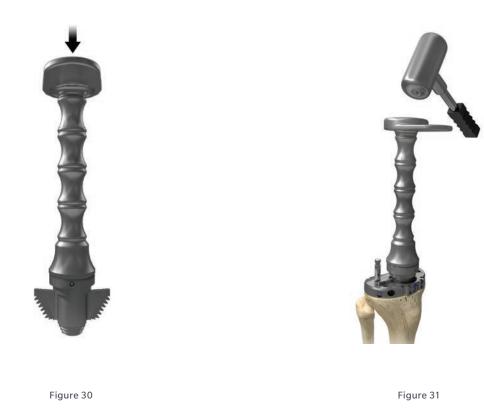


Boss and Offset Adapter Preparation (cont.)

Select a neutral tibial reamer (shorter) to prepare for just the tibial tray boss or the offset tibial reamer (longer) to prepare for the tibial tray boss and the 2.5 mm, 5 mm or 7.5 mm offset adapter.

Note: Tibial and femoral neutral and offset reamers are different. Femoral reamers have two black lines near the connection point for ease of identification and are also denoted "FEM". Tibial reamers do not have black bands and are marked "TIB". Attach the reamer to a T-handle, and using manual pressure ream until the reamer stop bottoms out on the reamer bushing (Figure 29).

Caution: Care should be taken when using a larger offset with a small tibia to reduce the potential for tibial fracture or perforation of the cortex.

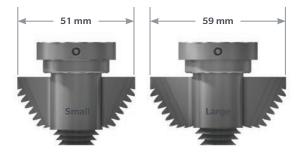


Cruciate Wing Preparation

To add tibial implant rotational stability, small or large cruciate wings can be added to the modular boss on the bottom of the tibial tray.

● Note: Tibial augment blocks and offset stem adapters can be used with cruciate wings.

Push the top button on the modular impact handle and attach the small or large cruciate wing punch, then release the button (Figure 30).



Impact the punch through the sled until the punch is fully seated and remove (Figure 31).

Note: The small cruciate wings can be used with all sled sizes. The large cruciate wing cannot be used with 59 mm and 63 mm trays.



Figure 33

Tibial Augment Resection

Tibial augment resections can be made using either medial or lateral specific augment resection blocks attached to the mini-alignment handle and tibial sled (Figure 32). The augment blocks slide on to the bottom of the mini-alignment handle and are secured via a magnet. Secure the augment block to the tibia with 1/8" drill bits (Figure 33). Remove the mini-alignment handle and sled.



Tibial Augment Resection (cont.)

Use a reciprocating saw to make the vertical augment resection through the cut block, being careful to only cut down to the appropriate augment depth (Figure 34).

● Note: Augment depths are denoted with engraved markings.

Resect the tibia through the appropriate slot (5 mm, 10 mm or 15 mm thick augments) using a .054" saw blade (Figure 35).





Figure 37a



Figure 37b

Trial Tibial Tray

Select the trial tibial tray size that corresponds to the tibial sled size that was previously used.

Insert the screw head of the trial boss up through the central hole in the trial tray and slide it along the slot ensuring that the boss tab fits in the tray keyhole slot. Tighten modular boss with 3.5 mm hex driver from the top (Figure 36).

Trial Tibial Augments

If tibial augments are needed, 5 mm, 10 mm or 15 mm augment trials can be attached below the tray medially or laterally by sliding the augment notch into the slot on the tray (Figure 37a).

Cruciate Wing Option

If used, place a small or large cruciate wing over modular boss before assembling the offset adapter or trial stem. It is helpful to keep the tibial tray upside down while attaching the cruciate wing to reduce the risk of dropping it. Once assembled, the offset adapter trial or trial stem will keep the cruciate wing in place.

Note: Augments can be used with cruciate wings. If both are used together, assemble the augments to the tray before attaching the cruciate wing (Figure 37b).



Trial Tibial Tray (cont.)

Offset Adapter Option

Thread the head of the offset adapter into the bottom of the boss by rotating the offset adapter clockwise. Rotate the offset adapter aligning the reference mark determined with the tibial sled coin to the anterior indicator mark on the trial boss (Figure 38).

Note: Offset adapters are available in 2.5, 5.0 and 7.5 mm (shown below). While holding the offset adapter at the appropriate reference mark, tighten the offset adapter using a 3.5 mm hex driver through the bottom (Figure 39).

Caution: Care should be taken to ensure the offset adapter position does not change during tightening of the lock screw.







Figure 41

Trial Tibial Tray (cont.)

Trial Stem

Thread the trial stem into either the bottom of the boss or the offset adapter by rotating it clockwise (Figure 40).

● Note: If an offset adapter is not used, thread the trial stem directly into the tibial tray boss (Figure 40a).

Early Trialing

EARLY TRIALING



Femoral Reaming

Use a .375" drill to penetrate the cortex and dense cancellous bone to a depth of approximately 1 to 2" (Figure 42).



Femoral Reaming (cont.)

Progressively ream using the cylindrical fluted reamers until cortical chatter is obtained (Figure 43). Refer back to the Tibial and Femoral Intramedullary (IM) Reamers Section on page 5 for reamer information. Note the femoral trial stem lengths on the reaming depth and diameter.

Attention: Use black mark to reference femoral reamer depths.

When reaming is complete, engage the fins of the reamer into the bone $\frac{1}{8}$ " further for secure fixation by tapping the end of the reamer with a mallet. Leave the reamer in place.

Slide the appropriate left or right 5 degree valgus wing over the reamer and place the bottom plate of the wing against the distal femur (Figure 44).



Distal Femoral Resection

Note: As part of the early trialing process, further distal femoral resection may NOT be necessary. If this is determined to be the case, please skip this page and continue on with the Femoral Sizing section on page 29.

Attach the 5 degree valgus tower by sliding the pegs into the open holes of the valgus wing (Figure 45).

Note: The tower is universal, and can only be positioned in one direction with the appropriate left or right valgus wing.

Attach the distal resection block to the tower via the integral magnetic feature. Secure the distal resection block with ¹/₈" drill bits or bone nails (Figure 45). The distal resection block includes a 1 mm clean-up slot and 5, 10, and 15 mm distal augment slots. The block can be shifted proximally 2 mm using the designated pin holes.

Remove the reamer and tower and complete the distal resection through the selected slot using a .054" saw blade (Figure 46).

Figure 46

The goal of the distal resection is to provide a flat surface to begin joint line restoration and establish a 5 degree femoral valgus angle. Distal femoral defects are common in revision surgeries.

- Note: Take care in maintaining the appropriate joint line position and not moving the joint line proximal. The joint line should be 3 cm distal to the medial epicondyle. The distal block shows a reference mark for the medial epicondyle.
- Solution Note: If 4-in-1 cuts are needed, please see Appendix A.

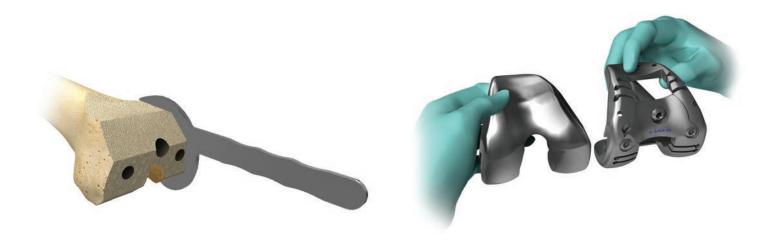


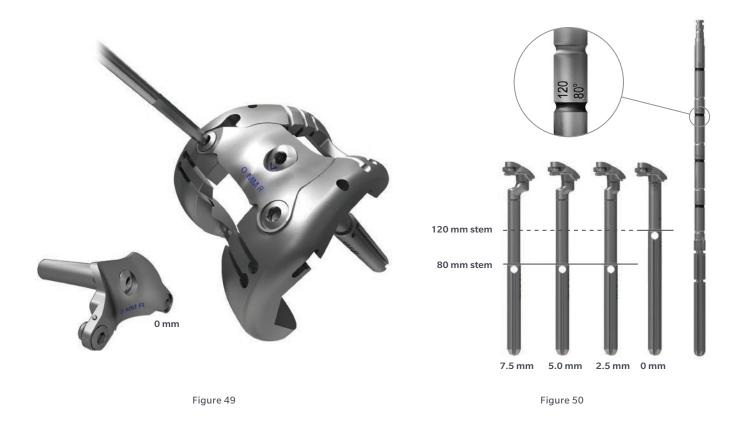
Figure 48

Femoral Sizing

Determining the size of the component being removed can be helpful with initial femoral sizing. After the existing femoral component is removed, lateral femoral templates sizes 55, 57.5, 60, 62.5, 65, 67.5, 70, 72.5, 75 and 80 can be used to approximate femoral size (Figure 47). The handle of the template indicates the anterior-posterior (A/P) position of the femoral boss without offset. The machined grooves in the template correspond to the available 5, 10, and 15 mm distal augments and 5 and 10 mm posterior augments and can be used to approximate femoral augments.

Using the femoral templates and the primary femoral implant as a guide (Figure 48), select the appropriately sized cut-through femoral trial.

Note: If femoral rotation correction is needed, it is necessary to use a 4-in-1 cutting block. (See Appendix A).



Femoral Positioning

No Offset

The modular boss allows a trial stem to be attached to the femoral trial without resecting the box.

Assemble the 0 mm modular boss (non-offset) to the trial stem with diameter and length used to achieve cortical chatter. Attach stem and modular boss to the cut-through femoral trial (Figure 49).

Note: Use the longer stem length noted on the reamer, with non-offset (0 mm) modular boss. Use the stem length marked with the small "o" with the 2.5 mm, 5.0 mm and 7.5 mm offset modular boss (Figure 50). The 40 mm shorter stem length accounts for the length of the offset.



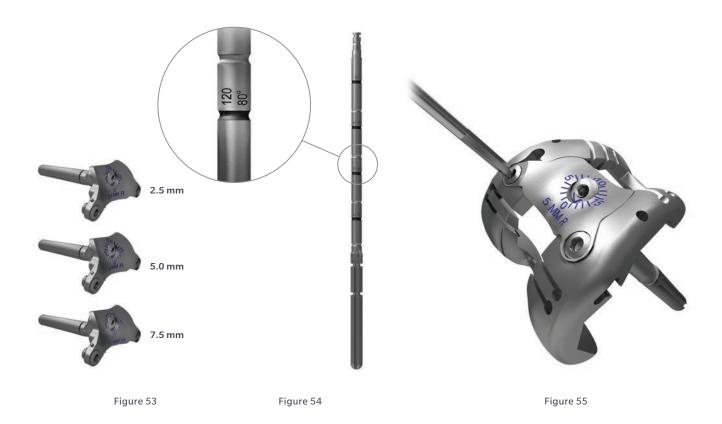
Figure 52

Femoral Positioning (cont.)

No Offset

The cut-through femoral trial can also be used to guide resections for distal and/or posterior augments later when the femoral position is confirmed.

● Note: Distal femoral augment trials (5, 10 or 15 mm) can be attached through slots in the femoral trial (Figure 51). Posterior augment trials can be attached with a 3.5 mm hex screwdriver (Figure 51). Insert the femoral trial/stem construct and assess femoral coverage and position (Figure 52). If the 0 mm boss does not provide adequate coverage, as shown in Figure 52, a 2.5 mm, 5 mm or 7.5 mm modular offset boss will be necessary to adjust the A/P and (or) M/L position.



Femoral Positioning (cont.)

2.5, 5, or 7.5 mm Offset

Depending on the magnitude of offset required for adequate coverage, select the appropriate left or right offset modular boss: 2.5 mm, 5.0 mm or 7.5 mm (Figure 53).

- Note: When the 2.5 mm, 5 mm and 7.5 mm offset modular bosses are used (Figure 54). The 40 mm shorter stem length accounts for the length of the offset adapter.
- Note: Offsets allow for A/P and M/L femoral position adjustments to achieve the best possible patient fit.

Secure the modular boss to the cut-through femoral trial that corresponds to the size of the lateral template selected previously using the two 3.5 mm hex bolts (Figure 55).

Select a trial stem with diameter and length matching the diameter and depth used to achieve cortical chatter. Thread the selected trial stem to the femoral trial by turning the stem clockwise.



Figure 57

Femoral Positioning (cont.)

2.5, 5, or 7.5 mm Offset (cont.)

The offset rotation can be adjusted a full 360 degrees to adjust the overall medial/lateral and anterior/ posterior femoral positions, using a 3.5 mm hex screwdriver on the central screw (Figure 56).

The cut-through femoral trial may need to be pulled away from the femur to adjust the offset rotation, depending on bone interface anteriorly and/ or posteriorly. If the femoral position needs to be adjusted, remove the trial from the femur and adjust the modular boss.

Adjust femoral trial position to achieve the best possible bone coverage and flexion gap restoration (Figure 57).





Figure 59

Trial Bearing Insertion

Select a trial bearing size corresponding to the tray size and select a bearing thickness. Bearing thicknesses are available from 10 mm to 24 mm in 2 mm increments. Insert the trial bearing, WITHOUT the post, onto the trial tray by first engaging the posterior of the bearing to the tray and then pushing down on the anterior portion until it snaps into place (Figure 58).

Note: The locking bearing can only be removed using the bearing removal tool. While holding the removal tool, use thumb to pull back on top lever, slide handle into anterior opening on the bearing, release top lever, lift bearing up and then pull out.

Flexion/Extension Gap Analysis

With the trial bearing in place, flex and extend the knee (Figure 59). Evaluate femoral and tibial component positions, flexion and extension gaps, joint line, and any augments that may be needed. Distal femoral augments will tighten the extension gap and can help move the joint line more distally. The joint line should be approximately 3 cm distal to the medial epicondyle and 2.5 cm distal to the lateral epicondyle.⁵



Flexion/Extension Gap Analysis (cont.)

Relative to the stem, on average, posterior condyles change 2 mm while the anterior flange changes 0.4 mm between sides. A larger femoral size will tighten the flexion gap. A thicker tibial bearing will tighten flexion and extension gaps, while resecting more tibia will loosen flexion and extension gaps (see trialing matrix below). Once satisfied with the positioning and balancing, pin the femoral cutthrough trial in place (Figure 60). Note: If a box resection guide will be used in a later step, do not pin the femoral trial through the anterior medial hole since it will interfere with the box guide in later steps (Figure 60).

	Loose in Extension	Tight in Extension	Stable in Extension
Loose in Flexion	 Increase poly bearing thickness Add/increase tibial augments Augment distal femur and upsize femur with posterior augments Augment distal femur and offset femur posteriorly 	 Resect distal femur and use thicker poly bearing Resect distal femur and upsize femur with posterior augments Resect distal femur and offset femur posteriorly 	 Upsize femur with posterior augments Offset femur posteriorly
Tight in Flexion	 Downsize femur and add distal augments Offset femur anteriorly to be flush with anterior cortex and add distal augments 	Decrease tibial poly thicknessResect tibia	 Downsize femur Offset femur anteriorly to be flush with anterior cortex
Stable in Flexion	Augment distal femur	Resect distal femur	Trialing adequate

Revision Knee Trialing Stability Matrix*

*To ensure proper patella tracking, joint line should be 3 cm distal to medial epicondyle

Femoral Preparation



Figure 62

Boss and Offset Adapter Preparation

Loosen the two side screws in the modular boss, and utilizing the slap hammer (or by hand), remove the modular boss and trial stem (Figures 61 and 62).



Figure 64

Boss and Offset Adapter Preparation (cont.)

Secure a left or right specific reamer housing to the cut-through femoral trial with two 3.5 mm hex bolts (Figure 63).

Pull the reamer housing knob outward to insert the appropriate reamer bushing, corresponding with the previously selected offset magnitude (0, 2.5, 5 or 7.5 mm). The bushing can be rotated in either direction to dial in the offset reference determined with the modular boss, or 4-in-1 coin if used (Figure 64). Use the posterior reference mark on the reamer housing to align the corresponding bushing mark (Figure 64 inset). Release the knob to lock rotation in position once lines are aligned.

Note: Positions 8–12 are not available on the 7.5 mm reamer bushing to reduce the risk of anterior breakout.



Figure 66

Boss and Offset Adapter Preparation (cont.)

Attach either the neutral (no offset required) or offset reamer to the T-handle. Ream by hand through the offset reamer bushing with either the neutral or offset reamer until the reamer stop hits the reamer bushing (Figure 65).

Note: There is a Boss reamer (neutral) and an Offset reamer for both the tibia and the femur. Femoral reamers have two black lines near the connection point for easier identification. The femoral reamers are also marked "FEM". Tibial reamers do not have black bands and are marked "TIB".

Once reaming is complete, remove the reamer bushing and housing.

Intercondylar Box Resection Option 1

With the cut-through femoral trial in place, resect along each interior edge of the trial with a reciprocating or oscillating saw. Make wall cuts first to the depth of the box, then proceed with the vertical cut utilizing a small oscillating blade or a reciprocating blade until intercondylar bone is removed.

Intercondylar Box Resection Option 2

Secure a left or right specific box resection guide with two 3.5 mm hex bolts (Figure 66).

Note: Do not use the anterior medial pin hole location on the femoral trial when using the box resection guide.





Figure 68

Intercondylar Box Resection Option 2 (cont.)

Connect the chisel to the impactor handle by pushing in the top button on the handle, attaching the chisel and then releasing the button. Drive the chisel half way through the captured guide and leave it in place (Figure 67). Resect the box walls (Figure 68), then complete by driving the chisel until it stops against the bottom of the trial.



Figure 70

Intercondylar Box Resection Option 2 (cont.)

Place the femoral box gauge into the resected intercondylar area to verify the depth and width of the prepared distal femoral box (Figure 69).

Femoral Augment Resection

The femoral cut-through trial contains 5, 10 and 15 mm distal augment cut slots and 5 and 10 mm posterior augment cut slots. Make appropriate distal and posterior augment cuts if necessary (Figure 70). Slide-on distal augment trials and screw-down posterior augment trials are used for trialing.

Caution: Take appropriate care with protecting collateral ligaments when resecting through distal and posterior augment slots.



Figure 72

Femoral Trial Assembly

If an offset is needed, thread an offset adapter corresponding to the offset magnitude previously determined within the procedure onto a femoral modular box corresponding to the femoral size, in either a right or left orientation, which is indicated by an R or L on the box shown in (Figure 71).

If an offset is not needed, thread the trial stem directly onto the modular box.

Rotate the offset adapter to match the rotation previously determined within the procedure and tighten the adapter using a 3.5 mm hex screwdriver from the bottom of the adapter (Figure 72). It can also be tightened through the femoral box by turning a 3.5 hex screwdriver counterclockwise.

Caution: Care should be taken to ensure the offset adapter position does not change during tightening of the locking screw.



Figure 74

Femoral Trial Assembly (cont.)

Thread a trial stem onto the offset adapter by rotating it clockwise (Figure 73).

Secure the modular box to the cut-through femoral trial, using the two 3.5 mm hex bolts on the modular box (Figure 74).



Femoral Trial Assembly (cont.)

● Note: Bowed 160 mm and 200 mm stems have a thumb screw to allow the bow to be positioned in the proper orientation (Figure 75).



Femoral Trial Assembly (cont.)

If distal augments are needed, select the appropriate size and slide on from the side. If posterior augments are needed, select the appropriate size and attach using a 3.5 mm hex screwdriver (Figure 76). For half size femoral trial augments, use the lower whole size. Note: Posterior augments are universal, the bolt slides from side to side to accommodate a medial or lateral position. Do not over tighten the posterior augment trial bolt.



Femoral Trial Assembly (cont.)

Insert completed femoral trial onto the femur (Figure 77).

Trial Tibial Bearing

Once the tibial plateau is prepared with the trial tray, trial augments and trial stem, select a trial bearing size corresponding to the tray size and select a bearing thickness. Bearing thicknesses are available from 10 mm up to 24 mm, in 2 mm increments. Insert trial bearing with either a Modular SSK PS or PSC (constrained) post onto the tibial tray. Modular SSK PS and PSC posts are threaded into the bearing using a 2.5 mm hex driver (Figure 78).

Figure 78

Note: The SSK PS post allows for +/- 15 degrees of internal/external rotation and unlimited varus/ valgus movement.

The SSK PSC post allows for +/- 0.5 degrees of internal/external rotation and 1 degree of varus/ valgus movement.





Figure 80

Trial Tibial Bearing (cont.)

Insert the trial bearing onto the trial tray by engaging the posterior of the bearing to the tray first and then pushing down on the anterior until it snaps into place anteriorly (Figure 79). The locking bearing can only be removed using the bearing removal tool. Now that the completed trial construct is inserted, proceed through range of motion (Figure 80).



Trial Tibial Bearing (cont.)

To remove bearing trial, pull back on the lever of the trial puller to disengage the bearing trial from the tibial tray trial (Figure 81). Pull back on the thumb pad and insert the puller tip into the slot of the anterior portion of the trial. Press the tab, release the thumb pad and slide the trial out anteriorly and upwards.

Implant Assembly



Figure 83

Figure 84

Tibial Augments

If an augment block is utilized, position the augment on the underside of the tray and secure with two bolts from the bottom, using a 2.5 mm hex screwdriver (Figure 82). Start both screws first before fully tightening.

Note: If a cruciate wing and augment block(s) are utilized, make certain to attach block augments first. Attach and impact the cruciate wing after augments have been attached.

Cruciate Wing Augment

If a cruciate wing augment is used, first position it over the tibial tray stem boss and then align the anterior reference mark to the tibial boss mark (Figure 83).

Note: If a block augment is not used, verify the cruciate wing rotation in relation to the underside of the tray prior to impacting.

Attach the cruciate wing impactor head by pushing the top button of the handle in, attach the impactor head, then release the button (Figure 84). While protecting the tibial tray with a soft cloth, firmly impact the cruciate wing using the impactor head.

Note: Tibial augments, offset adapters, and stem extensions can all be used with the cruciate wing augment. Be sure to impact the cruciate wing before attaching the offset adapter and stem.

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Figure 85



Figure 86

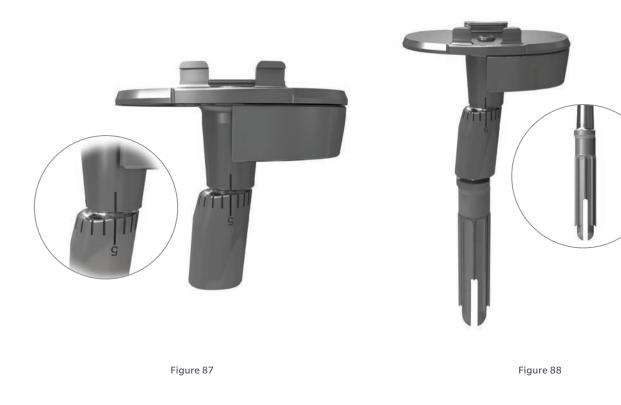
Non-Offset Tibial Stem

If a stem extension is used without an offset adapter, insert the stem extension into the tibial tray stem boss. If a slotted stem is used, be sure to position it in the proper orientation with the slot in the sagittal plane, prior to impacting (Figure 85). While protecting the components with a soft cloth, firmly impact the end of the stem several times with a mallet to engage the morse tapers. Complete the assembly by securing the stem screw through the tray using a 3.5 mm hex screwdriver (Figure 85).

Note: One tibial stem screw is packaged with the tibial tray and one tibial stem screw is packaged with the stem extension. Only one of those screws will be used in assembly.

Offset Tibial Stem

If an offset adapter is used, first insert the offset stem screw (included with the offset adapter) into the top of the stem extension using a 3.5 mm hex screwdriver (Figure 86).



Offset Tibial Stem (cont.)

Insert the offset adapter into the tibial tray stem boss (Figure 87).

Rotate the offset adapter to the predetermined rotation using the reference mark on the anterior of the stem boss (Figure 87 inset).

While protecting the offset adapter and tibial tray with a soft cloth, firmly impact the end of the offset adapter to engage the morse tapers. Insert the stem into the offset adapter. If a stem has a slotted end, rotate the slot to the desired position, typically in the sagittal plane (Figure 88). While protecting the tray and stem with a soft cloth, firmly impact the stem several times to engage the morse tapers.

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Figure 89

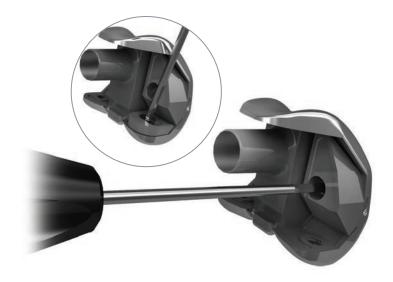
Figure 90

Offset Tibial Stem (cont.)

Tighten the 2.5 mm set screw on the offset adapter (Figure 89).

Insert the tibial stem screw through the top of the tray and tighten with a 3.5 mm hex screwdriver (Figure 90).

Digitally pressurize cement into the proximal tibia and apply cement under the tibial tray and insert the tibial assembly onto the tibia. Impact the implant with the femoral/tibial impactor being careful to match the patient's correct rotational alignment.







Offset Screw



Femoral Stem Screw Tibial Stem Screw DO NOT USE

Figure 92

Femoral Augments

If distal augments are used, attach the distal augment implant onto the femoral component. Insert the 3.5 mm hex bolt through the distal augment block and tighten with a 3.5 mm hex screwdriver (Figure 91). Repeat the process for the posterior augment block.

Note: Place the posterior augment prior to the distal augment. Also note that the posterior augments are universal. Position the augment to align with the medial or lateral edge of the implant, then position the bolt in the appropriate hole to thread into the femoral component.

Non-Offset Femoral Stem

First, remove the tibial stem screw from the top of the stem. It will not be used for any of the femoral assembly (Figure 92).





Figure 94

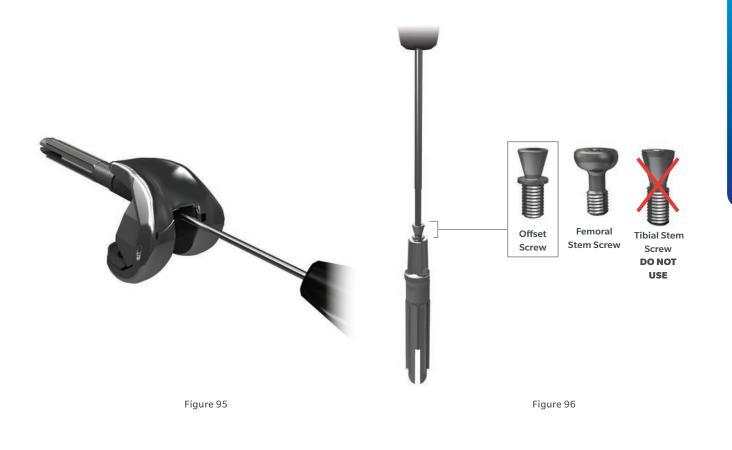
Non-Offset Femoral Stem (cont.)

Insert the femoral stem screw into the intracondylar screw hole (Figure 93).

While holding the stem screw with one finger, begin to engage the femoral screw threads by turning the femoral stem clockwise (Figure 94). Once the threads have been started, place the femur on a soft cloth and cover the tip of the stem with a soft cloth. The table must also be fully supported with four legs touching the ground (do not use a Mayo stand).

Impact the tip of the stem with two forceful strikes.

Note: If a bowed stem or slotted stem is used, be sure to orient the stem in the proper position prior to impacting.



Non-Offset Femoral Stem (cont.)

IMPORTANT: Complete the tightening of the Vanguard 360 femoral stem screw with the 3.5 mm hex screwdriver (Figure 95).

Tighten the femoral screw with enough force until an audible squeak is heard.

Offset Femoral Stem

If an offset adapter is used, first remove the tibial stem screw from the top of the stem, it will not be needed for the femoral assembly. Next, insert the offset stem screw, included with the offset adapter, into the top of the stem extension and tighten using a 3.5 mm hex screwdriver (Figure 96).

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Figure 97

Figure 98

Offset Femoral Stem (cont.)

Insert the femoral stem screw into the 360 intracondylar screw hole (reference Figure 93). While holding the screw with one finger, begin to engage the femoral stem screw by turning the offset adapter clockwise.

Rotate the offset adapter to the predetermined rotation using the reference mark on the posterior of the stem boss (Figure 97).

While protecting the offset adapter with a soft cloth, firmly impact several times to engage the morse tapers.

Insert the stem into the offset adapter (Figure 98). If a stem has a slotted end, rotate the slot (or bow) to the desired position, typically in the coronal plane. Again, while protecting the femoral component and stem with a soft cloth, firmly impact the stem several times to engage the morse tapers.



Figure 100

Offset Femoral Stem (cont.)

Tighten the 2.5 mm set screw on the offset adapter (Figure 99).

IMPORTANT: Tighten the femoral stem screw through the top of the intercondylar box with a 3.5 mm hex screwdriver (Figure 100).

IMPORTANT: Tighten the femoral screw with enough force until an audible squeak is heard.

Digitally pressurize cement into the anterior, posterior and distal areas of the femur and apply cement to the anterior, posterior, and distal aspect of the femoral component and impact the component into place. Carefully clean out any excess cement using a curette or similar instrument.



Tibial Bearing and Locking Bar Insertion

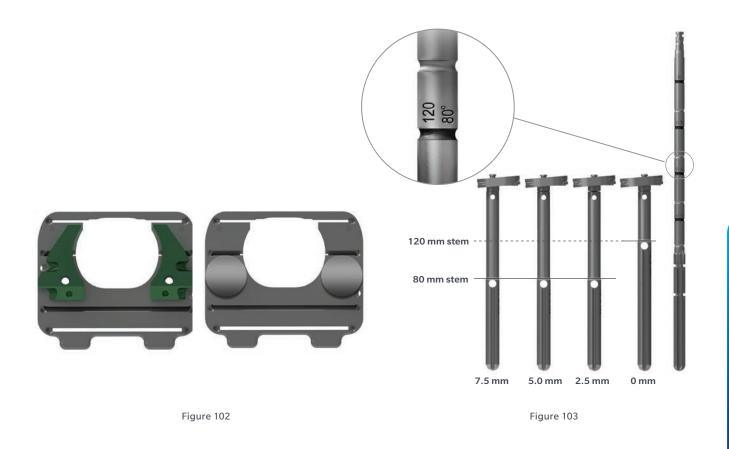
Place the Vanguard SSK 360 polyethylene tibial bearing on the tibial baseplate and push posteriorly as far as possible. The polyethylene bearing must be flush on the tibial baseplate in all directions. Insert the locking bar, packaged with the tibial baseplate, into the medial side of the anterior baseplate/ polyethylene interface as far as possible, using finger pressure only. Place the large curved end of the locking bar. Place the smaller square end in the notch of the anterior post of the tibial baseplate (Figure 101).

Make sure the smaller square end catches on the post of the tibial tray and does not block the path of the locking bar. Squeeze the forceps to gradually insert the locking bar until it audibly clicks into place.

Note: Visual and audible confirmation should be made to ensure complete insertion of the locking bar.

Appendix A – 4-in-1 Resection

APPENDIX A 4-IN-1 RESECTIONS



4-in-1 Resections

Depending on the available femoral bone stock, and positioning of the original primary bone resections, it may be necessary to make one or more of the 4-in-1 resections.

For example, if the primary knee resections were made with too much internal rotation, the 4-in-1 block can be externally rotated to correct the resections.

Choose the appropriate Vanguard 360 Revision 4-in-1 resection block that matches the lateral template size. Sizes include: 55, 57.5, 60, 62.5, 65, 67.5, 70, 72.5, 75, and 80.

The 4-in-1 block medial/lateral width matches the distal and posterior medial/lateral width of the distal and posterior sections of the femoral implant. The 4-in-1 block thickness is 9 mm to replicate the distal implant thickness, and the 9 mm posterior thickness matches the posterior implant thickness.

Note: If distal augment resections were made, 5 mm magnetic spacers, or distal femoral augment trials, can be attached (Figure 102) to the 4-in-1 block to fill augment spaces. For half sizes (i.e., 62.5) femoral trial augments, use the lower whole size.

Use the 40 mm longer stem length denoted on the reamer depth when using the non-offset (0 mm) coin. Use the stem length marked with a small "o" with the 2.5 mm, 5 mm and 7.5 mm offset 4-in-1 coins (Figure 103). The 40 mm shorter stem length accounts for the length of the offset adapter.



Figure 104

Figure 105

4-in-1 Resections (cont.)

Starting with a 0 mm coin (non-offset), thread the trial stem onto the coin (Figure 104).

Insert the coin through the front of the 4-in-1 block (Figure 105).



4-in-1 Resections (cont.)

Insert the coin through the front of the 4-in-1 block. Be sure to align the bottom mark on the outside of the 4-in-1 coin to either a L (left) or R (right) knee (Figure 106 insets). Snap in the coin, with trial stem attached, through the front of the 4-in-1 block. Use a 2.5 mm hex screwdriver in the top medial hole of the 4-in-1 block to secure the coin (Figure 68 inset). To tighten, turn clockwise. To release, push in and turn counterclockwise. Insert 4-in-1 block with trial stem into femur (Figure 107).

● Note: Be careful not to back the screw out completely. Only 2-3 turns are required.

Evaluate the 4-in-1 block position for medial and lateral coverage as well as anterior and posterior position (Figure 107). Use the transepicondylar axis to determine femoral rotation.

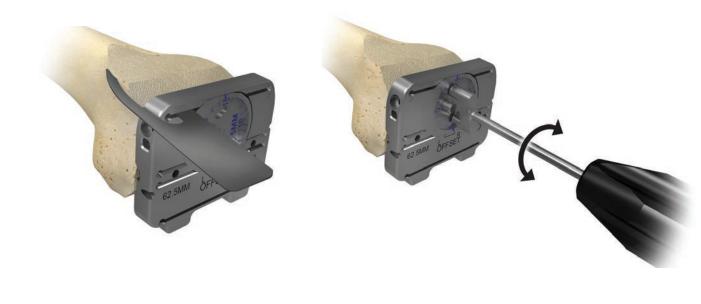


Figure 108

Figure 109

4-in-1 Resections (cont.)

A feeler gauge can be used through the cut slots to help evaluate position (Figure 108). If the 0 mm coin does not provide a good position, remove the coin and trial stem, select a 2.5 mm offset coin and attach the trial stem. If the coin is locked in position, use a 2.5 mm hex driver to unlock by turning counterclockwise. Assemble the trial stem and coin and insert into the 4-in-1 block. Use the coin driver to spin the coin and determine optimal 4-in-1 block position (Figure 109). If an appropriate position is still not found, repeat the process with 5 mm or 7.5 mm offset coins. Gap spacers can also be used in conjunction with the 4-in-1 block to help determine 4-in-1 block rotation and to measure flexion/extension gaps.

Caution: Care should be taken when using a large offset with a small femur to reduce the potential for femoral fracture.

Note: Positions 8–12 are not available on the 7.5 mm offset coin to reduce the risk of anterior breakout.



4-in-1 Resections (cont.)

Once optimum position is determined, pin the 4-in-1 block. The outer holes are converging, the inner holes are parallel. Note the offset magnitude and direction at the "L" position for a left knee or the "R" position for a right knee (Figure 110).

Be sure to unlock the coin with a 2.5 mm hex screwdriver prior to removal. Use the slap hammer to remove the coin housing and trial stem (Figure 111).

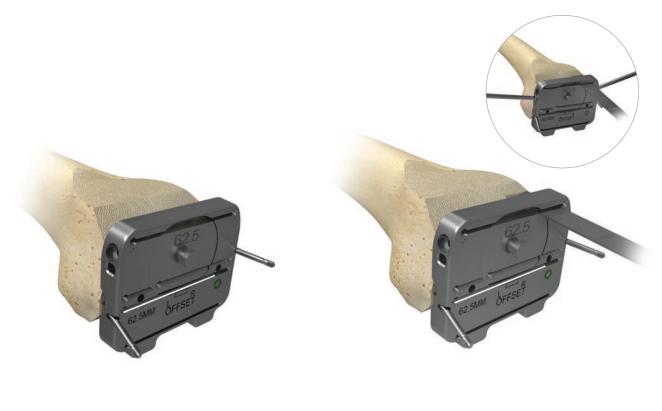


Figure 112

Figure 113

4-in-1 Resections (cont.)

After removing the coin housing and trial stem, snap the 4-in-1 cut block insert into place (Figure 112).

Resect the anterior and posterior bone, and the anterior and posterior chamfers, with a .054" saw blade (Figure 113).

Two 3.5 mm hex screwdrivers can be inserted in the side holes (second from the top) of the block to help secure it during cutting (Figure 113 inset). Also, the 4-in-1 cut block insert can be locked in place using a 2.5 mm hex screwdriver in one or both top side holes.

Note: With the 4-in-1 cut block insert in place, only part of the anterior chamfer resection can be made. Remove the insert to complete the resection.

Once the appropriate resections have been made, proceed to pages 30-45 for the remaining femoral preparation steps.

Appendix B – Construct Length Matrix

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Vanguard 360 Stem Construction Matrix

Tibia Tray without Offset Adapter

uct Length

All dimensions from underside of tibia tray. Tray boss is 25 mm + stem length.

Tibia Tray with Offset Adapter

Stem Length	Total Construct Length
40 mm	105 mm
80 mm	145 mm
120 mm	185 mm
160 mm	225 mm
200 mm	265 mm

All dimensions from underside of tibia tray. Tray boss is 25 mm + offset adapter is 40 mm = 65 mm + stem length.

Femoral Component without Offset Adapter

Stem Length	Total Construct Length
40 mm	86 mm
80 mm	126 mm
120 mm	166 mm
160 mm	206 mm
200 mm	246 mm

All dimensions taken from distal femoral resection level. Femoral Boss is 46 mm + stem length.

Femoral Component with Offset Adapter

Stem Length	Total Construct Length
40 mm	126 mm
80 mm	166 mm
120 mm	206 mm
160 mm	246 mm
200 mm	286 mm

All dimensions taken from distal femoral resection level. Femoral Boss is 46 mm + offset adapter is 40 mm = 86 mm + stem length. Biomet manufactures a variety of knee joint replacement prostheses intended for application with or without bone cement. Knee joint replacement components include femoral, tibial, and patellar components. Components are available in a variety of designs and size ranges intended for both primary and revision applications. Specialty components are available including; femoral stems, femoral screws, femoral augments, tibial stems, tibial screws, tibial augments, tibial cement plugs and modular pegs.

INDICATIONS

- Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis or traumatic arthritis where one or more compartments are involved.
- 2. Correction of varus, valgus, or posttraumatic deformity.
- 3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

The Regenerex femoral augments are indicated for use with the Vanguard Total Knee System.

The Regenerex tibial augments are indicated for use with standard and offset Biomet Tibial Trays.

Femoral components and tibial tray components with porous coatings are indicated for cemented and uncemented biological fixation application. Non-coated (Interlok) devices and all-polyethylene patellar components are indicated for cemented application only. Regenerex components are intended only for uncemented biologic fixation application.

CONTRAINDICATIONS

Absolute contraindications include: infection, sepsis, and osteomyelitis. Relative contraindications include: 1) an uncooperative patient or a patient with neurologic disorders who is incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, 7) vascular insufficiency, muscular atrophy, neuromuscular disease, and/or 8) incomplete or deficient soft tissue surrounding the knee.

Biomet Microplasty Tibial Trays are contraindicated for use with constrained bearings.

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