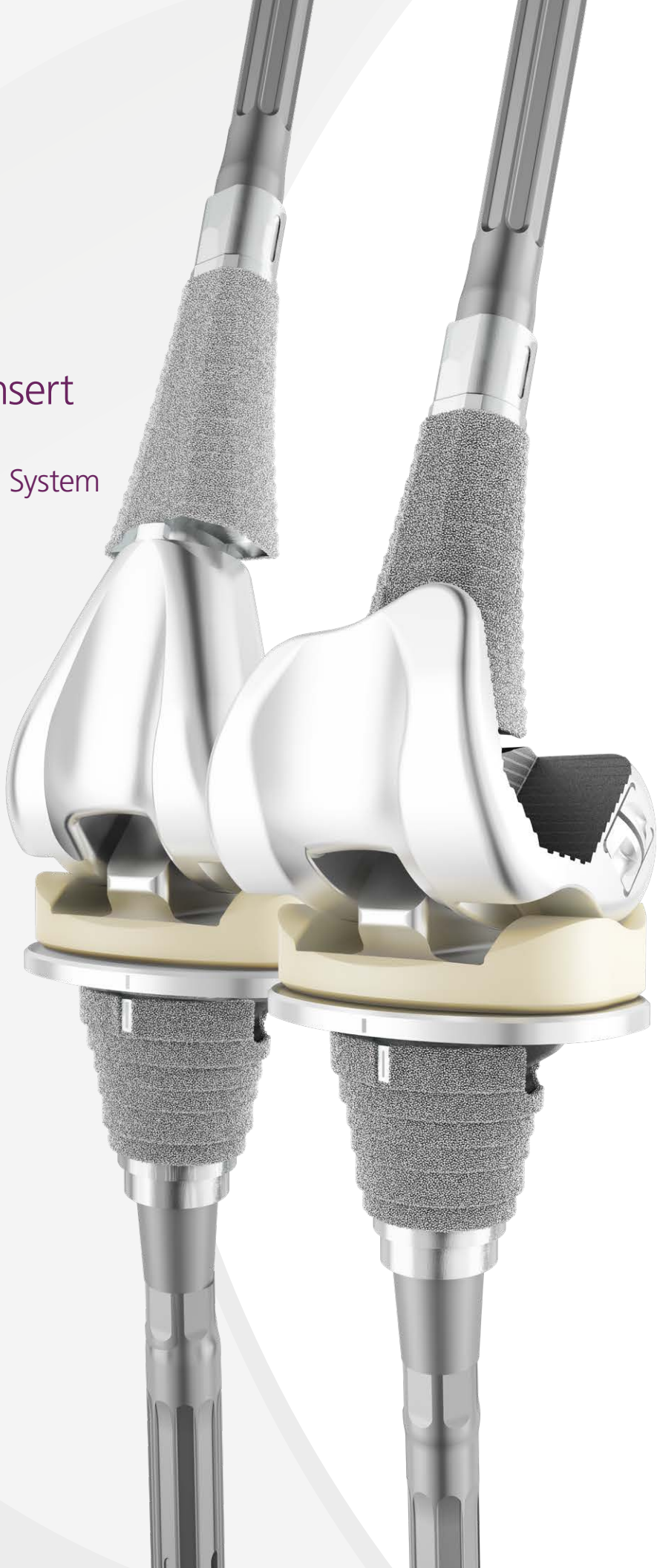
Attune®
Knee System

Revision Solutions

ATTUNE® Revision LPS Insert
with
S-ROM® NOILES™ Rotating Hinge System
and LPS System
Surgical Technique



DePuy Synthes
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

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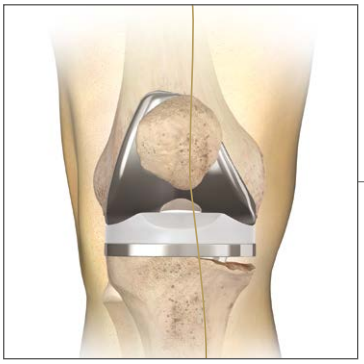

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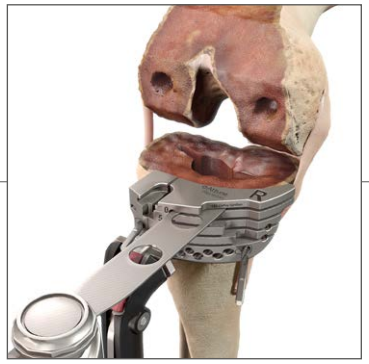

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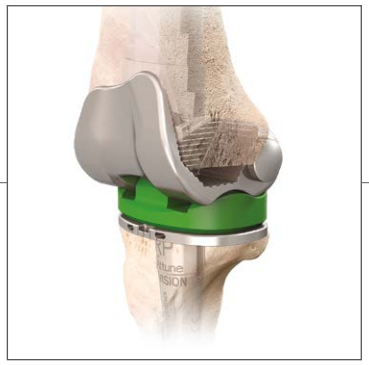

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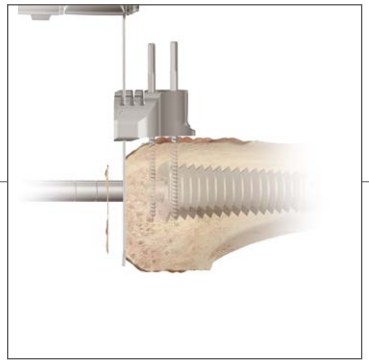

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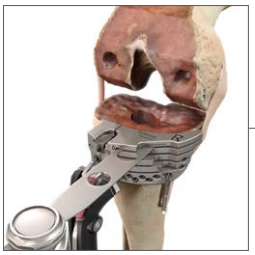

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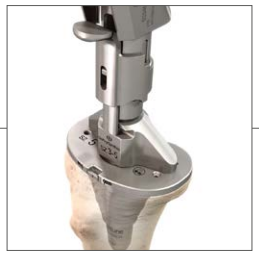
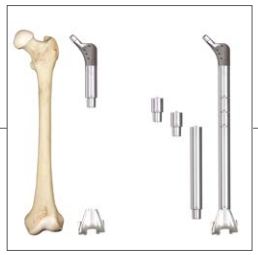


Final Tibial Preparation



Femoral Preparation

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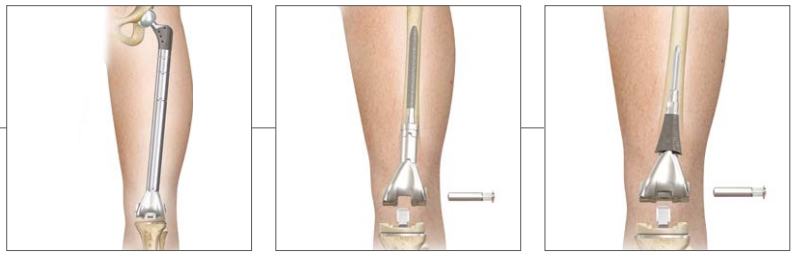


Final Implantation

S-ROM NOILES Rotating Hinge Knee System

Incision and Exposure

Initial Incision

When possible, follow the scar from the primary procedure. Where parallel incisions are present, the more lateral is usually preferred, as the blood supply to the extensor surface is medially dominant (Figure 1). Where a transverse patellectomy scar is present, the incision should transect it at 90 degrees.

Where there are multiple incision scars or substantial cutaneous damage (burn cases, skin grafting, etc.), one may wish to consult a plastic surgeon prior to surgery to design the incision, determine the efficacy of pre-operative soft tissue expansion and plan for appropriate soft tissue coverage at closure.

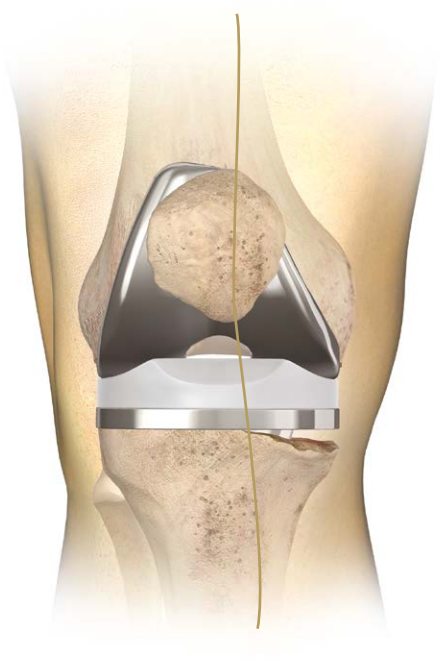


Figure 1

Capsular Incision

The fascial incision extends from the rectus femoris proximal margin to the distal margin of the tibial tubercle following the patella's medial border, maintaining a 3-4 mm cuff for reapproximation of the vastus medialis aponeurosis at closure (Figure 2). Where mobilization of the extensor mechanism and patella is problematic, extend the skin and capsular incisions proximally.

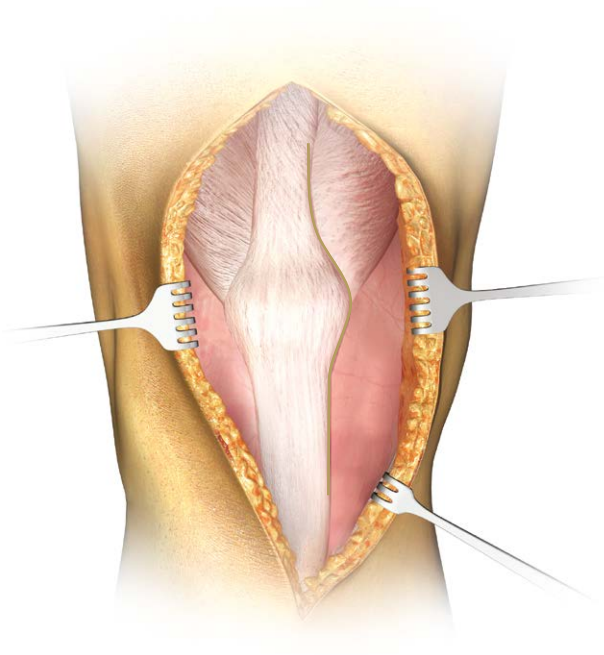


Figure 2

Incision and Exposure

Occasionally an early retinacular release is indicated to assist with patellar eversion. Where eversion difficulties persist, a quadriceps snip, a proximal inverted quadriceps incision (modified V-Y) or a tibial-tubercle osteotomy may be indicated. Perform appropriate ligamentous release based upon pre-operative and intra-operative evaluation (Figure 3). Release fibrous adhesions to re-establish the suprapatellar pouch and medial and lateral gutters. In many revision cases, the posterior cruciate ligament will be absent or non-functional; when this is the situation, excise any residual portion. Exercise care when everting the patella. Frequently, subluxing the patella laterally is adequate. Doing so will help avoid patella tendon avulsion.

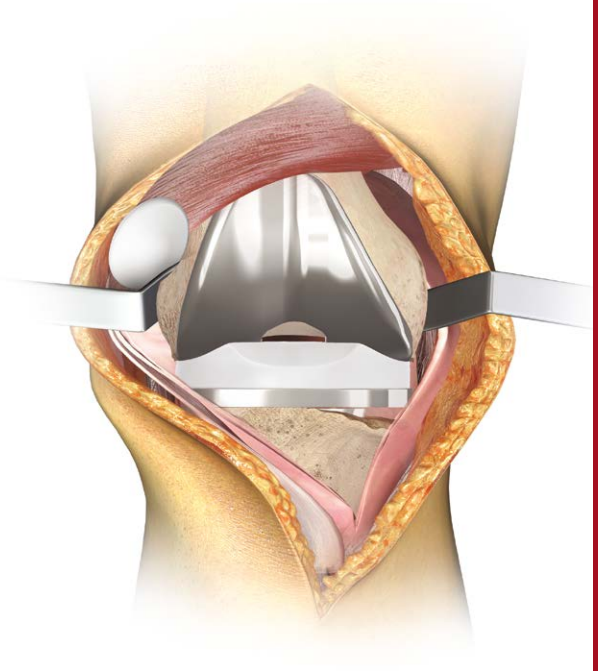


Figure 3

Implant Extraction from the Primary Procedure

Take care to preserve as much bone as possible. To this end, assemble a selection of tools, including thin Osteotomes, an Oscillating Saw, a Gigli Saw, a highspeed Burr and various extraction devices, but many cases will require only the thin Osteotome. Carefully disrupt the bone/cement or bone prosthesis interface before attempting extraction (Figure 4).

Disengage the implanted components and extract as gently as possible, in such manner as to avoid fracture and unnecessary sacrifice of bone stock. Where the entire prosthesis is to be replaced, it is advantageous to remove the femoral component first, as this will enhance access to the proximal tibia. Clear all residual methyl methacrylate with hand (chisels) or power tools.

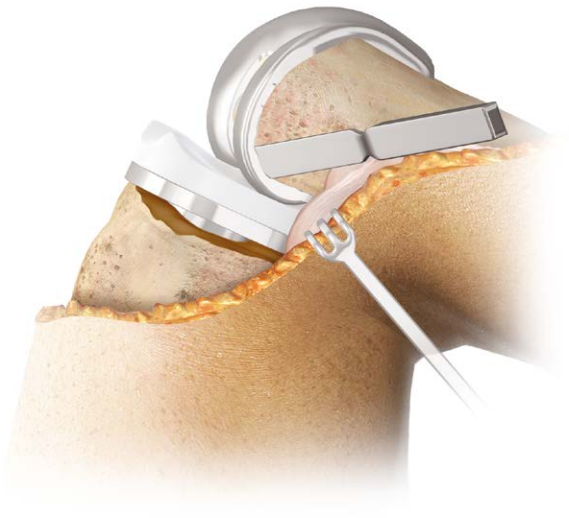


Figure 4

Intra-operative Evaluation and Tibial Preparation

The surgeon should establish two anatomic conditions to facilitate revision arthroplasty: the level of the joint line and the disparity in the flexion and extension gaps.

Joint Line Evaluation

In an average knee in full extension, the true joint line can be approximated in reference to several landmarks.

- It lies 12–16 mm distal to the femoral PCL attachment
- It lies approximately 3 cm distal to the medial epicondyle and 2.5 cm distal to the lateral epicondyle
- It lies distal to the inferior pole of the patella (approximately one finger width)

Level with the old meniscal scar, if available.

Additional pre-operative joint line assessment tools include:

1) Review of original pre-operative roentgenogram of the Total Knee Arthroplasty (TKA)
2) Review of roentgenogram of contralateral knee if non-implanted

Tibial Preparation

For Tibial Preparation refer to the ATTUNE Revision Rotating Platform (RP) Surgical Technique.

Preparation of Femoral Diaphysis

Intramedullary Femoral Alignment System

This technique is designed to flow in a logical sequence, from reaming the diaphysis, to broaching the metaphysis and cutting the bone. The length and diameter of the stem extension is determined with templates applied to pre-operative roentgenograms.

Figure 5

Begin the procedure with the preparation of the medullary canal (Figures 5 and 6).

Enter the medullary canal with a 9 mm drill to a depth of 3-5 cm (Figure 7). Take care that the drill avoids the cortices. It is helpful to palpate the distal femoral shaft as the drill is advanced.

Where impedance of the intramedullary canal is anticipated, adjust the entry point accordingly.

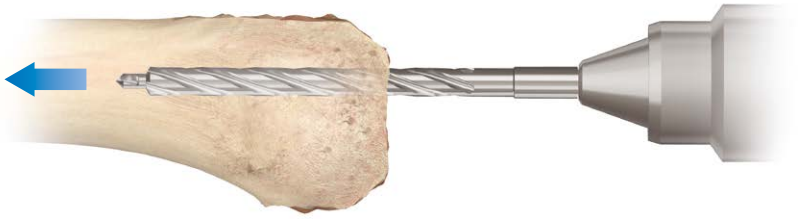


Figure 6

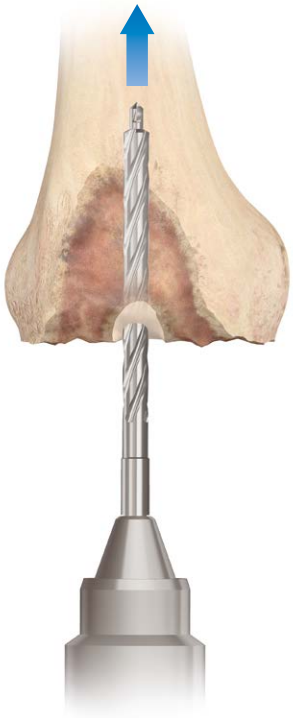


Figure 7

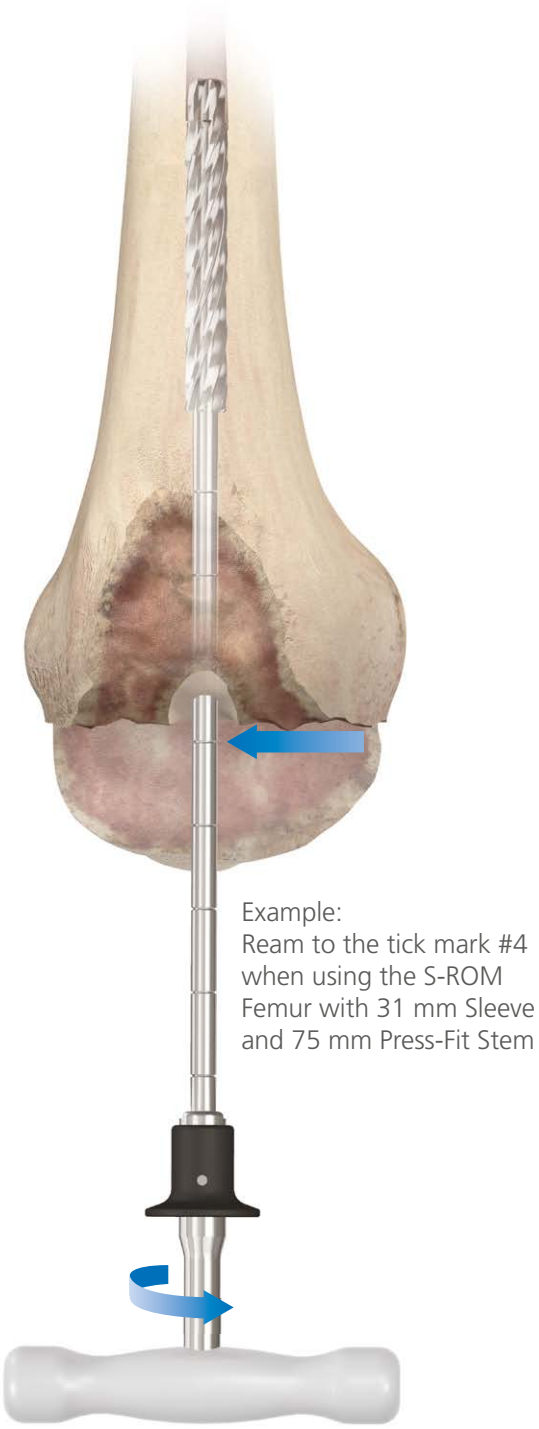
Reaming the Femoral Medullary Canal

Connect the Reamer Handle to a small diameter M.B.T. Revision Reamer. If power reaming, it will be necessary to attach the modified Hudson Adapter to the Straight Reamer.

Use the Reamer Depth Chart on the next page to determine reamer depth for each combination of components. Another option to determine reamer depth is to measure the trial assembly against the reamer and note the corresponding depth mark for reaming (Figure 8).

The S-ROM Femoral Component accepts the following stems, only with the use of a femoral sleeve:

- Universal Fluted Stems of 75, 115 and 150 mm in diameters of 10-24 mm in 2 mm increments
- Cemented Stems available in lengths of 30 and 60 mm lengths and a diameter 13 mm or 15 mm
- Cemented Tapered Stems available in lengths of 90 mm (13 mm and 15 mm diameter) and 120 mm and 150 mm (13 mm diameter only)



Example:
Ream to the tick mark #4 when using the S-ROM Femur with 31 mm Sleeve and 75 mm Press-Fit Stem

Figure 8

INFORMATION

The Reamer shaft contains markings in 25.4 mm increments to accommodate the various Universal Stem/Sleeve length combinations.

Reaming the Femoral Medullary Canal

In 1 mm diameter increments, sequentially open the medullary canal with M.B.T. Revision Reamers of progressively greater size until firm endosteal engagement is established.

Take care to ream the canal in line with the femoral axis to avoid putting the implant in flexion.

It is important that simple cortical contact of the tip not be construed as engagement.

Cemented Stem Use

Where a cemented stem extension is indicated, perform final reaming with a 15 mm diameter reamer for the 13 mm diameter stem extension; similarly a 17 mm diameter Reamer is used to accommodate the 15 mm diameter Stem Extension.

This allows for creation of a cement mantle.

Reamer Depth Chart

S-ROM Femur		20 mm 31 mm 34 mm	40 mm 46 mm
Cemented Stems	30 mm	2	2
	60 mm	3	3
	90 mm	4	4
	120 mm	5	6
	150 mm	6	7
Press-Fit Stems	75 mm	4	4
	115 mm	5	5
	150 mm	6	7

INFORMATION

Do not reverse ream.

Preparation of the Femoral Metaphysis – Sleeve Use

After reaming the intramedullary canal, attach the Threaded Shaft to the Broach Reamer and then to the appropriate Stem Trial as determined by straight reaming (Figure 9).

Ream to the 20 mm, 31 mm, 34 mm etch mark on the Threaded Shaft (Figure 10).

Figure 9

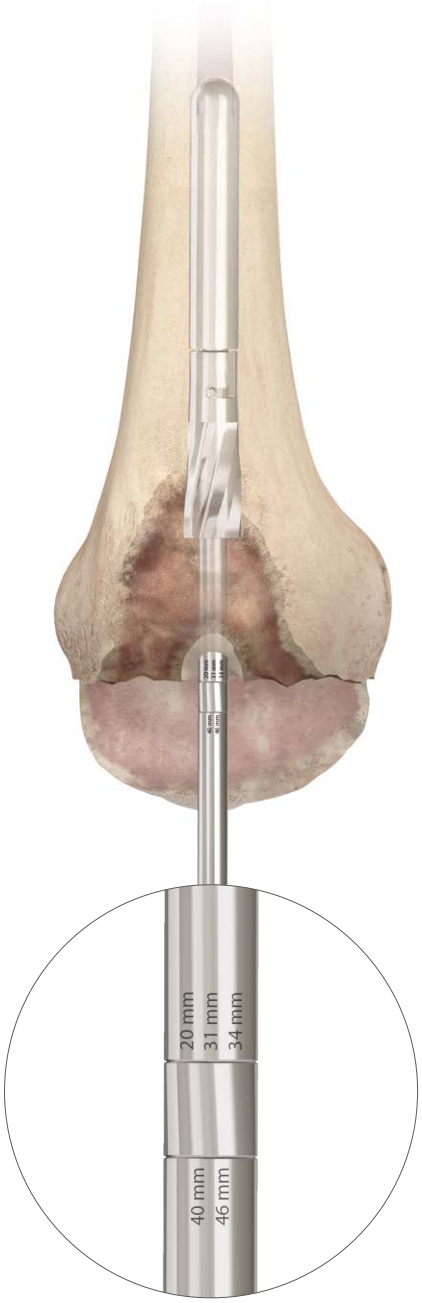


Figure 10

Preparation of the Femoral Metaphysis – Sleeve Use

When using the Broach Reamer, the next smaller diameter Stem Trial may be used to allow for easier reaming. The Broach Reamer will be necessary when utilizing a 20 mm Sleeve and for the beginning of larger sequential broaching when using a 31 mm or larger Sleeve.

After broach reaming has been completed, attach the 31 mm Broach to the Broach Handle. Attach the appropriate Stem Trial to the broach as determined by straight reaming. Give close attention to the medial orientation of the broach (Figure 11).

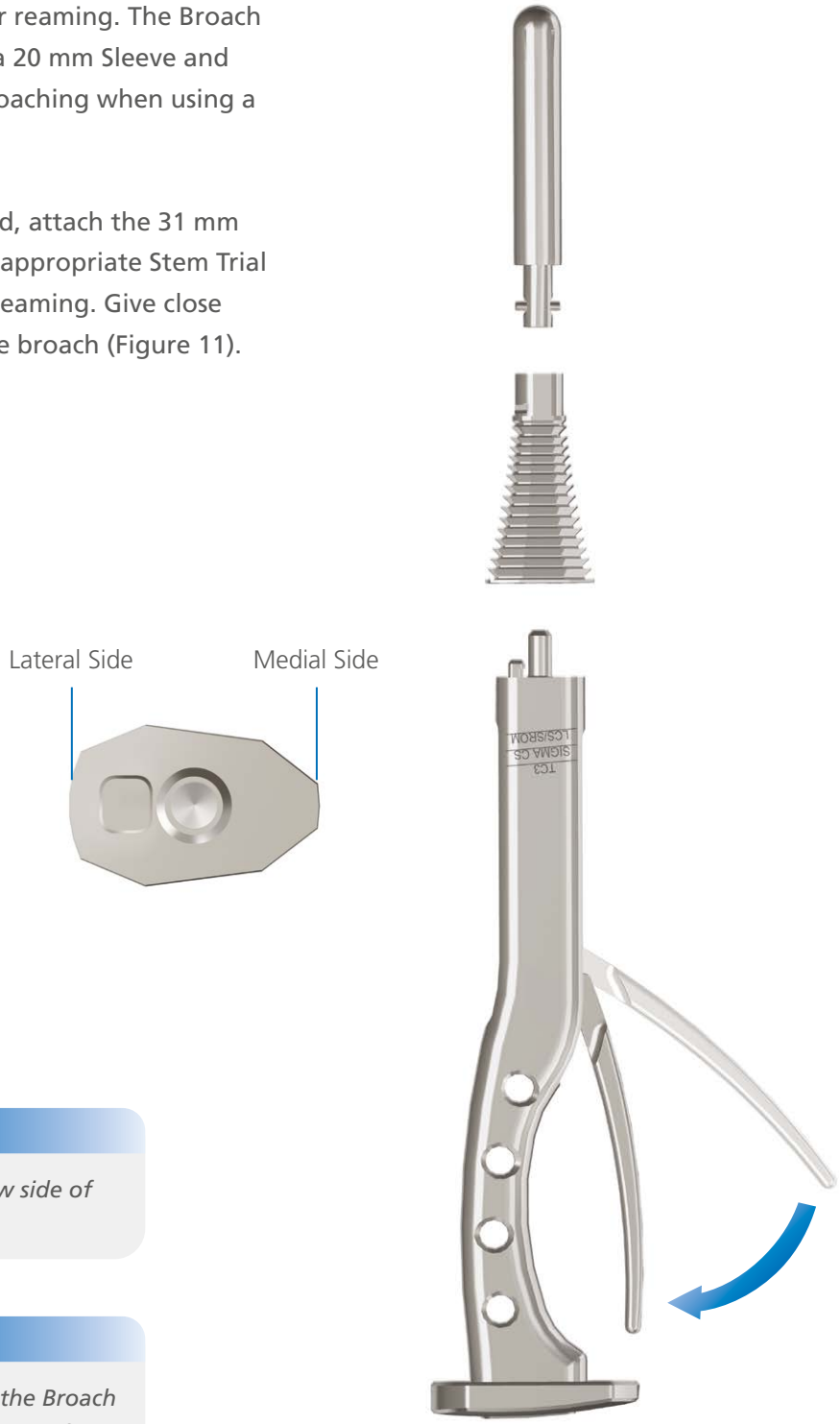


Figure 11

INFORMATION

The Broach is asymmetrical; and the narrow side of the Broach must point medially.

INFORMATION

When prepping for a 20 mm Sleeve, leave the Broach Reamer and threaded shaft in the canal and perform the subsequent femoral cuts off the Reamer.

Preparation of the Femoral Metaphysis – Sleeve Use

Sequentially broach to the desired dimension of 31, 34, 40 or 46 mm. When the LCS/S-ROM etch mark on the Broach Handle is at the planned distal resection level, check the Broach's rotational stability. If the Broach (not the handle) moves in the canal, it is not rotationally stable (Figure 12).

If the stability of the Broach is unsatisfactory, move up to the next Broach size. The size of the last broach used will be the Femoral Sleeve size. The Broach depth sets the extension gap/joint line.

In patients with a large degree of distal femoral bow, closely monitor the anterior progression of the Broach during impaction. Excessive anterior placement of the Broach may result in a loose flexion gap.

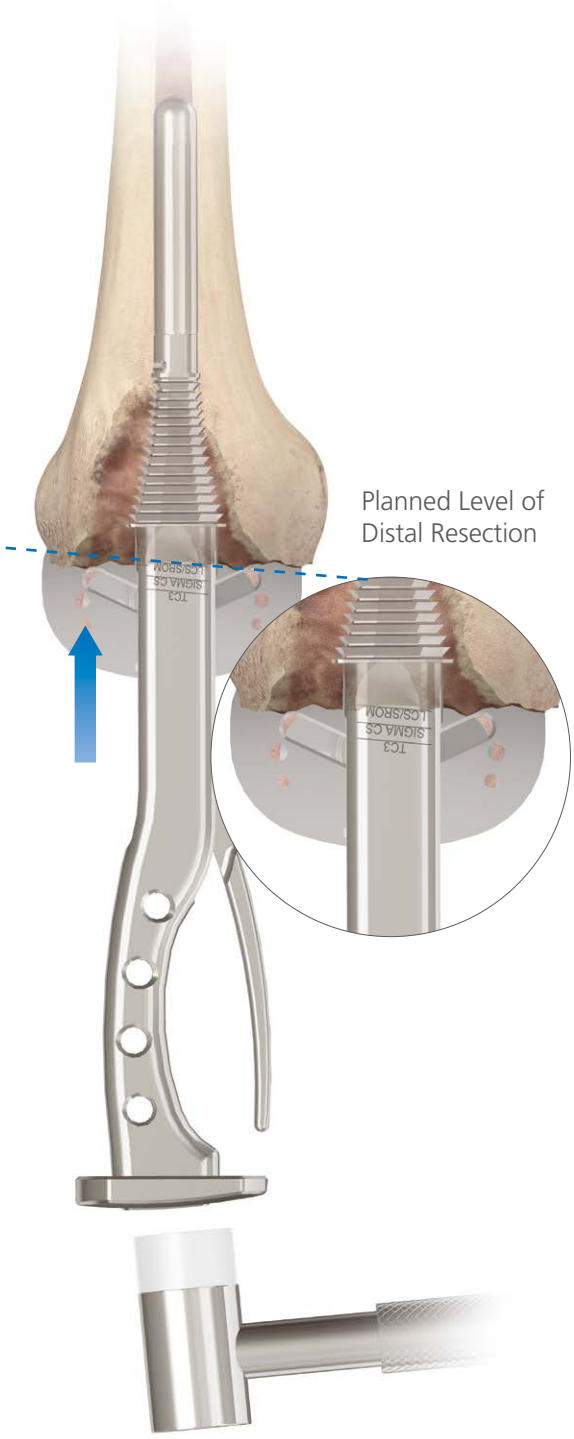


Figure 12

Preparation of the Femoral Metaphysis – Sleeve Use

After Broaching is complete, remove the Broach Handle from the Broach. With the Broach seated in the femur, attach the Threaded Shaft to the Broach (Figure 13).

Distal, anterior, chamfer, and notch cuts will reference off the Threaded Shaft/Broach assembly.

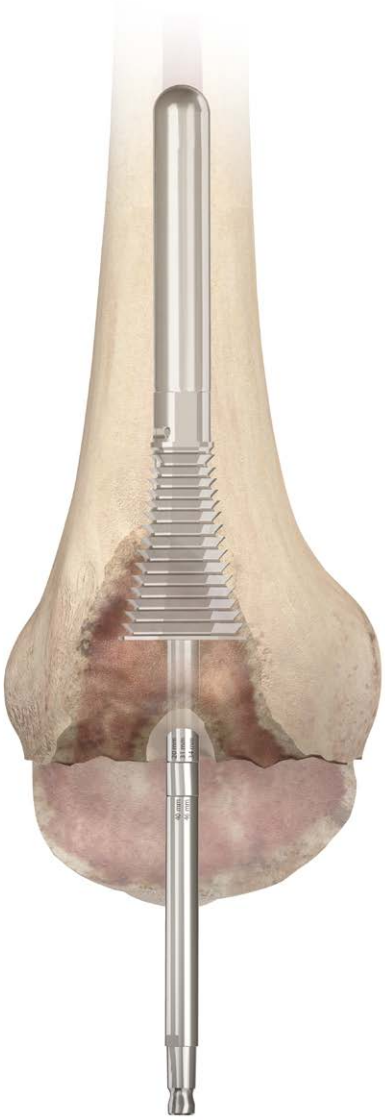


Figure 13

Femoral Preparation – Distal Resection

Distal Resection

Set the Valgus angle to 7 degrees and Left/Right on the Distal Femoral Alignment Guide by compressing the two triggers and lock in place by rotating the blue locking lever clockwise. Place the Distal Femoral Alignment Guide on the Threaded Shaft and seat against the distal femur (Figure 14). Rotate the knob on the Femoral Resection Guide counter clockwise until the arrow is pointing to the padlock symbol. Slide the Distal Femoral Connector into the Femoral Resection Guide. Rotate the knob on the Distal Femoral Resection Guide clockwise. Every click moves the Revision Distal Cutting Block 1 mm proximal or distal. Turn the knob clockwise from 15 all the way down to 0 (which is the padlock symbol). This will set the block up for a 0 mm resection (Figure 15).

Slide the Revision Distal Cutting Block onto the Distal Femoral Block Connector. The tang on the Distal Femoral Connector will slide into the 0 mm cutting slot on the Cutting Block. The trigger should engage in the hole behind the 0 mm slot (Figure 16). Position the Resection Guide over the two legs of the Distal Femoral Alignment Guide until the Distal Cutting Block touches the anterior femur (Figure 17).

INFORMATION

An open resection will resect 4 mm less femur. When a 0 mm open resection is desired, the dial should be set to 4 mm.

INFORMATION

The Revision Distal Block is equipped with 0, 4, and 8 mm saw slots. Please keep in mind that if the resection level is not at 0 (the padlock symbol) this will alter the resection. If the resection knob is set at 2, for instance, the saw slots will perform 2, 6, and 10 mm resections.

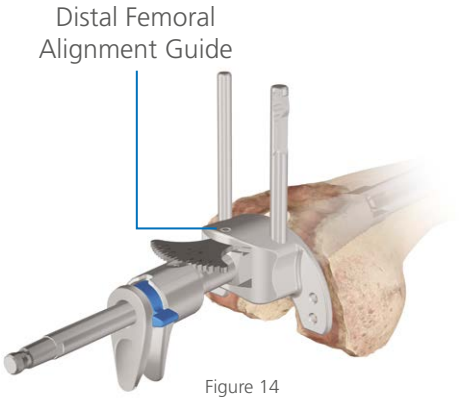


Figure 14

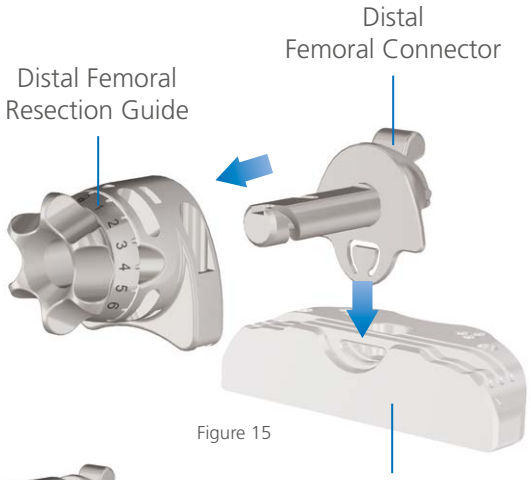


Figure 15

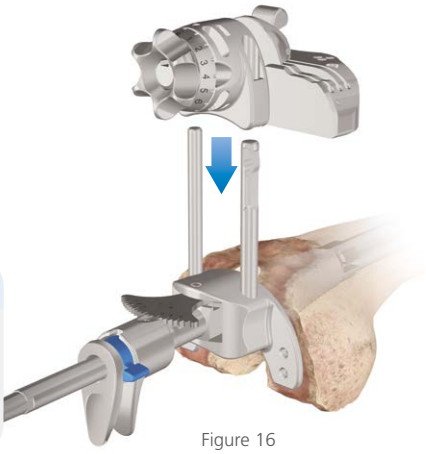


Figure 16

Figure 17

Femoral Preparation – Distal Resection

Rest the Femoral Alignment Guide against the most prominent distal condyle. If no Distal Augments are needed, proceed with pinning the Distal Resection Block and making the distal cuts through the 0 mm resection slot (Figures 18 and 19).

If it is determined that a 5 mm or a 10 mm Distal Augment will be needed on only one condyle, perform a 0 mm clean-up cut first on the prominent condyle. Then turn the dial on the Femoral Resection Guide to 5 mm or 10 mm and make the cut on the other condyle through the 0 mm resection slot.

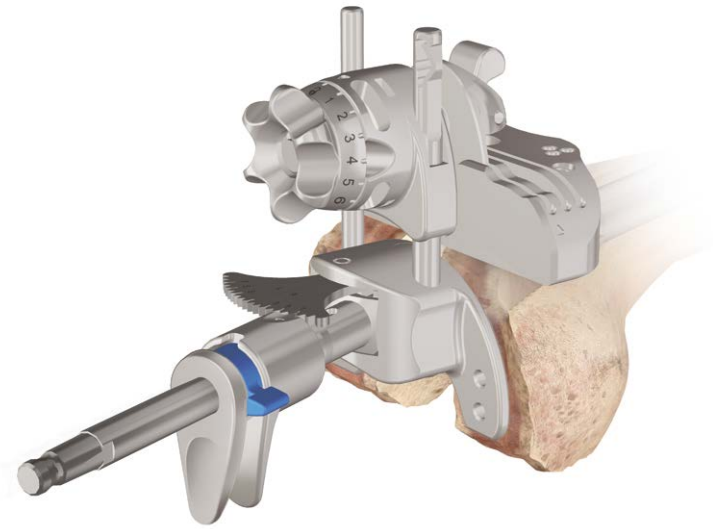


Figure 18

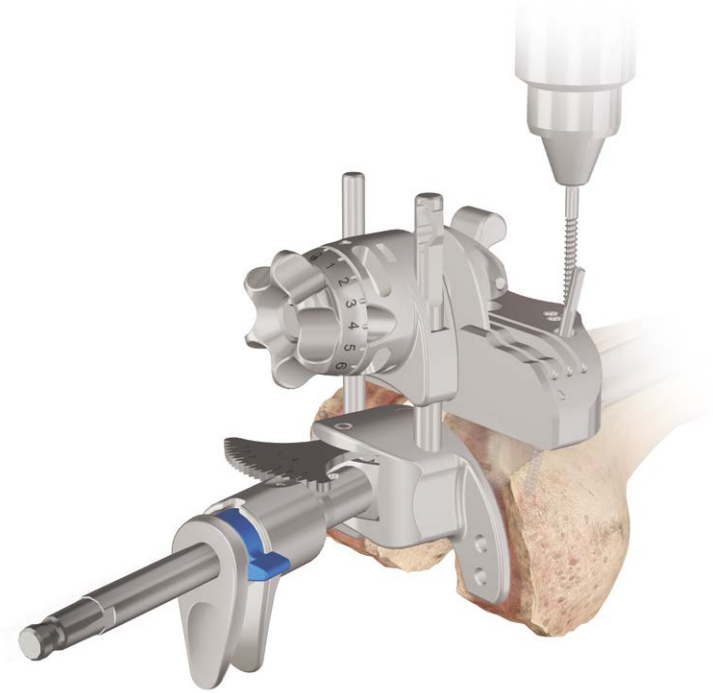


Figure 19

INFORMATION

Do not use the saw slots on the Distal Block to make augment cuts. The augment slots on this block are set up in 4 mm increments instead of the needed 5 mm increments for the S-ROM Knee System.

INFORMATION

When adding 5 or 10 mm Distal Augments to both sides of the femur, it may be necessary to re-evaluate the depth the sleeve was broached to, based upon the addition of augments. If the augments require the broach to be distalized, rebroaching should occur with a larger broach in order to distalize the sleeve in the canal without losing press-fit.

Femoral Preparation – Distal Resection

Once the pins are in place, unlock the Distal Cutting Block from the Distal Femoral Connector, using your thumb and index finger to release the attachment. Slide the Femoral Resection Guide upwards on the Alignment Guide legs until the block connector disengages from the Cutting Block and in one motion remove the Femoral Alignment Guide by pulling the instruments distally over the Threaded Shaft (Figure 20).

In many cases, little, if any, bone is removed from the distal femur as the joint line is effectively elevated with the removal of the primary femoral component. As the level of resection is based on the preservation of bone stock, each condyle is cut only to the level required to establish a viable surface, with augmentation employed to correct imbalance.

The resection is then performed through the slot appropriate for each condyle, using a standard 1.19 mm thick Blade (Figure 21).

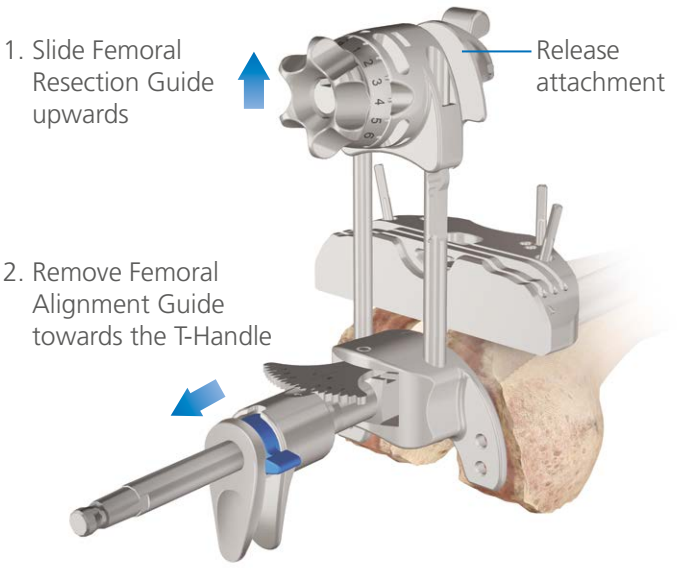


Figure 20

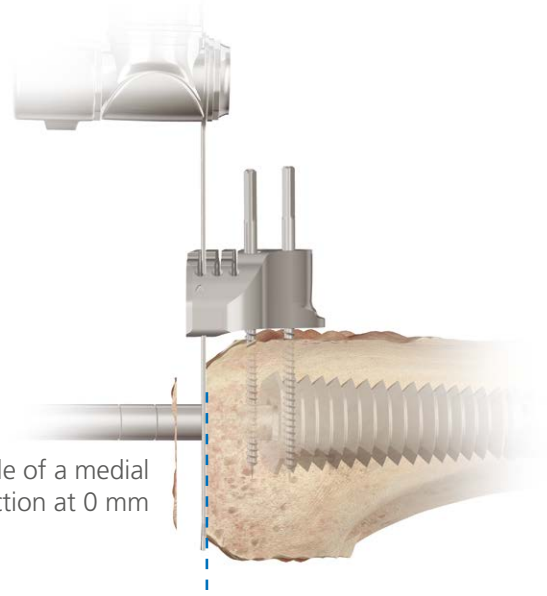


Figure 21

INFORMATION

If a ½ in. wide Standard Saw Blade is used it can complete both medial and lateral distal femoral cuts with the entire Jig still in place.

Femoral A/P and Chamfer Cuts

The Femoral Cutting Guide is size specific (two blocks – X-Small/Small and Medium). Determine the femoral component size by pre-operative templating and comparing the Femoral Component Trial to the size of the femur. Use the size which gives the best medial/lateral (M/L) coverage.

Slide the appropriately sized Cutting Guide over the Threaded Shaft. Use the corresponding hole for a left or a right knee (Figure 22).

Place the guide into neutral rotation by aligning the anterior cortex parallel with the anterior portion of the guide. The SIGMA® System Angel Wing (part number: 96-6530) may be helpful in this step. Also use the femoral epicondylar axis as the rotational reference.

INFORMATION

If distal augmentation will be used, use 5 or 10 mm Box Cut Guide Spacers on the appropriate condyle(s). Establish the proper rotation of the A/P Block first, then pin through one each of the medial and lateral pin holes. Remove the Block from the pins, then put the appropriate spacer(s) over the pins before replacing the A/P Block. These spacers should rest between the Cutting Guide and the distal condyle(s) to fill these gaps appropriately (part numbers: 5 mm - 63-3305A and 10 mm - 63-3306A).

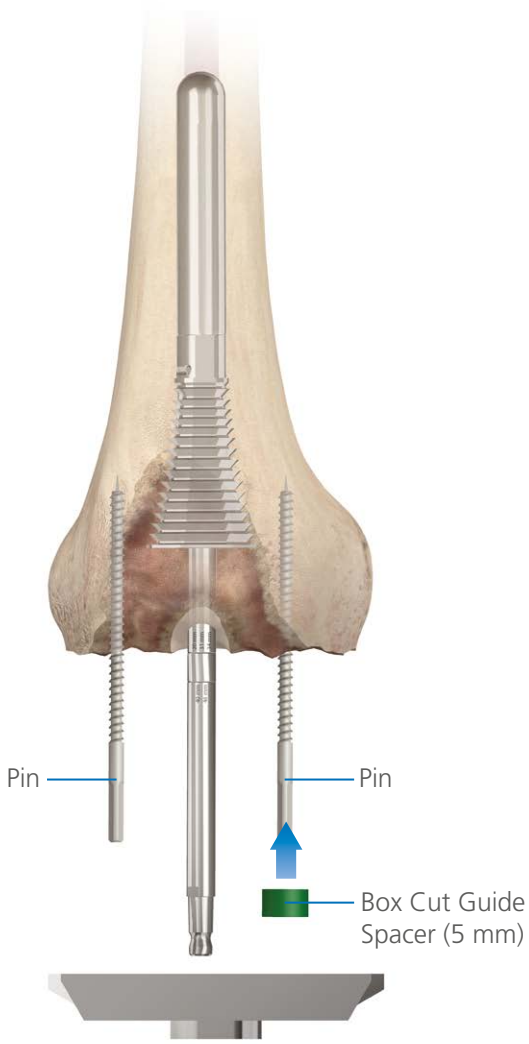


Figure 22

Achieve fixation of the cutting guide with 1/8 in. Drill Pins, introduced through the convergent holes on the side of the Block. These Pins will need to be temporarily removed later to move to the Notch Guide (Figure 23).

Attach the Removable Handles to the Cutting Guide (optional).

Figure 23

Femoral A/P and Chamfer Cuts

Make the anterior cut first. Proceed to make the anterior chamfer cut through the captured slot. If the block was previously pinned, temporarily remove one pin at a time while making the resection (Figure 24).

Make the posterior chamfer cut by holding the Saw Blade flush with the Cutting Guide. If anterior pins are being used for fixation, remove the pin while resecting, then replace. Care should be taken to avoid damaging posterior soft tissue (Figure 25).

If not previously pinned, place at least one 1/8 in drill pin on each side of the guide. These will be used to position the Box Cut Guide. Next, remove the convergent pins.

Finally, remove the Femoral Cutting Guide, leaving the 1/8 in. drill pins in place (Figure 26).

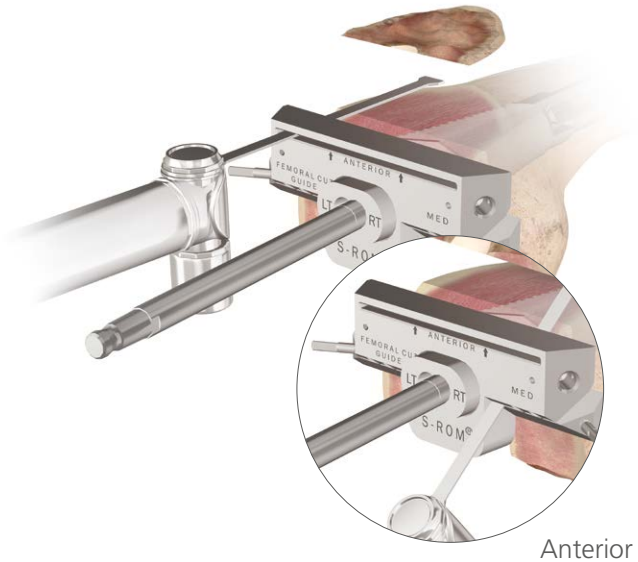


Figure 24 Anterior Chamfer Cut

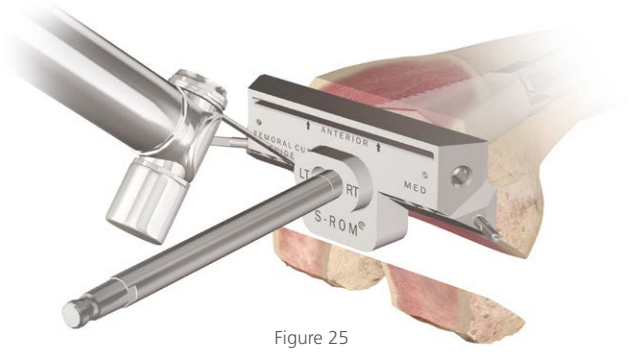


Figure 25

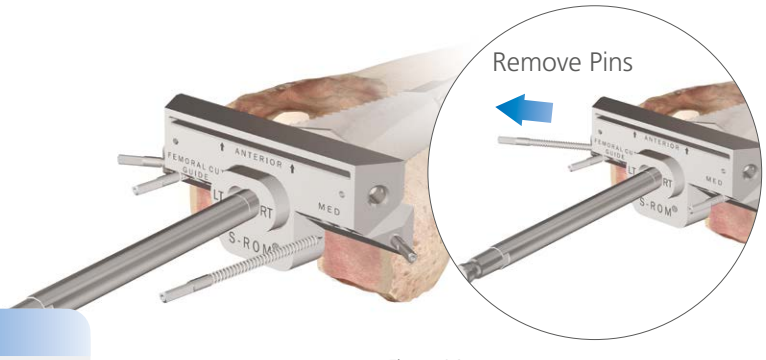


Figure 26

INFORMATION

It may be easier to remove the threaded shaft first, before trying to slide the blocks off the pins.

Femoral Box Cuts

Use 5 or 10 mm Box Cut Guide Spacers if distal Augmentation Blocks will be used.

Slide the Hinge Femoral Box Cut Guide over the 1⁄8 in. drill pins placed in the previous step or align with the lines marked off the Femoral Cutting Guide. If Distal Augmentation Blocks will be used, slide 5 or 10 mm Box Cut Guide Spacers over the drill pins before positioning the Box Cut Guide (Figure 27).

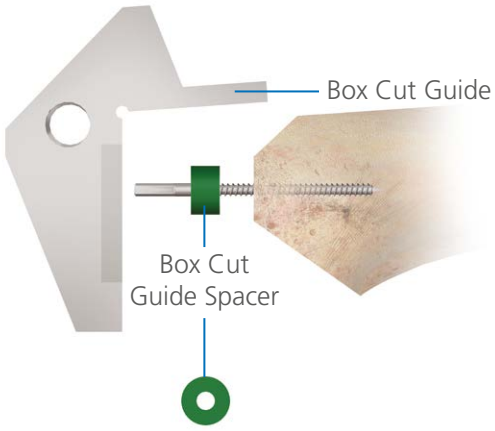


Figure 27

Four additional 1⁄8 in. drill holes are provided on the anterior surface of the Box Cut Guide; 1⁄8 in. drill pins are recommended for additional stability.

Holding the Saw Blade flat against the inner surface of the Box Cut Guide, make the side cuts for the center box (Figure 28).

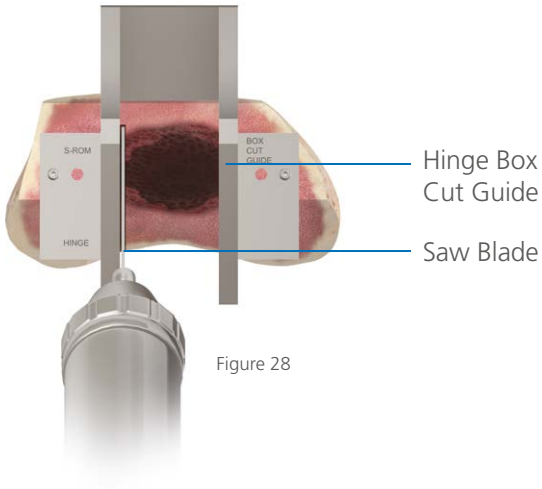


Figure 28

Use a narrow Saw Blade (12.7 mm or 0.5 in), placed on the sloped guide surface, to remove the bone block of the center box (Figure 29).

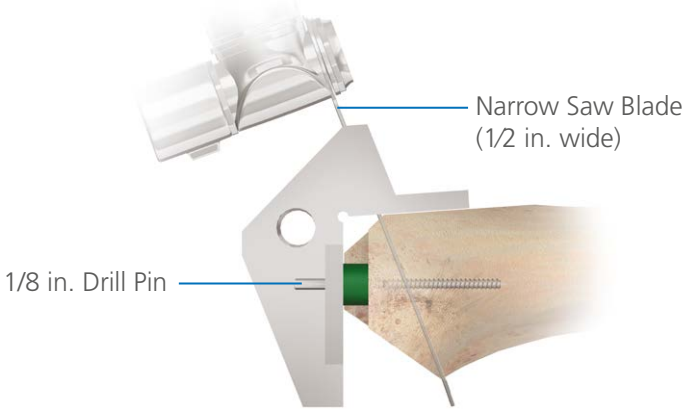
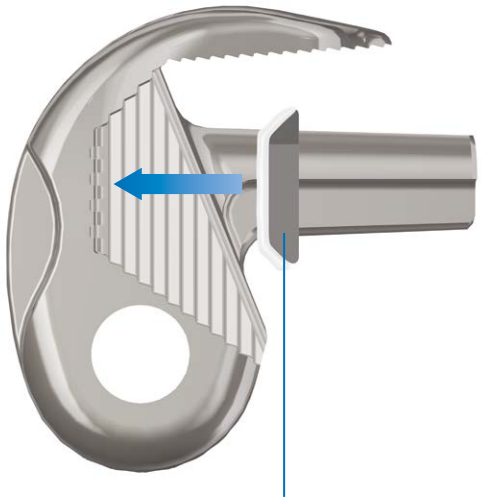


Figure 29

Femoral Trial Insertion

Two femoral Augmentation Blocks are available for the S-ROM NOILES Rotating Hinge Total Knee System. They are the 5 and 10 mm Distal Blocks. One size fits all, i.e. X-Small, Small and Medium hinge femoral components. If distal augmentation is required, attach the Augmentation Block Trial(s) with bone wax to the Femoral Component Trial (Figure 30).



Distal Femoral Augment Block Trial

Figure 30

Implant Cat. No.	Femoral Location	Use with S-ROM NOILES Rotating Hinge Femoral Size	Augment Thickness	Trial Cat. No.
623805	Distal	All Sizes	5 mm	633785
623810	Distal	All Sizes	10 mm	633790

Femoral Trial Insertion

Connect the Stem Trial into the appropriate Femoral Sleeve Trial. The diameter of the Stem Trial will be the same as the final Straight Reamer used; the size of the Femoral Sleeve Trial will be the same as the final Femoral Broach used (Figure 31).

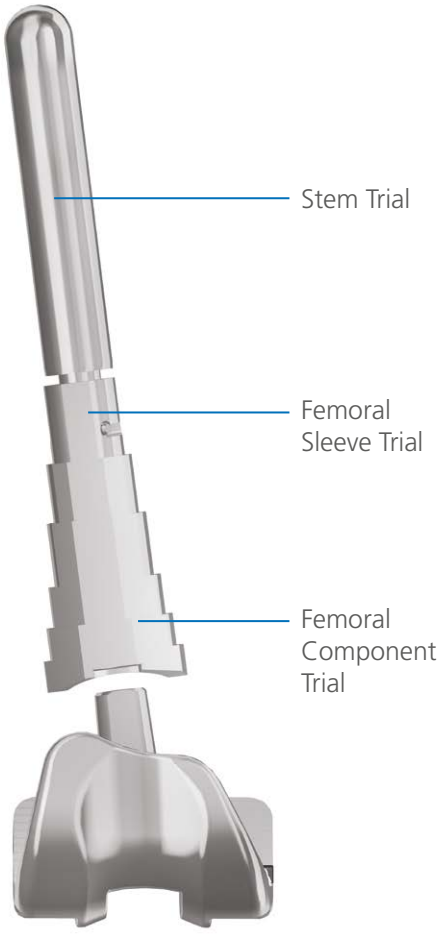


Figure 31

Slide the Sleeve/Stem Trial assembly into the prepared cavity in the femoral canal to allow the assembly to self-align with the broached surfaces (Figure 32).

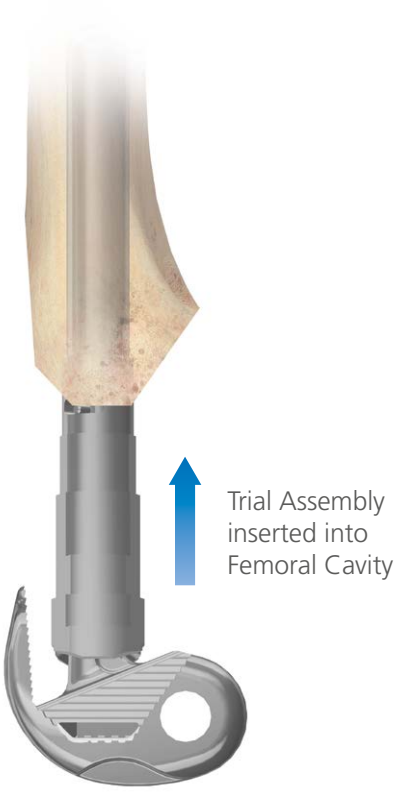


Figure 32

INFORMATION

The narrow side of the Sleeve Trial points medially.

Femoral Trial Insertion

Slide the Femoral Component Trial onto the resected femur, aligning the anterior cut with the posterior aspect of the patellar flange. After the Femoral Component Trial engages the Femoral Sleeve Trial, impact using the Femoral Driver on the Universal Handle (Figure 33). Check accuracy of the bone cuts. Revise or rebroach if necessary.

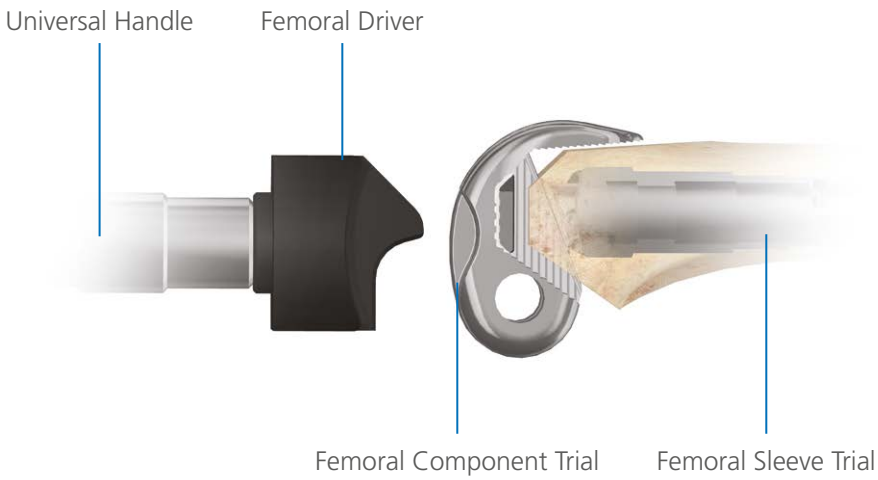
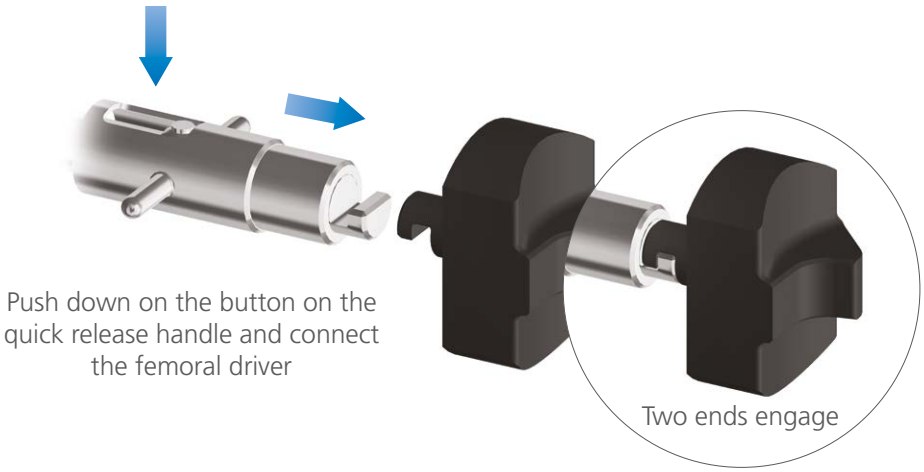


Figure 33



INFORMATION

If Distal Augmentation Blocks will be used, fix Distal Augment Block Trials to the Femoral Trial with bone wax before impacting the Trial onto the femur.

Trialing

Perform trial reduction after assembling the Femoral Trial and Tibial Trial components. Use only the ATTUNE Revision LPS Insert Trial size that matches the size of the S-ROM NOILES Femoral Component being used.

The ATTUNE Revision LPS Insert Trials must be used in conjunction with the ATTUNE Revision LPS Insert Trial Adaptor in order to assemble to the ATTUNE Revision RP Base Trial. Introduce the metal ATTUNE Revision LPS Insert Trial Adaptor to the ATTUNE Revision RP Base Trial by **sliding it** until it "clicks" into place (Figure 34).

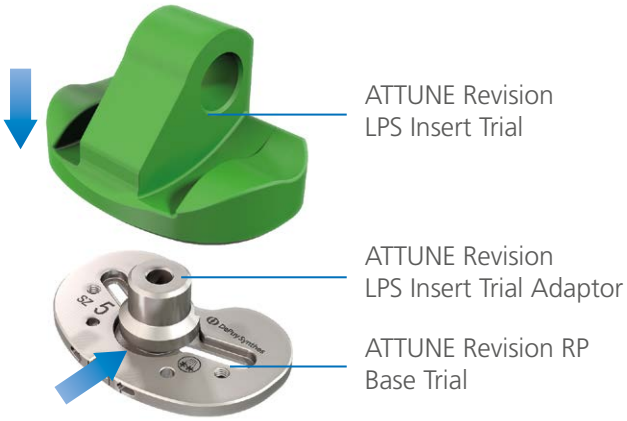


Figure 34

Place the LPS Insert Trial onto the secure LPS Insert Trial Adaptor (Figure 35).

Figure 35

Trialing

Slide the condyles of the Femoral Trial into the ATTUNE Revision LPS Insert Trial. If the Trial Hinge Pin is not in place and the Insert Trial lifts off the tibial baseplate or the femur lifts off the Insert Trial during flexion, check the posterior area for soft tissue, osteophyte or bone impingement (Figure 36).

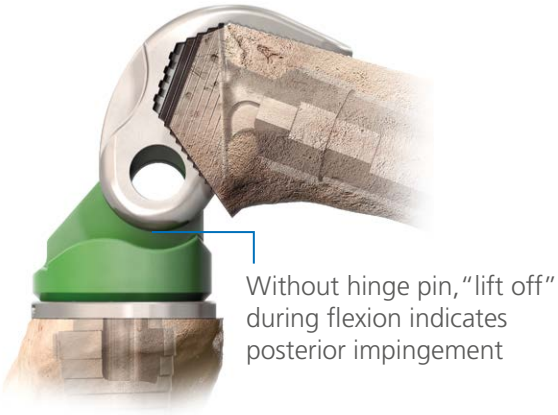


Figure 36

The Trial Hinge Pin may be inserted into the S-ROM Femoral Trial either medially or laterally to secure the Insert Trial to the Femoral Trial (Figure 37).

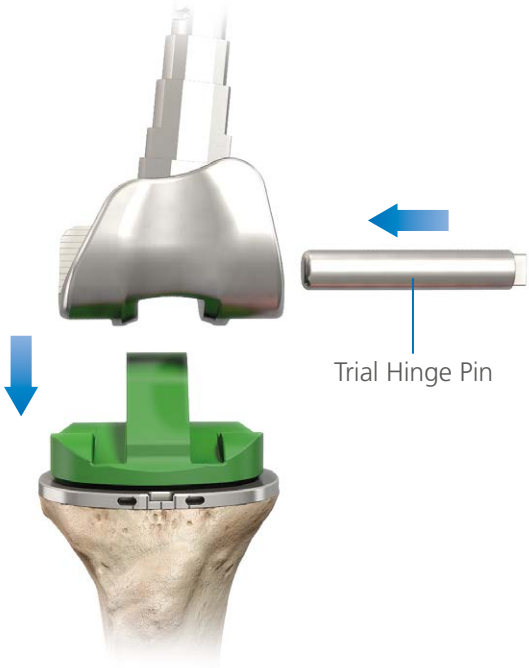


Figure 37

Trialing

It is easier to insert the Hinge Pin Trial prior to placing the insert trial into the tibial baseplate. (Figure 38).

With the leg in full extension, evaluate the mechanical axis. The center of the femoral head, knee and talus should all be in line (Figure 39).

The knee should be stable throughout the full range of motion.

Check ligament tension and leg length.

Revision of the tibial or femoral resection may be required if satisfactory stability cannot be achieved. Accommodate additional bone resection with rebroaching.

Figure 38

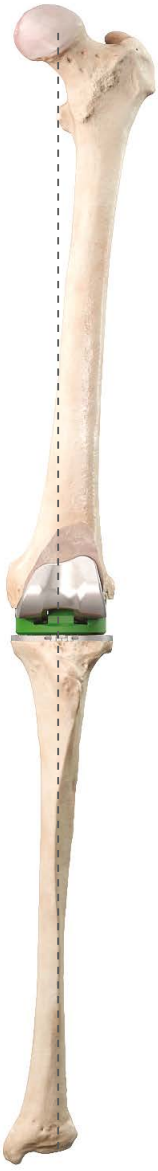


Figure 39

INFORMATION

In patients with severe soft tissue loss, flexion of the knee beyond 90 degrees may cause distraction and subluxation of the tibial plateau out of the modular tibial base. In this instance, fit the patient with a post-operative brace, limiting flexion to 90 degrees and no more for at least three months. This helps soft tissue establishment of flexion tension. Consult the S-ROM NOILES Rotating Hinge System Instructions for Use.

Trial Removal

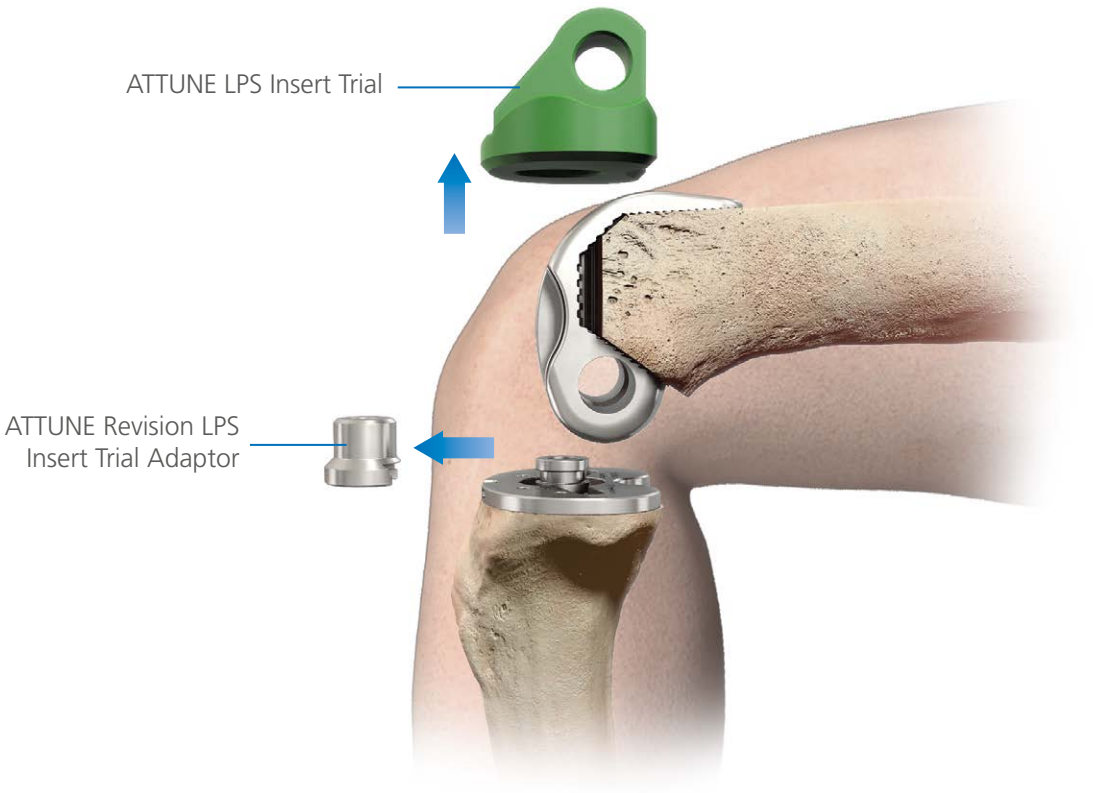


Figure 40

Remove the Trial Hinge Pin. Extract the femoral trials and ensure that the rotational alignment of the assembly is preserved. This is used as a reference when assembling the modular implant.

To remove the Insert Trial, fully flex the knee and grasp the top of the ATTUNE Revision LPS Insert Trial spine. Pull the Insert Trial vertically until it has disengaged from the Insert Trial Adaptor. Finally, slide the Insert Trial Adaptor to release it from the ATTUNE Revision RP Base Trial (Figure 40).

For Final Tibial Implantation refer to the ATTUNE Revision RP Surgical Technique.

Cementing Technique

During cementing of implants, movement of the components should be minimized while the cement is curing.

Prepare the sclerotic bone to ensure a continuous cement mantle with good cement interdigitation of 2 mm - 4 mm. This can be done by drilling holes and cleansing the bone with pulsatile lavage, taking care to dry the bone afterwards. Pack residual small cavity bone defects with cancellous autograft, allograft, or synthetic bone substitutes.

Apply a thick layer of cement to the bone, the implant surface or to both.

INFORMATION

Caution: Blood lamination can reduce the mechanical properties of the cement; therefore, it is vital to choose cement that reaches its working phase quickly. If applying cement to both the implant and bone, implantation should be completed early in its dough state to ensure good cement-cement adhesion and reduce the risk of dry laminations; which can weaken the cement.

INFORMATION

Caution: Application of the cement to the roughened implant surface early in the dough state has been demonstrated to increase the fixation strength of the cement to the implant.[2]

For additional reference see the Guidance for Cementing Total Knee Replacements document.

Implant Assembly – Sleeve and Stem Use

Implant Assembly - Sleeve and Stem Use

Implant assembly order (with Sleeve and Stem use): (Figure 41).

- Add Distal Augments if necessary
- Attach Stem to Sleeve
- Attach Sleeve construct to femoral construct

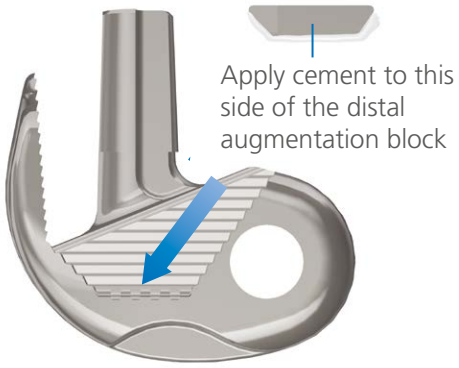


Figure 41

Implantation

After assembling the femoral components, prepare one package of bone cement according to instructions.

Apply cement to the Augmentation Block(s) on the side which contacts the femoral component, and to the corresponding surface(s) of the femoral component.

Attach the Augmentation Block(s) to the femoral component. Use an Augment Block Clamp to secure to the femoral component until the cement is fully cured (Figure 42).

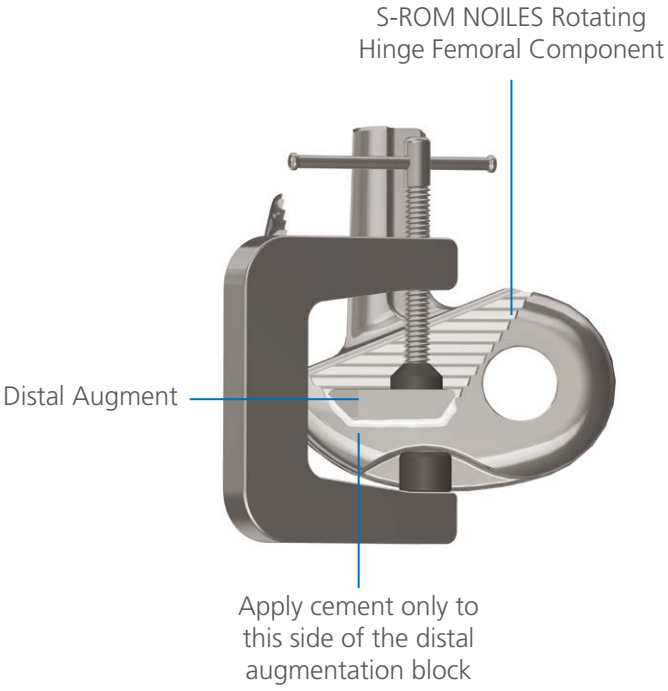


Figure 42

INFORMATION

When distal Augmentation Blocks are used with the S-ROM NOILES Rotating Hinge Femoral Component, place the Augment Block Clamp into the distal condylar "pocket" of the femoral component.

Implant Assembly – Sleeve and Stem Use

To attach the Universal Stem to the Universal Femoral Sleeve, thread the Stem onto the Sleeve. Grasp the Sleeve with the Tibial Sleeve Clamp and use the Stem Extension Wrench to grasp the Universal Stem and tighten. Apply sufficient force to both Wrenches to ensure that the Stem is secure (Figure 43).

Place the femoral component on a firm, stable surface. Place the appropriate Sleeve and Stem construct on top of the fixed Stem of the femoral component. Use the Sleeve and femoral construct trial to help set the final Sleeve and femur implant rotation (Figure 44).

Figure 43

Figure 44

Implant Assembly – Sleeve and Stem Use

Slide the Femoral Stem/Sleeve Impactor on top of the Stem and forcefully apply three strikes with a Mallet to engage the two component assemblies (Figure 45).

The definitive components are implanted in the following order:

- Tibial tray (with Stem, Sleeve or Tibial Augments)
- Femoral component (with Stem, Sleeve and Augments)
- ATTUNE Revision LPS Insert

Implant the femoral component using the Femoral Impactor (Figure 46).

Figure 45

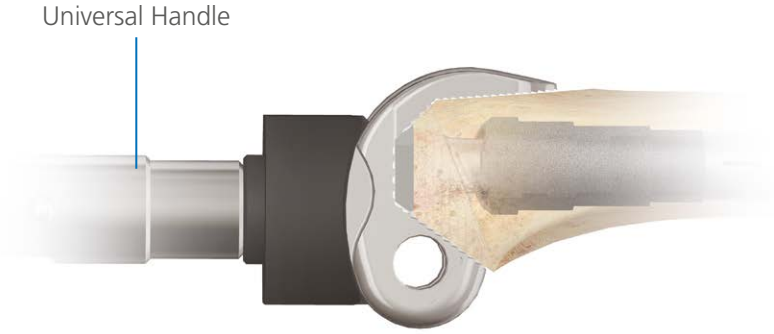


Figure 46

Implant Assembly and Final Trialing

After the femoral component and Tibial Tray have been cemented into place, do one final check with the ATTUNE Revision LPS Insert Trials.

The ATTUNE Revision RP Tibial Base and the ATTUNE LPS Insert Trial Post may be utilized with the ATTUNE LPS Insert Trial to perform a Trial reduction (Figure 47).

Once desired flexion/extension balance is achieved, note the final Insert Trial thickness used.

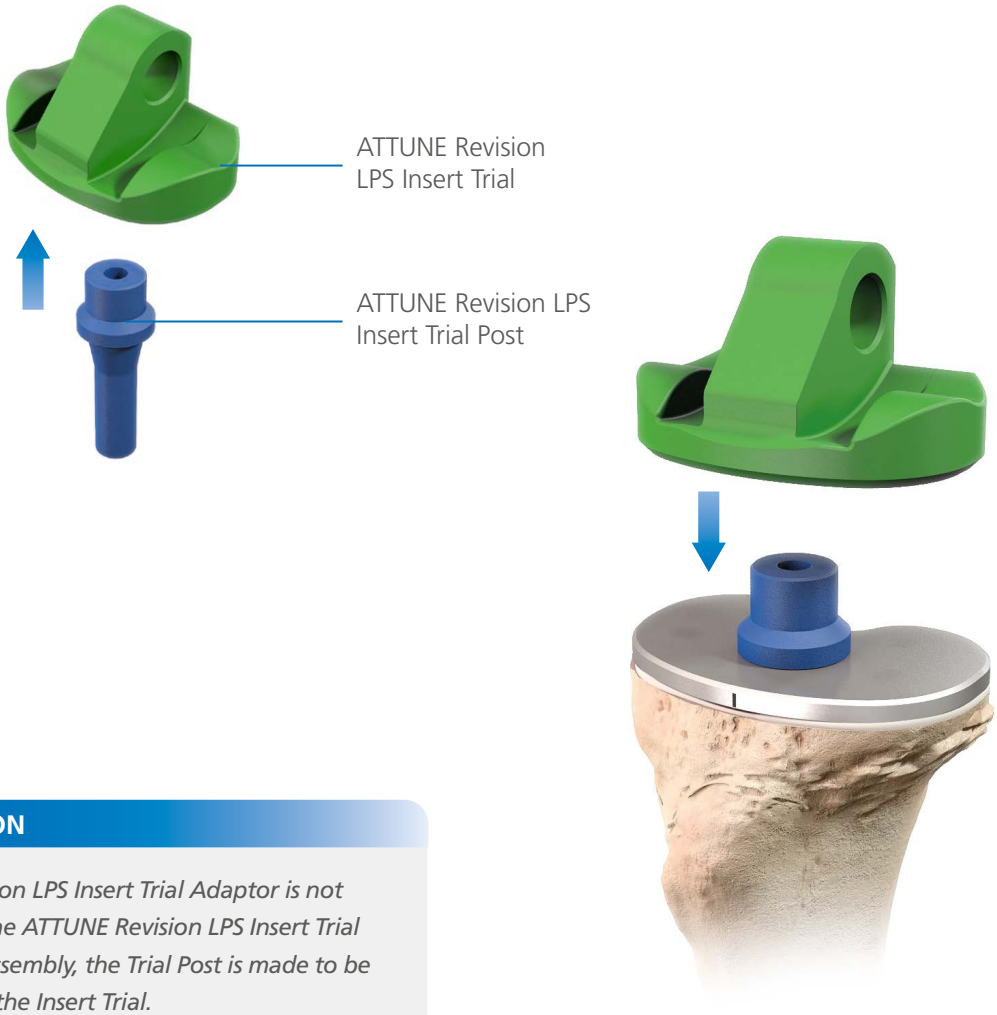


Figure 47

INFORMATION

The ATTUNE Revision LPS Insert Trial Adaptor is not compatible with the ATTUNE Revision LPS Insert Trial Post. For ease of assembly, the Trial Post is made to be used directly with the Insert Trial.

Final Implantation

Put the condyles of the Femoral Component into the corresponding recesses in the tibial plateau.

Use the Hinge Pin to mate the S-ROM Hinge Femoral Component to the ATTUNE Revision LPS Insert Bearing through the Hinged Insert Bearing Implant. Orient the rectangular head of the Hinge Pin with the rectangular recess in the Femoral Component (Figure 48). Squeeze the "clothes pin" of the Hinge Pin together and insert the Hinge Pin into the Femoral Component. Make sure the Hinge Pin is securely locked in place (Figure 49). Place the ATTUNE Revision LPS Insert Post into the cone of the ATTUNE Revision RP Tibial Base (Figure 50).

Test the knee through full range of motion (Figure 51).

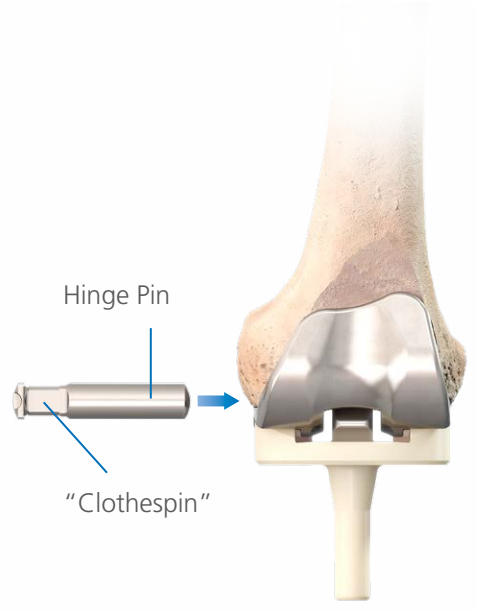


Figure 48

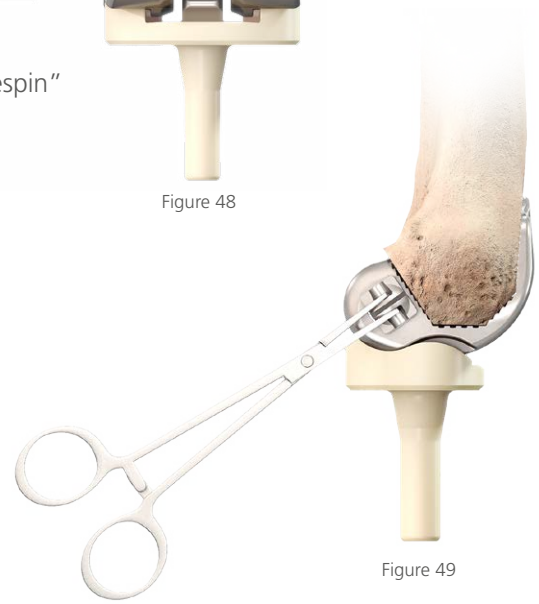


Figure 49

INFORMATION

The Hinge Pin can be inserted from either the medial or lateral side

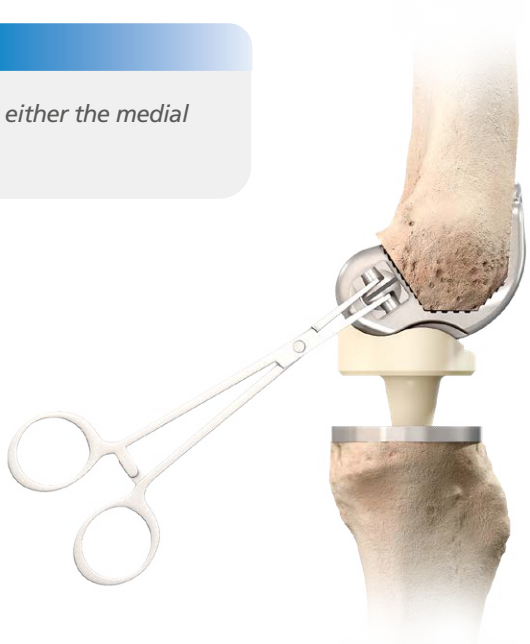


Figure 50

Figure 51

Initial Patellar Resection

Use the Caliper to estimate the thickness of the patella (Figure 52).

Resect approximately 7 mm of bone from the posterior patella surface using an Oscillating Saw.

Assess the thickness of the resected/removed bone in order to properly duplicate the original thickness.

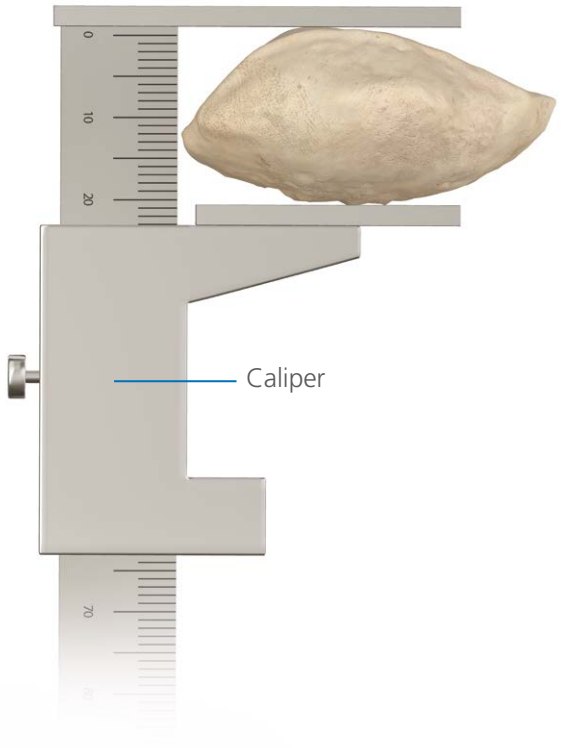


Figure 52

Initial Patellar Resection

Patella Domes are available in four diameters (Figure 53).

Select a patella trial with the diameter that best matches the patient's patella.

Select the Patella Reamer Depth Adjuster that is the same diameter as the patella trial.

Insert the Patella Reamer Depth Adjuster into the Patella Restraining Instrument. Rotate the depth adjuster 120 degrees clockwise to lock into position (Figure 54).

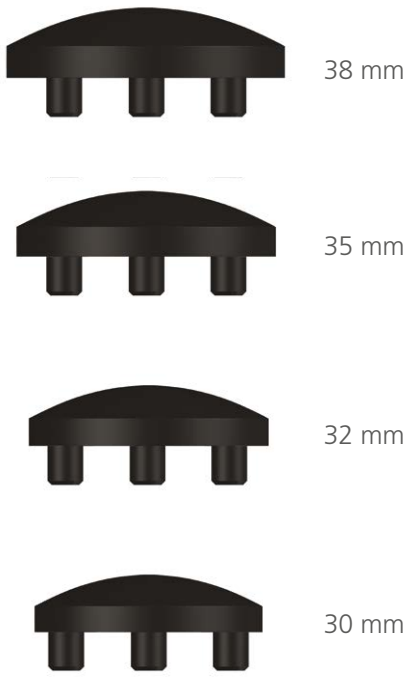


Figure 53

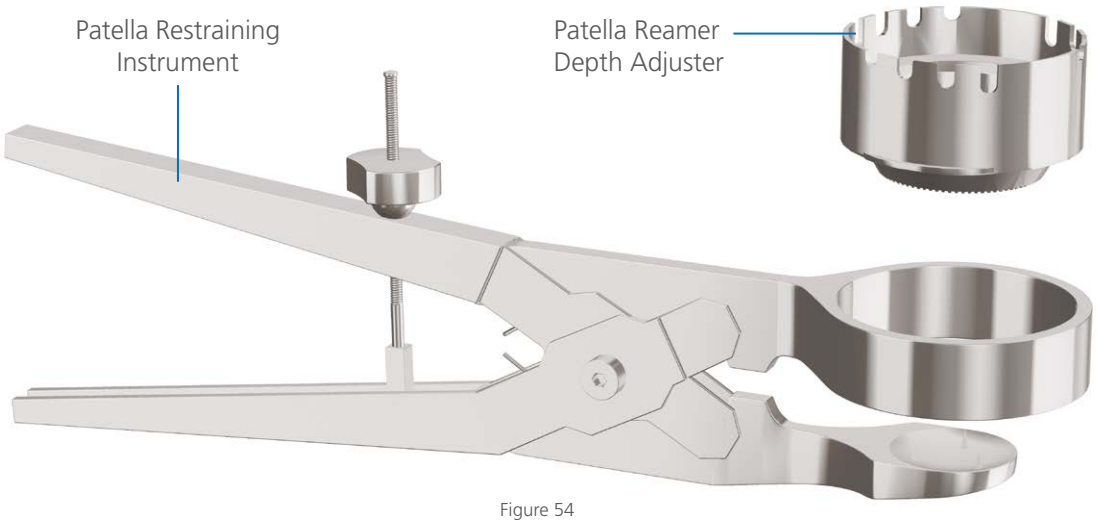


Figure 54

Patella Reaming

Clamp the Patella Restraining Instrument assembly onto the patella. Lock into position by turning the Thumb Nut clockwise.

Insert the Patella Reamer Bushing into the appropriate set of slots on the Patella Reamer Depth Adjuster. Slots on the depth adjuster are marked 1, 2, 3 and 4, which indicate the reaming depth in millimeters. To determine the correct slot, use the formula shown in table as a guide.

Thickness of selected patella component		Assessed thickness of bone resected and removed		Select Slot number
9 mm	**-**	**7 mm**	**=**	**2**

Select the Patella Reamer that matches the diameter of the patella component to be used and insert through the Patella Reamer Bushing into the Patella Reamer Depth Adjuster. Ensure that the Patella Reamer is making full contact with the bone prior to reaming. Ream until the Patella Reamer flange makes contact with the Patella Reamer Bushing (Figure 55).

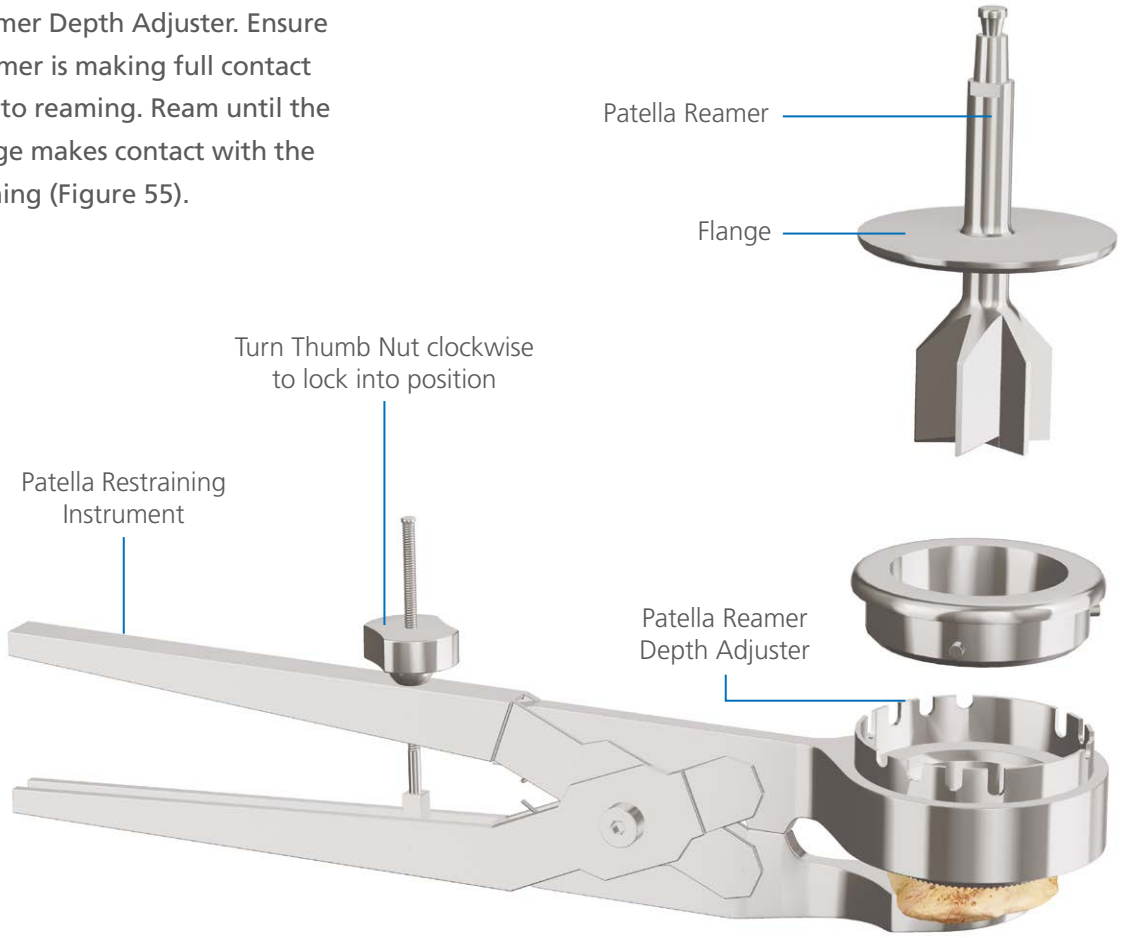


Figure 55

Patella Drilling

Remove the Patella Reamer and insert the Patella Drill Guide into the Patella Reamer Bushing. The Locating "Pin" on the Drill Guide will insert into the hole in the Patella Restraining Instrument (Figure 56).

Select the 3⁄16 in. Patella Shoulder Drill and prepare the three patella peg holes by drilling through the three larger holes in the Patella Drill Guide (Figure 57).

The depth of the holes drilled is correct for the length of the pegs on the selected Patella Button.

Optional: Select the 1⁄8 in. Patella Shoulder Drill and drill through the four smaller holes to enhance the cement fixation to the patellar bone.

Loosen the Thumb Nut on the Patella Restraining Instrument and remove the entire assembly from the patella bone.

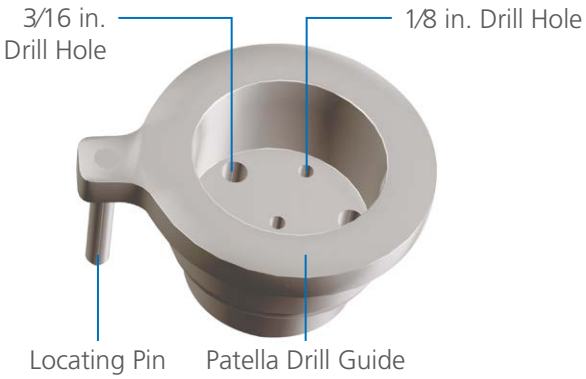


Figure 56

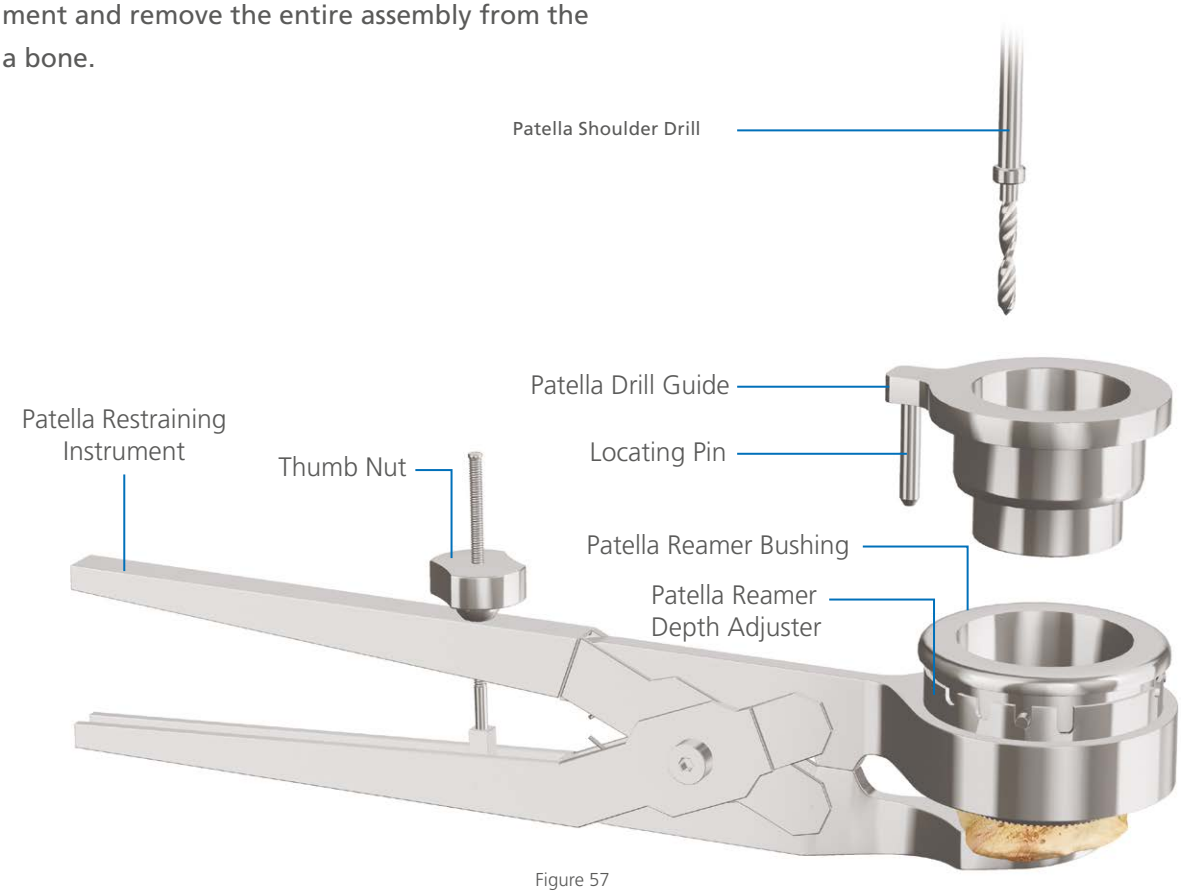


Figure 57

Trial Reduction and Implantation

Place the appropriate diameter Patella Trial into the prepared patella bone. Assess the overall thickness of the patella construct to ensure that it is the desired thickness, i.e. equal to or 1-2 mm less than the original patella thickness. A “no-thumbs” trial reduction and patella tracking evaluation can now be performed.

The appropriately sized Patella Dome may now be cemented into place. A Patella Cement Clamp is provided for this purpose (Figure 58).

Figure 58

INFORMATION

If the reconstructed patella is too thick, repeat the reaming and drilling steps using the number 2, 3 or 4 slot on the Patella Reamer Depth Adjuster. If a greater thickness must be removed, take additional resection from the patella. The reaming and drilling steps must be repeated. (Take care to make sure the patella bone is not cut too thin. Maintain at least 10 mm of patella bone to prevent drill or peg penetration of the anterior cortex).

LPS Total Femur Replacement

Pre-operative Planning

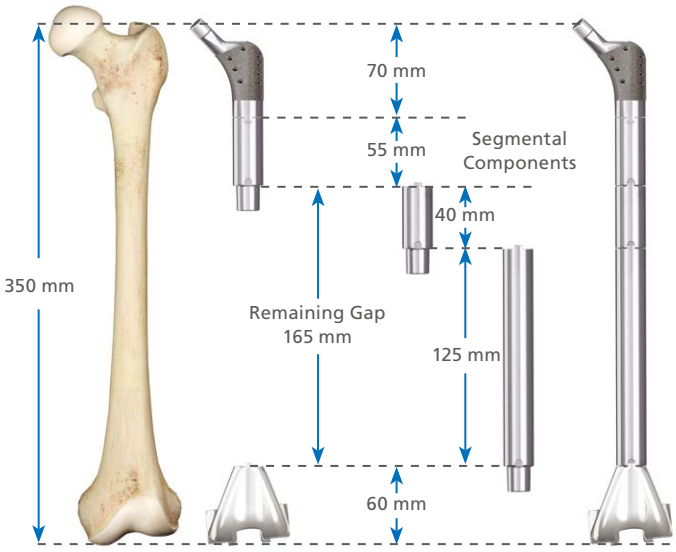
The LPS System can be used to replace the entire femur. The following technique reviews the intended design and use of the instruments and implants for this procedure and provides a general framework. Utilize techniques that best meet the needs of each case, since each case is unique and has specific challenges. Consider the following recommendations:

Using pre-operative templating, use the full lower extremity radiographs to help determine the length of femur to be replaced by the prosthesis and if there are any special needs in reconstructing the acetabulum and proximal tibia.

The minimum total femoral construct when using the X-small distal femoral component is 185 mm, which includes the proximal femoral body (70 mm), total segmental (55 mm) and distal femoral (60 mm) components (Figure 59).

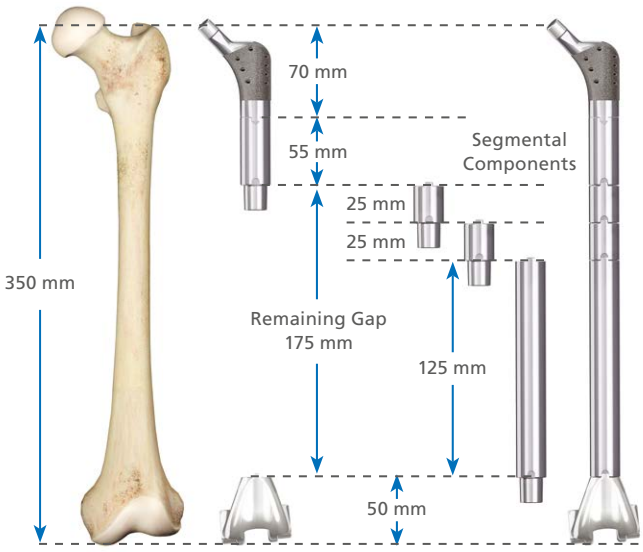
The minimum total femoral construct when using the XX-small distal femoral component is 175 mm, which includes the proximal femoral body (70 mm), total segmental component (55 mm) and distal femoral (50 mm) component (Figure 60). Use additional segmental components to replace missing femoral bone.

Refer to the chart on **page 58** for information on which segmental components to use for varying lengths of missing bone.



X-small

Figure 59



XX-small

Figure 60

Exposure and Intra-operative Planning

Use the surgical approach based upon the surgeon's pre-operative plan and exposure preference. During the reconstruction, take care to avoid stretch injury to the neurovascular structures in this extensive procedure. Perform the acetabular reconstruction as required. If using a fixed acetabular component, consider using the PINNACLE® Revision Acetabular Cup System Standard or Deep Profile Revision Cups with GRIPTION™ Coating which are designed to allow for rim screws and/or domed screws. This will allow for additional fixation. Also consider using a large femoral head (>32 mm), a constrained liner or a tripolar construct for stability. Leg length estimate is important for a successful surgical outcome. An example of one estimate method utilizes a horizontal line made 1 cm below the proposed tibial resection level using an osteotome, electrocautery, marking pen or methylene blue.

Another estimation method is to get an X-ray of the contralateral leg, measure the length with a ruler, and then match the length of the operated leg to that estimate. This is a constrained system so the goal is to recreate the leg with the knee's joint line in the proper position. Establish the proper joint line for the knee, match the leg length to the contralateral leg, and use constraint at the hip so you don't overlengthen the patient. To determine joint line in the knee, use the patella to make sure you don't end up with a patella baja or alta. Place a Steinmann Pin in the ilium, superior to the acetabulum midline. Extend the limb and measure the distance between the pin and marked horizontal line on the tibia and record the length prior to any resection (Figure 61). It is important to measure the knee in full extension. Avoid estimate with the knee in flexion for consistency of measurement results. Remove the Steinmann pin and mark the hole with an electrocautery or marking pen so the Steinmann Pin location can be found and reinserted later during the trial reduction process.

Excise the femur according to standard oncologic principles for a neoplasm or as dictated by the underlying pathology, such as post infection, end-stage revision arthroplasty, etc.

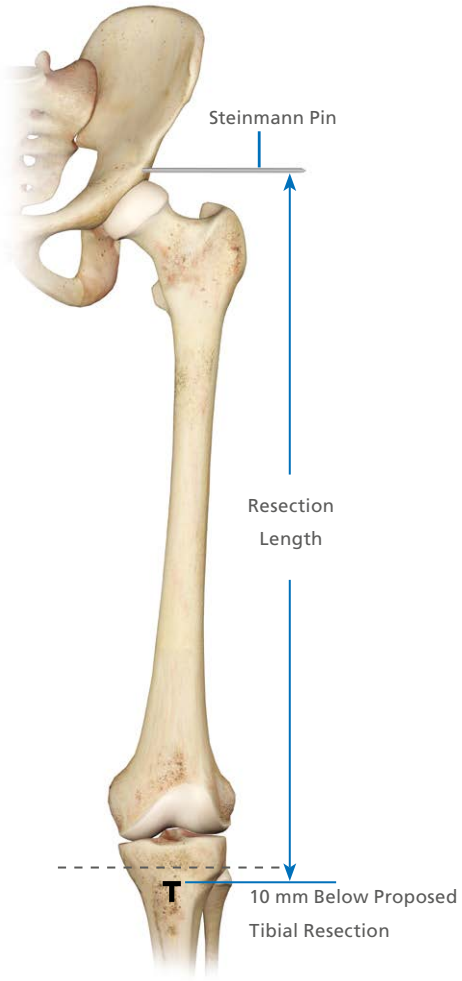


Figure 61

Tibial Preparation and Initial Trial Reduction

For Tibial Preparation information, refer to the ATTUNE Revision RP Surgical Technique.

Trial Reduction

Assemble the total femoral trial components for an initial trial reduction to check for the correct approximation of the femoral replacement. The trial construct consists of a proximal femoral body, total femoral segmental, segmental and distal femoral replacement trial components (Figure 62).

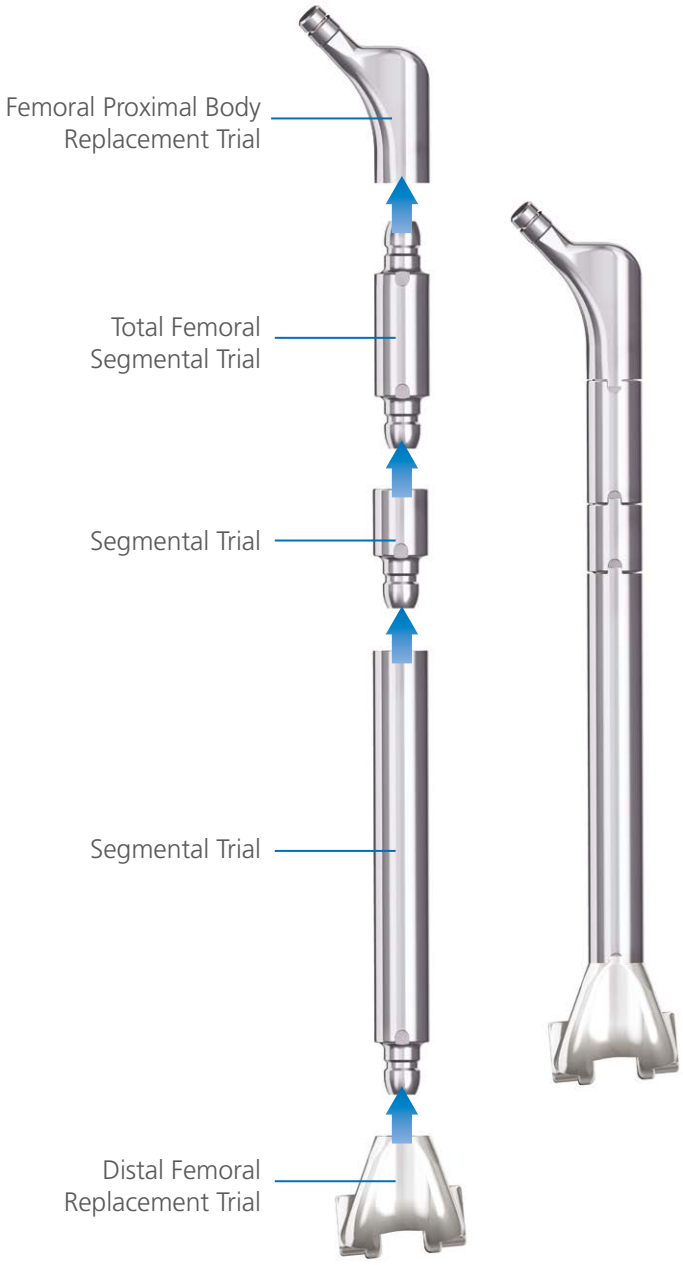


Figure 62

Trialing

Perform trial reduction after assembling the Femoral Trial and Tibial Trial components. Use only the ATTUNE Revision LPS Insert Trial size that matches the size of the LPS Distal Femur Replacement being used.

The ATTUNE Revision LPS Insert Trials must be used in conjunction with the ATTUNE Revision LPS Insert Trial Adaptor in order to assemble to the ATTUNE Revision RP Base Trial. Introduce the metal ATTUNE Revision LPS Insert Trial Adaptor to the ATTUNE Revision RP Base Trial by **sliding it** until it "clicks" into place (Figure 63).

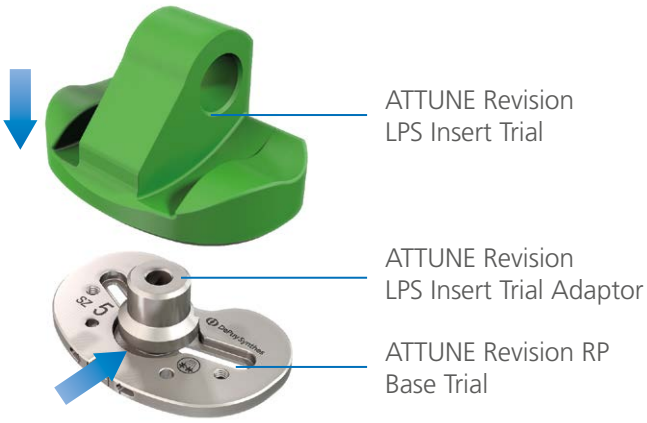


Figure 63

Place the LPS Insert Trial onto the secure LPS Insert Trial Adaptor (Figure 64).

Figure 64

The LPS Hinge Pin Trial may be inserted into the LPS Distal Femur Replacement either medially or laterally to secure the Insert Trial to the Femoral Component (Figure 65).

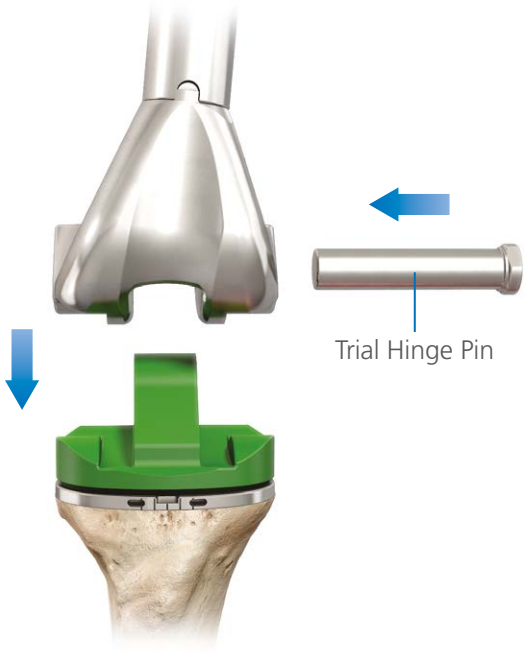


Figure 65

Trial Reduction

Insert the Steinmann Pin into the previously drilled hole in the ilium. Check the femur's length against the estimate recorded prior to the resection, using whatever method previously selected. Make femoral length changes by changing the segmental trial lengths, which offer 5 mm increment capability. Compare the knee joint line to the opposite side for proper height. Alternatively, the medial malleoli may be compared on each leg to evaluate leg length (Figure 66).

The joint line is determined by the level of the distal surface of the distal femoral component. Take the knee through a range of motion from extension to flexion and take note of patella tracking. Adjust the segmental components accordingly to ensure proper patellar tracking. Assess proper anteversion and stability (Figure 67).

Make fine adjustments to leg length using the range of different femoral head lengths. Use varying tibial insert polyethylene heights to provide joint stability and to adjust leg length.

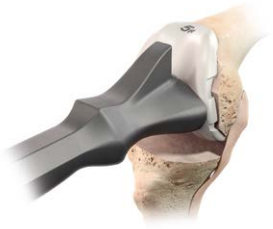


Figure 66

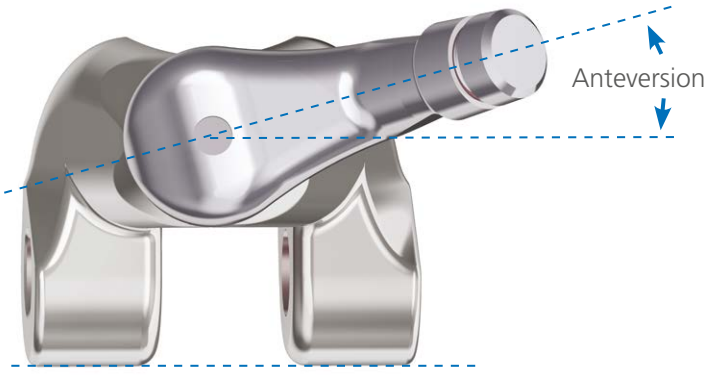


Figure 67

Trial Removal

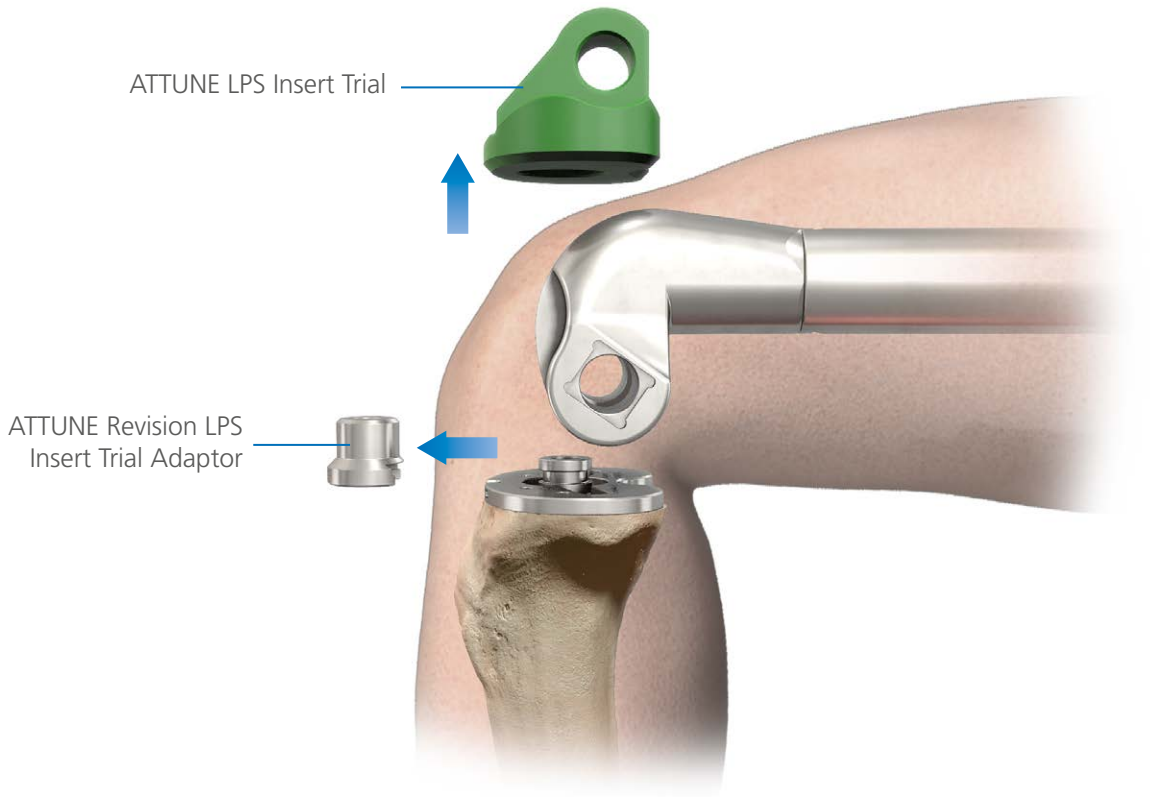


Figure 68

Remove the LPS Hinge Pin and Femoral Trials.

To remove the Insert Trial, fully flex the knee and grasp the top of the ATTUNE Revision LPS Insert Trial spine. Pull the Insert Trial vertically until it has disengaged from the Insert Trial Adaptor. Finally, slide the Insert Trial Adaptor to release it from the ATTUNE Revision RP Base Trial (Figure 68).

For Final Tibial Implantation refer to the ATTUNE Revision RP Surgical Technique.

Cementing Technique

During cementing of implants, movement of the components should be minimized while the cement is curing.

Prepare the sclerotic bone to ensure a continuous cement mantle with good cement interdigitation of 2 mm - 4 mm. This can be done by drilling holes and cleansing the bone with pulsatile lavage, taking care to dry the bone afterwards. Pack residual small cavity bone defects with cancellous autograft, allograft, or synthetic bone substitutes.

Apply a thick layer of cement to the bone, the implant surface or to both.

INFORMATION

Caution: Blood lamination can reduce the mechanical properties of the cement; therefore, it is vital to choose cement that reaches its working phase quickly. If applying cement to both the implant and bone, implantation should be completed early in its dough state to ensure good cement-cement adhesion and reduce the risk of dry laminations; which can weaken the cement.

INFORMATION

Caution: Application of the cement to the roughened implant surface early in the dough state has been demonstrated to increase the fixation strength of the cement to the implant.[2]

For additional reference see the Guidance for Cementing Total Knee Replacements document.

Implant Assembly and Insertion

After trial reduction, assemble the implants using the femoral impaction stand on the back table. The implant component alignment should duplicate the trial component's orientation so that femoral anteversion and proper femoral/tibial construct alignment is correct. Place the distal femoral replacement component on the femoral impaction stand.

Stack the component tapers to assemble the total femoral and segmental components and the proximal femoral body replacement component. Use the Impaction Cap to impact on the proximal femoral replacement body to impact the tapers together (Figure 69). There should be approximately a 1 mm gap between the component bodies.

Implant Insertion

If using SMARTSET™ MV Bone Cement, mix and deliver according to the manufacturer's recommendation. Impact and hold the cemented tibial tray component still until the cement is cured.

Place the total femur implant construct into the remaining femoral soft tissue envelope. Reduce the femoral replacement into the chosen acetabular and tibial components. Trial femoral heads and trial tibial inserts can be evaluated to make assessments in choosing final implant sizes.

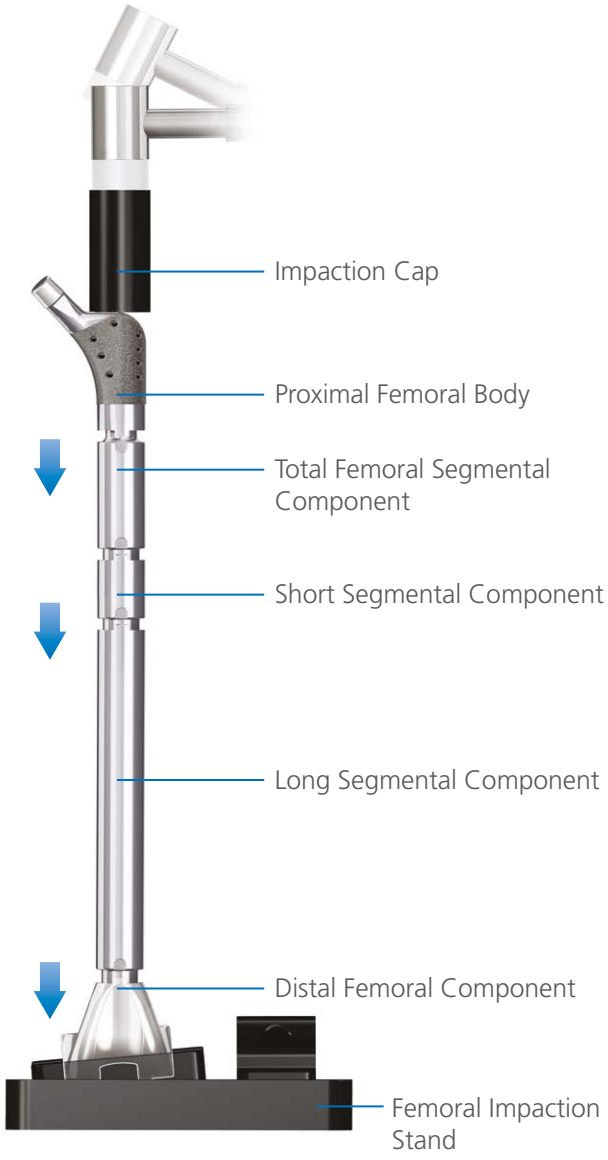


Figure 69

Implant Assembly and Final Trialing

After the femoral component and Tibial Tray have been cemented into place, do one final check with the ATTUNE Revision LPS Insert Trials.

The ATTUNE Revision RP Tibial Base and the ATTUNE LPS Insert Trial Post may be utilized with the ATTUNE LPS Insert Trial to perform a Trial reduction (Figure 70).

Once desired flexion/extension balance is achieved, note the final Insert Trial thickness used.

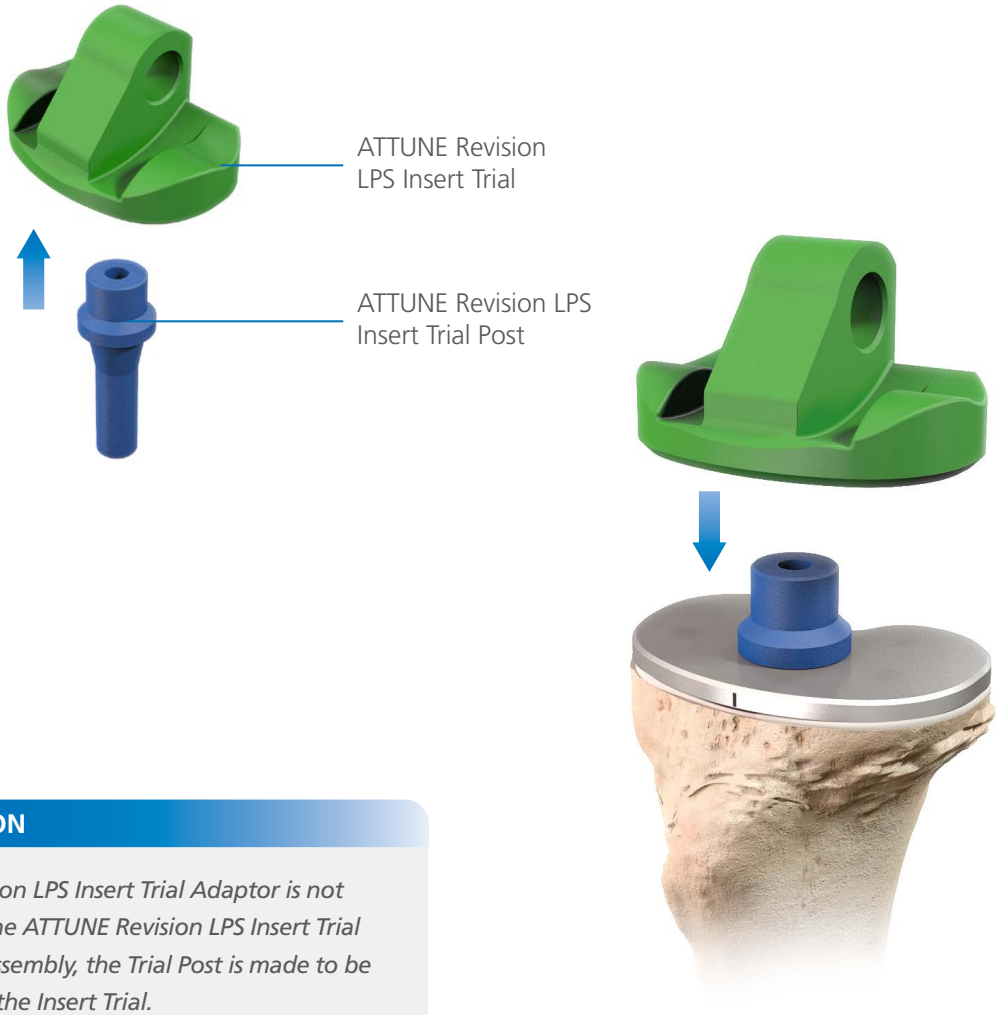


Figure 70

INFORMATION

The ATTUNE Revision LPS Insert Trial Adaptor is not compatible with the ATTUNE Revision LPS Insert Trial Post. For ease of assembly, the Trial Post is made to be used directly with the Insert Trial.

Final Implantation

Once the total prosthesis is positioned in-vivo, perform the final leg length and joint line checks with a trial femoral head (Figure 71).

Also evaluate the range of motion to make sure there is no impingement of the acetabulum. Now is the time to reposition the parts before proceeding with the operation. Check the version to make sure it is correct.

Remove the trial femoral head, place the selected femoral head onto the proximal femoral body taper and, utilizing the femoral head impactor, impact it with a Mallet blow, engaging the Morse taper. Reduce the femoral replacement into the acetabular component.

Put the condyles of the Femoral Component into the corresponding recesses in the tibial plateau. Use the Hinge Pin to mate the LPS Distal Femur Replacement to the ATTUNE Revision LPS Insert Bearing through the Hinged Insert Bearing Implant. Orient the rectangular head of the Hinge Pin with the rectangular recess in the Femoral Component. Squeeze the "clothes pin" of the Hinge Pin together and insert the Hinge Pin into the Femoral Component. Make sure the Hinge Pin is securely locked in place.

Place the ATTUNE Revision LPS Insert Post into the cone of the ATTUNE Revision RP Tibial Base.

Take care that the foot is in the proper plane when running the leg through range of motion (because it is a rotating platform implant). Place the patella in its anatomic position first then run the leg through its range of motion. Make sure that the tibia does not become externally rotated during this process.

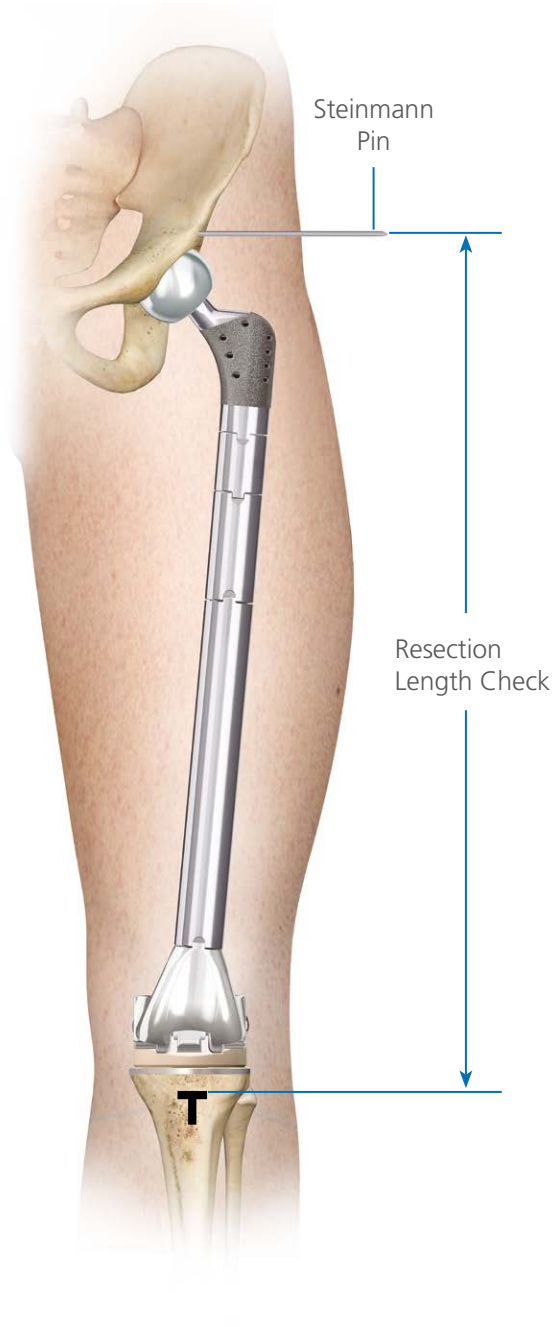


Figure 71

INFORMATION

The Hinge Pin can be inserted from either the medial or lateral side

Closure

With the components securely in place, soft tissue closure is important to successful procedure completion. If the hip capsule is present, place a purse-string suture around the residual capsule and secure it over the chosen bipolar or acetabular component. Use the proximal femoral body replacement component to reattach the greater trochanter when present. This feature works by utilizing the reattachment holes provided in the proximal femoral body component. Attach the greater trochanter and abductor with either a heavy suture or MERSILENE™ Polyester Fiber Suture. If the abductors are extensively shortened, use the proximal femoral replacement body with the trochanteric build-up for reattachment.

If possible, suture the gluteus medius muscle to the lateral femoral muscles and then fasten the fascia lata to the proximal femoral replacement component holes. This assists in securing the gluteus musculature until scar tissue is formed with the surrounding soft tissue protecting against early subluxation.

LPS Distal Femur Replacement

Pre-operative Planning

Pre-operative Planning

Reconstruction of the distal femur due to significant bone loss or trauma can be performed utilizing the LPS System. The following technique reviews the intended design and use of the instruments and implants for this procedure and provides a general framework. Utilize techniques that best meet the needs of each case, since each case is unique and with its own challenges. Consider the following recommendations:

- Perform pre-operative planning and radiographic analysis for every case. Use the LPS System Templates for pre-operative planning to assess the approximate resection level; position of the distal femoral replacement and segmental component(s) (if needed) to restore the joint line; and determine the diameter and length of the femoral Stem Extension that could be used to provide adequate fixation and stability in the remaining host femur diaphyseal bone.

Exposure and Tibial Preparation

Exposure

Use a surgical approach that best achieves the exposure needed for extensive removal of bone in the distal femur and proximal tibia areas. Leg length estimate and alignment are important checks to be done prior to any bone resection. During surgery, take care to avoid stretch injury to the neurovascular structures. If performing the reconstruction for primary bone sarcoma, the pre-operative imaging studies, such as plain radiographs, CT scans and MRI of the femur, must be reviewed to determine a safe resection level.

Tibial Preparation

For Tibial Preparation refer to the ATTUNE Revision Rotating Platform Surgical Technique.

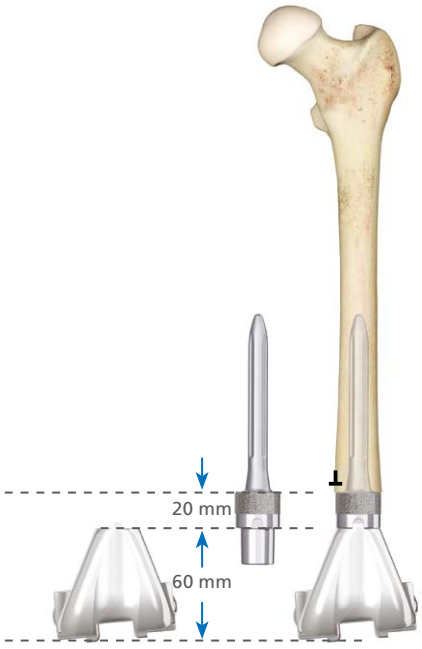
Femoral Preparation

Intra-operative Planning

The minimum distal femur resection level is 80 mm when using the X-small distal femoral replacement component with LPS Stems (Figure 72).

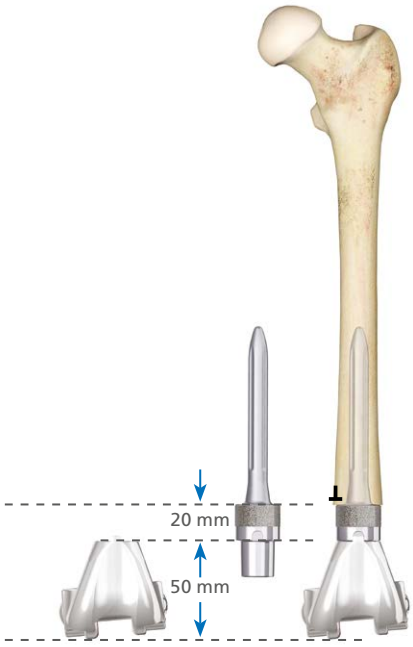
The minimum distal femur resection is 70 mm when using the XX-small distal femoral replacement component. This minimum resection level includes the distal femoral replacement component lengths of 50 mm and 60 mm respectively plus the 20 mm stem component collar height (Figure 73).

For selecting a size for the femoral component, it is important to consider the soft tissue envelope which must be closed. If the soft tissue envelope is extremely tight, use the size XX-small. If there is a large amount of dead space around the joint, consider using the X-small distal femoral component.



X-small Distal Femur

Figure 72



XX-small Distal Femur

Figure 73

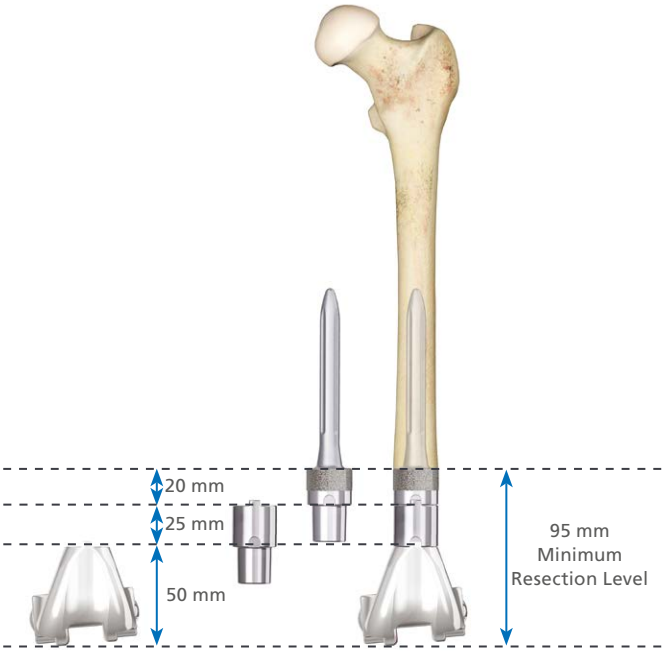
INFORMATION

For a size X-small, add 10 mm to the minimum resection height.

Femoral Preparation

Additional replacement length is often needed. The 25 mm segmental component is the shortest segment available, which means the minimum resection level with a segment is 95 mm for a size XX-small femoral and to 105 mm for a size X-small femoral component (Figure 74).

After the initial 25 mm segmental component, segmental components are available in 5 mm increments alone or in combination with other segmental components to adjust leg length 5 mm at a time.



XX-small Distal Femur

Figure 74

Femoral Preparation

This chart demonstrates the segmental component lengths available along with the combination capabilities to replace bone in 5 mm increments.

Segmental Components

Segmental Stack Chart	
Remaining Gap (mm)	Segmental Components (mm)
25	25
30	30
35	35
40	40
45	45
50	25 + 25
55	25 + 30
60	25 + 35
65	65
70	25 + 45 or 30 + 40
75	30 + 45 or 35 + 40
80	35 + 45
85	85
90	25 + 65
95	30 + 65
100	35 + 65
105	105
110	25 + 85 or 45 + 65
115	30 + 85
120	35 + 85
125	125
130	25 + 105 or 45 + 85
135	30 + 105
140	35 + 105
145	40 + 105
150	25 + 125 or 45 + 105
155	30 + 125
160	35 + 125
165	40 + 125
170	45 + 125
175	125 + 25 + 25
180	125 + 25 + 30
190	125 + 65
195	125 + 25 + 45
200	125 + 35 + 40
205	125 + 35 + 45
210	125 + 85
215	125 + 25 + 65
220	125 + 30 + 65
225	125 + 35 + 65
230	125 + 105
235	125 + 25 + 85
240	125 + 30 + 85
245	125 + 35 + 85
250	125 + 40 + 85

Femoral Preparation

After achieving distal femur and proximal tibia exposure, mark the proposed distal femur resection level with the extremity fully extended in a reproducible position. Avoid estimating with the knee in flexion for consistency of measurement results. Make a horizontal line on the femur 1 cm above the proposed resection level as a reference for use in leg length measurement. Then mark a perpendicular vertical line on the anterior cortex midline in line with the femoral trochlear groove. This mark serves as a reference for correct femoral prosthesis rotational alignment (Figure 75).

If applicable, consideration of Prophylactic Banding using a 1.7 mm DePuy Synthes Trauma Cable, 1-2 cm above the proposed level of resection, is possible. The Cable may help lessen the risk of a stress riser as you are working inside the femur. Using the appropriate technique and Cable Passer, wrap the Cable around the bone, avoiding the neurovascular bundle, and tension the Cable to the desired level. Confirm the placement of the Crimp on the bone, complete crimping, and cut the cable as close to the Cable Crimp as possible. The Crimp may be used as a guide or landmark to help set femoral rotation throughout the operation.

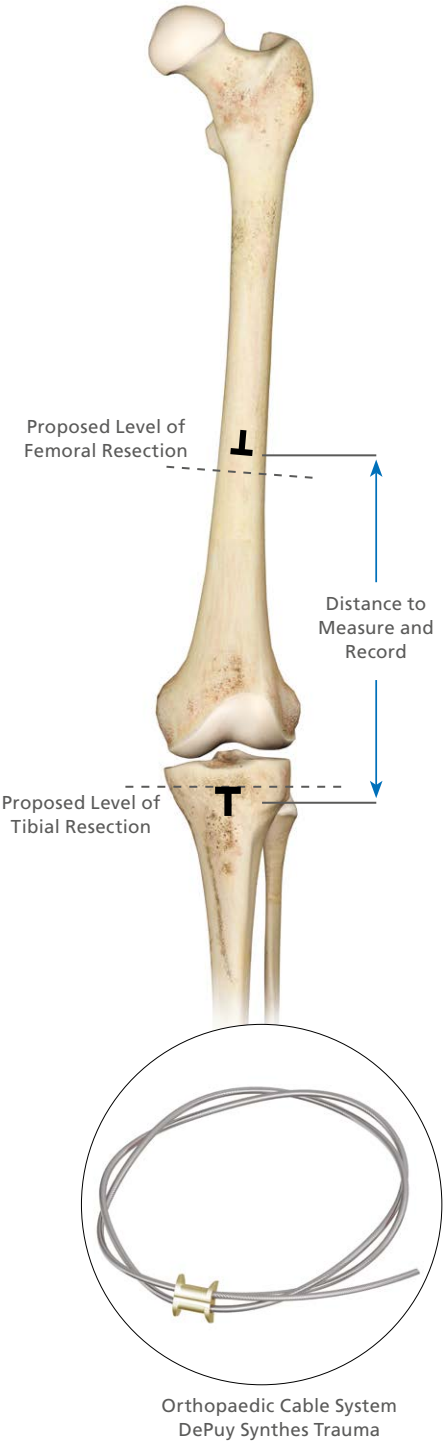


Figure 75

Femoral Preparation

Femoral Canal Preparation - Distal Femur Resection

When a distal femoral tumor resection is required, excise the tumor and affected soft tissue prior to any tibial bone resection, except in the case of an extra-articular resection. In this case, it is technically easier to osteotomize or resect the patella first, then cut the tibia and finally cut the femur. Once the bone and soft tissue resection have been performed, prepare the remaining host femur.

Femoral Medullary Canal Preparation

Following femoral resection, prepare the remaining femoral canal for the appropriate Stem extension. A flexible IM reamer is recommended for the bowed Stem extension and a straight AML™ System Reamer is recommended for the straight Stem extension.

Cemented Stem Application Options

If using a cemented Stem, choose a final Stem that is smaller than the last Reamer used to allow for a circumferential cement mantle around the Stem. For example, if a 15 mm IM Reamer was last used, an 11 mm Stem would have a 2 mm cement mantle per side.

Porous Stem Application Options

When using a porous Stem, the reaming technique utilized will depend on a number of factors such as the patient age, bone quality, curvature of the remaining femur, etc. The following are general guidelines, as the surgeon will need to choose the technique based on individual patient needs.

INFORMATION

Do not ream the femoral canal to cortical bone for a cemented application. Leave some cancellous bone for cement interdigitation.

Femoral Preparation

When using a Straight Porous Stem, under ream by 0.5 mm for press-fit application using a Straight Reamer. For an 11.5 mm Porous Straight Stem, it is recommended to stop reaming with an 11 mm Reamer. If the remaining bone is fragile, consider line-to-line reaming.

When using a Bowed Porous Stem, under reaming by 0.5 mm with a Flexible Reamer for press-fit application is a technique that can be considered. Line-to-line reaming may be indicated if needed to allow the implant to pass through the remaining femur's curvature or if the remaining bone is fragile (refer to **pages 69 - 70** for additional insight).

The LPS System Stem Extensions are available in 100 and 125 mm straight or 150 and 200 mm bowed lengths in cemented and porous-coated styles (refer to the chart on **page 62**).

Finish Preparation Using the Calcar Planer/ Bevel Reamer

Once reaming is completed, prepare the osteotomy surface to help assure the stem's proper fit. The Calcar Planer/Bevel Reamer is designed to produce an even cut surface and an angled relief (bevel) in the bone to match the stem extension flare under the collar. This helps to ensure complete stem extension seating on the prepared diaphyseal bone surface.

Use a Calcar Planer and insert a Bevel Reamer with a pilot that is at least 1 mm smaller than the last IM Reamer used (Figure 76) and insert it into the femoral canal. Sequential use of the Bevel Reamer with the pilots prepares the bevel in the remaining bone with more efficiency and precision. Attach the assembled Planer and Bevel Reamer with a pilot to a Power using the appropriate adapter. The Calcar Planer/Bevel Reamer should be under power prior to planing the resection cut. This will reduce any resected bone chipping by the Calcar Planer cutting blades.

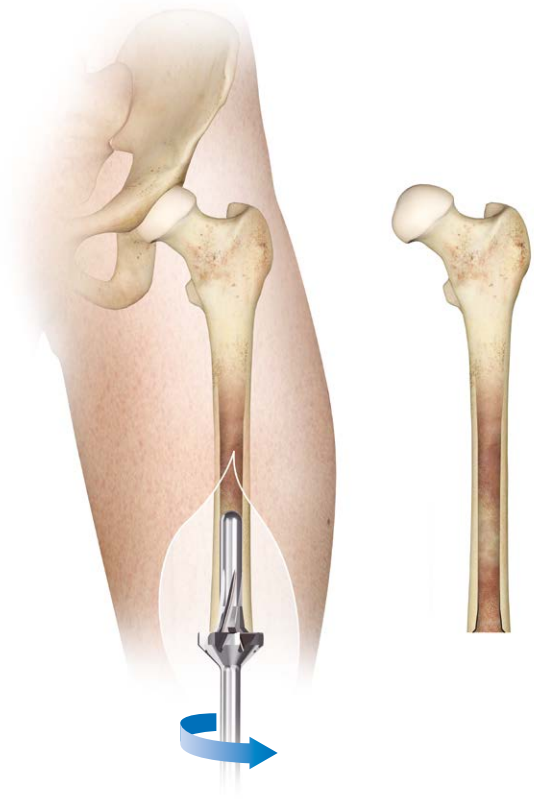


Figure 76

Femoral Preparation

The following are recommendations for the Calcar Planer/Bevel Reamer for use with Cemented or Porous Stems:

For a Porous Stem Extension:

Begin reaming with a Calcar Planer/Bevel Reamer with a pilot that is at least 1 mm less than the final IM Reamer used Progressively increase the size of the Bevel Reamer until you reach a size that matches the intended stem extension size.
(For example, if a 15.5 mm Stem is the chosen implant, the final Bevel Reamer with a pilot will also be 15.5 mm).

For a Cemented Stem Extension:

Begin reaming with a Calcar Planer/Bevel Reamer with a pilot that is at least 1 mm less than the final IM Reamer used. Progressively increase the size of the Bevel Reamer until you reach a size that matches the final IM Reamer size used. (For example, if the last IM Reamer used was 15 mm, the 15 mm Bevel Reamer pilot will be the final Bevel Reamer used, irrespective of the Stem size chosen, to allow for an adequate cement mantle).

INFORMATION

The shaft of the bevel reamer is undersized by 0.5 mm per side from the stated size.

Trial Reduction

Resurface the patella using the SIGMA® Knee Dome Patella component. Following the femur's preparation for the Stem Extension, perform a trial reduction. Replace the missing bone from the distal femur resection to the expected joint line level. Utilizing this measurement, assemble the appropriate distal femoral replacement component, segmental component(s) and Distal Femoral Stem Trials that would fill the missing bone gap (see the chart on **page 58**).

INFORMATION

Reference the LPS System Pocket Reference Guide, for complete ordering information.

Stem Extensions

Cemented Stems (Straight)
10 mm diameter x 100 mm length
11 mm diameter x 100 mm length
12 mm diameter x 100 mm length
12 mm diameter x 125 mm length
13 mm diameter x 125 mm length
14 mm diameter x 125 mm length
15 mm diameter x 125 mm length
16 mm diameter x 125 mm length
17 mm diameter x 125 mm length

Porous Stems (Straight)
11.5 mm diameter x 100 mm length
12.5 mm diameter x 100 mm length
13.5 mm diameter x 100 mm length
13.5 mm diameter x 125 mm length
14.5 mm diameter x 125 mm length
15.5 mm diameter x 125 mm length
16.5 mm diameter x 125 mm length
17.5 mm diameter x 125 mm length
18.5 mm diameter x 125 mm length

Cemented Stems (Bowed)
11 mm diameter x 150 mm length
12 mm diameter x 150 mm length
13 mm diameter x 150 mm length
14 mm diameter x 150 mm length
15 mm diameter x 150 mm length
16 mm diameter x 150 mm length
17 mm diameter x 150 mm length
11 mm diameter x 200 mm length
13 mm diameter x 200 mm length
15 mm diameter x 200 mm length
17 mm diameter x 200 mm length

Porous Stems (Bowed)
12.5 mm diameter x 150 mm length
13.5 mm diameter x 150 mm length
14.5 mm diameter x 150 mm length
15.5 mm diameter x 150 mm length
16.5 mm diameter x 150 mm length
17.5 mm diameter x 150 mm length
18.5 mm diameter x 150 mm length
12.5 mm diameter x 200 mm length
14.5 mm diameter x 200 mm length
16.5 mm diameter x 200 mm length
18.5 mm diameter x 200 mm length

Femoral Preparation

If the distal femur is available in one piece, an alternate method is to estimate the resected bone from the osteotomy to the end of the condyles. Then assemble the trial components and from the joint line to the resection line, evaluate the match of the trial to the resected bone (Figure 77).

The trial components are designed to snap together and match the length of the implant components (Figure 78). Utilize the properly sized Stem Trial to provide enough stability to prevent “spinning” when performing a trial reduction.

The Stem Trial should closely match the last IM Reamer used or it can be 1-2 mm smaller depending on fit.

Insert trial constructs by hand. Do not impact them into the canal.

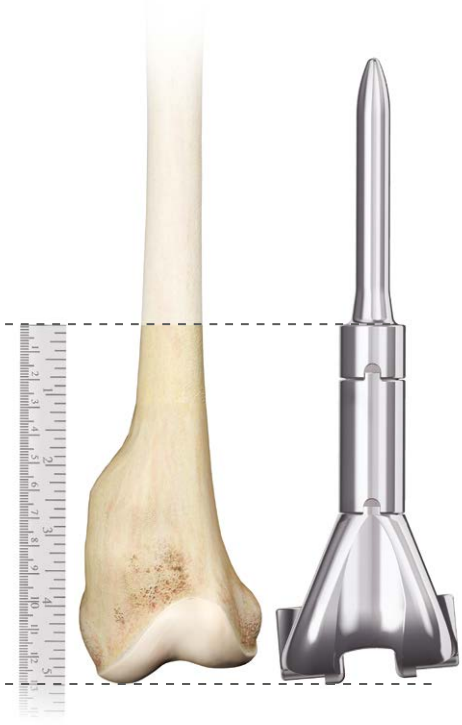


Figure 77

Figure 78

Trialing

Perform trial reduction after assembling the Femoral Trial and Tibial Trial components. Use only the ATTUNE Revision LPS Insert Trial size that matches the size of the LPS Distal Femur Replacement being used.

The ATTUNE Revision LPS Insert Trials must be used in conjunction with the ATTUNE Revision LPS Insert Trial Adaptor in order to assemble to the ATTUNE Revision RP Base Trial. Introduce the metal ATTUNE Revision LPS Insert Trial Adaptor to the ATTUNE Revision RP Base Trial by **sliding it** until it "clicks" into place (Figure 79).

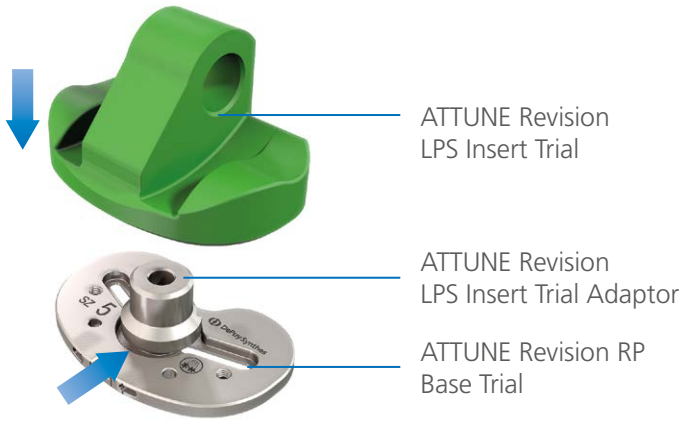


Figure 79

Place the LPS Insert Trial onto the secure LPS Insert Trial Adaptor (Figure 80).

Figure 80

The LPS Hinge Pin Trial may be inserted into the LPS Distal Femur Replacement either medially or laterally to secure the Insert Trial to the Femoral Component (Figure 81).

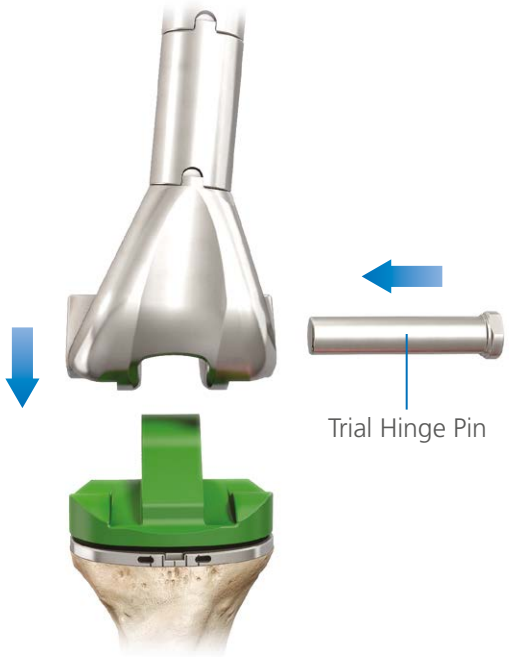


Figure 81

Trial Reduction

The 150 and 200 mm trial stems are bowed and need to be inserted in proper orientation to match the femur's anterior bow. Insert the trial construct into the remaining distal femur and use it to assess fit, joint line, joint stability, soft tissue tension and range of motion (Figure 82).

If the soft tissues are tight and are adversely affecting the range of motion, consider soft tissue releases. However, if the leg is excessively tight in extension, reducing the length of the segmental components or the tibial polyethylene insert can help this, but the proper joint line must be maintained. The leg length can be adjusted with the segmental trials, which allows for 5 mm increments of correction.

When the knee is balanced in full extension, confirm that the joint line is in the proper place.

- If there is a patella baja, use less tibial poly and longer distal segmental components
- If the patella is in the proper position, continue on with the procedure
- If there is patella alta, use more tibial polyethylene and shorter distal segmental components

If the femoral component needs to be shortened a few millimeters and removing segmental components is not an option, consider cutting a few millimeters off of the remaining proximal femoral bone. Consider the need to prepare the canal again by re-reaming with Straight Reamers and Bevel Reamers to adequately prepare for the chosen construct. Use the trial construct to assess proper component rotational orientation. Once proper orientation is established, use the anti-rotation slot (tab) on the trial as a reference to mark the femur. This mark serves as an Alignment Guide when inserting the final implant (Figure 82).

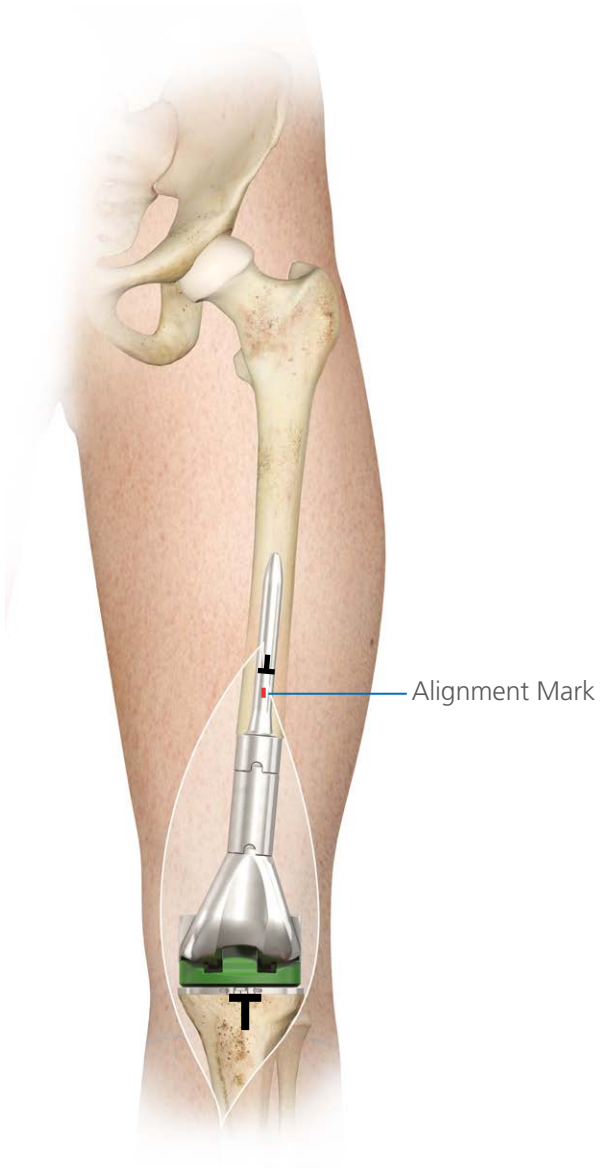


Figure 82

Trial Removal

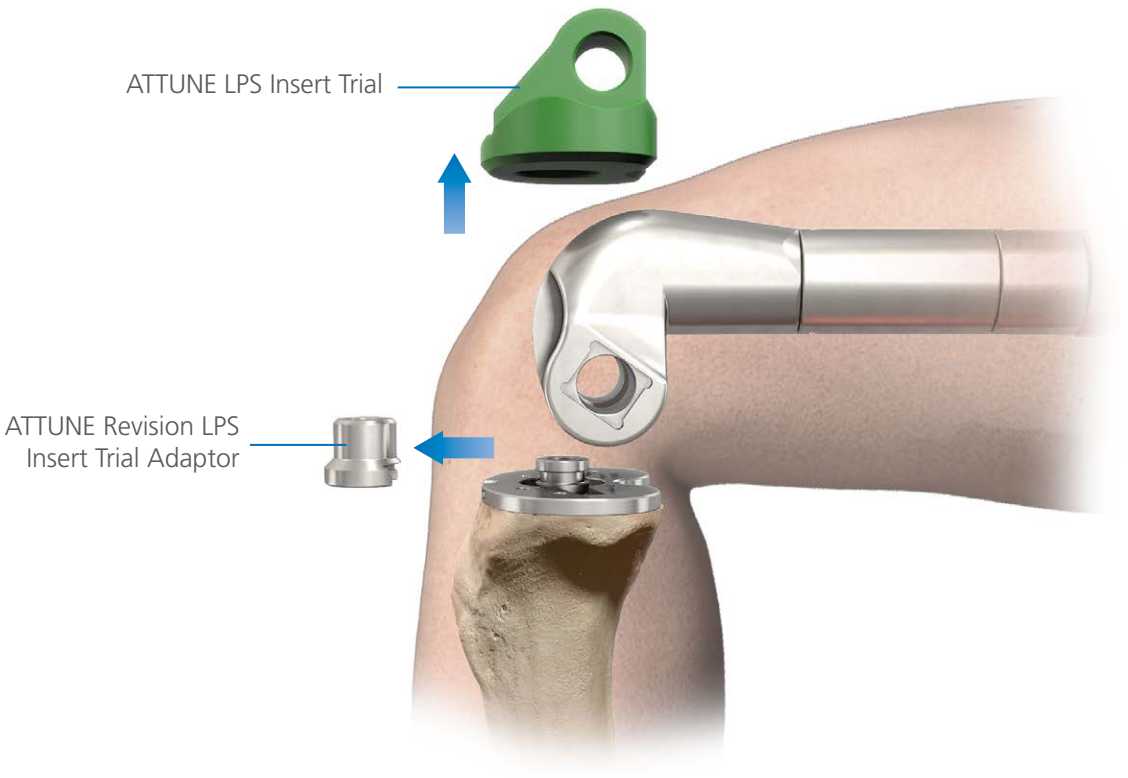


Figure 83

Remove the LPS Hinge Pin and Femoral Trials.

To remove the Insert Trial, fully flex the knee and grasp the top of the ATTUNE Revision LPS Insert Trial spine. Pull the Insert Trial vertically until it has disengaged from the Insert Trial Adaptor. Finally, slide the Insert Trial Adaptor to release it from the ATTUNE Revision RP Base Trial (Figure 83).

For Final Tibial Implantation refer to the ATTUNE Revision RP Surgical Technique.

Cementing Technique

During cementing of implants, movement of the components should be minimized while the cement is curing.

Prepare the sclerotic bone to ensure a continuous cement mantle with good cement interdigitation of 2 mm - 4 mm. This can be done by drilling holes and cleansing the bone with pulsatile lavage, taking care to dry the bone afterwards. Pack residual small cavity bone defects with cancellous autograft, allograft, or synthetic bone substitutes.

Apply a thick layer of cement to the bone, the implant surface or to both.

INFORMATION

Caution: Blood lamination can reduce the mechanical properties of the cement; therefore, it is vital to choose cement that reaches its working phase quickly. If applying cement to both the implant and bone, implantation should be completed early in its dough state to ensure good cement-cement adhesion and reduce the risk of dry laminations; which can weaken the cement.

INFORMATION

Caution: Application of the cement to the roughened implant surface early in the dough state has been demonstrated to increase the fixation strength of the cement to the implant.[2]

For additional reference see the Guidance for Cementing Total Knee Replacements document.

Femoral Implant Assembly

Once the trial segments yield a satisfactory result with the trial reduction, assemble the appropriate implant components. Use the Femoral Impaction Stand to help stabilize the implant components for assembly and impaction. It is important to orient the implant components along the same axis as the trial components. The implant components use a Morse-taper design for locking. Assemble the implant components by hand and place the Impaction Cap over the Stem component. Then impact the components together using a Mallet to securely seat the tapers together (Figure 84). There should be approximately a 1 mm gap between the component bodies.

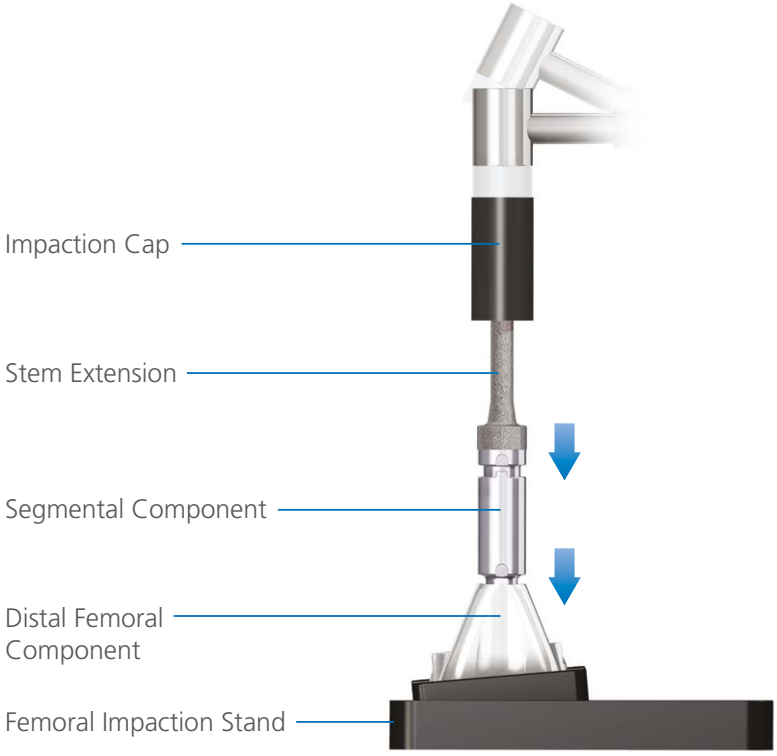


Figure 84

Femoral Implant Insertion

Implant Insertion

If using SMARTSET™ MV Bone Cement to fix the Distal Femoral Stem Extension to host bone, follow the manufacturer's recommended procedures to mix, deliver and pressurize the bone cement. Give meticulous attention to the distal femoral component's rotation. If it is internally rotated, it may potentially result to patellar instability. Use the alignment mark previously placed on the femur and the implant's anti-rotation slot for proper implant orientation. Note that the 150 and 200 mm Stems are bowed and the correct bow-to-femur orientation must be accomplished.

Use the Distal Femoral Impactor with the implant construct to assist in the insertion of the implant into the femoral canal. The Distal Femoral Impactor mates with the distal femoral replacement component. Use a Mallet to impact the assembled construct (Figure 85).

If using a Porous Stem, hand place the construct in the canal until the stem engages the canal. At this point, the stem should be roughly 1 cm proud of the cut surface of the bone. If it has engaged the femoral canal properly, impact the construct into place using a Mallet to strike the inserter and align the anti-rotation tab with a mark on the femur for proper alignment. Roughly 100 gentle Mallet strikes should be used to fully seat the porous stem. If the Stem engages the canal and is more than 1 cm proud, consider re-reaming the bone to get the stem to seat further. If the Stem contacts the bone without the porous stem engaging solidly, the Stem's diameter should be increased. If using a Cemented Stem, insert it and align it as noted above. Use a Curette to remove excess bone cement from around the implant collar.

INFORMATION

Placement of a "prophylactic" Cerclage Wire around the proximal end of the remaining diaphysis may potentially decrease the risk of intra-operative fracture during press-fit insertion of a Porous Stem Extension, particularly with fragile bone.

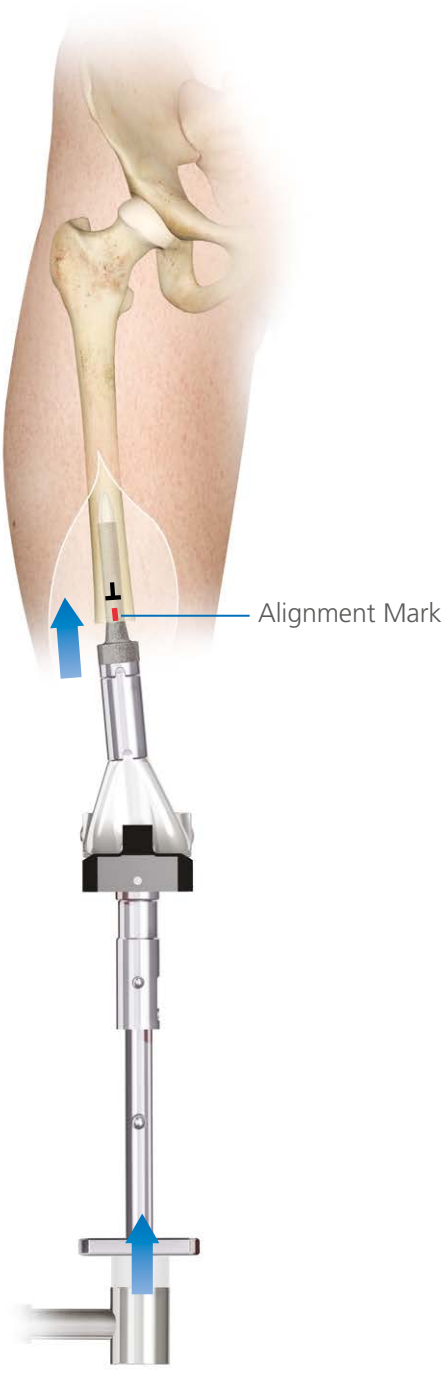


Figure 85

Femoral Implant Insertion

When using a Bowed Porous Stem, curvature of the remaining bone in comparison to the implant needs to be appraised especially for the impact of mismatch conditions. Under reaming by 0.5 mm with a Flexible Reamer is a technique that can be considered. Insertional feel and non-advancement with component impaction should be an indication to remove the construct and try to pass the same Flexible Reamer another four to six times and evaluate the insertional feel again. If the construct still presents with non-advancement, line-to-line reaming should be considered. The construct should then be inserted into the medullary canal and attention to insertional feel and advancement assessed again.

Should the implant construct with a Porous Stem not advance and become lodged in the femoral canal, there is a technique for removal. Disassemble the implant construct from the stem extension using the Disassembly Tool. The exposed Porous Stem Extension Taper is threaded. Place the Slap Handle through the Inserter/Extractor. Completely thread the Inserter/Extractor into the Porous Stem Thread until it is fully seated. Use the Slap Handle to provide the extraction force to the lodged Porous Stem Extension until it is removed from the femur. Make sure the tapers are clean and dry before re-assembly. Reinsert the implant construct after re-reaming.

The Stem Extension shoulder should be flush to the femur's cut surface when using either the cemented or Porous Stem Extension (Figure 86).

Give meticulous attention to the distal femoral component's rotation. If it is internally rotated, it may potentially result to patellar instability. Perform a final trial reduction. Evaluate stability and leg length adjustments by using the ATTUNE Revision LPS Insert Trials prior to choosing the final insert component.

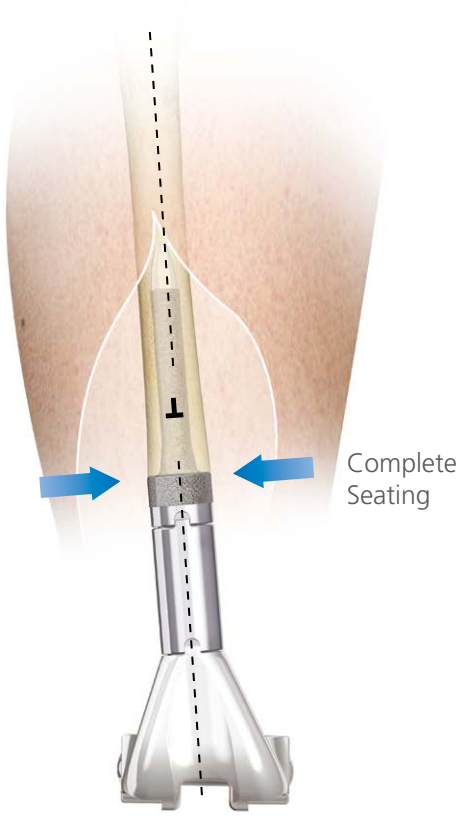


Figure 86

Implant Assembly and Final Trialing

After the femoral component and Tibial Tray have been cemented into place, do one final check with the ATTUNE Revision LPS Insert Trials.

The ATTUNE Revision RP Tibial Base and the ATTUNE LPS Insert Trial Post may be utilized with the ATTUNE LPS Insert Trial to perform a Trial reduction (Figure 87).

Once desired flexion/extension balance is achieved, note the final Insert Trial thickness used.

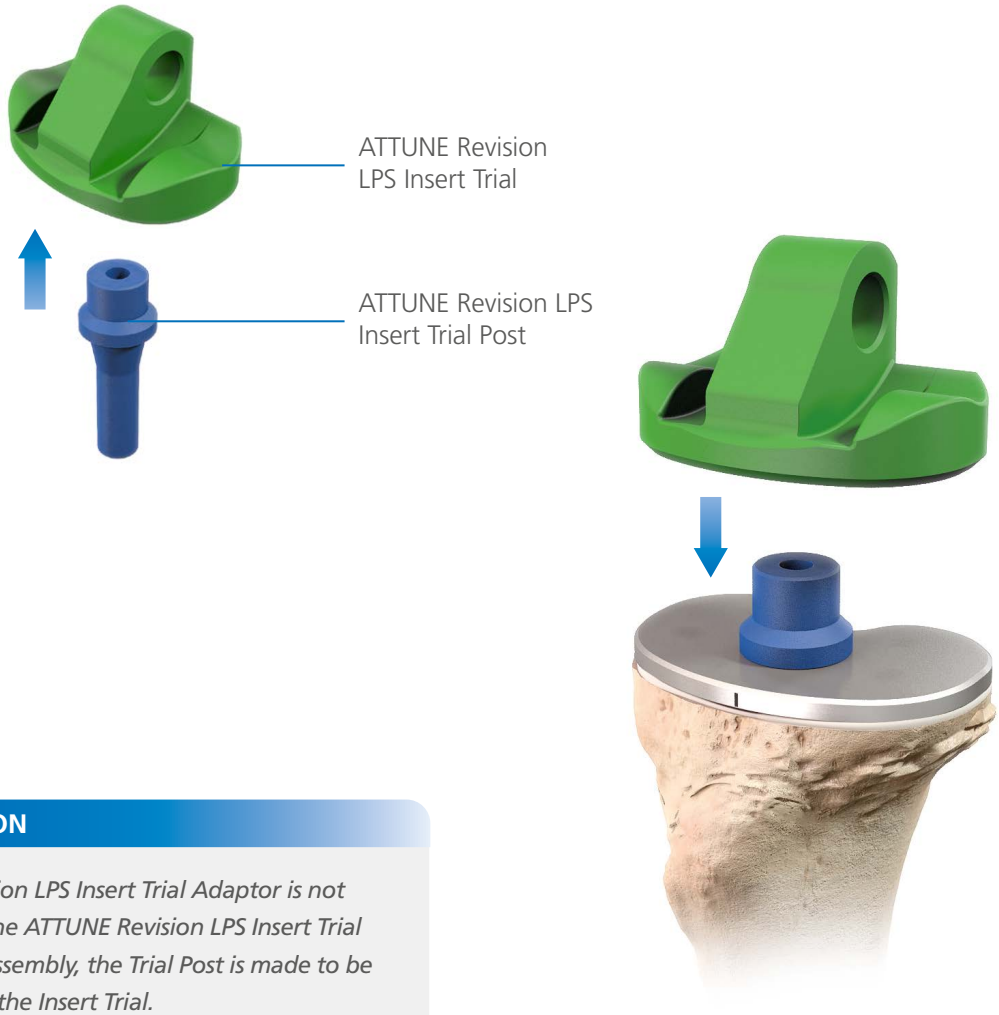


Figure 87

INFORMATION

The ATTUNE Revision LPS Insert Trial Adaptor is not compatible with the ATTUNE Revision LPS Insert Trial Post. For ease of assembly, the Trial Post is made to be used directly with the Insert Trial.

Final Implantation

Put the condyles of the Femoral Component into the corresponding recesses in the tibial plateau. Use the Hinge Pin to mate the LPS Distal Femur Replacement to the ATTUNE Revision LPS Insert Bearing through the Hinged Insert Bearing Implant. Orient the rectangular head of the Hinge Pin with the rectangular recess in the Femoral Component. Squeeze the "clothes pin" of the Hinge Pin together and insert the Hinge Pin into the Femoral Component. Make sure the Hinge Pin is securely locked in place.

Place the ATTUNE Revision LPS Insert Post into the cone of the ATTUNE Revision RP Tibial Base (Figure 88).

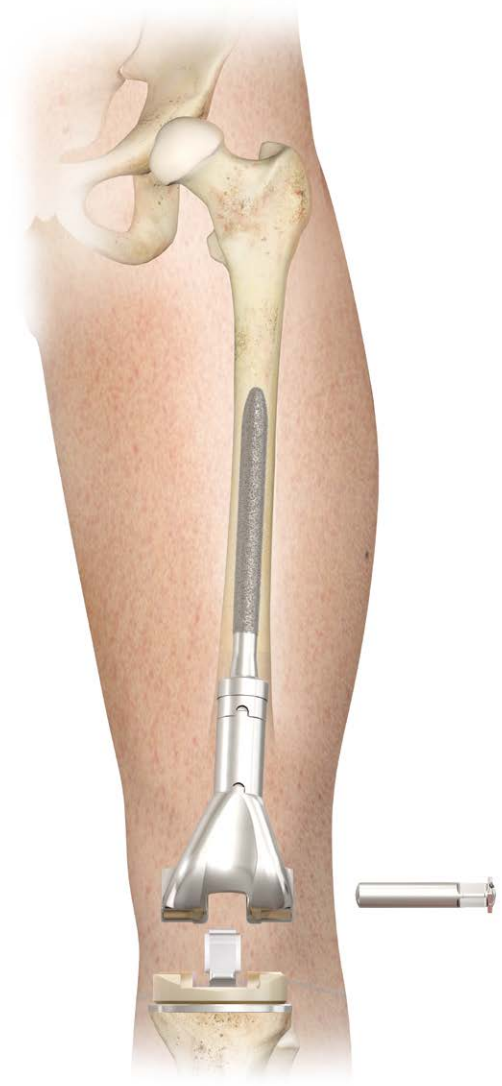


Figure 88

INFORMATION

The Hinge Pin can be inserted from either the medial or lateral side

Closure

If knee flexion beyond 90 degrees causes luxation of the hinged insert bearing out of the base of the tibial component, this could be due to grossly inadequate soft tissue integrity. In that situation, the patient must have a knee brace post-operatively to limit flexion to 90 degrees.

In such cases, consider closing the wound with the knee in full extension. One of the most important aspects of this procedure is the soft tissue reconstruction, which is done based on individual patient needs. Soft tissue closure should completely cover the prosthesis.

In oncologic applications when soft tissues are resected to achieve a wide bone tumor margin, the amount of remaining soft tissue coverage is reduced. In this case, remaining musculature mobilization may be necessary to achieve proper soft tissue coverage around the prosthesis.

Perform wound closure in multiple layers to potentially reduce hematoma formation. Perform meticulous wound closure to potentially reduce wound complications that may preclude immediate physical therapy or other adjuvant oncologic treatments, such as radiation therapy or chemotherapy (Figure 89).

Occasionally, if there is significant soft tissue fibrosis (e.g. from prior surgery, trauma, irradiation, etc.), then extremity shortening may be necessary to reduce soft tissue tension and allow wound closure without undue tension. Typically the wound is closed over large bore drains to potentially reduce hematoma collection.

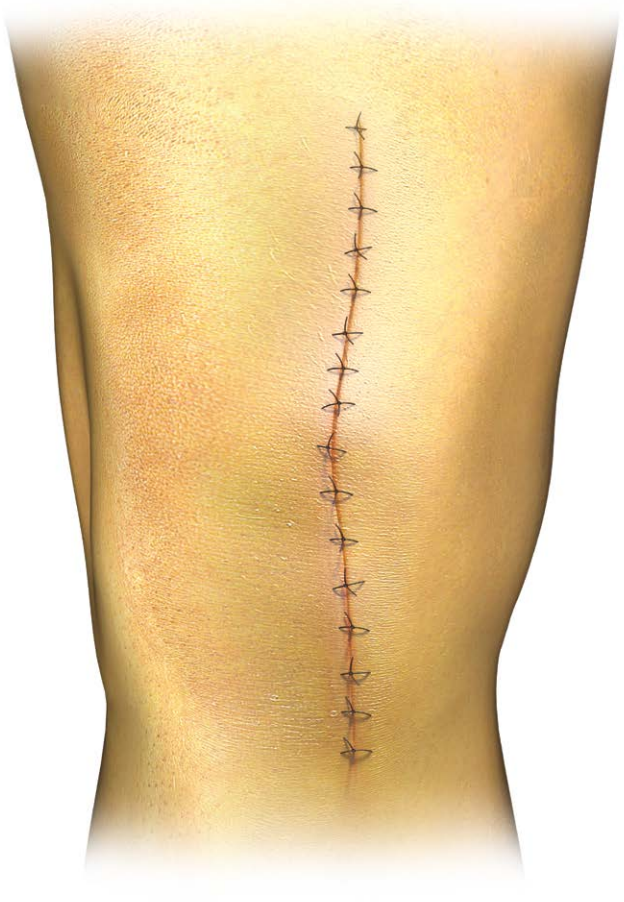


Figure 89

Tibial Preparation and Femoral Preparation - with Metaphyseal Sleeve

Tibial Preparation

For Tibial Preparation information, refer to the ATTUNE Revision RP Surgical Technique.

Femoral Preparation

Make the appropriate distal resection as required. The minimum distal resection is 50 mm for a size XX-small femoral and 60 mm for a size X-small femoral component.

Prepare the femoral canal with the M.B.T. Revision Reamers. Begin with the introductory Reamer and subsequently ream to larger sized Reamers until the desired fit is achieved. The Reamers are available in 1 mm increments, beginning at a diameter of 10 mm. The final reamer must be even sized to match the final Universal Stem size. Use Reamers to prepare the canal. When using the press-fit Universal Stems, line-to-line reaming is suggested (for example, use a 16 mm reamer for a 16 mm press-fit Universal stem) (Figure 90).

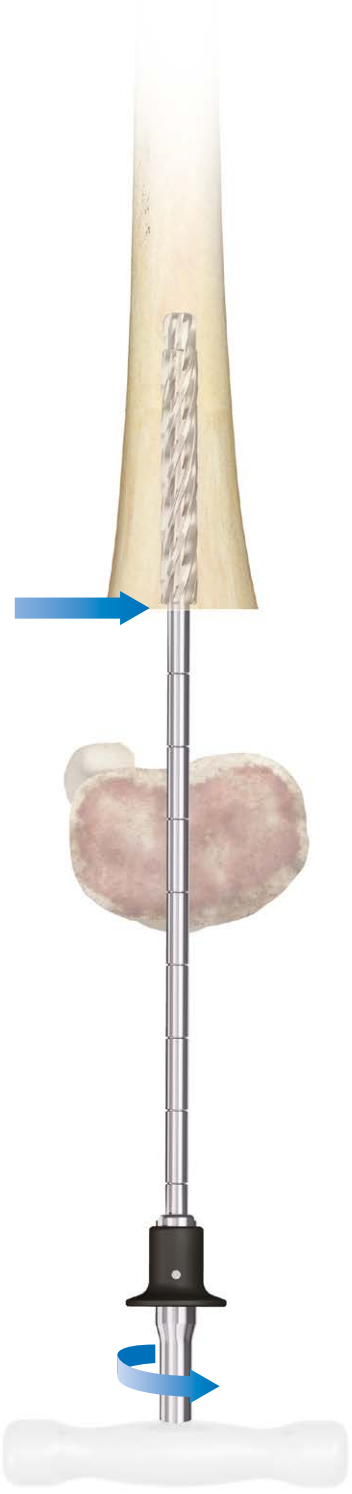


Figure 90

INFORMATION

Since the Metaphyseal Sleeve will not be fully seated into the remaining bone stock, it may be necessary to take slightly more bone than 50 or 60 mm. Typically the Sleeve sits proud by about 5-15 mm. Additionally, this Metaphyseal Sleeve technique does NOT use LPS Stems. Instead, it uses Universal Press-fit Stems, so the M.B.T. Revision Reamers should be utilized.

Femoral Preparation - with Metaphyseal Sleeve

If power reaming, it will be necessary to attach the modified Hudson adapter to the Straight Reamer. Note that the reamer shaft contains markings in 25 mm increments to accommodate the various Universal Stem/Sleeve length combinations. Another option to determine reamer depth is to estimate the trial assembly against the Reamer.

After reaming the intramedullary canal, attach the Threaded Shaft to the Broach Reamer and then to the appropriate Stem Trial as determined by straight reaming (Figure 91). Ream as appropriate to open the canal to accept the smallest Femoral Broach.

Consider sinking the Broach Reamer halfway into the host bone to ensure that the Metaphyseal Sleeve can be left a bit proud.

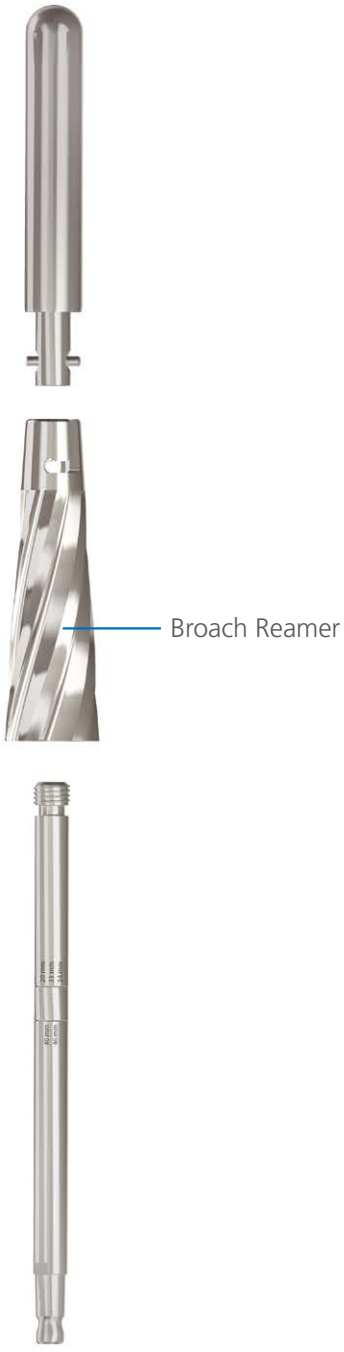


Figure 91

Femoral Preparation - with Metaphyseal Sleeve

The Broach Reamer will be necessary when utilizing a 20 mm Sleeve and for the beginning of larger sequential broaching when a 31 mm or larger Sleeve is used. After broach reaming has been completed, attach the 31 mm Broach to the Broach Impactor (Figure 92). Attach the appropriate Stem Trial to the Broach as determined by straight reaming.

Sequentially Broach to the desired dimension of 31, 34, 40, or 46 mm. At each size, assess the Broach's rotational stability. If the stability of the Broach is unsatisfactory, move up to the next larger Broach size. The last Broach used will be the Femoral Sleeve size. The Sleeve can be prepared to sit slightly proud depending on the amount and quality of remaining bone.

If the Broach sits completely flush with the cut surface of the distal femur, there is a risk of the Sleeve "stove-piping" and migrating up the canal over time. Leaving the Broach a few millimeters proud (approximately 5-15 mm, with no more than half of the Broach left proud) will help to prevent this migration. A fully Porous Sleeve is recommended in such instances.

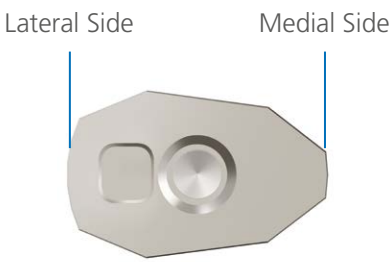


Figure 92

INFORMATION

The medial side of the Broach should be oriented toward the medial side of the femoral bone.

Trialing

After broaching is complete, the femoral bone is ready for trialing. There are three corresponding Trials for the Offset Sleeve Adapters, corresponding to the 0, 5, and 10 mm Offset Adapter options. These Offset Adapters will adjust the amount of distal offset of the final component by either 0 mm, 5 mm, or 10 mm respectively. These Trials have the same spring-coil lock trialing system as the rest of the LPS System Instrumentation.

The Offset Sleeve Adapters can connect a distal femoral component to a Femoral Sleeve or can mate with a segmental component to connect the construct to a Femoral Sleeve.

The 0 mm Offset Adapter will mate with any of the Porous Sleeves, but the locking tabs on the distal femoral component will not allow for independent rotation of the femoral component. How you orient your Femoral Broach will lock in the rotation of your femoral component if this Offset Adapter is utilized.

If flexibility in determining femoral rotation after broaching is desired, consider the use of a 5 mm or 10 mm Offset Adapter. To change the Offset Adapter, completely thread the Inserter/Extractor into the Offset Adapter thread until it is fully seated (Figure 93), and pull on the handle to disengage the Offset Adapter from the distal femoral or segmental components (Figure 94).

Figure 93

Figure 94

INFORMATION

The 0 mm Offset Adapter is not compatible with the 20 mm Cemented Femoral Sleeve.

Trialing

Insert trial constructs by hand. Do not impact them into the canal. If the Stem Trial will not advance into the canal, consider reaming the canal again or decrease the size of the Stem Trial. Insert the trial construct into the distal femur and use it to assess fit, joint line, joint stability, soft tissue tension and range of motion. If the soft tissues are tight and are adversely affecting the range of motion, consider soft tissue releases. However, if the leg has been excessively lengthened, reducing leg length will correct the problem. The leg length can be adjusted with the segmental trials, which allow for 5 mm increments of correction.

Once full extension has been achieved, next check the joint line of the knee. Compare the knee joint line to the opposite side for proper height. As an additional check, flex the knee to determine the anatomic position of the patella. If a patella baja exists, where the patella is impinging on the poly, bring down the joint line by increasing the length of the Offset Adapter or the segmental components, and use a thinner polyethylene Insert to match. If a patella alta exists, add more tibia (thick tray or a thicker polyethylene insert) and decrease the length of the Offset Adapters or the segmental components to match.

If the segmental trials used are at the minimum length of 25 mm and the joint line is too far distal, consider recutting the femoral osteotomy to adjust for the discrepancy. If the femoral cut is revised, re-ream the femur more proximally and re-broach the bone to prepare the bone for a Femoral Sleeve. If re-reaming is not performed, the Stem's distal end may encounter unreamed bone and an intra-operative fracture may occur. Use the trial construct to assess proper component rotational orientation. Once proper orientation is established, use the anti-rotation slot (tab) on the Trial as a reference to mark the femur. This mark serves as an alignment guide when inserting the final implant (Figure 95).

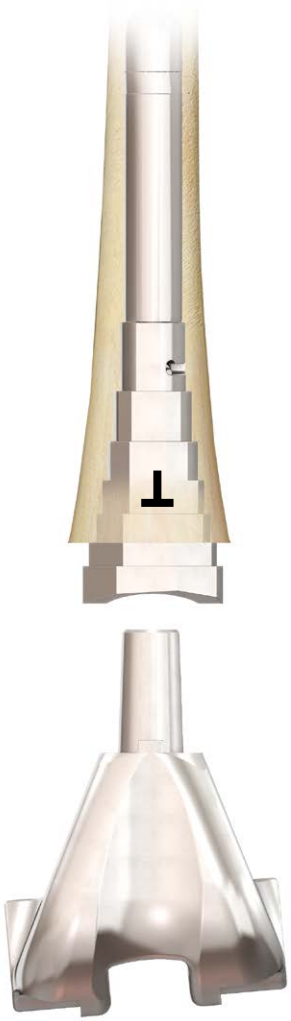


Figure 95

Trialing

Perform trial reduction after assembling the Femoral Trial and Tibial Trial components. Use only the ATTUNE Revision LPS Insert Trial size that matches the size of the LPS Distal Femur Replacement being used.

The ATTUNE Revision LPS Insert Trials must be used in conjunction with the ATTUNE Revision LPS Insert Trial Adaptor in order to assemble to the ATTUNE Revision RP Base Trial. Introduce the metal ATTUNE Revision LPS Insert Trial Adaptor to the ATTUNE Revision RP Base Trial by **sliding it** until it "clicks" into place (Figure 96.

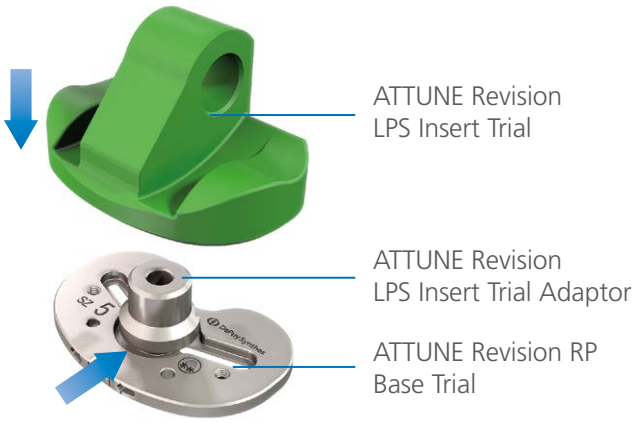


Figure 96

Place the LPS Insert Trial onto the secure LPS Insert Trial Adaptor (Figure 97).

Figure 97

The LPS Hinge Pin Trial may be inserted into the LPS Distal Femur Replacement either medially or laterally to secure the Insert Trial to the Femoral Component (Figure 98).

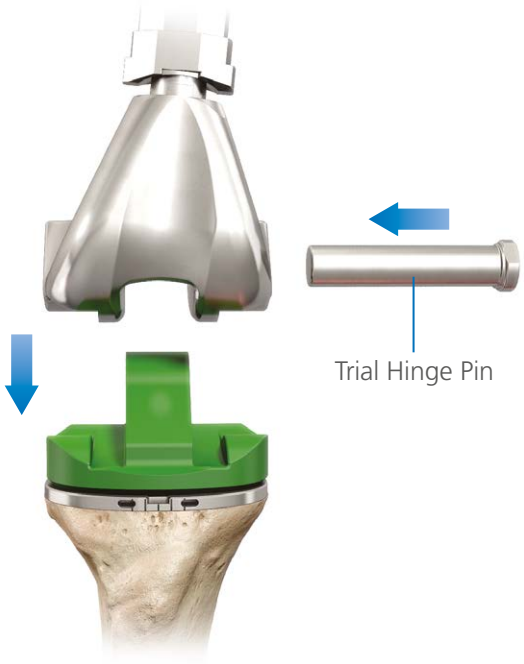


Figure 98

Trial Removal

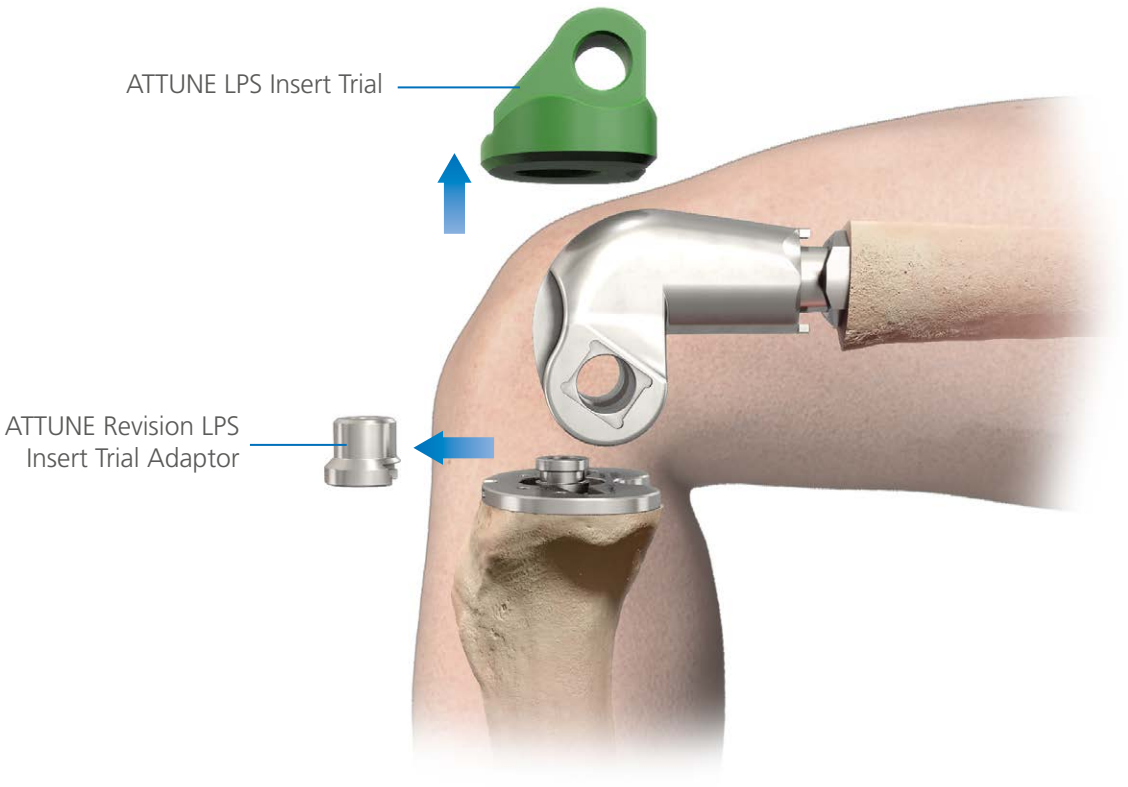


Figure 99

Remove the LPS Hinge Pin and Femoral Trials.

To remove the Insert Trial, fully flex the knee and grasp the top of the ATTUNE Revision LPS Insert Trial spine. Pull the Insert Trial vertically until it has disengaged from the Insert Trial Adaptor. Finally, slide the Insert Trial Adaptor to release it from the ATTUNE Revision RP Base Trial (Figure 99).

For Final Tibial Implantation refer to the ATTUNE Revision RP Surgical Technique.

Cementing Technique

During cementing of implants, movement of the components should be minimized while the cement is curing.

Prepare the sclerotic bone to ensure a continuous cement mantle with good cement interdigitation of 2 mm - 4 mm. This can be done by drilling holes and cleansing the bone with pulsatile lavage, taking care to dry the bone afterwards. Pack residual small cavity bone defects with cancellous autograft, allograft, or synthetic bone substitutes.

Apply a thick layer of cement to the bone, the implant surface or to both.

INFORMATION

Caution: Blood lamination can reduce the mechanical properties of the cement; therefore, it is vital to choose cement that reaches its working phase quickly. If applying cement to both the implant and bone, implantation should be completed early in its dough state to ensure good cement-cement adhesion and reduce the risk of dry laminations; which can weaken the cement.

INFORMATION

Caution: Application of the cement to the roughened implant surface early in the dough state has been demonstrated to increase the fixation strength of the cement to the implant.[2]

For additional reference see the Guidance for Cementing Total Knee Replacements document.

Femoral Implant Assembly

Once the trial segments yield a satisfactory result with the trial reduction, assemble the appropriate implant assembly components. Use the Femoral Impaction Stand to stabilize the implant components for assembly and impaction (Figure 100). The implant components use a Morse-taper design for locking.

First assemble the distal femoral replacement component, any segment components (if necessary) and Offset Sleeve Adapter. Once impacted together, assemble the chosen Universal stem to the Universal Femoral Sleeve by threading the Stem onto the Sleeve (Figure 101).

Figure 100

Figure 101

Femoral Implant Assembly

Grasp the Sleeve with the Revision Sleeve Clamp and use the Stem Extension Wrench to grasp the Universal Stem. Tighten as shown. Apply sufficient force to both Wrenches to secure the Stem (Figure 102).

Figure 102

Femoral Implant Assembly

Then assemble the Sleeve/Stem to the chosen distal femoral component construct and impact using the femoral Stem/Sleeve Impactor found in the Femoral Adapter Instrument Case (Figure 103).

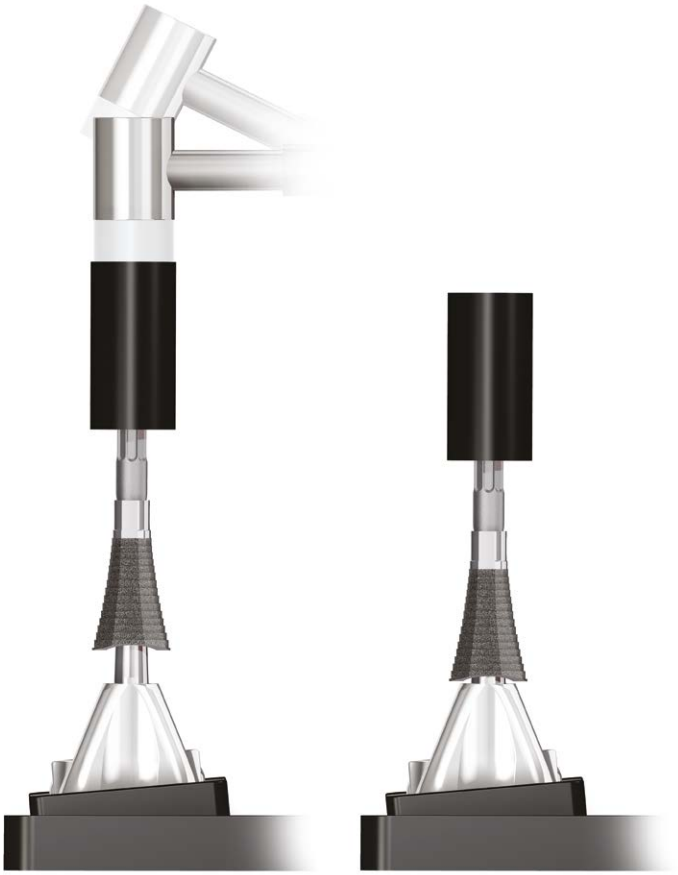


Figure 103

Implant Assembly and Final Trialing

After the femoral component and Tibial Tray have been cemented into place, do one final check with the ATTUNE Revision LPS Insert Trials.

The ATTUNE Revision RP Tibial Base and the ATTUNE LPS Insert Trial Post may be utilized with the ATTUNE LPS Insert Trial to perform a Trial reduction (Figure 104).

Once desired flexion/extension balance is achieved, note the final Insert Trial thickness used.

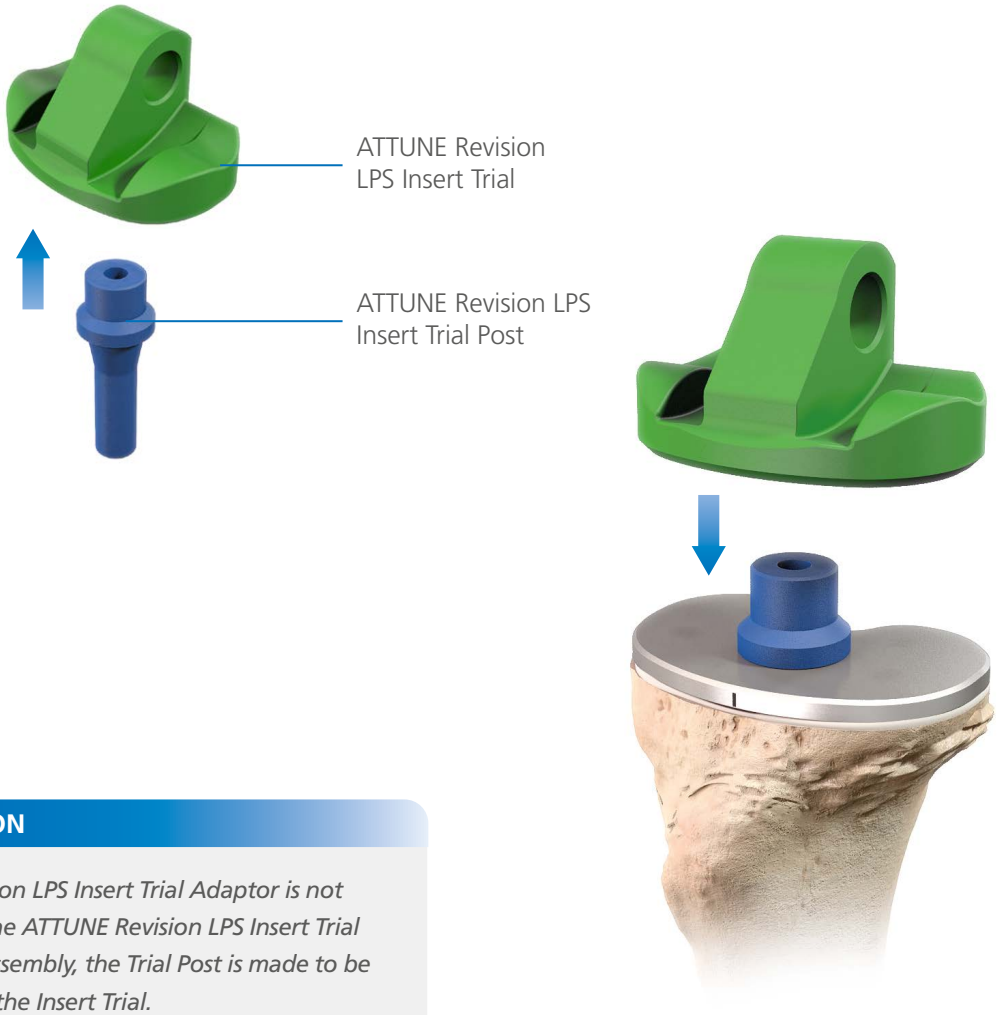


Figure 104

INFORMATION

The ATTUNE Revision LPS Insert Trial Adaptor is not compatible with the ATTUNE Revision LPS Insert Trial Post. For ease of assembly, the Trial Post is made to be used directly with the Insert Trial.

Final Implantation

Put the condyles of the Femoral Component into the corresponding recesses in the tibial plateau.

Use the Hinge Pin to mate the LPS Distal Femur Replacement to the ATTUNE Revision LPS Insert Bearing through the Hinged Insert Bearing Implant. Orient the rectangular head of the Hinge Pin with the rectangular recess in the Femoral Component.

Squeeze the "clothes pin" of the Hinge Pin together and insert the Hinge Pin into the Femoral Component. Make sure the Hinge Pin is securely locked in place.

Place the ATTUNE Revision LPS Insert Post into the cone of the ATTUNE Revision RP Tibial Base (Figure 105).

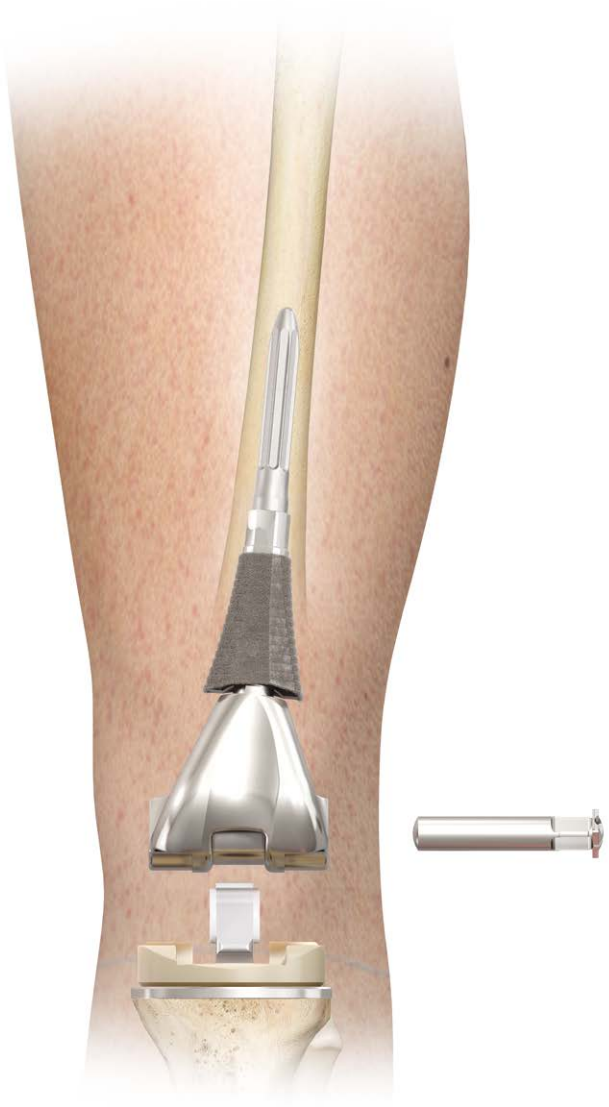


Figure 105

INFORMATION

The Hinge Pin can be inserted from either the medial or lateral side

Closure

If knee flexion beyond 90 degrees causes luxation of the hinged insert bearing out of the base of the tibial component, this could be due to grossly inadequate soft tissue integrity. In that situation, the patient must have a knee brace post-operatively to limit flexion to 90 degrees.

In such cases, consider closing the wound with the knee in full extension. One of the most important aspects of this procedure is the soft tissue reconstruction, which is done based on individual patient needs. Soft tissue closure should completely cover the prosthesis.

In oncologic applications when soft tissues are resected to achieve a wide bone tumor margin, the amount of remaining soft tissue coverage is reduced. In this case, remaining musculature mobilization may be necessary to achieve proper soft tissue coverage around the prosthesis.

Perform wound closure in multiple layers to potentially reduce hematoma formation. Perform meticulous wound closure to potentially reduce wound complications that may preclude immediate physical therapy or other adjuvant oncologic treatments, such as radiation therapy or chemotherapy (Figure 106).

Occasionally, if there is significant soft tissue fibrosis (e.g. from prior surgery, trauma, irradiation, etc.), then extremity shortening may be necessary to reduce soft tissue tension and allow wound closure without undue tension. Typically the wound is closed over large bore drains to potentially reduce hematoma collection.

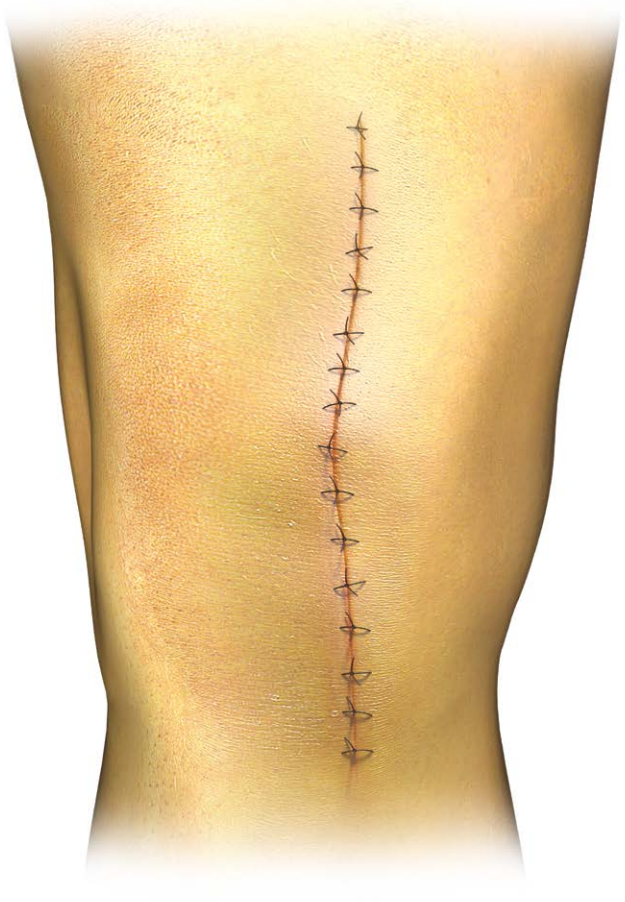


Figure 106

ATTUNE LPS Insert To Tray Compatibility

	LPS XX-Small Femoral Component	LPS X-Small Femoral Component S-ROM X-Small Femoral Component	S-ROM Small Femoral Component	S-ROM Medium Femoral Component
ATTUNE Revision RP Tibial Base Size 2	X			
ATTUNE Revision RP Tibial Base Size 3	X	X		
ATTUNE Revision RP Tibial Base Size 4	X	X	X	
ATTUNE Revision RP Tibial Base Size 5	X	X	X	X
ATTUNE Revision RP Tibial Base Size 6	X	X	X	X
ATTUNE Revision RP Tibial Base Size 7	X	X	X	X
ATTUNE Revision RP Tibial Base Size 8	X	X	X	X
ATTUNE Revision RP Tibial Base Size 9	X	X	X	X
ATTUNE Revision RP Tibial Base Size 10	X	X	X	X

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ATTUNE Revision LPS Inserts must match S-ROM or LPS Femoral Components size-to-size.
For example, XX-Small femoral component = XX-Small polyethylene; Small femoral component = Small polyethylene, etc.

For complete indications, contraindications, precautions, and warnings, reference full product insert.

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.

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