S-ROM® NOILES™ ROTATING HINGE

Surgical Technique
and
Reference Guide

DePuy
a Johnson & Johnson company

Revision total knee arthroplasty presents many complex problems for the orthopaedic surgeon. Hard tissue defects can be caused by significant bone loss, massive osteolysis, malalignment and infection. Soft tissue defects include ligament compromise, imbalance and significant instability. Additionally, the procedure is technically demanding and requires a full armamentarium of implants for proper management of the surgical problems encountered.

The S-ROM® Noiles™ Rotating Hinge Knee is a system that allows intraoperative construction of a "customized" implant to handle any hard or soft tissue defects seen at revision surgery. Diaphyseal stems are fluted and slotted to provide intramedullary fixation and load sharing. Modular sleeves provided for the metaphyseal region are textured and stepped to ensure metaphyseal loading as well as metaphyseal filling. The knee componentry is a mobile-bearing/rotating platform. This mobile-bearing reduces torsional stresses about the knee and is fully congruent to minimize polyethylene wear. An intramedullary-mounted system of instrumentation is based on reaming the diaphysis, broaching the metaphysis and cutting the bone in a logical sequence that is very time-efficient.[1]

S-ROM® NOILES™ ROTATING HINGE KNEE

Revision Surgical Procedure

IMount™ Approach: Tibia and Femur

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Surgical Procedure Contents

IMount Instrumentation Approach: Tibia and Femur

Reference Guide Contents

Note: This surgical procedure shows the tibia being prepared first, followed by the femur. This sequence may be reversed at the discretion of the surgeon.

This device has been cleared for cemented application.

Saw Blade Selection

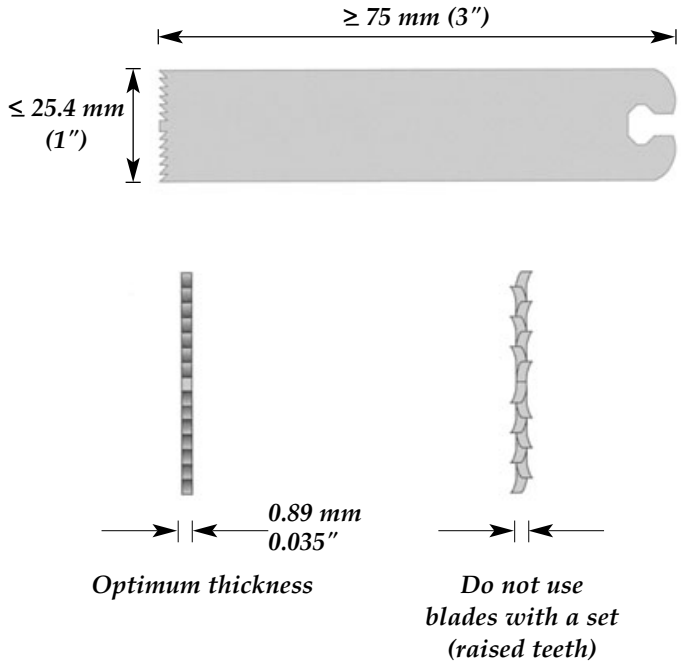
All resections for the S-ROM Noiles Rotating Hinge Knee can be made using an oscillating saw. Nominal specifications for acceptable saw blades are shown below [fig. 1]:

1. Any standard length greater than or equal to 75 mm (3").

2. Any standard width up to 25.4 mm (1") for cuts except the center portion of the box cut. This cut should be made with a narrow width saw blade, i.e. 12.7 mm (0.5") wide.

3. Any standard thickness when resections are made using opening cutting blocks. When the saw capture or slots are used, it is important that the saw blade does not employ a set (raised teeth) and has a thickness of **0.89 mm (0.035").**

DePuy AMK blades will work with the S-ROM system. See Instrument Listing for details (page 40).

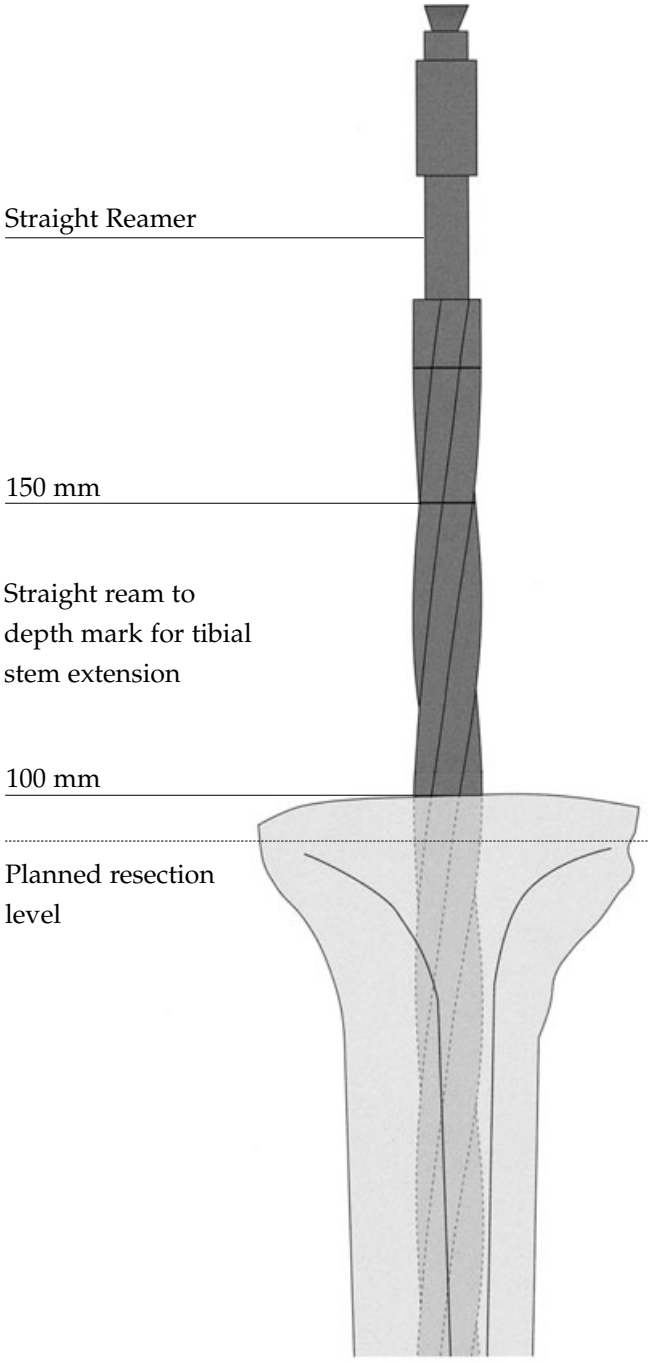


[figure 1]

Tibial Canal Preparation

Preoperative templating is recommended to approximate tibial stem extension diameter and length and tibial sleeve size.

Open the tibial intramedullary canal with the 11 mm starter drill. Ream the tibial intramedullary canal to the desired diameter by working up to the final size where cortical engagement is achieved. The minimum depth to the tibial resection plane for the 100 and 150 mm tibial stem extensions are indicated by two grooves on the reamer. The mark for the desired stem depth should be advanced to the planned resection level [fig. 2]. When there is significant metaphyseal bone loss, the 150 mm stem is recommended. This bypasses the stress-risers and provides good fixation in sound bone.



[figure 2]

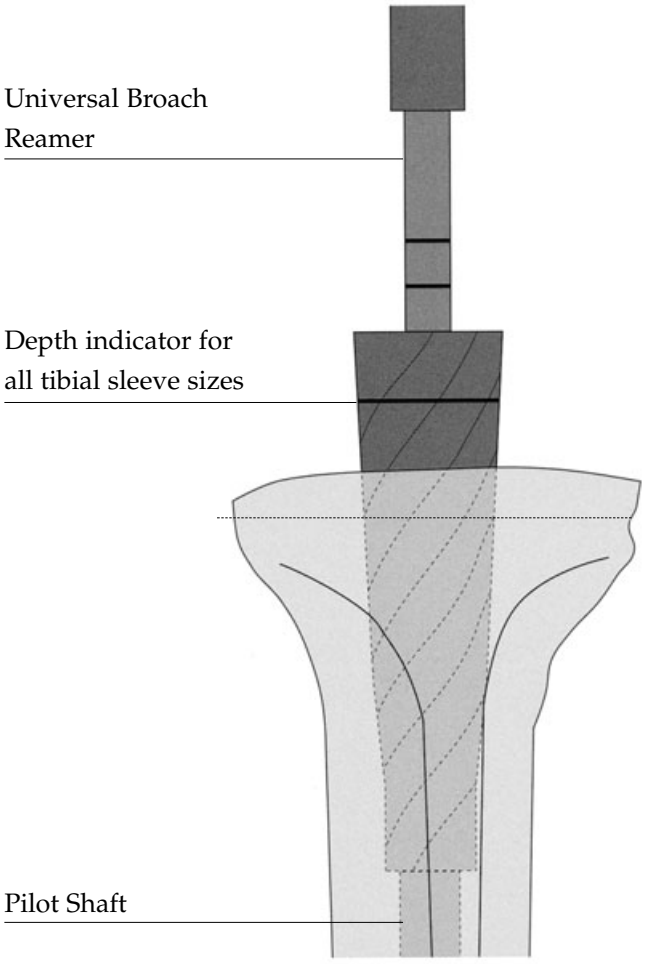
A. Attach a pilot shaft of the same diameter as the final straight reamer to the universal broach reamer. The pilot shafts are 100 mm long.

B. Ream the canal. The groove within the cutting portion of the reamer body is the depth mark for tibial reaming and should be advanced to the planned resection level [fig. 3].

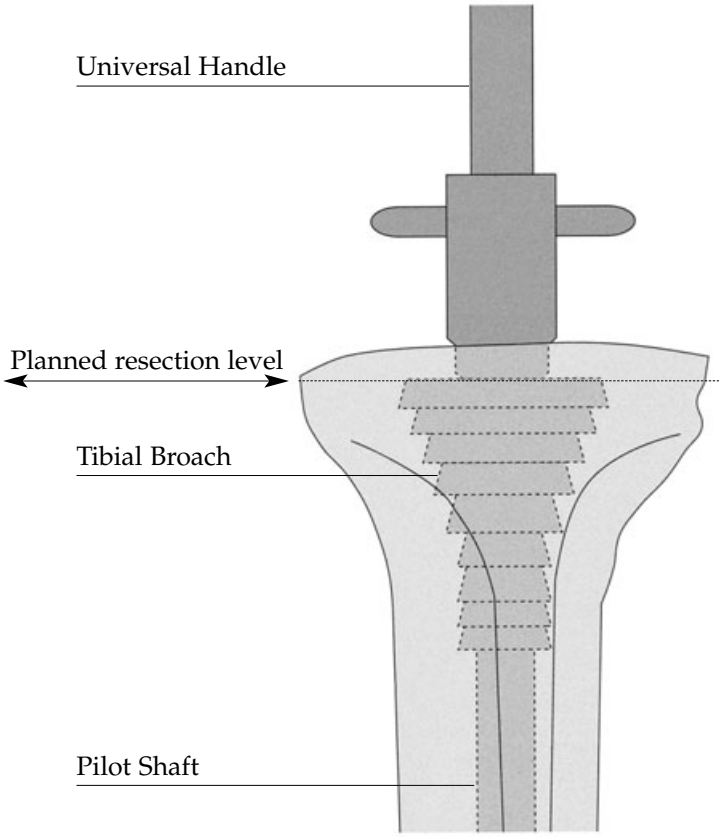
Note: Bone quality dictates necessity of broach reaming.

C. Attach a universal handle and a pilot shaft (the same diameter as the final straight reamer) to the 37 mm tibial broach. The broaches are asymmetrical. Ensure the "tibial anterior" engraving on the handle points anteriorly.

D. Drive the broach into the tibia until the top surface of the broach is at the planned resection plane. Check for rotational stability. If the broach is unstable or the defect is unfilled, repeat with consecutively larger broaches until the desired fit is achieved. Remove the universal handle, leaving the last broach in place [fig. 4].

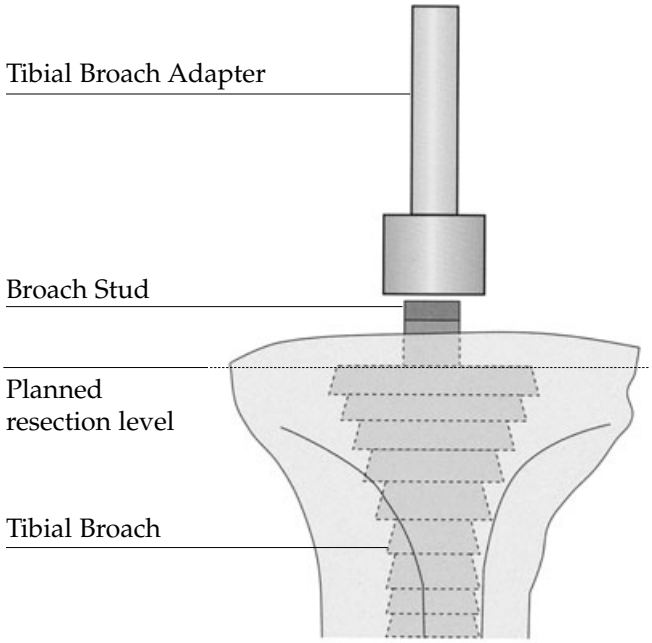


[figure 3]

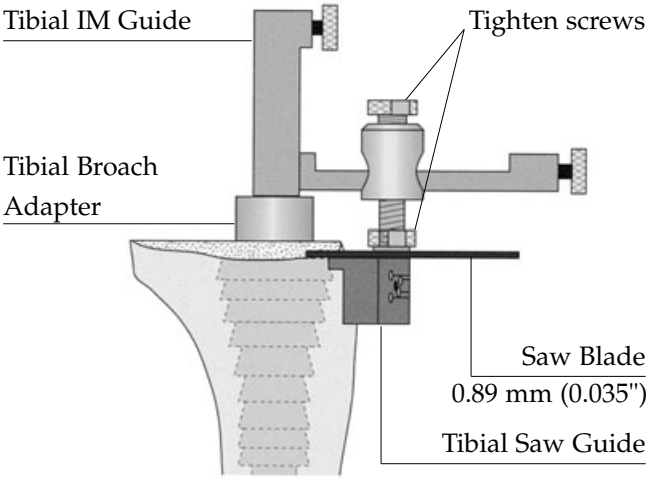


[figure 4]

Proximal Tibial Cut



[figure 5]



[figure 6]

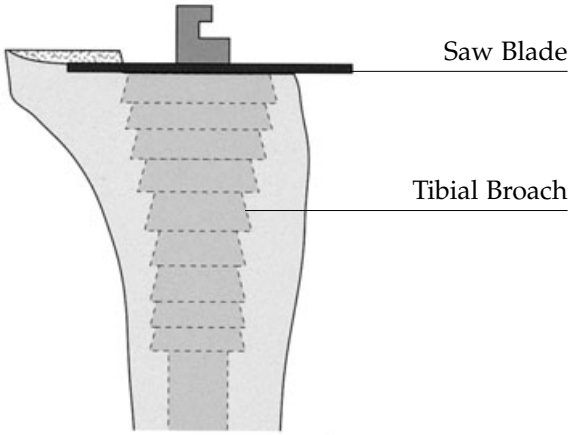
Note: If desired, the proximal tibial cut can be made directly off the top surface of the broach without using the tibial saw guide [fig. 7]. Proceed directly to step C.

A. Slide the tibial broach adapter over the broach stud [fig. 5].

B. Attach the tibial saw guide to the tibial IM guide and slide the assembly onto the broach adapter. The cutting surface of the saw guide is now parallel to the top of the broach. Do not pin the guide to the tibia; the drills will hit the broach. Achieve the necessary stability by tightening the thumbscrews on the IM guide [fig. 6].

C. Resect the proximal tibia with an oscillating saw. If the blade will not reach the posterior, remove the IM guide assembly and adapter and use the surface of the broach to complete the cuts [fig. 7].

D. Leave the broach in place to serve as part of the tibial trial later in the procedure.



[figure 7]

Femoral Canal Reaming

Preoperative templating is recommended to approximate femoral stem extension diameter and length and femoral sleeve size.

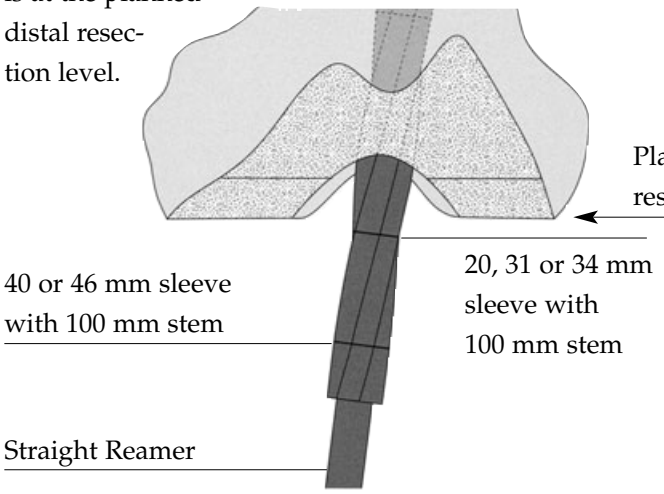
Straight Reaming

Open the femoral intramedullary canal with the 11 mm starter drill. The starter hole provides the correct offset from the anterior cortex for reamer entry. Ream the femoral intramedullary canal up to the desired stem extension diameter. The appropriate depths for 20, 31 and 34 mm sleeves and 40 and 46 mm sleeves with 100 mm stem extensions are indicated by grooves on the reamer [fig. 8]. In the case of significant metaphyseal bone loss, a 150 mm bowed stem extension is recommended. This bypasses the stress-risers and provides good fixation in sound bone. Use flexible reamers for 150 mm bowed stem preparation. (see Appendix p. 29)

Broach Reaming

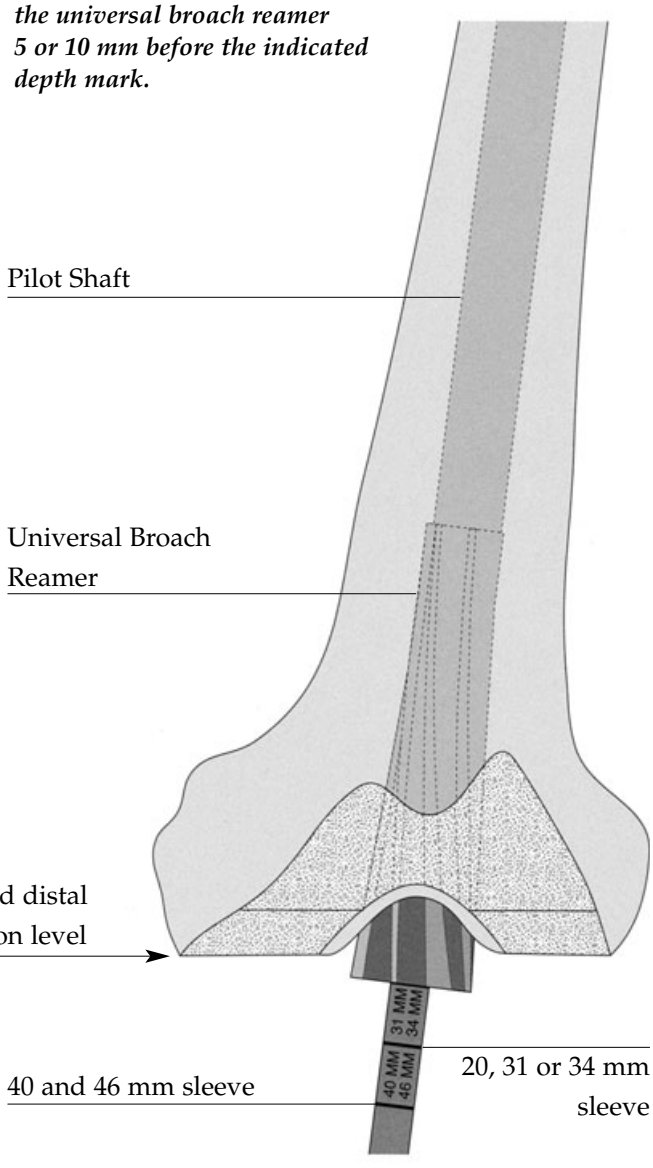
Attach a pilot shaft of the same diameter as the final straight reamer to the universal broach reamer. The grooves on the reamer shaft indicate the distal resection line for each of the femoral sleeves. Ream the distal femur to the desired depth [fig. 9].

Ream until the depth mark for the desired sleeve size is at the planned distal resection level.



[figure 8]

Note: If 5 or 10 mm distal augmentation blocks will be used on both the medial and lateral condyles, stop the advance of the universal broach reamer 5 or 10 mm before the indicated depth mark.



[figure 9]

Depth markings indicate the distal resection line for each femoral sleeve size.

Femoral Broaching

A. Start with the 31 mm femoral broach. Attach a pilot shaft of the same diameter as the final straight reamer to the broach. Attach the broach to a universal handle.

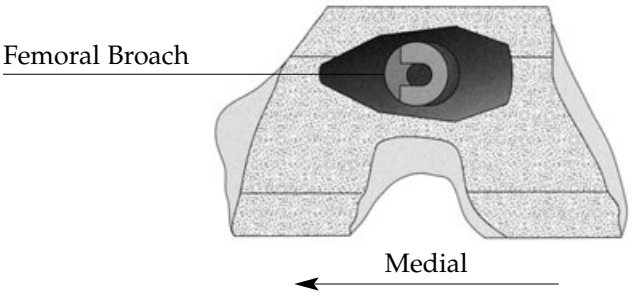
Note: If a 20 mm cemented sleeve is necessary, refer to Appendix, p. 33.

B. Carefully broach the distal femur. **Note that the broach is asymmetrical** and that the narrow side of the broach must point medially [fig. 10]. The line on the universal handle indicates the level of the distal femoral resection [fig. 11].

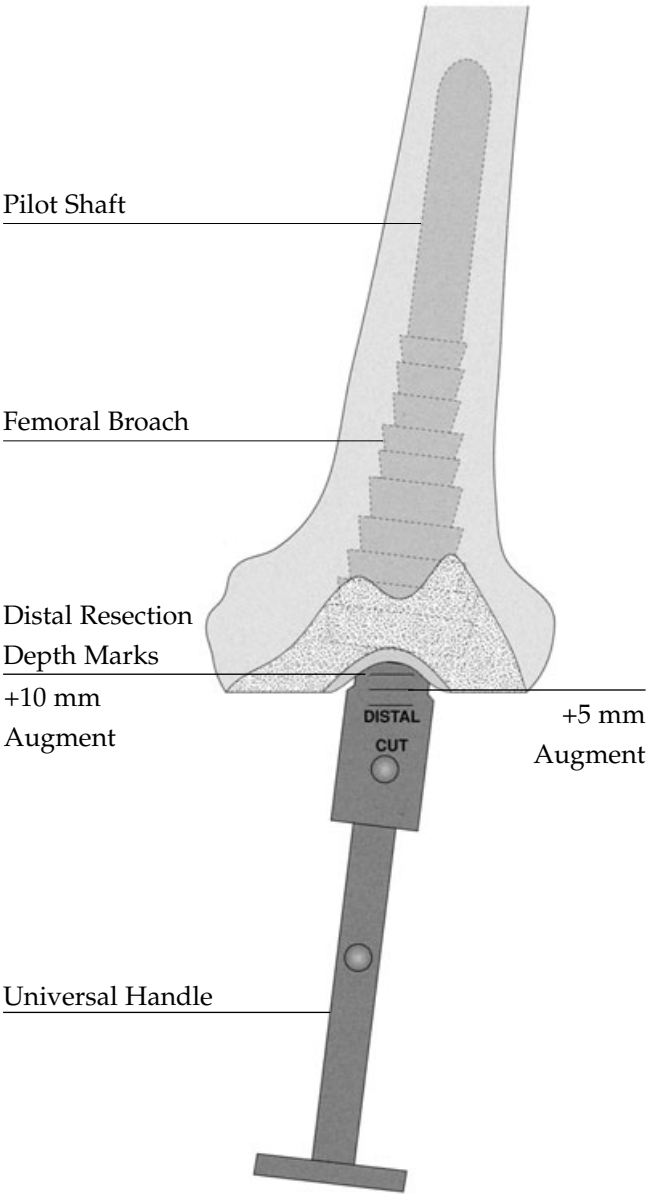
C. When the depth mark is at the distal resection level, check the rotational stability of the broach. If the stability of the broach is unsatisfactory, move up to the next broach size.

D. Once the desired stability is achieved, disconnect the universal handle from the broach, but leave the broach in place. The last broach used will be the femoral sleeve size.

Note: If 5 or 10 mm distal augmentation blocks will be used on both the medial and lateral condyles, stop the advance of the broach 5 or 10 mm before the plane of the anticipated distal femoral resection, as indicated by the distal resection depth marks on the universal handle.



[figure 10]



[figure 11]

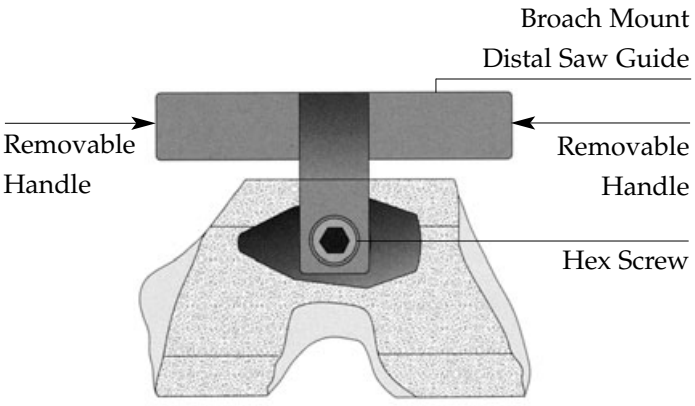
Femoral Distal Resection

A. Thread the hex screw in the broach mount distal saw guide into the threads in the end of the broach. Adjust the rotation of the saw guide so the horizontal portion is parallel to the anterior femoral surface. Tighten the hex screw using the hex screwdriver [fig. 12]. For further stability, screw the removable handles onto the saw guide.

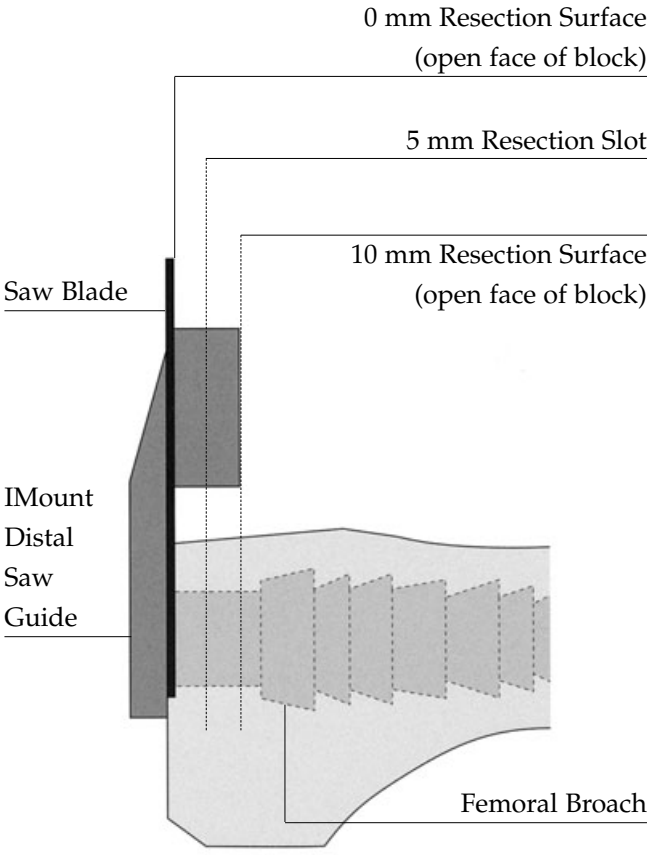
B. Using a saw blade, determine the amount of bone to be resected. A minimal cut will usually be made off the nominal resection surface. By inserting the hex screwdriver into the screw and tapping the handle, the distal saw guide/broach assembly may be driven into the femur to resect more bone [fig. 13].

C. If an augmentation block is used on only one side, make the distal resection on that side through the middle (5 mm resection) slot or off the 10 mm resection surface. If 5 or 10 mm distal augmentation blocks will be used on both condyles, stop the broach 5 or 10 mm from the plane of the intended distal resection. Make the distal resection through the middle (5 mm) slot or off the primal surface (10 mm) [fig. 13].

D. Perform the distal resection. Remove the broach mount distal saw guide.



[figure 12]



[figure 13]

Femoral Cut Guide Placement

A. The femoral cutting guide is size specific (2 blocks – xs/small and medium). Determine the femoral component size by preoperative templating and comparing the femoral component trial to the size of the femur. Use the size giving the best medial/lateral (M/L) coverage.

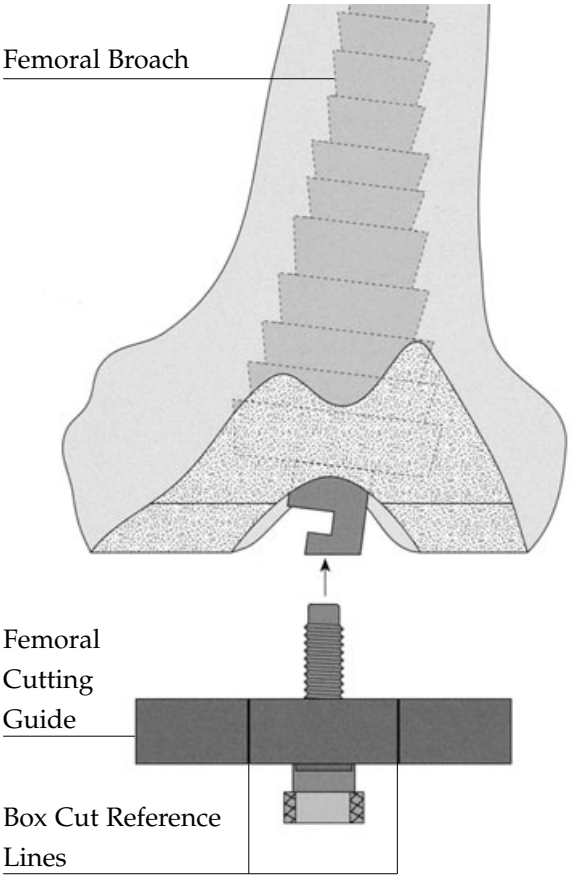
B. Set the thumbscrew on the femoral cutting guide to the approximate center of its slot [fig. 15] and tighten.

C. Thread the hex screw of the femoral cutting guide into the threads in the end of the broach. Place the guide into neutral rotation by aligning the anterior cortex parallel with the anterior portion of the guide. Tighten the hex screw using the hex screwdriver [fig. 15].

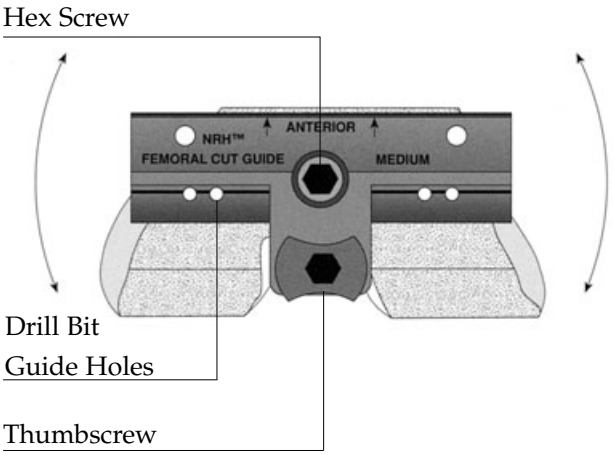
Note: If distal augmentation blocks will be used, there should be a gap of 5 or 10 mm between the cutting guide and the distal condyle(s) of the affected side(s).

D. Loosen the thumbscrew on the femoral cutting guide and fine-tune the guide to the desired external rotation. Use the femoral epicondylar axis as the rotational reference [fig. 15].

E. Tighten the thumbscrew. Achieve additional fixation of the cutting guide with ⅛" drill points, introduced through the holes designated. (These pins will be required to be temporarily removed later to complete the resections.)

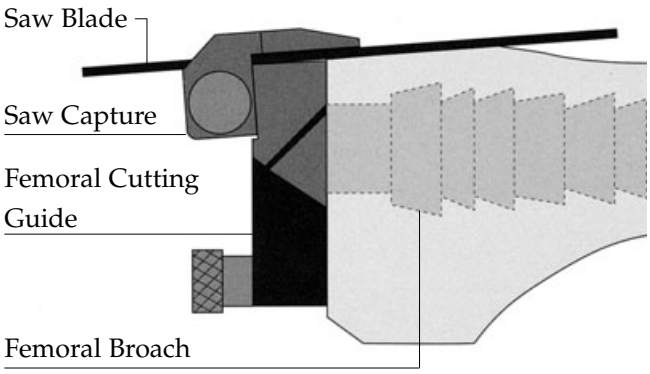


[figure 14]



[figure 15]

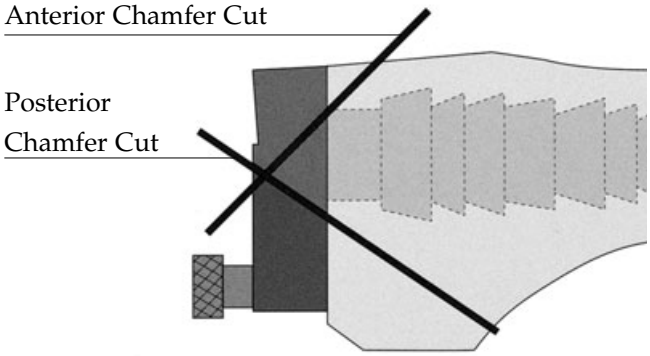
Femoral Anterior and Chamfer Cuts



[figure 16]

Note: Important! When 1/8" drill points are used for rotational stability, complete chamfer cuts on one side at a time, with only the contralateral drill point in place. Then place a drill point on the completed side, remove the drill point on the contralateral side and finish the cut sequence.

(Saw Blade Positions)



[figure 17]

A. Attach removable handles to the saw capture. Place the saw capture onto the femoral cutting guide [fig. 16].

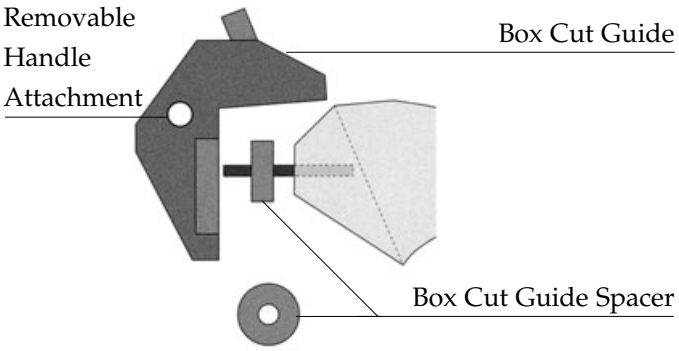
B. Make the anterior cut. Remove the saw capture and ensure the cut is flat.

C. Make the anterior chamfer cut through the captive slot [fig. 17]. If the block was previously pinned, temporarily remove one pin at a time while making the resection.

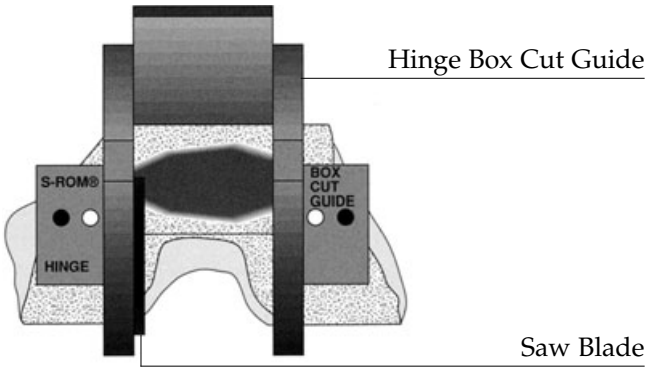
D. Make the posterior chamfer cut by holding the saw blade flush with the cutting guide. Again, if pins are being used for fixation, remove the pin while resecting, then replace. Care should be taken to avoid damaging posterior soft tissue [fig. 17].

E. If not previously pinned, place at least one ⅛" drill point on each side of the guide. These will be used to position the box cut guide [fig. 15, page 10]. Alternatively, two lines are engraved on the anterior surface of the cutting block. These lines are used to mark the anterior surface of the femur and further help position the box cut guide [fig. 14, page 10].

F. Remove the femoral cutting guide and femoral broach/pilot assembly while leaving the ⅛" drill point(s) in place.



[figure 18]



[figure 19]

USE 5 OR 10 MM BOX CUT GUIDE SPACERS IF DISTAL AUGMENTATION BLOCKS WILL BE USED [fig. 18]

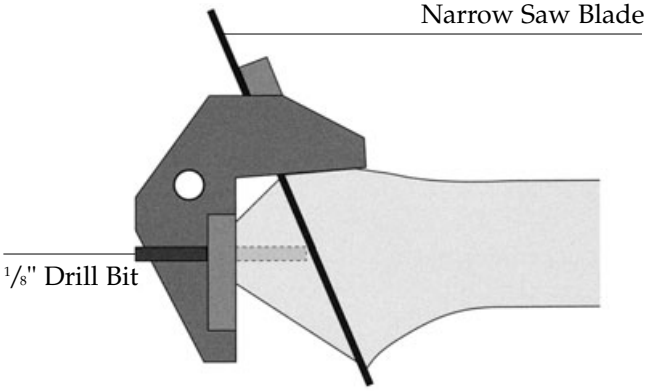
A. Slide the hinge femoral box cut guide over the ⅛" drill points placed in the previous step or align with the lines marked off the femoral cutting guide. If distal augmentation blocks will be used, slide 5 or 10 mm box cut guide spacers over the drill points before positioning the box cut guide [fig. 18]. Attach removable handles to the box cut guide for additional stability.

   Four additional ⅛" drill holes are provided on the anterior surface of the box cut guide; ⅛" drill points are recommended for additional stability.

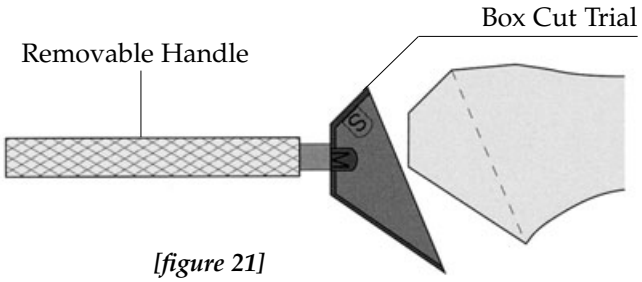
B. Holding the saw blade flat against the inner surface of the box cut guide, make the side cuts for the center box as illustrated above [figs. 19, 20].

C. Use a narrow saw blade (12.7 mm or 0.5"), placed on the sloped guide surface, to remove the bone block of the center box [fig. 20].

D. Check the depth of the box with the box cut trial. Revise resection if necessary [fig. 21].



[figure 20]



[figure 21]

Femoral Trial Insertion

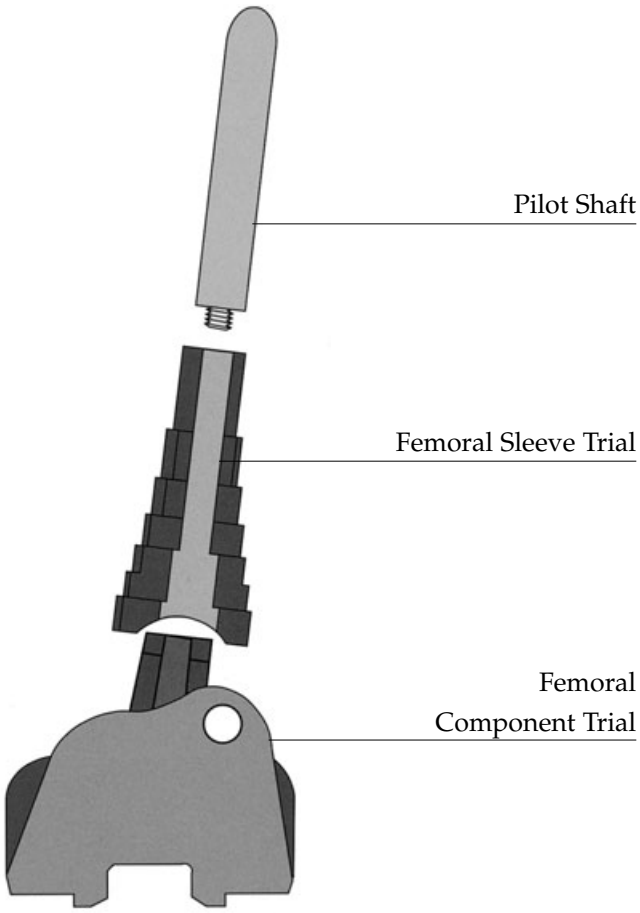
A. Screw a pilot shaft into the appropriate femoral sleeve trial. The diameter of the pilot shaft will be the same as the final straight reamer used; the size of the femoral sleeve trial will be the same as the final femoral broach used [fig. 24]. (See Appendix on page 29 for bowed stem).

B. Slide the sleeve/shaft assembly into the prepared cavity in the femoral canal to allow the assembly to self align with the broached surfaces.

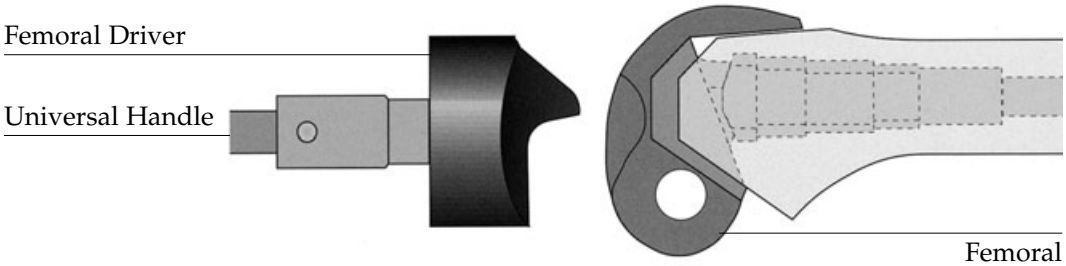
Note: The narrow side of the sleeve trial points medially.

C. 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. Check accuracy of the bone cuts. Revise or rebroach if necessary [fig. 25].

Note: 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.

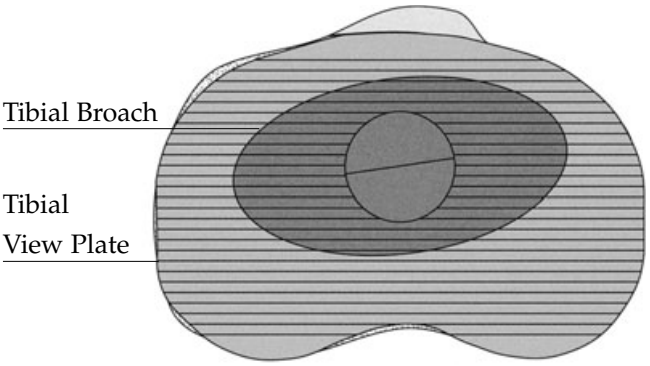


[figure 24]



[figure 25]

TIBIAL TRIAL ASSEMBLY

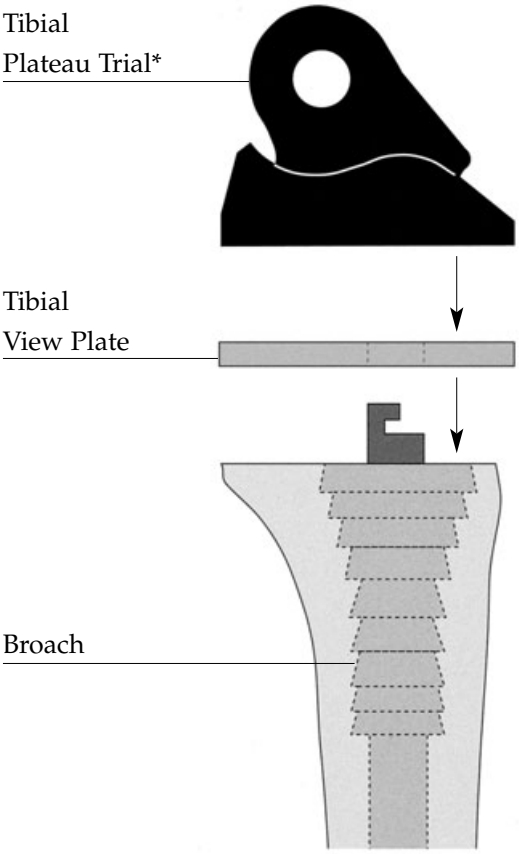


[figure 26]

A. Slide the tibial view plate which best covers the proximal tibia over the broach stud with the grooves toward the bone surface. Note the view plate size, as it will dictate the size of the modular tibial base that will be used. The tibial view plate is transparent to help visualize tibial coverage. The grooves match those in the implant to aid in orienting the tibial sleeve to the tibial base during assembly [fig. 26].

B. Slide the appropriately sized plateau trial (based on previous femoral sizing) over the stud on the broach. Select the thickness that allows full extension, while avoiding excessive hyperextension [fig. 27].

**** Tibial plateau size must match femoral component size.***



[figure 27]

TRIAL REDUCTION

A. Slide the condyles of the femoral trial into the plateau trial. Do not insert the hinge pin trial [fig. 28].

B. With the leg in full extension, evaluate the resection of the mechanical axis. The center of the femoral head, knee and talus should all be in line [fig. 29].

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

D. If the condyles lift off the plateau during flexion, check the posterior area for soft tissue, osteophyte or bone impingement [fig. 28].

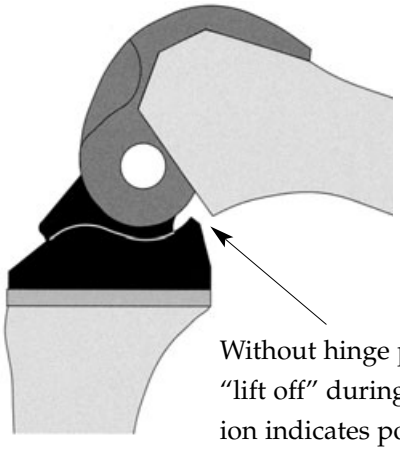
E. Insert the hinge pin trial and repeat the range of motion check.

F. Check ligament tension and leg length.

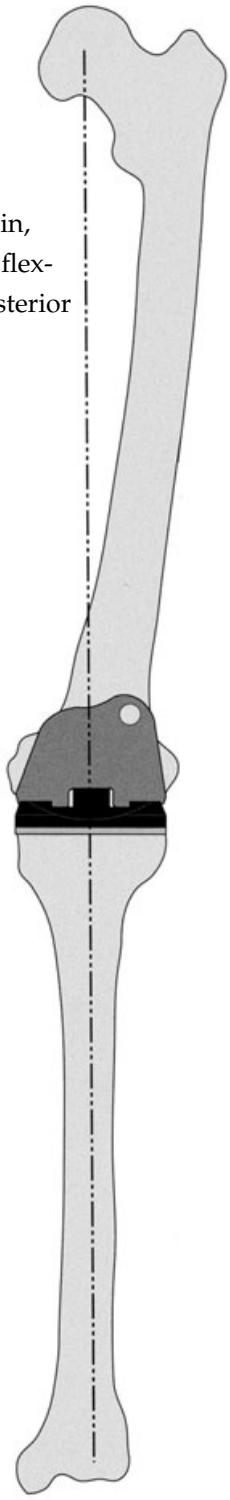
G. Revision of the tibial or femoral resection may be required if satisfactory stability cannot be achieved. Accompany additional bone resection with rebroaching.

H. Remove 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.

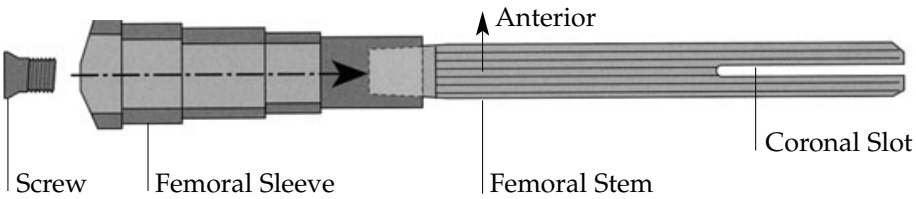
Note: In patients with severe soft tissue loss, flexion of the knee beyond 90 degrees may cause distraction and luxation of the tibial plateau out of the modular tibial base. In this instance, fit the patient with a postoperative brace, limiting flexion to 90 degrees and no more for at least three months. This helps soft tissue establishment of flexion tension. Consult package insert.



[figure 28]



[figure 29]



[figure 30]

The narrow side of the femoral sleeve points medially

[figure 31]

Note: If using a distal femoral augmentation block, see Appendix page 35.

A. Insert the femoral stem extension into the femoral sleeve. Ensure that the slot and/or bow are in the correct planes and that the narrow side of the femoral sleeve points medially [figs. 30, 31].

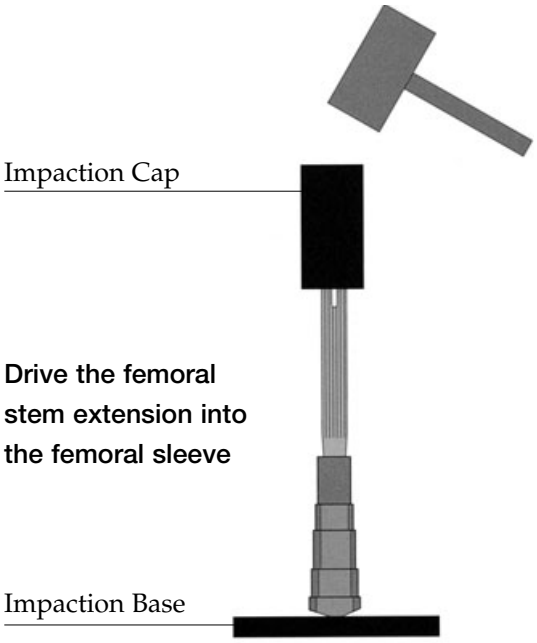
   If using a 150 mm stem extension, refer to the bowed stem technique in the Appendix (page 30). If no stem extension is used, assemble the femoral sleeve plug as described in the Appendix (page 31). However, if anatomically possible, it is recommended that the sleeve and stem always be used on the femoral side with the hinge.

B. Insert the screw through the femoral sleeve and into the threads in the femoral stem extension, tighten the screw securely with the hex screwdriver [fig. 30].

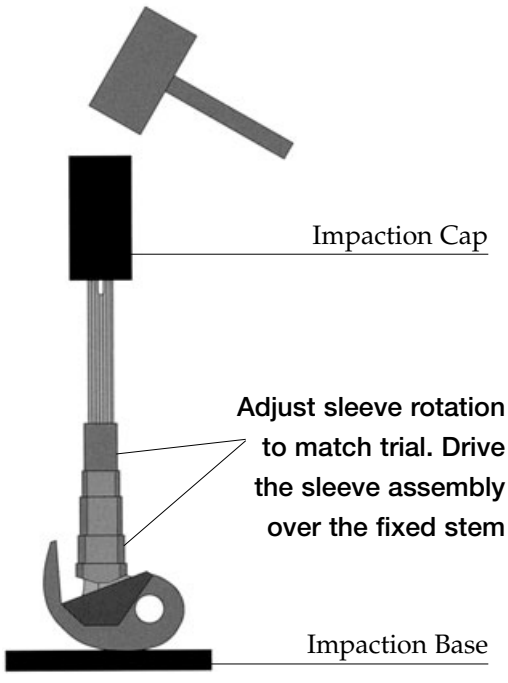
C. Utilizing the impaction base and cap, drive the femoral stem extension into the femoral sleeve to lock the tapers (six solid blows are required). **Retighten the screw** [fig. 32].

D. Position the sleeve/stem extension assembly over the stem of the femoral component. Adjust rotational alignment with reference to trial assembly [fig. 33].

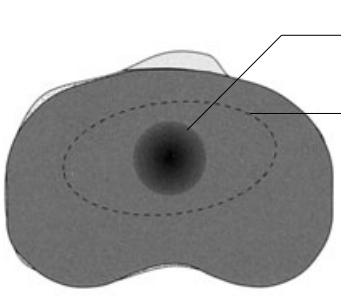
E. Drive the sleeve/stem extension assembly onto the stem to lock the tapers (six solid blows are required).



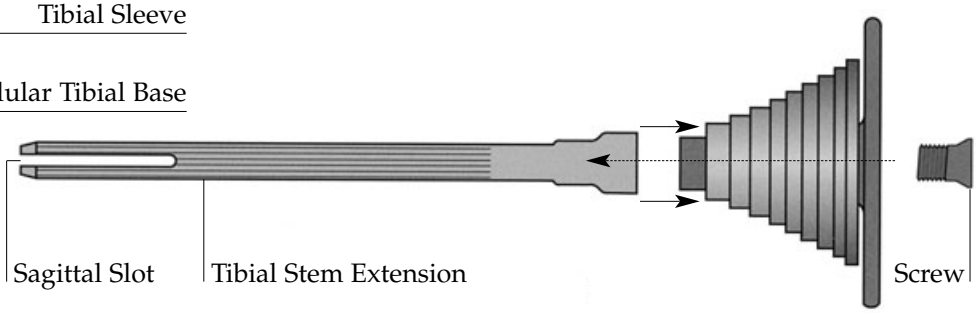
[figure 32]



[figure 33]



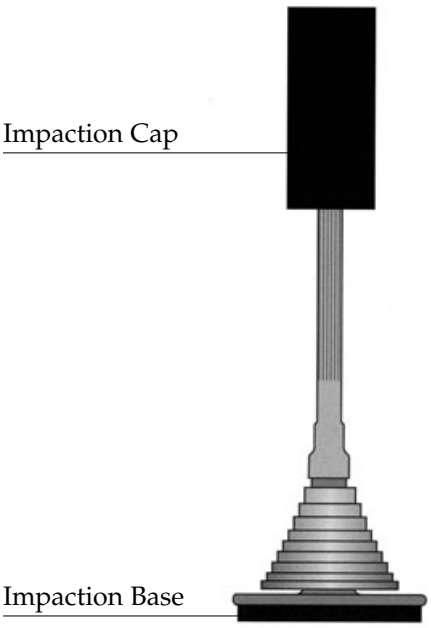
[figure 34]



[figure 35]

A. Slide the tibial sleeve (same size as last broach used) into the prepared cavity in the tibia, leaving one or two steps proud of the cut surface. If the sleeve is loose in the cavity, use the tibial view plate to determine orientation as described earlier.

B. Slide the modular tibial base into the tibial sleeve, adjusting rotation to optimize coverage [fig. 34]. Lightly tap the tibial base into the tibial sleeve to lock the tapers in rotational alignment. Remove the tibial base sleeve assembly from the tibia and place, inverted, onto the impaction base on the back table [fig. 36].



[figure 36]

C. Slide the tibial stem extension over the stem on the modular tibial base [fig. 36]. If a stem extension is not used, assemble the tibial base cap as described in the Appendix (page 32).

D. Adjust the stem rotation so the sagittal slot is correctly aligned. Insert the screw through the hole in the modular tibial base and into the threads of the tibial stem extension. Tighten the screw securely with the hex screwdriver [fig. 35].

E. Position the impaction cap on the end of the stem extension and impact until the stem contacts the sleeve. Drive the tibial sleeve/stem extension onto the stem of the tibial base to lock the tapers (six solid blows are required after the stem contacts the sleeve) [fig. 36].
Retighten the screw.

Note: In contrast to the femoral side, it is possible to use the tibial stem without using the metaphyseal sleeve. In most hinge situations, which are done for severe hard or soft tissue insufficiency, use both sleeve and stem to make a more stable construct and better utilize the implant with the host bone.

An alternate to A and B.
After tibial broaching and trialing with the appropriate view plate, attach the modular handle and remove the construct. Turning the construct upside down, use this as a guide for tibial assembly. Push the sleeve and stem onto the tibial component, matching the orientation of the view plate and broach. Insert the screw and tighten. Place the tibia inverted onto the impaction base on the back table [fig. 36]. Proceed to Step E.

COMPONENT IMPLANTATION

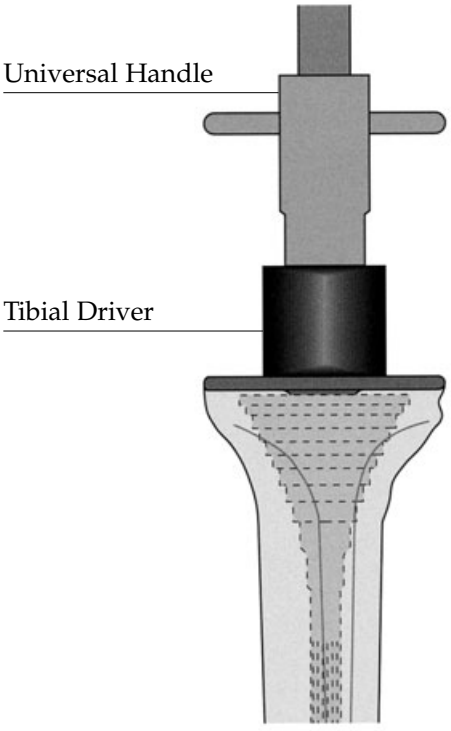
Note: Prepare a minimum of two packets of bone cement prior to component insertion.

A. Assemble the tibial driver onto a universal handle and drive the tibial base assembly into the tibia [fig. 37].

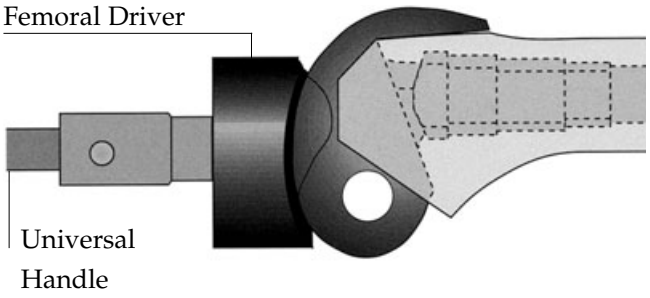
B. Assemble the femoral driver onto a universal handle and drive the femoral component assembly into the femur [fig. 38].

C. Insert the trial plateau post into the modular tibial base, place the tibial plateau trial over the trial post and recheck range of motion to ensure correct plateau thickness and lack of impingement posteriorly [fig. 39].

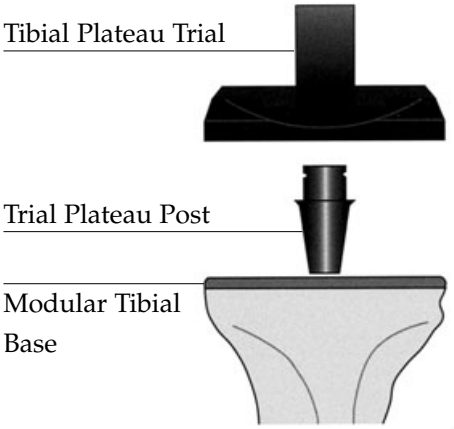
D. Slide the S-ROM Noiles Rotating Hinge tibial post/plateau assembly into the bearing hole in the modular tibial base [fig. 40].



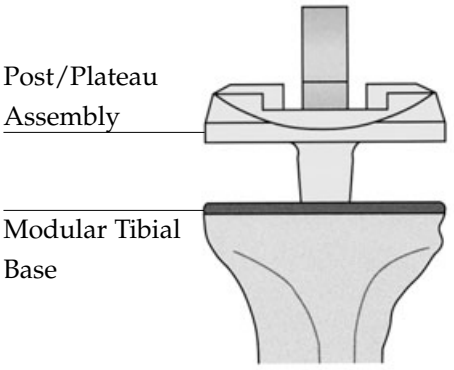
[figure 37]



[figure 38]



[figure 39]



[figure 40]

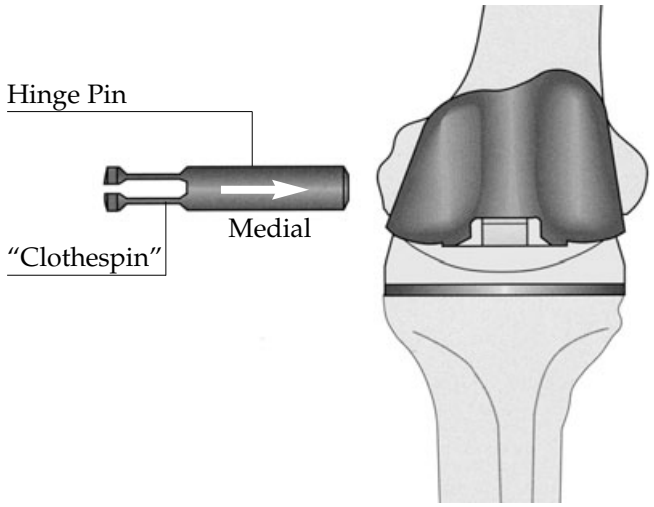
Bearing and Hinge Pin Insertion

A. Put the condyles of the femoral component into the corresponding recesses in the tibial plateau. Recheck range of motion and stability. Look for lift off due to impingement. Clear all cement around the implants.

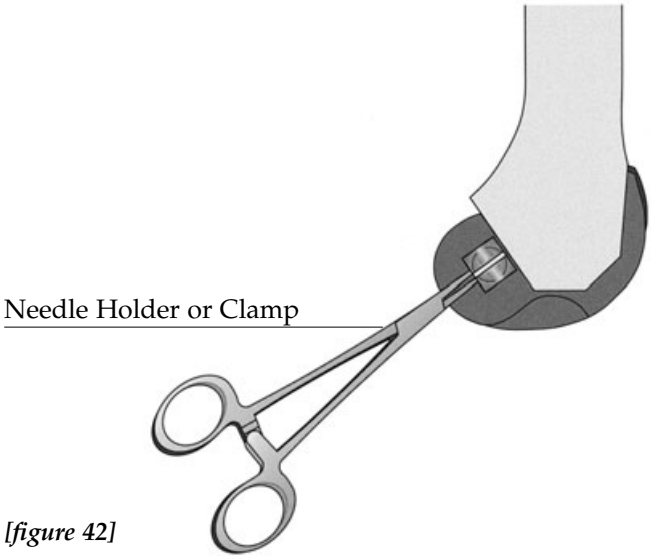
B. Insert the hinge pin through the hole on the medial side of the femoral component. Orient the rectangular head of the hinge pin with the rectangular recess in the femoral component [fig. 41].

C. Squeeze the "clothespin" of the hinge pin together and insert the hinge pin into the femoral component. Make sure the hinge pin is securely locked in place [fig. 42].

D. Test the knee through full range of motion.



[figure 41]



[figure 42]

PATELLA SURGICAL PROCEDURE

S-ROM Noiles Rotating Hinge Knee

Patella Surgical Procedure

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S-ROM patella domes are available in four diameters. As shown in Table 1 below, the thickness and peg length of each patella dome changes as the diameter changes. The peg diameter and the peg position is the same for each size patella dome.

The S-ROM patella dome is designed to be inset into the patellar bone from a minimum of 1 mm to a maximum of 4 mm. The depth of the inset is dependent upon the thickness of the patella dome selected and the thickness of the initial bone resection. Once these two thicknesses are known, the instrumentation is designed to ream and drill to the correct depth.

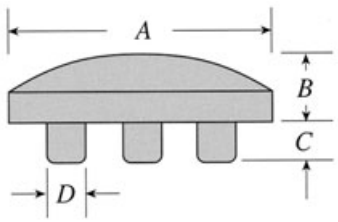
The primary surgical procedure calls for the initial resection of a nominal 7 mm of bone. After this resection is made, measure the thickness of the resected bone and subtract it from the thickness of the selected patella dome. The result of this subtraction step determines the slot that will be used in the patella reamer depth adjuster.

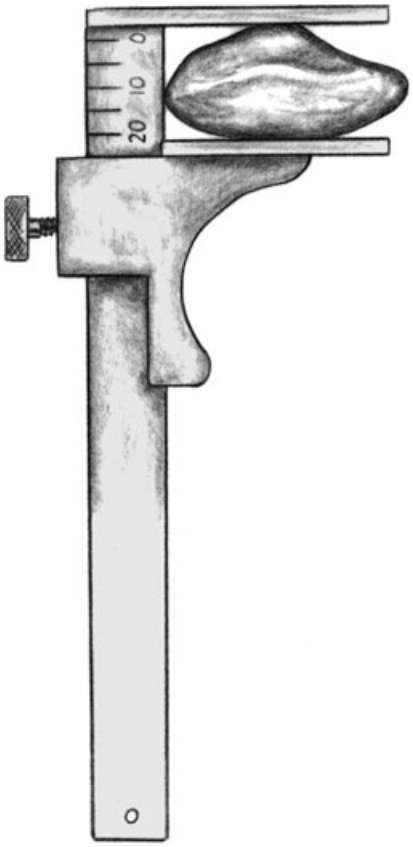
After the patella has been reamed to the correct inset depth as determined above, position the patellar drill guide. When used with the 3/16" patella shoulder drill, drill holes of the correct depth, diameter and position for each of the four patella domes.

In a revision situation, measure the original patella to ensure that at least 10 mm of bone remains. Determine the correct diameter implant by comparing the patella trials to the resected surface of the patellar bone. The "1" slot in the patella reamer depth adjuster is routinely used for both the reaming and drilling steps.

Table 1

Patella Dome Cat. No.	*Patella Diameter (A)*	*Patella Thickness (B)*	*Peg Length (C)*	*Peg Diameter (D)*
62-1630	30 mm	8.0 mm	3.5 mm	4.0 mm
62-1632	32 mm	8.5 mm	4.0 mm	4.0 mm
62-1635	35 mm	9.0 mm	5.0 mm	4.0 mm
62-1638	38 mm	10.0 mm	6.0 mm	4.0 mm



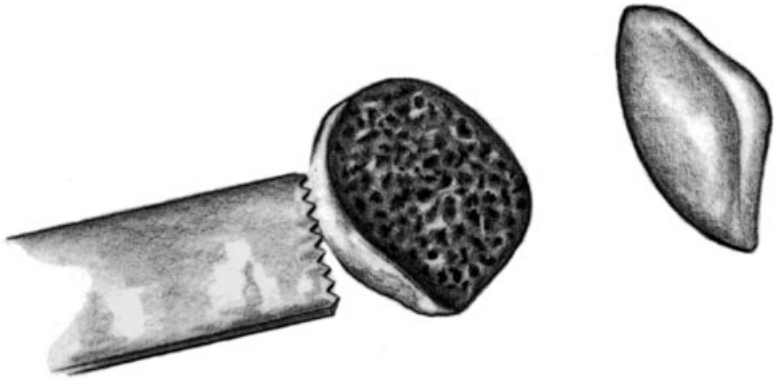


[figure 1]

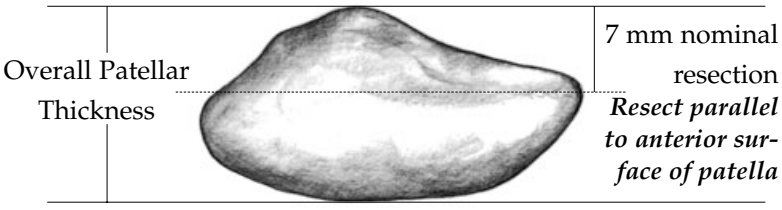
A. Measure and record the overall thickness of the patella using a caliper [fig. 1].

B. Resect approximately 7 mm of bone from the posterior patellar surface using an oscillating saw [fig. 2].

C. Measure and record the thickness of the resected/removed bone in order to properly duplicate the original thickness [fig. 3].



[figure 2]



(Anterior)

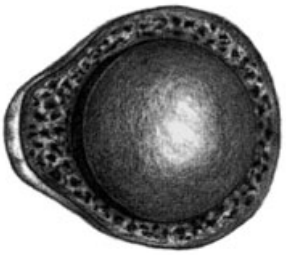
[figure 3]

Determine Patellar Diameter

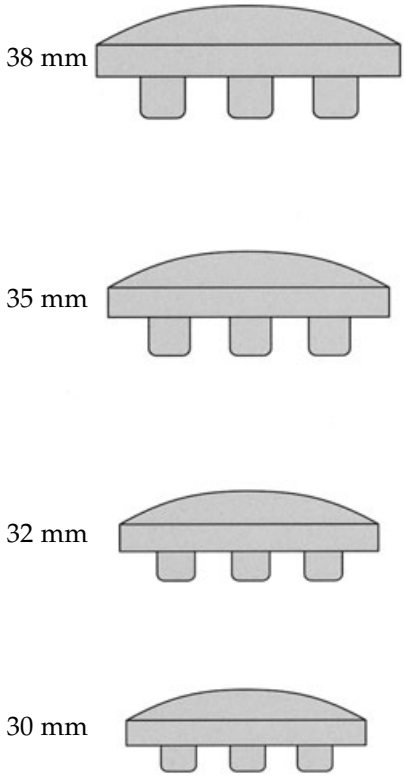
A. Patella domes are available in four diameters [fig. 4]. Select a patella trial with the diameter that best matches the patient's patella [fig. 5].

B. Select the patella reamer depth adjuster that is the same diameter as the patella trial.

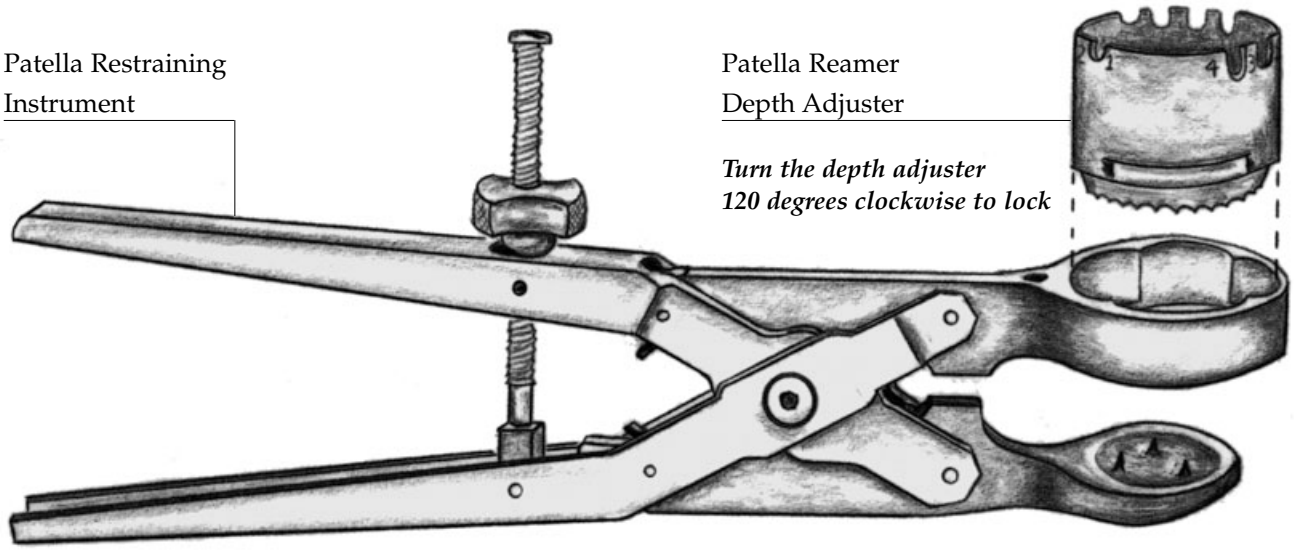
C. Insert the patella reamer depth adjuster into the patella restraining instrument. Rotate the depth adjuster 120 degrees clockwise to lock into position [fig. 6].



[figure 5]



[figure 4]



[figure 6]

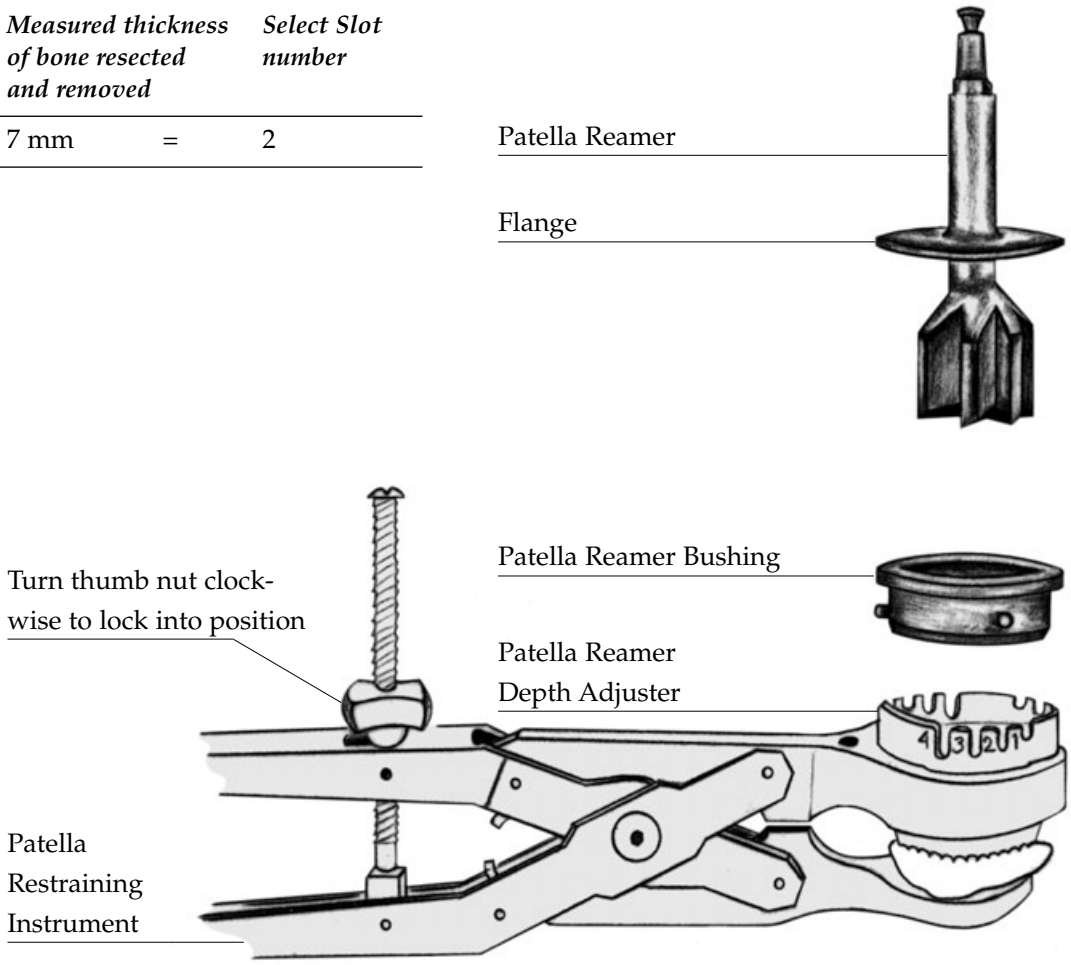
A. Clamp the patella restraining instrument assembly onto the patella. Lock into position by turning the thumb nut clockwise [fig. 7].

B. 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 2 as a guide.

C. Select the patella reamer that matches the diameter of the patellar 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.

Table 2

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



[figure 7]

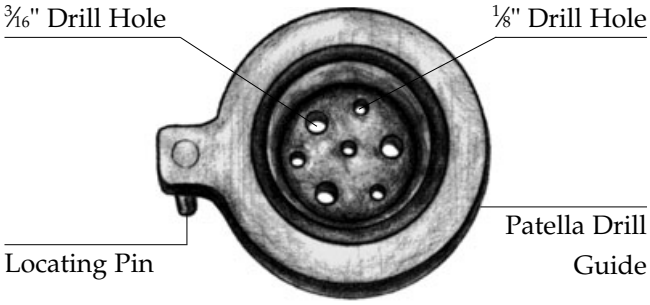
Drill Patella

A. 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 [fig. 8].

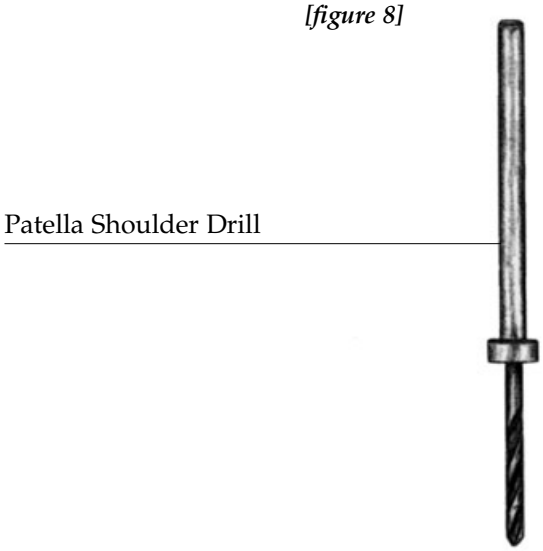
B. Select the 3/16" patella shoulder drill and prepare the three patella peg holes by drilling through the three larger holes in the patella drill guide. The depth of the holes drilled is correct for the length of the pegs on the selected patella button [fig. 9].

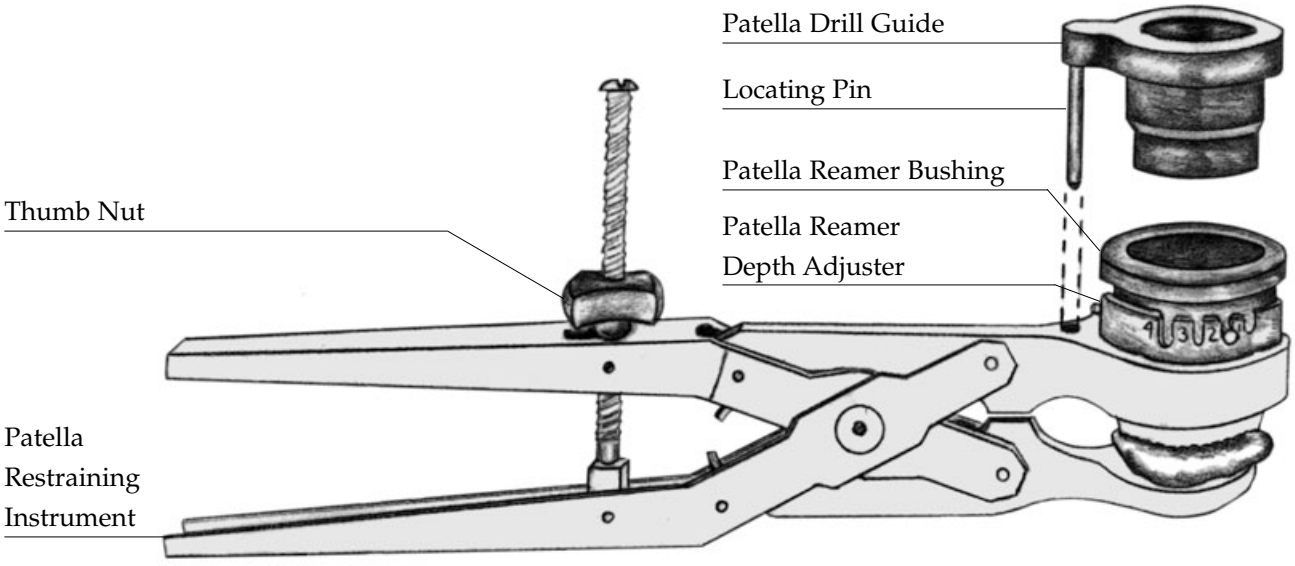
   Optional: Select the 1/8" patella shoulder drill and drill through the four smaller holes to enhance the cement fixation to the patellar bone.

C. Loosen the thumb nut on the patella restraining instrument and remove the entire assembly from the patellar bone.



[figure 8]



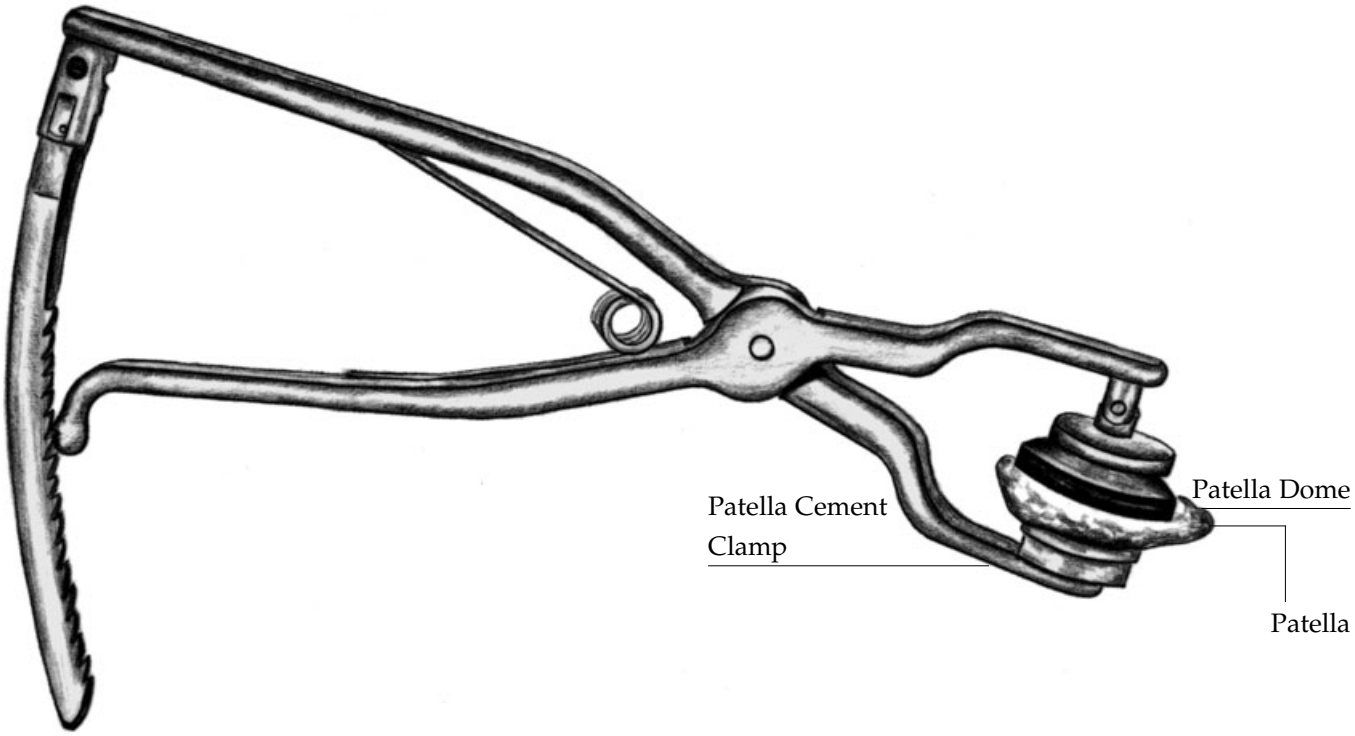


[figure 9]

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

Note: 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 patellar bone is not cut too thin. Maintain at least 10 mm of patellar bone to prevent drill or peg penetration of the anterior cortex).

B. The appropriately sized patella dome may now be cemented into place. A patella cement clamp is provided for this purpose [fig. 10].



[figure 10]

S-ROM Noiles Rotating Hinge Knee

Surgical Procedure Appendix

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SURGICAL PROCEDURE APPENDIX CONTENTS

S-ROM Noiles Rotating Hinge Knee

Surgical Procedure: Appendix

The devices comprising the S-ROM Total Knee System have been cleared for cemented use.

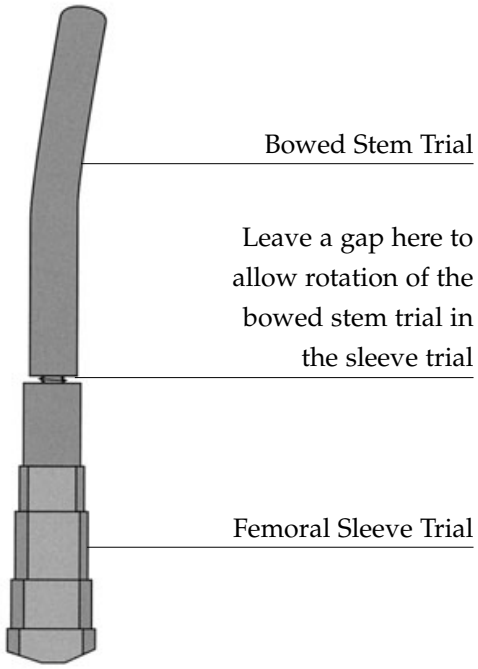
Table 1 Reaming Depth for 150 mm Extensions

Femoral Sleeve Size	*Reaming Depth*
20 mm	245 mm
31 mm	245 mm
34 mm	250 mm
40 mm	260 mm
46 mm	265 mm

FEMORAL CANAL REAMING

A. Ream the femoral canal using sequential flexible reamers to the desired stem diameter. The depth is dependent upon the eventual femoral sleeve which will be used. (Table 1) If a flexible reamer is not available, use a straight reamer 2 mm larger than the stem diameter.

B. Continue with femoral canal preparation as discussed in the S-ROM Noiles Rotating Hinge Surgical Procedure (pages 7-8).



[figure 1]

FEMORAL TRIAL INSERTION

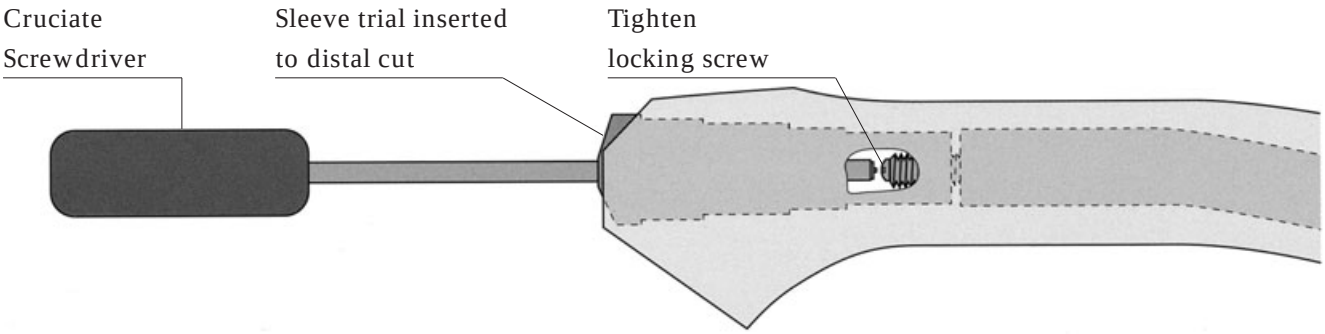
A. Screw the bowed stem trial, which matches the diameter of the final flexible reamer used, into the femoral sleeve trial. The femoral sleeve trial should match the size of the last femoral broach used. Do not tighten completely, but leave free to rotate [fig. 1].

B. Insert the trial assembly into the femoral canal, with the narrow side of the femoral sleeve trial orientated medially. Insert until the sleeve trial is at the distal resection line [fig. 2].

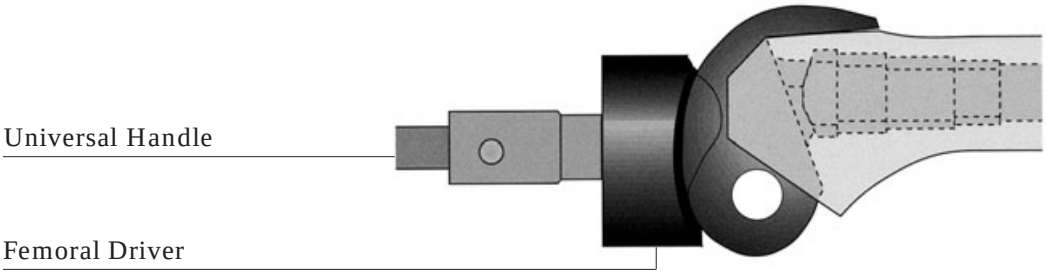
C. Tighten the bowed stem trial to the femoral sleeve trial by inserting the cruciate screwdriver through the sleeve into the screw in the stem trial. Turn clockwise and do not over tighten [fig. 2].

D. Slide the femoral component trial into the femoral sleeve trial, orienting the anterior flange with the anterior cut. After the femoral component trial engages the femoral sleeve trial, impact using the femoral driver and universal handle. If the assembly does not seat completely, the bow may be wedged in the canal. This requires either further reaming of the canal or downsizing of the stem. If the trial assembly cannot be inserted and removed easily, the implant may hang up during implantation [fig. 3].

E. Continue with surgical procedure (page 14).



[figure 2]



[figure 3]

COMPONENT ASSEMBLY

A. When assembling the femoral stem extension into the femoral sleeve, use the trial assembly as a visual reference to set the rotational alignment of the implants.

B. Continue with the surgical procedure to assemble the components (page 17).

A FEMORAL SLEEVE PLUG IS REQUIRED IF A FEMORAL SLEEVE IS USED WITHOUT A FEMORAL STEM EXTENSION

A. Prepare the femur as described in the S-ROM Noiles Rotating Hinge Surgical Procedure (pages 7-12), except:

   – Do not ream the intramedullary canal.

   – Use the 8 mm broach adapter on the universal broach reamer and femoral broaches.

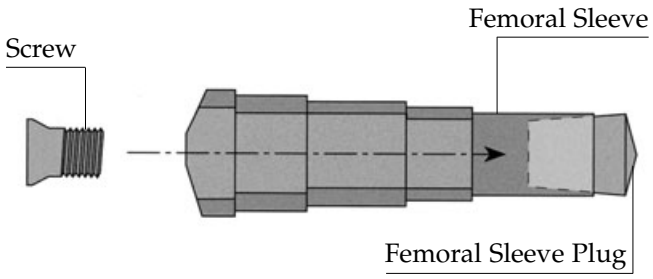
   – Use the femoral sleeve trial without a pilot shaft during trial insertion.

B. When assembling components, insert a femoral plug into the femoral sleeve from the bottom. Insert the screw through the femoral sleeve and into the threads in the plug. Tighten with the hex screwdriver [fig. 4].

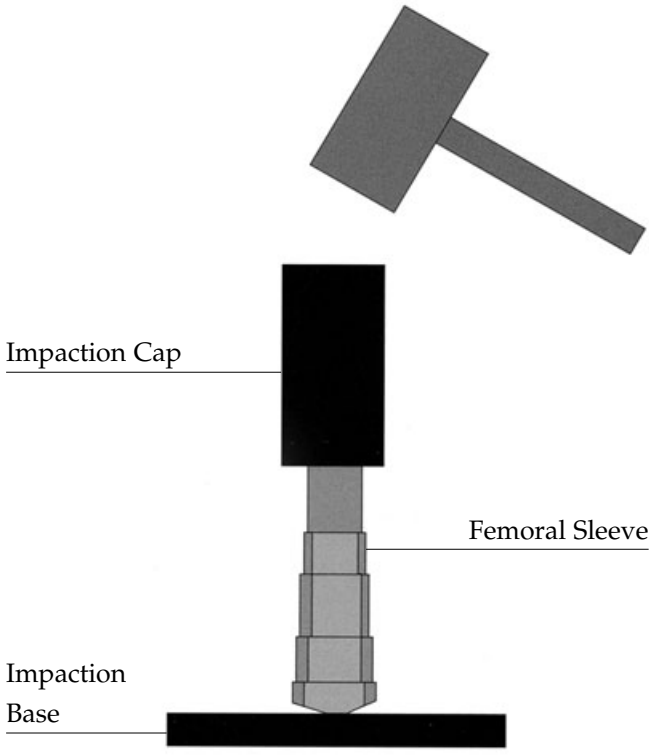
C. Drive the femoral plug into the femoral sleeve [fig. 5].

D. Retighten the screw.

E. Continue with surgical procedure (page 17).



[figure 4]



[figure 5]

A TIBIAL BASE CAP IS REQUIRED WHEN A TIBIAL SLEEVE IS USED WITHOUT A TIBIAL STEM EXTENSION

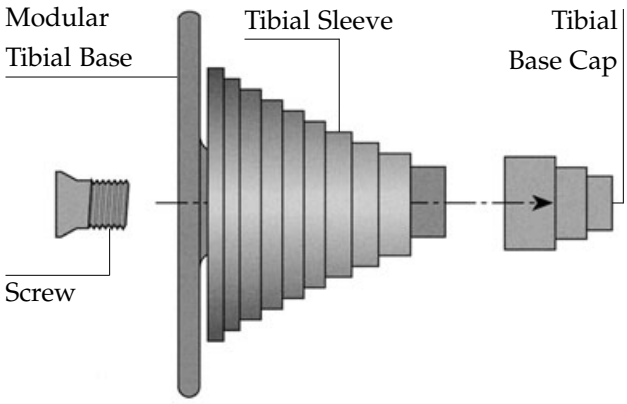
A. Prepare the tibia as discussed in the S-ROM Noiles Rotating Hinge Surgical Procedure (pages 4-7), but do not ream the intramedullary canal.

B. Use the 8 mm broach adapter on the universal broach reamer and tibial broaches.

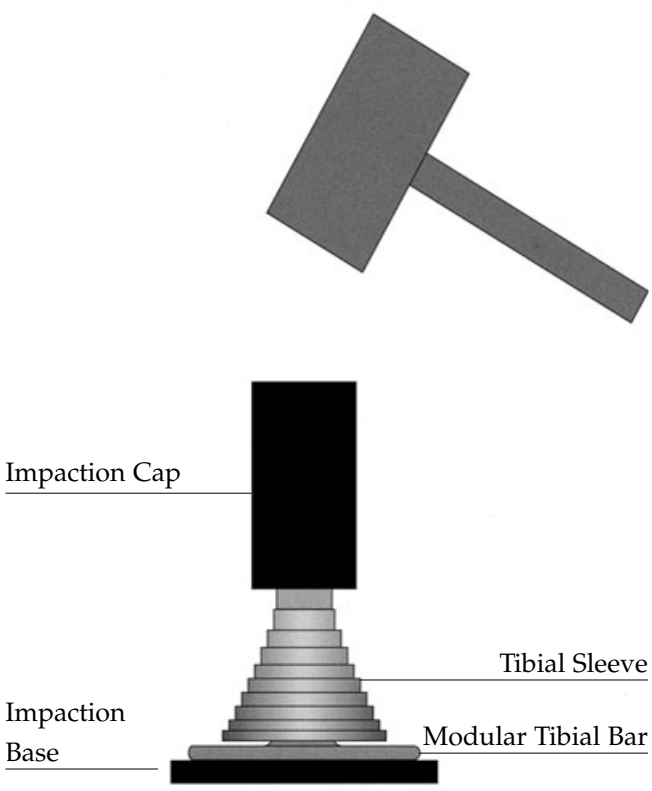
C. When assembling the components, insert a tibial base cap onto the distal end of the modular tibial base **after** the tibial sleeve is placed. Insert the screw through the modular tibial base and into the threads of the tibial base cap. Tighten with the hex screwdriver [fig. 6].

D. Drive the tibial base cap onto the modular tibial base. After it contacts the tibial sleeve, deliver six solid blows to lock the tapers [fig. 7].

E. Retighten the screw using the hex screwdriver. Continue with surgical procedure (page 18).



[figure 6]



[figure 7]

20 mm Femoral Sleeve

A. Prepare the femoral canal as described in the S-ROM Noiles Rotating Hinge Surgical Procedure (page 7). Advance the universal broach reamer until the most proximal depth mark (labeled "20, 31 and 34 mm") on the reamer shaft reaches the plane of the femoral distal resection. Remove the universal broach reamer.

Note: If femoral distal augmentation blocks will be used on both the medial and lateral sides, stop the universal broach reamer 5 or 10 mm from the distal resection.

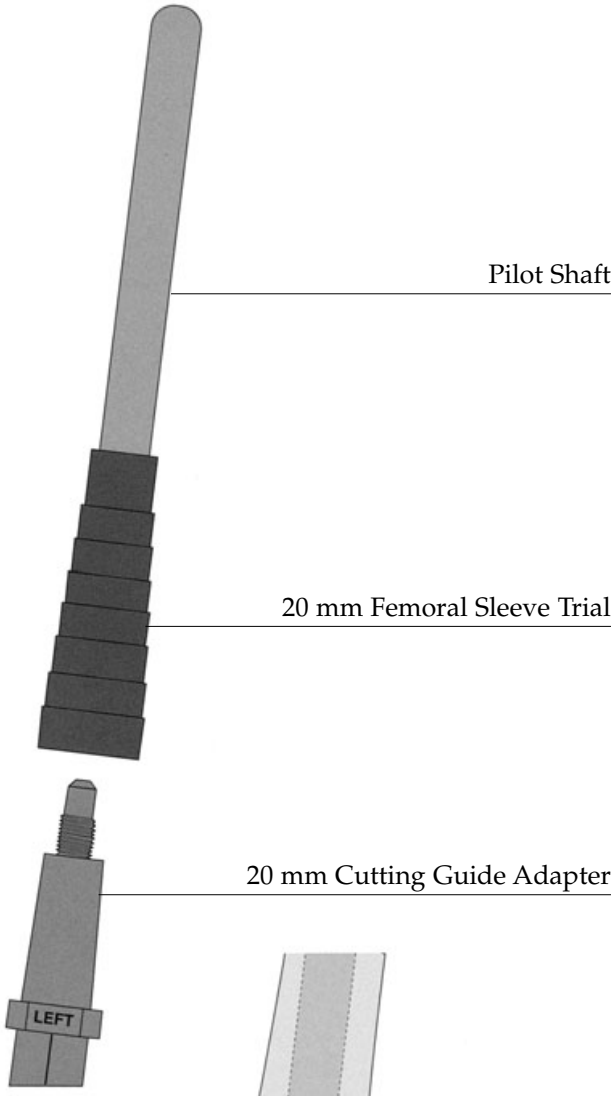
B. Screw the pilot shaft which matches the last straight reamer diameter into the 20 mm femoral sleeve trial [fig. 8].

C. Screw the 20 mm cutting guide adapter into the sleeve trial. This adapter provides the 7 valgus angle and tapped hole required for mounting the IMount cutting guides [fig. 8].

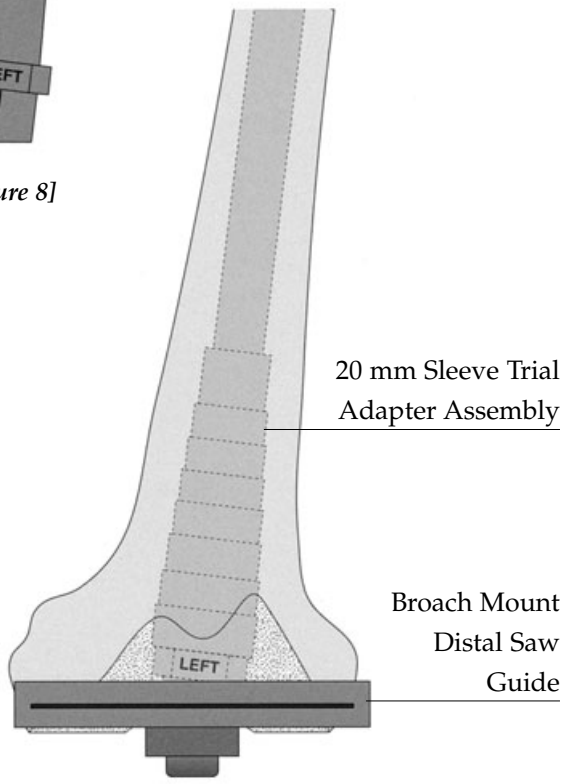
Note: Ignore the "posterior" engraving on the 20 mm sleeve trial for this step. Use the engraving only when assembling onto the S-ROM Noiles Rotating Hinge femoral component trial to avoid impinging on the femoral box.

D. Slide the femoral sleeve assembly partially into the femoral canal. The appropriate side (left or right) engraving must point anteriorly [fig. 8].

E. Proceed with the femoral distal resection as described in the S-ROM Noiles Rotating Hinge Surgical Procedure (page 9) [fig. 9].



[figure 8]



[figure 9]

FEMORAL AUGMENTATION BLOCKS

Two femoral augmentation blocks are available for the S-ROM Noiles Rotating Hinge Total Knee System. They are 5 and 10 mm distal blocks. One size fits all, i.e. x-small, small, and medium hinge femoral components.

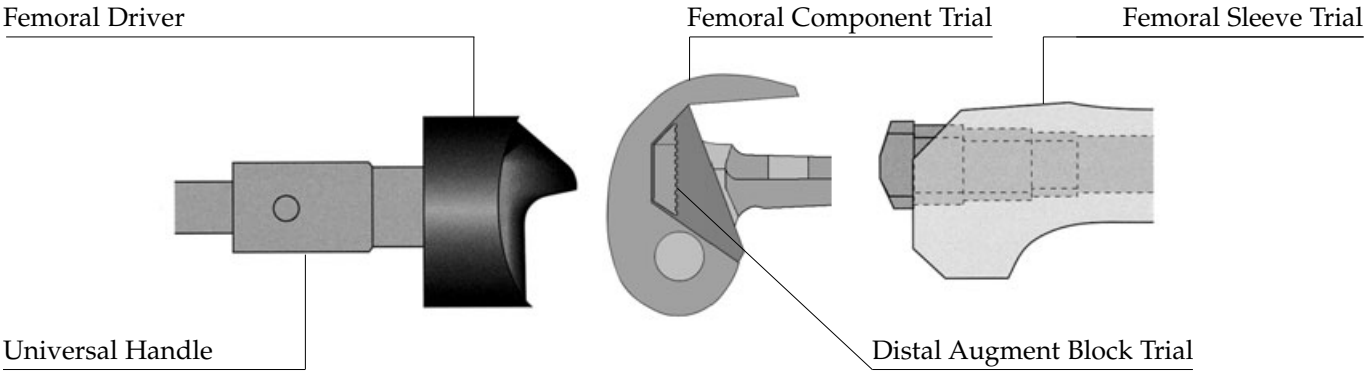
Implant Cat. No.	*Femoral Location*	*Use With S-ROM Noiles Rotating Hinge Femoral Size*	*Augmentation Thickness*	*Trial Cat. No.*
623805	Distal	all sizes	5 mm	633785
623810	Distal	all sizes	10 mm	633790

TRIAL REDUCTION

A. Slide the femoral sleeve trial assembly into the femoral canal. Insert only as deep as the distal resection.

B. Using bone wax, attach the augmentation block trial(s) as appropriate to the femoral component trial [fig. 10].

C. Proceed with the trial insertion as described in the S-ROM Noiles Rotating Hinge Surgical Procedure (page 13).



[figure 10]

IMPLANTATION

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

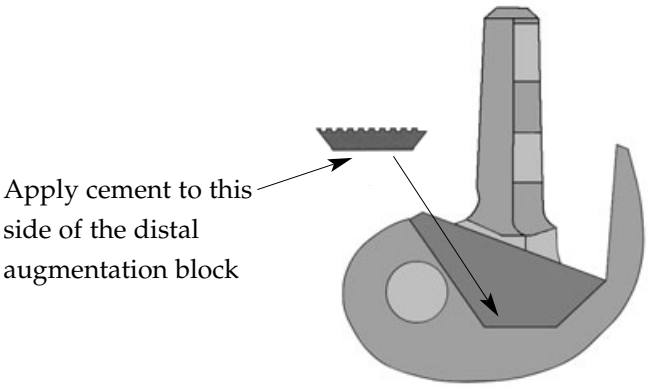
B. Apply cement to the augmentation block(s) on the side which contacts the femoral component, and to the corresponding surface(s) of the femoral component [fig. 11].

C. 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.

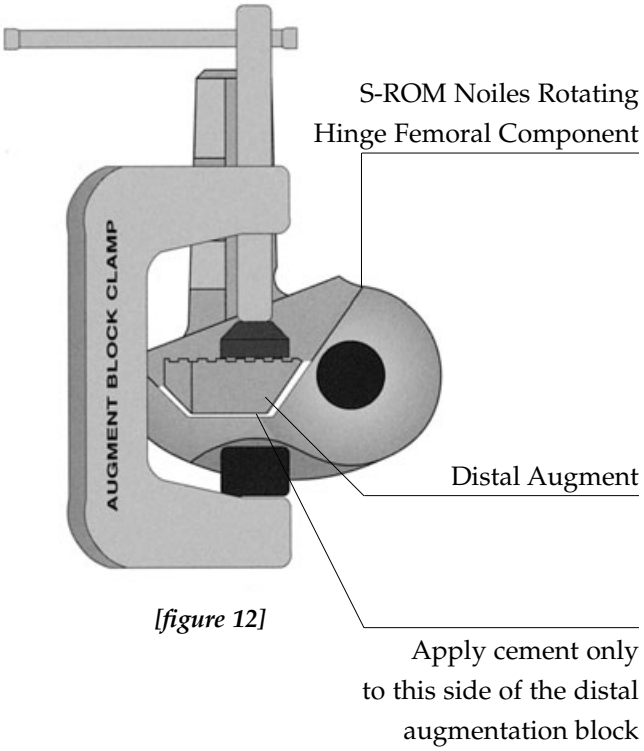
Note: When distal augmentation blocks are used with the S-ROM Noiles Rotating Hinge femoral component, place the augment block clamp into the distal condylar "pocket" of the femoral component [fig. 12].

D. The remainder of the mixed cement may be used to implant the patella and tibial component while the blocks are setting.

E. Continue with surgical procedure (page 16).

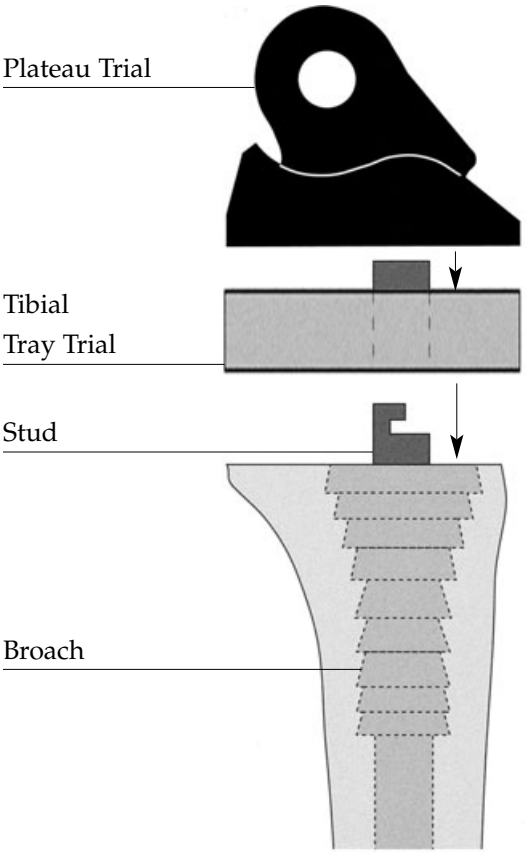


[figure 11]



[figure 12]

14 and 24 mm Modular Tibial Base

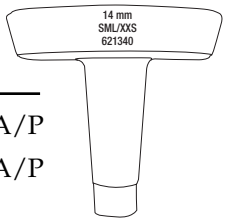


[figure 13]

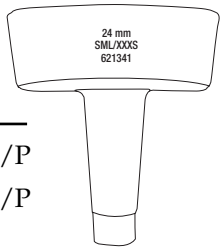
In cases of severe tibial bone loss, use the 14 or 24 mm tibial tray. The trays are similar to the standard modular tray but instead of being 4 mm thick, they are 14 or 24 mm thick. They accept the same stems and sleeves as the standard modular tray.

To use a 14 or 24 mm tray, follow the technique for tibial preparation (pages 4-6). After preparing the tibia, leave the final tibial broach in place. To trial, place the 14 or 24 mm trial over the stud of the broach. It is not necessary to use the view plate. The 14 and 24 mm trials are the thickness of the final implant. Place the appropriate tibial plateau trial over the stud of the 14 or 24 mm tray trial. Evaluate.

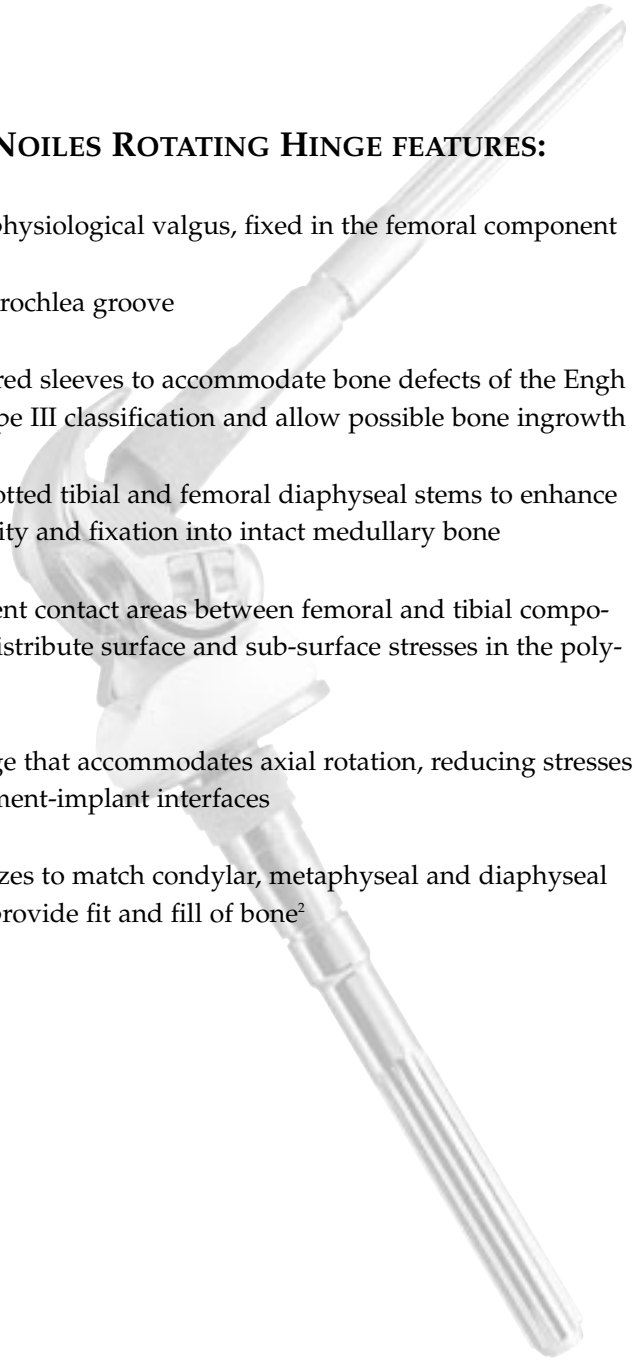
For assembly, follow the same "Final Tibial Component Assembly" steps as outlined in this technique, substituting the 14 or 24 mm tray for the standard tray (page 17).



14 mm	
Proximal	70 mm M/L x 47 mm A/P
Distal	60 mm M/L x 37 mm A/P

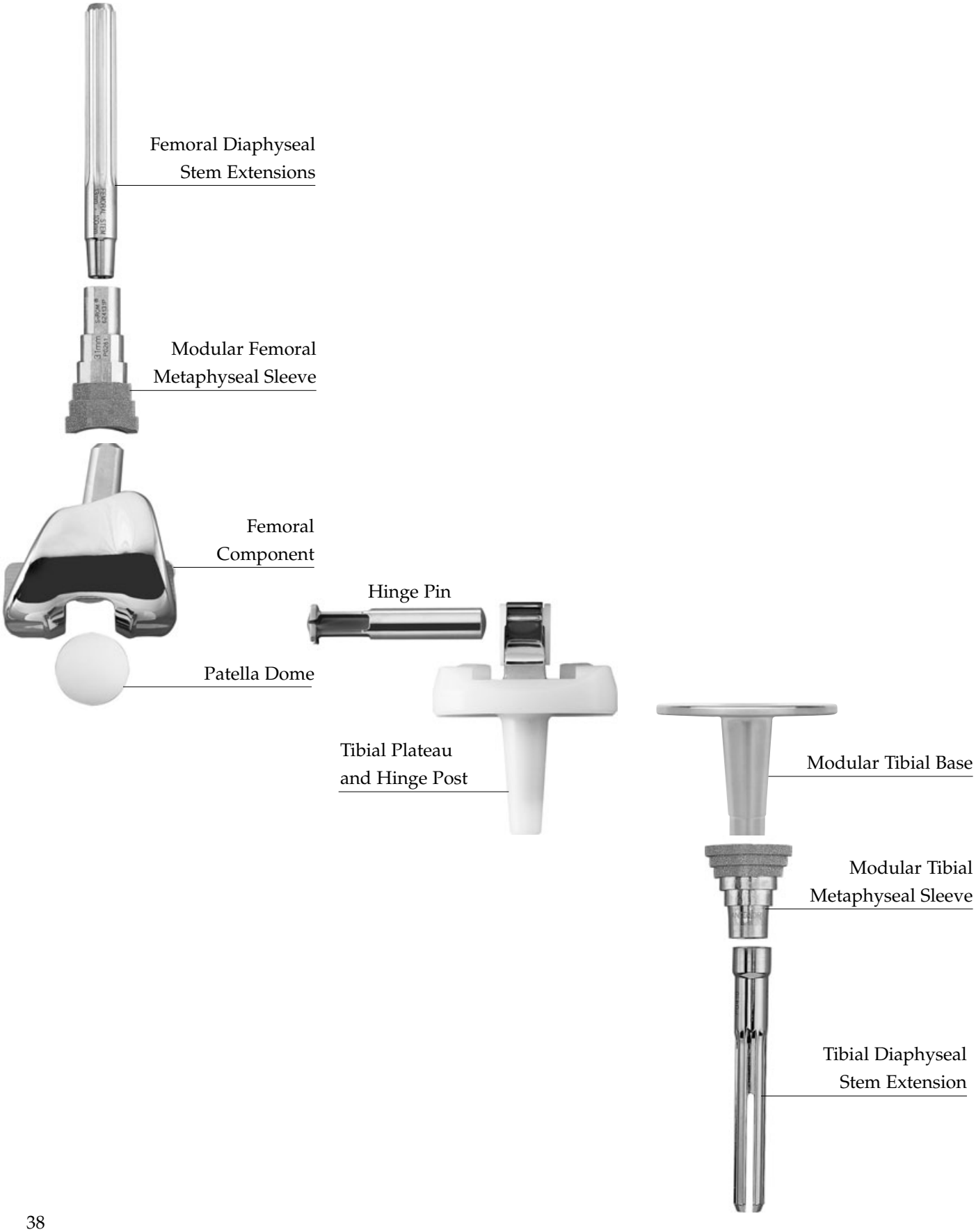


24 mm	
Proximal	70 mm M/L x 47 mm A/P
Distal	55 mm M/L x 35 mm A/P



The S-ROM Noiles Rotating Hinge features:

1. Seven degree physiological valgus, fixed in the femoral component
2. Deep femoral trochlea groove
3. Modular textured sleeves to accommodate bone defects of the Engh Type II and Type III classification and allow possible bone ingrowth
4. Splined and slotted tibial and femoral diaphyseal stems to enhance torsional stability and fixation into intact medullary bone
5. Broad, congruent contact areas between femoral and tibial components to best distribute surface and sub-surface stresses in the polyethylene
6. A rotating hinge that accommodates axial rotation, reducing stresses at the bone-cement-implant interfaces
7. Selections of sizes to match condylar, metaphyseal and diaphyseal anatomy and provide fit and fill of bone[2]


Femoral Diaphyseal
Stem Extensions
Modular Femoral
Metaphyseal Sleeve
Femoral
Component
Patella Dome
Hinge Pin
Tibial Plateau
and Hinge Post
Modular Tibial Base
Modular Tibial
Metaphyseal Sleeve
Tibial Diaphyseal
Stem Extension

IMPLANT LISTING

Femoral Components with Hinge Pin

Cat. No.	Size	M/L (mm)	A/P (mm)
62-3421L	X-Small A/P	66	58
62-3421R	X-Small A/P	66	58
62-3411L	Small	66	62
62-3411R	Small	66	62
62-3401L	Medium	71	66
62-3401R	Medium	71	66

Modular Tibial Bases

Cat. No.	Size	M/L (mm)	A/P (mm)
62-1320	X-Small	66	44
62-1321	Small	71	48
62-1322	Medium	76	51
62-1323	Large	81	54
62-1324	X-Large	87	58
62-1340	14 mm tray Small/XX Small	70/60	47/37
62-1341	24 mm tray Small/XX Small	70/55	47/35
62-6001	Cap with Screw*		

*The cap should be used when a tibial stem extension is not used. The cap adds approximately 20 mm to the keel length.
Note: Any size tibial base may be used with any size rotating hinge tibial plateau.

Tibial Plateaus with Hinge Bearing

Cat. No.	Use with Femoral Size	Thickness (mm)
62-1601	X-Small	12
62-1602	X-Small	16
62-1603	X-Small	21
62-1604	X-Small	26
62-1605	X-Small	31
62-1611	Small	12
62-1612	Small	16
62-1613	Small	21
62-1614	Small	26
62-1615	Small	31
62-1621	Medium	12
62-1622	Medium	16
62-1623	Medium	21
62-1624	Medium	26
62-1625	Medium	31

Note: The size of the rotating hinge femoral component determines the size of the rotating hinge tibial plateau.

Femoral Augmentation Blocks

Cat. No.	Use with Femoral Size	Distal Thickness (mm)
62-3805	X-Small/Small/Medium	5
62-3810	X-Small/Small/Medium	10

UHMWPE Patella Domes

Cat. No.	M/L	A/P (mm)	Length (mm)
62-1630	30	8	3.5
62-1632	32	8.5	4
62-1635	35	9	5
62-1638	38	10	6

Modular Femoral Sleeves

Cat. No.	M/L	A/P (mm)	Length (mm)
62-4101	20	20	65
62-4131P	31	21	65
62-4134P	34	23	73
62-4140P	40	25	81
62-4146P	46	25	89
62-6010*	Plug with Screw		8

*For use when a femoral stem extension is NOT used.

Modular Femoral Stem Extensions with Screw

Cat. No.	Diameter (mm)	Length (mm)
62-8110	11	100 Straight
62-8130	13	100 Straight
62-8150	15	100 Straight
62-8170	17	100 Straight
62-8190	19	100 Straight
62-8210	21	100 Straight
62-8115	11	150 Bowed
62-8135	13	150 Bowed
62-8155	15	150 Bowed
62-8175	17	150 Bowed

Note: Femoral stem must be used with a femoral sleeve.

Modular Tibial Sleeves

Cat. No.	M/L (mm)	A/P (mm)
62-1437P	37	24
62-1445P	45	26
62-1453P	53	29
62-1461P	61	32

Modular Tibial Stem Extensions with Screw

Cat. No.	Diameter (mm)	Length (mm)
62-7090	9	100 Straight
62-7110	11	100 Straight
62-7130	13	100 Straight
62-7150	15	100 Straight
62-7170	17	100 Straight
62-7190	19	100 Straight
62-7210	21	100 Straight
62-7095	9	150 Straight
62-7115	11	150 Straight
62-7135	13	150 Straight
62-7155	15	150 Straight

Tibial Augmentation Blocks
Use with Tibial Base Size

Cat. No.	Size	Thickness (mm)
62-1504	X-Small/Small	4
62-1508	X-Small/Small	8
62-1512	X-Small/Small	12
62-1514	Medium/Large	4
62-1518	Medium/Large	8
62-1522	Medium/Large	12
62-1524	X-Large	4
62-1528	X-Large	8
62-1532	X-Large	12

Note: Tibial augmentation CANNOT be used if a tibial sleeve is utilized.

NRH Tibial Instrumentation

Tibial Broaches

Cat. No.	Size (mm)
634550	37
634552	45
634554	53
634556	61

Tibial View Plates

Cat. No.	Size
633720	X-Small
633721	Small
633722	Medium
633723	Large
633724	X-Large

Modular Tray Trials

Cat. No.	Size (mm)
633291	14
633295	24

Tibial Plateau Trials

Cat. No.	Size	Size (mm)
633940	X-Small	12
633942	X-Small	16
633943	X-Small	21
633944	X-Small	26
633945	X-Small	31
633960	Small	12
633962	Small	16
633963	Small	21
633964	Small	26
633965	Small	31
633950	Medium	12
633952	Medium	16
633953	Medium	21
633954	Medium	26
633955	Medium	31
634560	Trial Plateau Post	
633701A	Tibial Broach Adapter	
633700A	Tibial I.M. Alignment Guide	
633705A	Tibial Saw Guide	
633712	Stylus	

NRH Femoral Instrumentation

Femoral Broaches

Cat. No.	Size (mm)
638880	31
638881	34
638882	40
638883	46

Femoral Cut Guides

Cat. No.	Size
633446	Broach Mount Distal Saw Guide
633386	X-Small/Small
633387	Medium
633385	Fem Box Cut Guide
634160	Box Trial
634170	Guide Handles
633399A	Saw Capture
633402	Distal Cutting Guide
633403	7 Degree Bushing
633404A	Distal Saw Guide
633409	8 mm Broach Adapter
633969	20 mm Femoral Sleeve Trial
633364	20 mm Cutting Guide Adapter

Femoral Trials

Cat. No.	Size
634161L	Left, X-Small
634161R	Right, X-Small
634151L	Left, Small
634151R	Right, Small
634132L	Left, Medium
634131R	Right, Medium
634133	Hinge Pin Trial

Femoral Sleeve Trials

Cat. No.	Size (mm)
633970	31
633971	34
633972	40
633973	46

NRH Femoral Instrumentation

Augment Spacers

Cat. No.	Size (mm)
633305A	5
633306A	10

Distal Augment Trials

Cat. No.	Size (mm)
633785	5
633790	10

Bowed Stem Trials

Cat. No.	Size (mm)
634211	11 x 150
634213	13 x 150
634215	15 x 150
634217	17 x 150
532502F	3.5 mm Screwdriver

NRH Common Instrumentation

Cat. No.	
633344	3.2 mm x 3" Drill Bit
633343	3.2 mm x 4" Drilll Bit
530302	Hudson to Zimmer Adapter
633348	11 mm Bone Drill
632903	Universal Broach Reamer
633801	Tibial Driver
633802	Femoral Driver

NRH Common Instrumentation

Cat. No.	
634182	Femoral Sleeve Separator
634180	Hex Screw Driver
633810	Augment Block Cement Clamp
633516	IM Rod

Straight Reamers

Cat. No.	Size (mm)
635509	9
635511	11
635513	13
635515	15
635517	17
635519	19
635521	21

NRH Common Instrumentation

Pilot Shafts

Cat. No.	Size (mm)
634409	9 x 100
634411	11 x 100
634413	13 x 100
634415	15 x 100
634417	17 x 100
634419	19 x 100
634421	21 x 100

Saw Blades (0.89 mm or 0.035")

Cat. No.	Size	Description
5627-41-000	1"	Old Stryker
5627-42-000	1/2"	Old Stryker
5627-43-000	1"	New Stryker
5627-44-000	1/2"	New Stryker
5627-45-000	1"	New Zimmer
5627-46-000	1/2"	New Zimmer
5627-47-000	1"	3M
5627-48-000	1/2"	3M
5627-49-000	1"	Old Zimmer
5627-50-000	1/2"	Old Zimmer

S-ROM MODULAR TOTAL KNEE SYSTEM • NOILES ROTATING HINGE KNEE SYSTEM

IMPORTANT

This essential product information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

INDICATIONS AND USAGE

The Noiles Rotating Hinge Knee is indicated for use with PMMA bone cement in primary or revision cases in patients: who have reached skeletal maturity and for whom the surgeon has decided to resect both cruciate ligaments or whose cruciate ligaments are absent or incompetent and who exhibit insufficiency of lateral/collateral ligaments and other soft supporting tissue due to the following conditions: rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, and arthritis secondary to a variety of diseases and anomalies, failure of a previous knee reconstruction procedure, trauma.

CONTRAINDICATIONS

- Active infection or history of general infections or local infectious disease.
- Vascular insufficiency, muscular atrophy or neuromuscular disease in the affected limb.
- Advanced loss of osteochondral structure that would preclude proper fixation of the prosthesis.
- Tumors of the supporting bone structure, systemic and metabolic disorders leading to progressive deterioration of solid bone support.
- Drug or alcohol addiction, or limiting neuropathic disease.
- Skeletal immaturity.
- Obesity or very active lifestyle that can produce loads on the prosthesis that can lead to failure of the fixation of the device or device itself.
- Allergic reaction to the implant materials.
- Inadequate flexor and extensor mechanism necessary to achieve a functional prosthetic joint.

WARNINGS

Improper prosthesis selection or alignment, inadequate fixation, use where contraindicated or in patients whose medical, physical, mental, or occupational conditions will likely result in extreme stresses to the implant, may result in premature failure due to loosening, fracture, or wear.

The S-ROM tibial base, tibial sleeve, tibial stem extension, and tibial augmentation blocks may not be used with the Noiles Posterior Stabilized Knee.

PRECAUTIONS

The Noiles Rotating Hinge Knee is designed to articulate from 6° hyperextension to 110° flexion. If, due to grossly inadequate soft tissue integrity, flexion beyond 90° causes luxation of the plateau assembly out of the tibial base, the patient must have a knee brace postoperatively to limit flexion to 90°. In such cases, the surgeon should consider closing the wound with the knee in full extension.

- The size of the tibial plateau assembly must correspond with the size of the femoral component.
- The size of the tibial augmentation block must correspond to the size of the tibial base.
- Femoral sleeves are required when using femoral stem extensions.
- A femoral plug is required with the femoral sleeve when a femoral stem extension is not used.
- A tibial cap is required with the tibial sleeve when a tibial stem extension is not used.
- Tibial augmentation blocks cannot be used when tibial sleeves are being used.
- The wear rate of prosthesis contact surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces. When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.

ADVERSE EFFECTS

Fracture may occur due to improper preparation of the implant site or if excessive force is used during seating of the implant. Transient peroneal palsy has been reported following total knee arthroplasty, especially after correction of severe flexion or valgus deformities.

Patients have complained of persistent pain and stiffness following total knee arthroplasty. In addition, patellar tendon rupture, femoral-tibial subluxation or dislocation, and persistent ligamentary laxity have been reported with the use of total knee implants. Infection and loosening have been reported following total joint arthroplasty, as have wear and failure due to fracture of knee prosthesis components.

REFERENCES

1. Jones, R. E., "Management of the Bone-Deficient Knee Management of Complex Revision Problems with a Modular Total Knee System" Orthopedics, Sept. 1996: 802-804.
2. Jones, R.E. , R.L. Barrack, "Modular, Mobile-Bearing Hinge Total Knee Arthroplasty," Presented at 2001 AAOS.

The S-ROM Noiles Rotating Hinge Knee has been cleared for cemented application.

For more information about the S-ROM Noiles Rotating Hinge Knee, visit our web site at **www.jnjgateway.com/sromknee**.

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