



Life
Uncompromised™

KineSpring® Knee Implant System Surgical Technique Guide

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Trademarks

KineSpring is a registered trademark of Moximed, Inc.

Patents

The KineSpring System family of products is offered by Moximed and may be protected by one or more of the following patents: US 7,632,310; US 7,655,041; US 7,763,020; and US 7,846,211; other patents pending.

Requests For Information

For information, contact the authorized EC Representative or Moximed Customer Service listed on the back cover.

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The KineSpring System

The KineSpring System is designed to treat pain and loss of function secondary to medial knee OA by absorbing joint overload. A complete system (one Femoral Base, one Tibial Base, and one Absorber) is implanted subcutaneously on the medial side of the knee using standard orthopaedic techniques. The bases are fixed to the bone using a series of bone screws, and each base is attached to a ball and socket joint which articulates with the central spring-like absorber component. The extra-capsular absorber unloads a portion of knee joint load, and the articulations maintain natural kinematics.

Bases

Titanium femoral and tibial bases are designed to provide optimal fit to the shape and contour of the bone. There are three Femoral Base contours (40°, 45°, 50°) that represent different angulations between the socket and the base surface to find a best fit with the patient's metaphyseal flare of the femoral epicondyle. The Femoral Base is also provided with a femoral placement guide, which temporarily attaches to the base and is used to position the base at the identified femoral target location. There is one Tibial Base shape available.

Each Low Contact (LC) Base has three small, 3 mm spacers on the undersurface to reduce the contact between the base and the underlying bone.

Absorber

The Absorber is provided pre-compressed with a restraining cable that is removed during the procedure. There are cut-outs at the femoral and tibial ends of the Absorber to facilitate cutting of the restraining cable. A clear, peel-away covering holds the ball and socket articulations in place during Absorber placement.



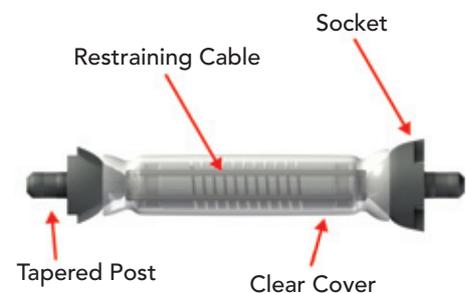
Femoral Placement Guide



Femoral Base



Tibial Base



Absorber

Procedure Pack

While standard orthopaedic techniques are used to implant the KineSpring System, a custom Procedure Pack facilitates correct placement and implantation of the device. All drill bits and K-wires in the Procedure Pack set can be used with power tools and standard drill chucks. The drill bits are also compatible with AO style couplings, and the K-wires are compatible with standard pin drivers. As with all instruments, please follow the standard precautions:

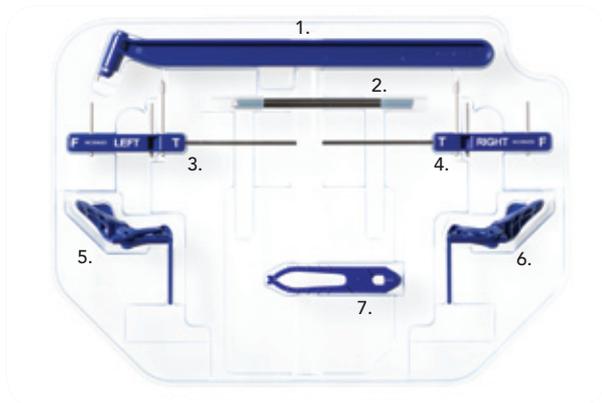
1. Inspect devices prior to use for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
2. Inspect devices immediately upon removal from the patient for any signs of breakage or fragmentation.

This single use Procedure Pack cannot be reused on another patient, as it is not designed to perform as intended after the first usage. Changes in mechanical, physical, and/or chemical characteristics after repeated use, cleaning, and/or resterilization may compromise the integrity of the design and/or materials; lead to contamination due to narrow gaps and/or spaces; and diminish safety and/or performance of the device. Absence of original labeling and packaging may lead to misuse, device damage, loss of sterility, eliminate traceability, and elevate risk of injury to the patient and/or user.

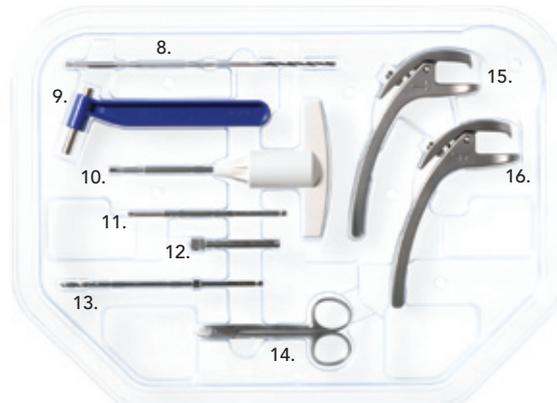
For a complete list of Indications, Contraindications, Cautions, Warnings, and Precautions, please review the Instructions for Use for the KineSpring Knee Implant System.

In addition to the Procedure Pack, general orthopaedic instruments commonly used in this procedure include:

- Scalpels
- Scissors
- Hemostats
- Power driver with drill chuck and K-wire collet
- Retractors
- Elevators
- Forceps



Top Level Tray



Bottom Level Tray

1. Targeting Tool
2. 2.4 mm K-wires
3. Alignment Guide, Left
4. Alignment Guide, Right
5. Femoral Trial, Left
6. Femoral Trial, Right
7. Socket Puller

8. 3.2 mm Cancellous Drill
9. Drill Guide, 3.2 mm
10. Torque Driver, 3.5 mm Hex, 4.0 Nm
11. 3.5 mm Hex Bit Driver
12. 4.3 mm Locking Drill Guide
13. 4.3 mm Locking Drill
14. Cable Cutter
15. Locking Tool, Tibial
16. Locking Tool, Femoral

1. Targeting Tool: Allows surgeon to place the target femoral K-wire. It contains two concentric, radiopaque rings to assist in placing the target femoral K-wire in the correct location and angulation.

2. 2.4 mm K-wires: Standard K-wires to assist with placement and temporary fixation of the KineSpring System.

3 - 4. Alignment Guide: Facilitates placement of K-wires that assist with correct location and orientation of the KineSpring System. The position of the femoral K-wire and the distal tibial K-wire represent the center of the ball at the femoral and tibial ends of the Absorber. The posterior tibial K-wire provides a stop against which the Absorber rests during Tibial Base fixation.

5 - 6. Femoral Trial: Assists the surgeon in selecting the correct Femoral Base contour. The indicator represents the orientation of the implanted Absorber, and when it is correctly positioned, the femoral trial measures which Femoral Base contour (40°, 45°, or 50°) best fits the patient anatomy.

7. Socket Puller: Attaches to the femoral socket and assists surgeon in mating the Absorber to the Femoral Base.

8. 3.2 mm Cancellous Drill: Standard drill bit used to drill the holes for the cancellous compression screws.

9. Drill Guide, 3.2 mm: Correctly aligns the 3.2 mm cancellous drill when drilling holes for the cancellous compression screws.

10. Torque Driver, 3.5 mm Hex, 4.0 Nm: Controls the torque applied during final tightening of the locking screws and during locking of the Absorber to the Bases. The 3.5 mm Hex can also be used to hand-tighten the cancellous compression screws.

11. 3.5 mm Hex Bit Driver: Standard 3.5 mm Hex bit driver that can be used to tighten all screws with a standard power driver.

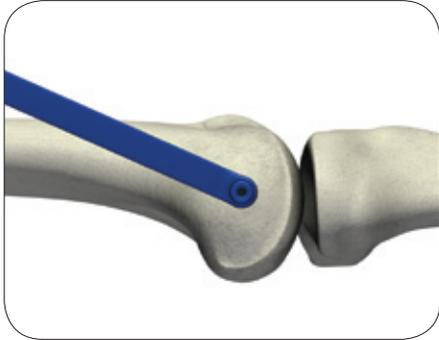
12. 4.3 mm Locking Drill Guide: Correctly aligns the 4.3 mm locking drill when drilling holes for the locking screws. This guide mates with the screw threads on the Bases and has a stop to indicate when the hole depth has been achieved.

13. 4.3 mm Locking Drill: Standard drill bit used to drill the holes for the locking screws.

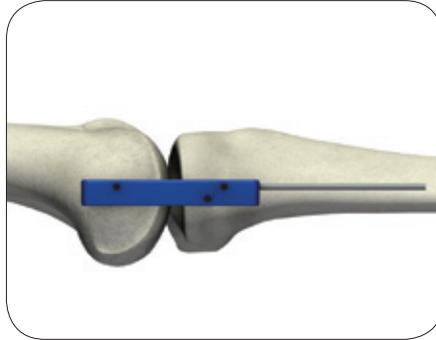
14. Cable Cutter: Used to cut the restraining cable that pre-compresses the Absorber.

15 - 16. Locking Tool: When tightened with the torque driver, the locking tool secures the socket taper of the Absorber into the Bases.

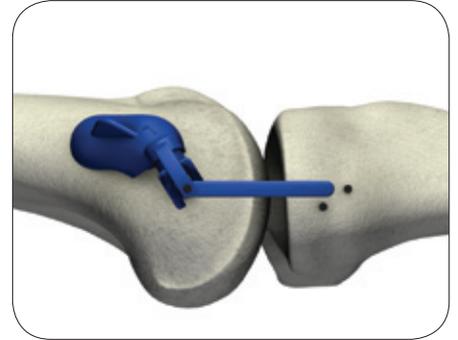
Procedure Summary



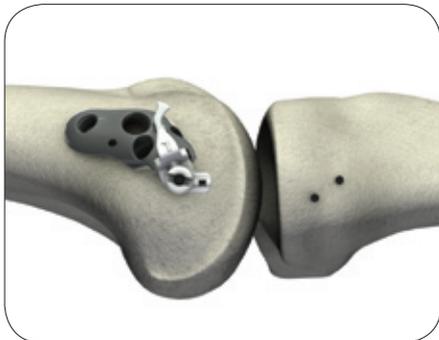
Step 1. Select femoral target



Step 2. Determine Absorber alignment



Step 3. Select Femoral Base



Step 4. Fix Femoral Base



Step 5. Connect Absorber & Tibial Base



Step 6. Insert Absorber in tunnel and place tapered post in base



Step 7. Connect Absorber & Femoral Base



Step 8. Align & fix Tibial Base under varus



Step 9. Activate Absorber

Preoperative Planning

Patient Set-up

Place the patient supine on the operating table with both limbs fully extended, but allow for peri-procedural knee flexion. Place a bump under the hip/thigh of the operative leg, and elevate the operative leg at the ankle to facilitate surgical access and allow unobstructed fluoroscopy.



C-arm

Position the C-arm under the table with only the imaging head extending above the patient. The C-arm should be roughly perpendicular to the operative limb, and the area along the operating table should be clear to allow the C-arm to slide away from the surgical site during the procedure.

C-arm Tips

- C-arm technician should stand on the side of the operative knee
- Position the target anatomy in the center of the image

True Lateral View

Achieve a true lateral fluoroscopic image with the femur in the center of the monitor. Roll the hip until the posterior femoral condyles are aligned. Move the entire leg medial or lateral to align the distal femoral condyles.

Tips for Obtaining True Lateral View

- Manage the hip/thigh to obtain true lateral views; manipulating the foot may inadvertently rotate the tibia and result in sub-optimal device placement
- Obtain true lateral view before sterile prep

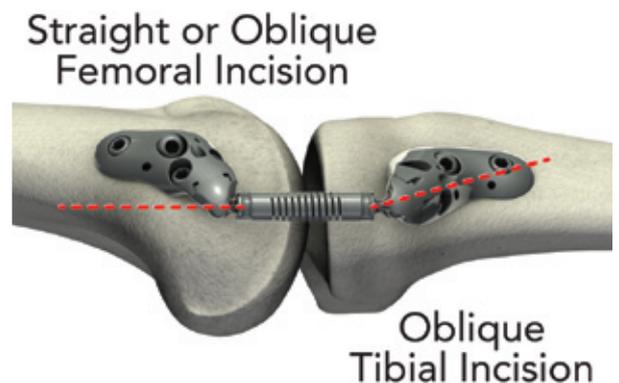
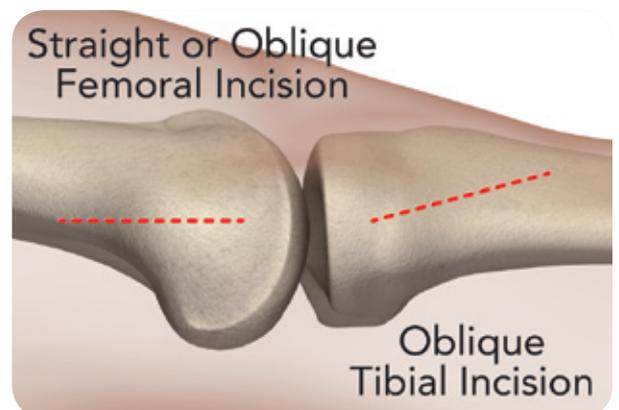
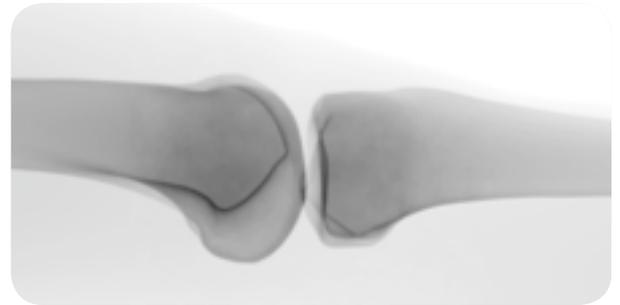
Approach and Exposure

Access the medial aspect of the operative knee from the patient's contralateral side. Two 5-8 cm incisions will be connected by a skin bridge and subcutaneous tissue tunnel. The Femoral Base will be placed sub-vastus on the femur, and the Tibial Base will be placed anterior to the insertion of the pes anserinus.

Tips for Approach and Exposure

- Generous incision lengths have been found to greatly improve procedural ease
- The Tibial Base placement is on the anterior-medial aspect of the tibia, and an oblique incision often facilitates accurate base positioning

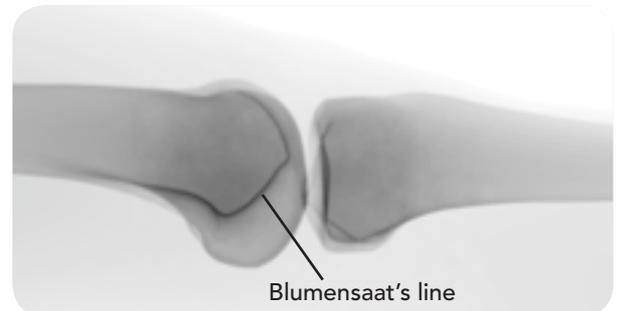
CAUTION: If visible, superficially use dissecting scissors to dissect small nerves as necessary. If visible, retract branches of the saphenous nerve, such as the infrapatellar branch. Leave saphenous nerve branches superficial to the absorber to avoid compression of cutaneous nerve branches between the device hardware, capsule and bone.



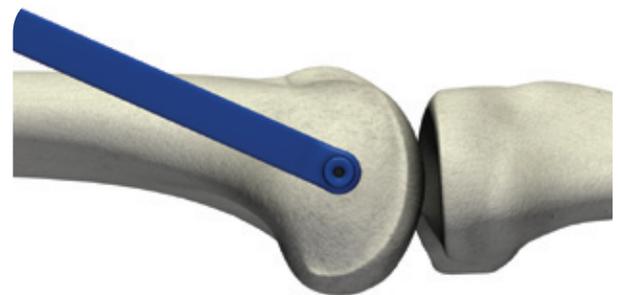
Note: Illustration depicts final device position to help the surgeon visualize the location of the incisions relative to the device.

Select Femoral Target

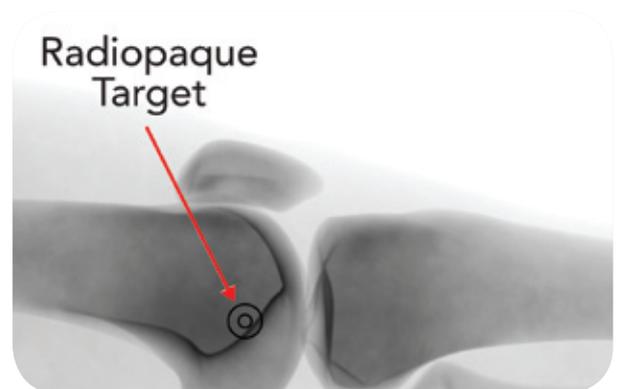
Under fluoroscopy, confirm a true lateral view.



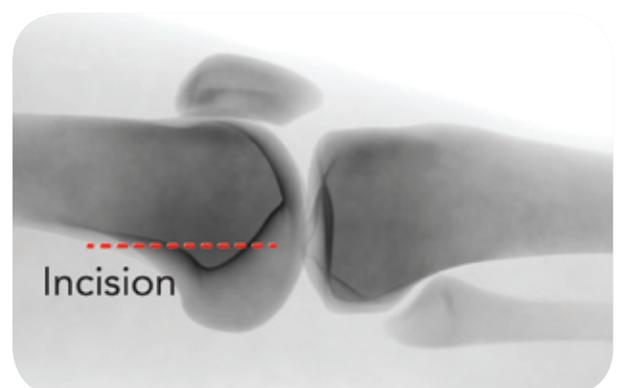
Place the Targeting Tool near the midpoint of Blumensaat's Line to plan the distal edge of the femoral incision.



Note: This initial targeting step assists with planning the general location of the femoral incision. More precise targeting occurs after the femoral incision is completed.

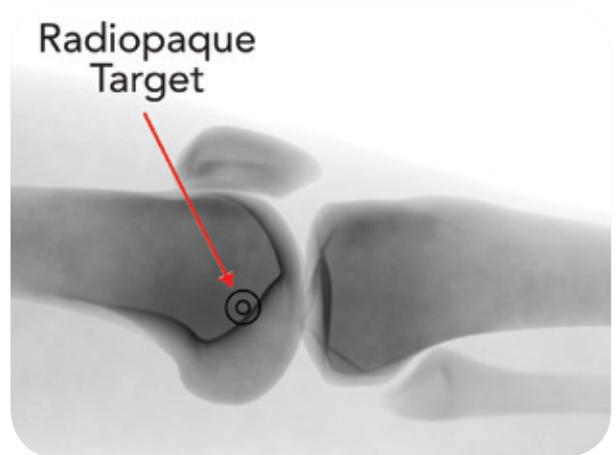


Make an incision that begins slightly distal to the midpoint of Blumensaat's line and extends away from the joint line. The incision should be 5-8 cm in length along the axis of the femoral shaft.



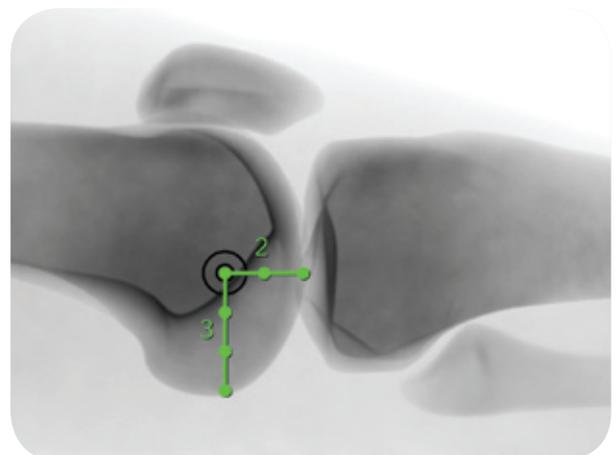
Insert the Targeting Tool into the desired position, then place a K-wire in the tool:

- Anterior to the midpoint of Blumensaat's Line
- Inner ring of Targeting Tool touches midpoint of Blumensaat's Line



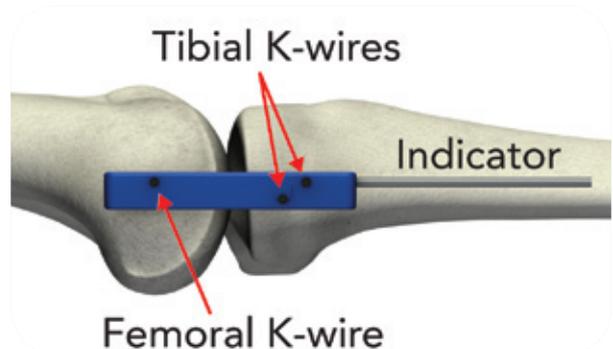
Tip: $\frac{\text{Distance to Distal Femoral Condyles}}{\text{Distance to Posterior Femoral Condyles}} = \frac{2}{3}$

Use a mallet to gradually insert the K-wire deep into the femoral condyle. The K-wire should appear as a dot within the rings and should never touch the outer ring. This confirms that the K-wire is entering the femur at the correct angle. Continue to insert the K-wire until 5 cm protrudes from above the Targeting Tool.

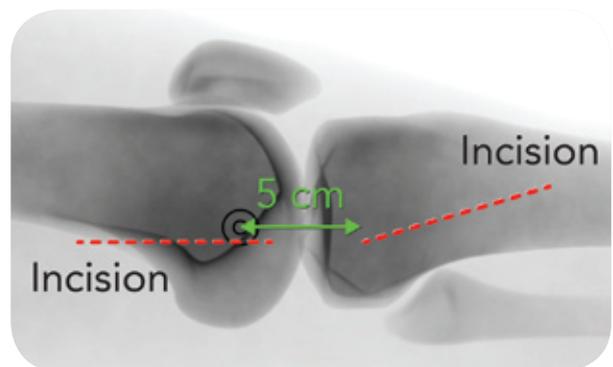


Determine Absorber Alignment

Confirm the knee is at full extension. Place the Alignment Guide over the femoral target K-wire, and align the indicator so that it is parallel to the tibial axis. Make an incision that begins at the proximal tibial K-wire hole and extends through the location of the distal tibial K-wire hole until the total incision length is 5-8 cm.



Create a tissue tunnel using blunt dissection between the two incisions. Allow for generous tunnel width that is free of fibrous attachments and provides sufficient clearance for a full and unobstructed range of motion. Create the tunnel for the absorber superficial to the capsule of the medial knee joint leaving maximal soft tissue superficial to the device, ensuring that the device is minimally prominent under the skin.



With the knee at full extension, orient the Alignment Guide indicator so that it is parallel to the tibial axis and press firmly to bone.

Insert a K-wire into the proximal tibial K-wire hole of the Alignment Guide. The proximal K-wire will be driven deeper than the subsequent distal K-wire. Next place a K-wire into the distal tibial hole of the Alignment Guide. Confirm alignment of the indicator under fluoroscopy. Remove the Alignment Guide.



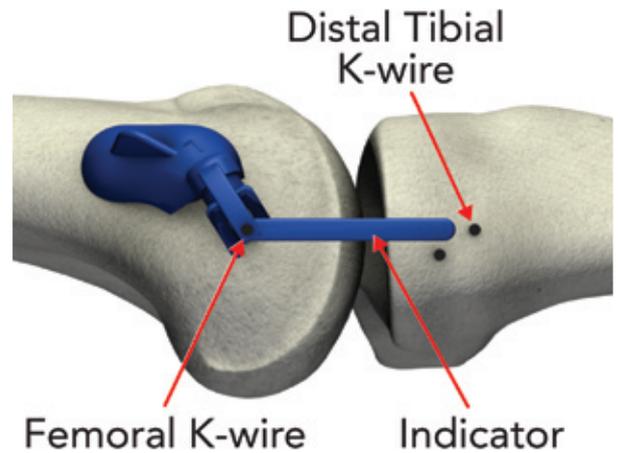
The distal K-wire represents the location of the tibial ball of the Absorber and will assist with Femoral Base selection and alignment. The proximal K-wire will support the Absorber prior to Tibial Base fixation.

Select Femoral Base

Retract vastus medialis to place the Femoral Base.

CAUTION: Manage the medial superior genicular artery, if visible, to avoid post-operative hematoma.

Insert the Femoral Trial over the target femoral K-wire and hold it firmly against bone, then align the indicator with the distal tibial K-wire. The indicator represents the correct orientation of the Absorber, and aligning the indicator with the distal tibial K-wire takes precedence over optimizing fit of the base on the bone.

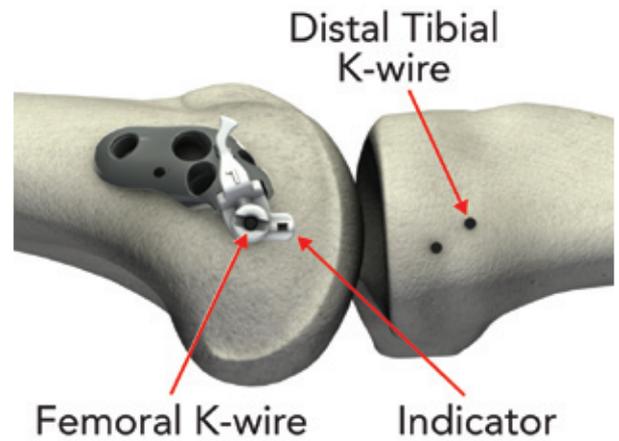


Once the indicator is correctly aligned, the pointer on the Femoral Trial will identify the Femoral Base whose contour (40°, 45°, or 50°) best matches the metaphyseal flare of the patient's femur. For clarification, the 45° contour is only chosen if the tip of the pointer lies in the white painted area (the image to the right indicates a 40° contour). Choose the Femoral Base indicated by the trial.



Fix Femoral Base

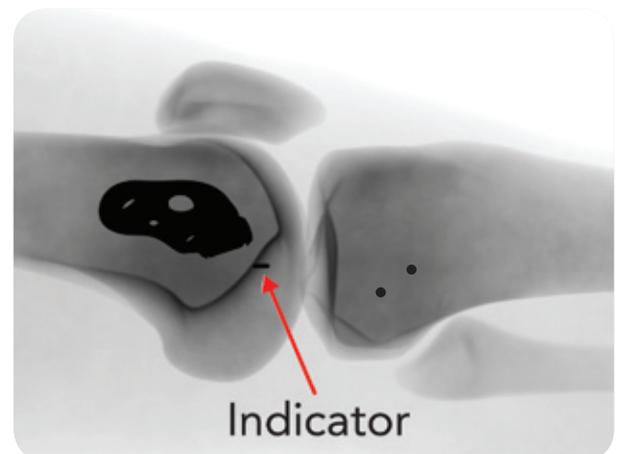
Place the Femoral Base over the target femoral K-wire. The indicator on the base should be aligned with the distal tibial K-wire.



While holding the Femoral Base firmly against bone, insert a K-wire into the base for stabilization and confirm position under fluoroscopy:

1. Knee is at full extension.
2. Tibial shaft is visible and indicator is aligned with distal tibial K-wire.

Manually confirm that the base is pressed to bone.



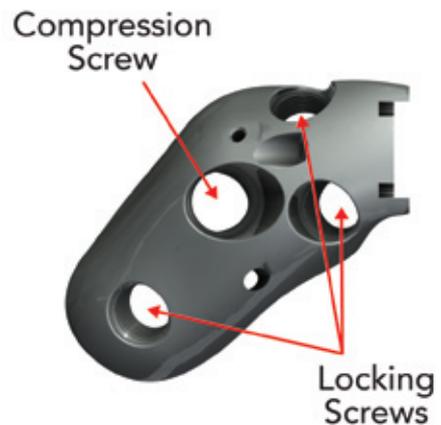
The compression screw should be inserted first to compress the base to the bone. Using the 3.2 mm drill guide, pre-drill a hole to accommodate a 6.5 x 40 mm cancellous compression screw in the center screw hole. Mind the drill depth, as the 3.2 mm drill does not have a hard stop. Insert the compression screw.

Using the 4.3 mm drill guide, pre-drill three holes to accommodate 5.0 mm locking screws. The 4.3 mm drill has a hard stop for the recommended 34 mm screw length. Insert the three locking screws. The order of screw insertion is not important, but the indicator of the Femoral Placement Guide should remain in the direction of the distal tibial K-wire.

Tip: Complete final tightening of all locking screws manually with the torque-limiting driver to avoid overtightening, which may lead to screw damage or difficult screw removal, if needed. Tighten the compression screw only until snug, and no more, so as not to strip the threads of the bone.

Remove the femoral K-wires, capture pin, and Femoral Placement Guide from the Femoral Base. Also remove the distal tibial K-wire. The proximal tibial K-wire should remain in the tibia.

Tip: To remove the white Femoral Placement Guide, grasp the proximal flare of the component with a hemostat. Pull the component away distally from the Femoral Base.



1. Lift Tab Of Femoral Placement Guide



2. Pull Femoral Placement Guide Away From Femoral Base

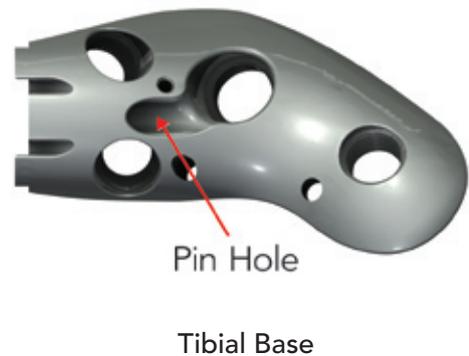
Connect Absorber and Tibial Base

Insert the tapered post of the socket on the Absorber into the Tibial Base.

Place the Tibial Locking Tool over the Absorber and Tibial Base so that the assembly is captured within the instrument. Confirm that the tibial socket is securely held by the Tibial Locking Tool and the pin is inserted into the pin hole on the Tibial Base.

Tip: Place the Tibial Locking Tool over the Absorber socket first, then mate the arm of the Locking Tool into the pin hole on the Tibial Base.

Insert the torque-limiting driver into the Tibial Locking Tool and tighten until two audible clicks are heard. Confirm that the gap between the base and socket is closed.



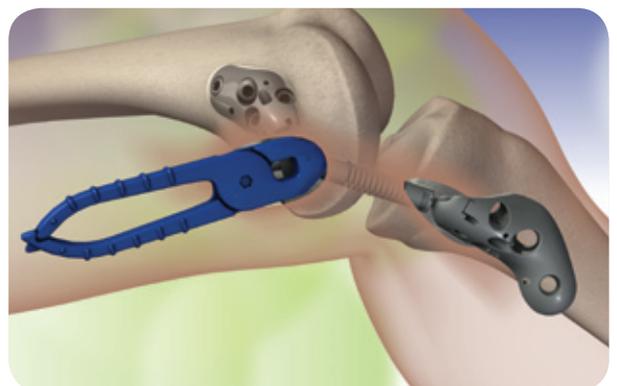
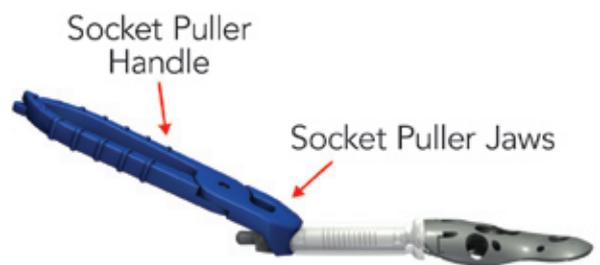
Place Absorber in Tunnel

Flex the knee to 45° and insert the Absorber through the tibial incision and through the tissue tunnel. Pull the Absorber far enough proximally so that the Tibial Base can be tucked into the incision.

Tip: To facilitate Tibial Base positioning, pull the Absorber proximally until the Tibial Base begins to enter the tissue tunnel. Then slide the assembly distally while keeping the Tibial Base inside the incision.

The Socket Puller may be used to assist placement of the tapered post into the Femoral Base. To do so, open the jaws of the Socket Puller with a scissor-like motion. Attach the Socket Puller to the femoral socket and close the jaws of the Socket Puller until the ends of the handle lock.

While grasping the handle of the Socket Puller, guide the tapered post of the Absorber socket into the Femoral Base, then remove the Socket Puller.



Connect Absorber and Femoral Base

Place the Femoral Locking Tool over the Absorber and Femoral Base so that the assembly is captured within the instrument. Confirm that the femoral socket is securely held by the Femoral Locking Tool and the pin is inserted into the pin hole on the Femoral Base.

Tip: The process should be identical to that used for the Absorber/Tibial Base assembly. Place the Femoral Locking Tool over the Absorber socket first, then mate the arm of the Locking Tool into the pin hole on the Femoral Base.

Insert the torque-limiting driver into the Femoral Locking Tool and tighten until two audible clicks are heard. Confirm that the gap between the base and socket is closed and free of tissue.



Femoral Base



Align and Fix Tibial Base

Place the knee in full extension and rest the distal end of the Absorber on the tibial K-wire. Confirm that the Absorber is parallel with the tibial shaft.

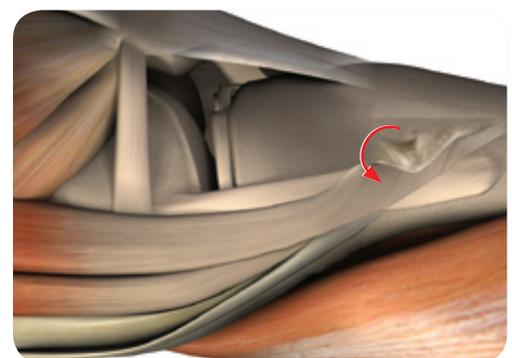
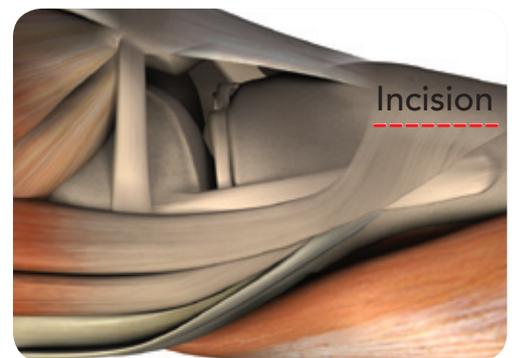
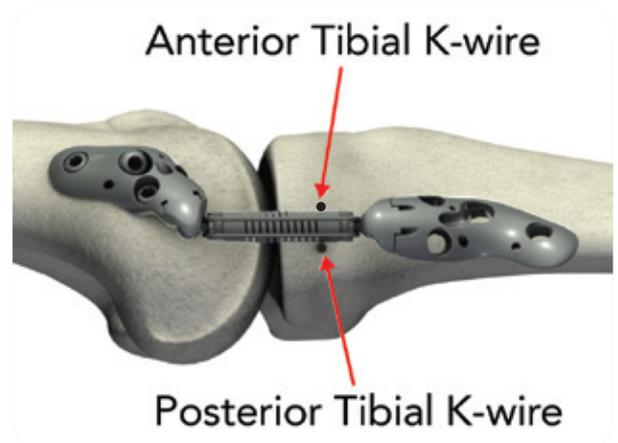
Tip: While holding the Absorber against the posterior K-wire, place a K-wire on the anterior side of the Absorber, opposite the existing K-wire. The two K-wires will help maintain correct Absorber positioning parallel to the tibial shaft.

Rotate the Tibial Base in the counter-clockwise direction so that the anterior edge of the base is roughly parallel with the tibial shaft.

The distal fibrous insertion of the pes anserine must be released prior to base fixation. To do so, perform sharp periosteal dissection and elevation of the conjoined tissues of the periosteum and pes anserine. Ensure that all pes anserine tissues are elevated from anterior to posterior to allow the base to sit on the bone free of any underlying fibrous insertion tissue of the pes anserine.

Important: Flex the knee just enough to unlock the knee from the screw home mechanism. Apply only enough varus stress to close the medial joint space while stabilizing the Tibial Base with two K-wires.

Once implanted, do not attempt to suture soft tissue under tension over tibial base; simply let it lie over the base.



Manually confirm that the base is pressed to bone and the Absorber is not impinging on the joint.

Tip: If the Absorber is impinging on the joint, elevate the proximal edge of the Tibial Base to increase the offset between the base and the tibia.

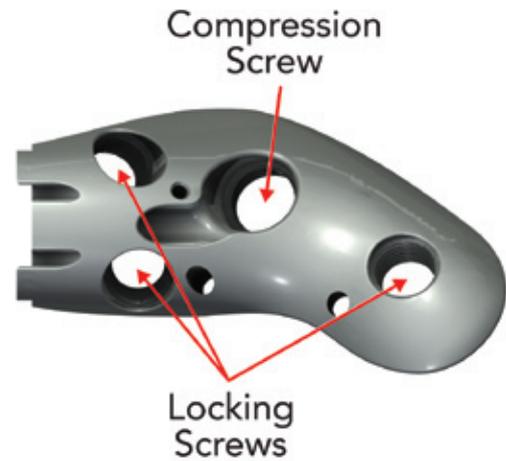
Tip: With the Tibial Base stabilized with two K-wires, confirm the following checks:

- Varus stress was held during K-wire insertion
- Anterior edge of Tibial Base is parallel to tibial shaft
- Absorber is parallel with tibial shaft
- Femoral socket and proximal Absorber do not impinge
- In the AP fluoroscopic view, the Absorber is not too close to the joint

After confirming desired device positioning, secure the Tibial Base with screws. The procedure is the same as that used to fix the Femoral Base.

The compression screw should be inserted first to compress the base to the bone. Using the 3.2 mm drill guide, pre-drill a hole to accommodate a 6.5 x 40 mm cancellous compression screw in the center screw hole. Insert the compression screw.

Warning: The 3.2 mm drill does not have a hard stop. Avoid penetrating the joint capsule when drilling the tibial screw holes.

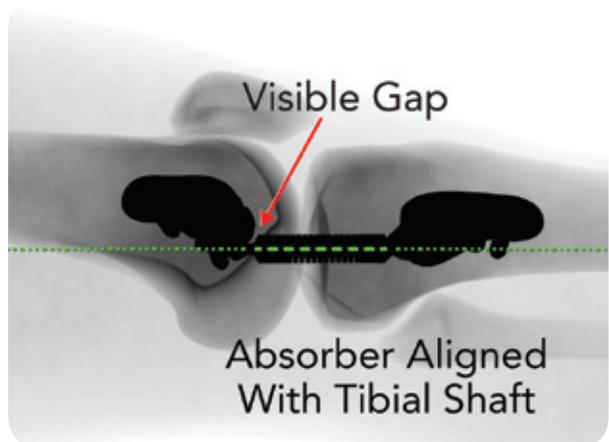


Using the 4.3 mm drill guide, pre-drill three holes to accommodate 5.0 mm locking screws. The 4.3 mm drill has a hard stop for the recommended 34 mm screw length. Insert the three locking screws, starting with the distal locking screw. The anterior edge of the Tibial Base and the Absorber should remain parallel to the tibial shaft.

Tip: Complete final tightening of all locking screws manually with the torque-limiting driver to avoid overtightening, which may lead to screw damage or difficult screw removal, if needed. Tighten the compression screw only until snug, and no more, so as not to strip the threads of the bone.

Remove all remaining K-wires.

Through the incision, grasp the tab of the clear peel-away covering with a long hemostat. With a firm but smooth action, tear the perforated tab distally along the axis of the Absorber. Remove the cover completely and discard.



Activate the Absorber

Cut and remove the restraining cable with the scissors. Assess motion in both lateral and AP fluoroscopy views. Check for full range of flexion/extension and varus/valgus motion without device impingement.

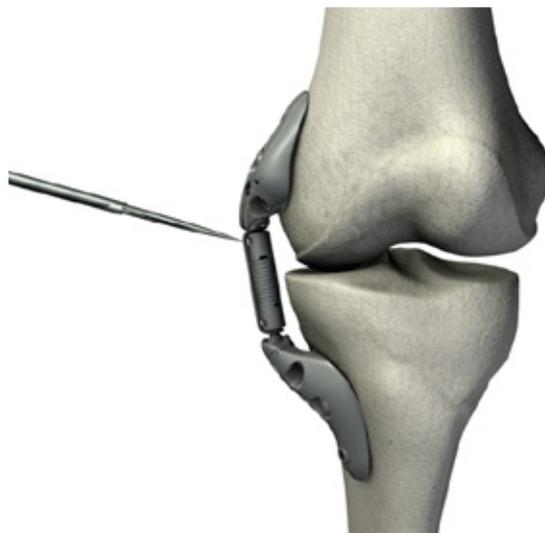
Tip: There are small cut-outs at the proximal and distal ends of the Absorber so that the scissors can access the cable.

Prior to closing, count the small parts used during surgery to make sure that none are left behind:

1. White Femoral Placement Guide
2. Capture Pin
3. Transparent Absorber Cover
4. Restraining Cable

Account for all of the instruments provided with the Procedure Pack.

Release the tourniquet, if used, and ensure hemostasis. Thoroughly irrigate the wound with the preferred solution and close.



Device Removal Technique - Taper Unlocking Tool

In the event that it is necessary to remove only the Absorber, consider the following technique. If the entire device is to be removed, simply remove all of the screws using standard technique, as described in step 3 below, then remove the entire system.

1. Position the knee in 40° to 60° of flexion. Orient the socket removal tool per the indicator on the handle. One end of the tool is labeled "T" for tibia, and one end is labeled "F" for femur.
2. Align the tabs of socket removal tool with the tabs in the base. Use a mallet to disengage the socket from the base. Complete this step for both the Femoral and Tibial Bases, then remove the Absorber.
3. Bases can be removed after all screws have been removed using standard technique, if necessary.

Tip: Use a new screwdriver to release the locking screws. Have a screw removal kit available, should a screw head become damaged during removal.

The Taper Unlocking Tool is supplied separately from the Procedure Pack. Please contact your Moximed representative to obtain the Taper Unlocking Tool.



Taper Unlocking Tool



Part Number	Description
1-1001	Single Spring Absorber
1-2018	LC Base Femoral 40° Left
1-2019	LC Base Femoral 40° Right
1-2020	LC Base Femoral 45° Left
1-2021	LC Base Femoral 45° Right
1-2022	LC Base Femoral 50° Left
1-2023	LC Base Femoral 50° Right
1-2024	LC Base Tibial 14mm Left
1-2025	LC Base Tibial 14mm Right
1-3000	Screw, Locking 5.0 x 34mm
1-3001	Screw, Cancellous 6.5 x 40mm
1-3002	Screw, Cancellous 6.5 x 50mm
1-3003	Screw, Locking 5.0 x 30mm
1-3006	Screw, Cancellous 6.5 x 35mm
1-3010	Screw, Cancellous 6.5 x 45mm
1-3011	Screw, Locking 5.0 x 34mm 6-PK
1-3012	Screw, Cancellous 6.5 x 40mm 2-PK
1-4022	Procedure Pack
1-4023	Taper Unlocking Tool



*Dedicated to improving the standard of care
for patients with Osteoarthritis*



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