

AperFix[®] System

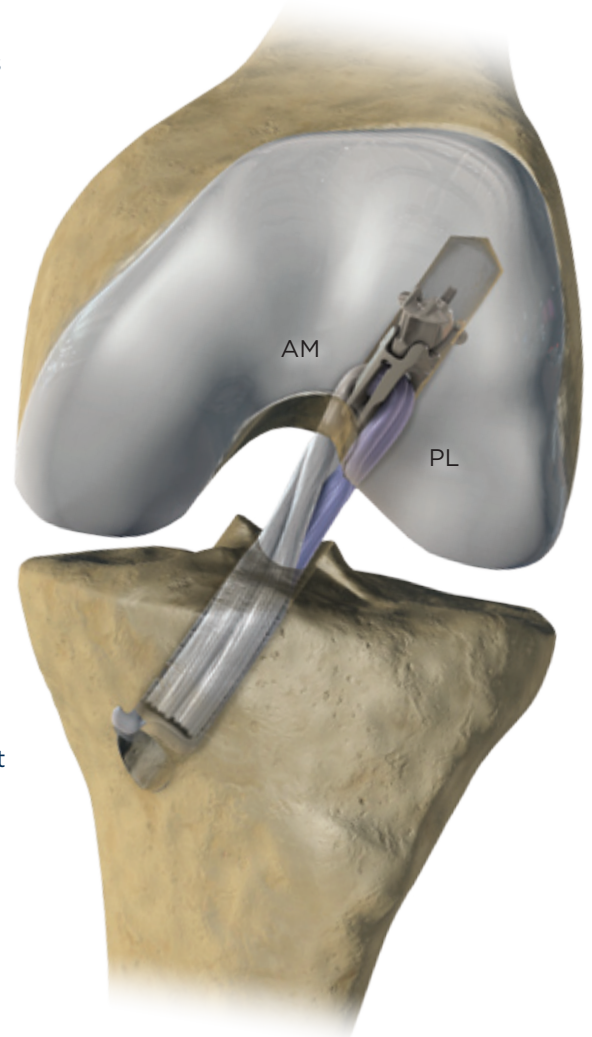
SURGICAL TECHNIQUE GUIDE

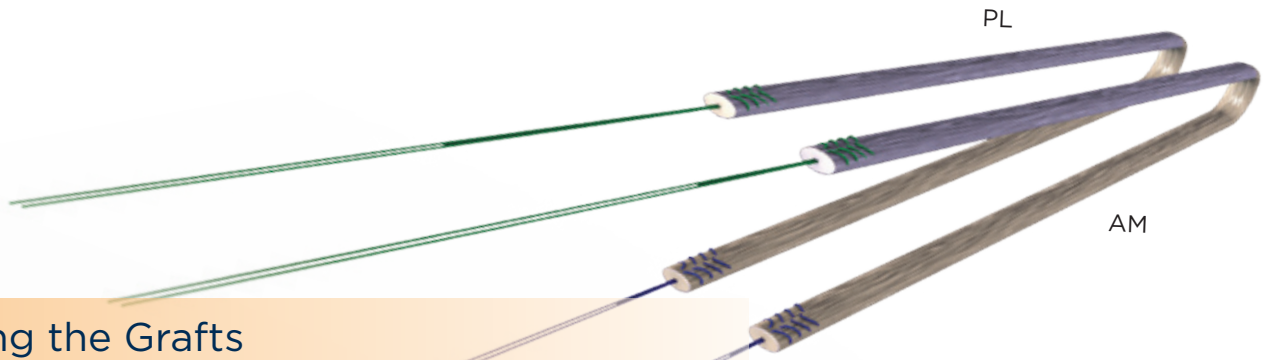
SINGLE TUNNEL. DOUBLE BUNDLE.[™]

The Cayenne Medical AperFix[®] System for Anterior Cruciate Ligament (ACL) reconstruction was designed to offer surgeons a strong fixation option for soft tissue grafts, with circumferential graft compression at the aperture, high pull-out strength and ease of use. A new technique was developed using the AperFix[®] System to reconstruct the ACL: the single-tunnel, double-bundle ACL reconstruction (STDB) which positions the bundles in a more anatomic orientation through a single femoral and tibial tunnel.

It is known that the ACL is composed of two bundles: the anteromedial bundle (AM) and the posterolateral bundle (PL):¹⁻³ Traditional transtibial ACL reconstruction recreates only the AM bundle. Recent data shows that this may not restore normal rotational knee kinematics.⁴⁻⁶ In order to address this deficiency in rotational stability, surgeons have developed techniques to reconstruct both the AM and PL bundles of the ACL using a double-bundle, two-tunnel reconstruction. These techniques, which require the placement of two tibial and two femoral tunnels, increase the complexity of the operation, which may result in increased complications and compromise revision surgery.

The AperFix[®] System STDB technique provides a simplified solution to reconstruct the ACL and restore native knee kinematics. This technique utilizes the implants' unique designs which allow for distinct bundle separation and anatomic placement of the AM and PL bundles at the femoral and tibial apertures. The surgeon is able to create a secure, stiff construct with a procedure that is less technically demanding, can be performed using a transtibial or anteromedial approach, minimizes tunnel widening and decreases operative time.





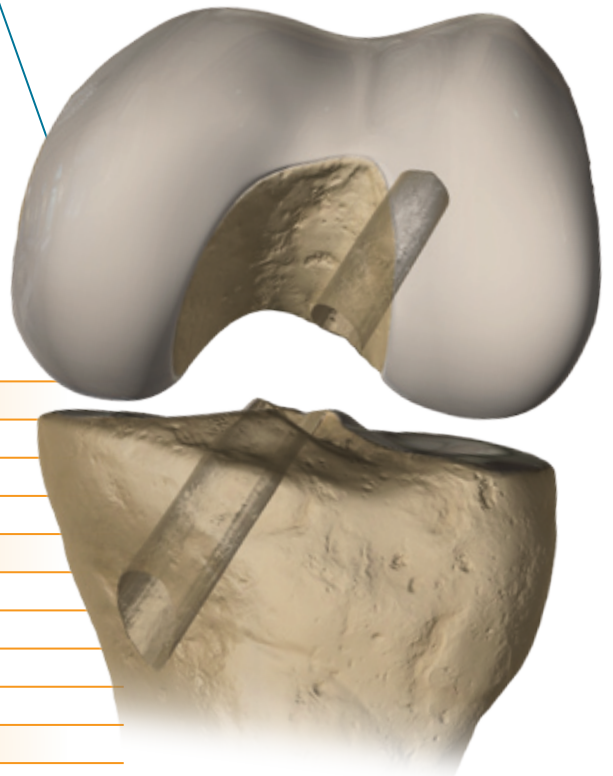
Preparing the Grafts

The AperFix soft tissue system can be used with hamstring autografts or various allografts. The following technique outlines graft preparation using the Gracilis and Semitendinosus tendons.

- 1** Whip stitch grafts with a sturdy suture (#2 nonabsorbable) in the usual fashion.

 - It is recommended to use two different colored sutures to distinguish between the AM and PL bundles. One end of the Semitendinosus Graft is stitched with a blue suture and the other end with a green suture. The same process is completed with the Gracilis Graft.
- 2** Pull the graft bundles through a Graft Sizing Block to determine the diameter of the implant to be used. Select a diameter through which the graft bundle fits tightly but still passes through.

 - Do not open the sterile AperFix Implants until proper sizing has been completed. Please refer to the sizing table below:
- 3** Create the tibial tunnel and femoral socket in the usual fashion. The femoral socket must be at least 30mm in length, and can be created utilizing a Transtibial or Anteromedial approach.



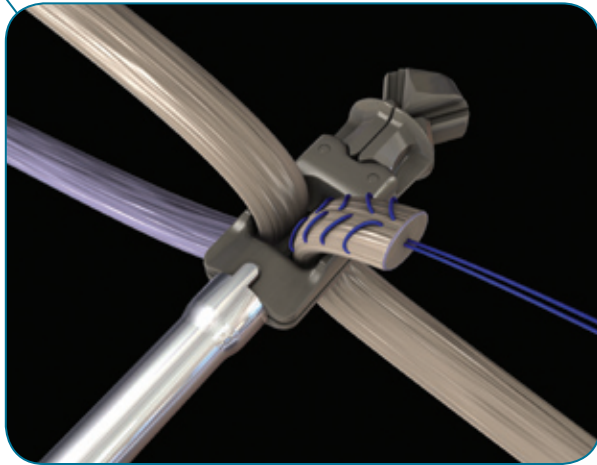
<i>If Femoral Tunnel Depth is:</i>	<i>Use:</i>
30mm or greater	29mm Implant
35mm or greater	29mm or 35mm Implant
<i>If Tendon Bundle Diameter is:</i>	<i>Use Femoral & Tibial:</i>
Less than 7.5mm	9mm Implants with 9mm Drills
7.5mm to 9mm	10mm Implants with 10mm Drills
9mm to 10mm	11mm Implants with 11mm Drills
<i>If Tendon Bundle Diameter is:</i>	<i>Use Tibial:*</i>
Less than 7mm	8mm Implants with 8mm Drills

*8mm AperFix Tibial Implant with the 8mm Tibial Drill can be used with the 9mm AperFix Femoral Implants and 9mm Femoral Drills, when following the AM portal technique.

Loading Grafts Into AperFix® Femoral Implant

4

Pass the prepared soft tissue double bundle grafts through the orifices of the AperFix Femoral Implant.



5

Wrap the sutures of the prepared tendons around the suture cleats of the inserter handle.

- To achieve optimal anatomical placement of bundles, it is recommended that the like-colored, sutured graft ends representing the AM bundle be wrapped on one suture cleat. The sutured ends representing the PL bundle should be wrapped on the opposite suture cleat.

6a

Make a horizontal mark on the tendon bundles at the inferior edge of the implant to serve as the aperture depth indicator.

AM PL

AM

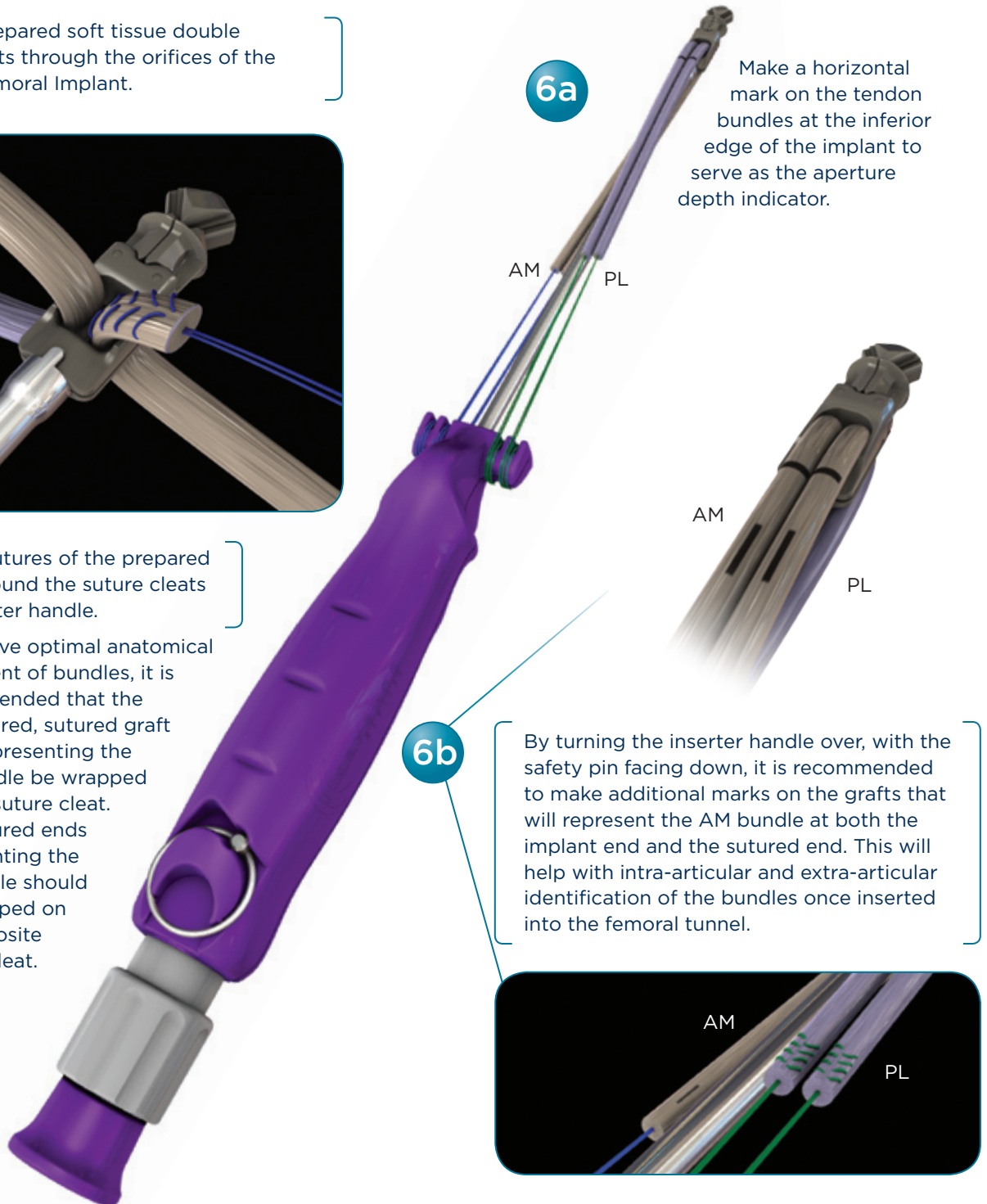
PL

6b

By turning the inserter handle over, with the safety pin facing down, it is recommended to make additional marks on the grafts that will represent the AM bundle at both the implant end and the sutured end. This will help with intra-articular and extra-articular identification of the bundles once inserted into the femoral tunnel.

AM

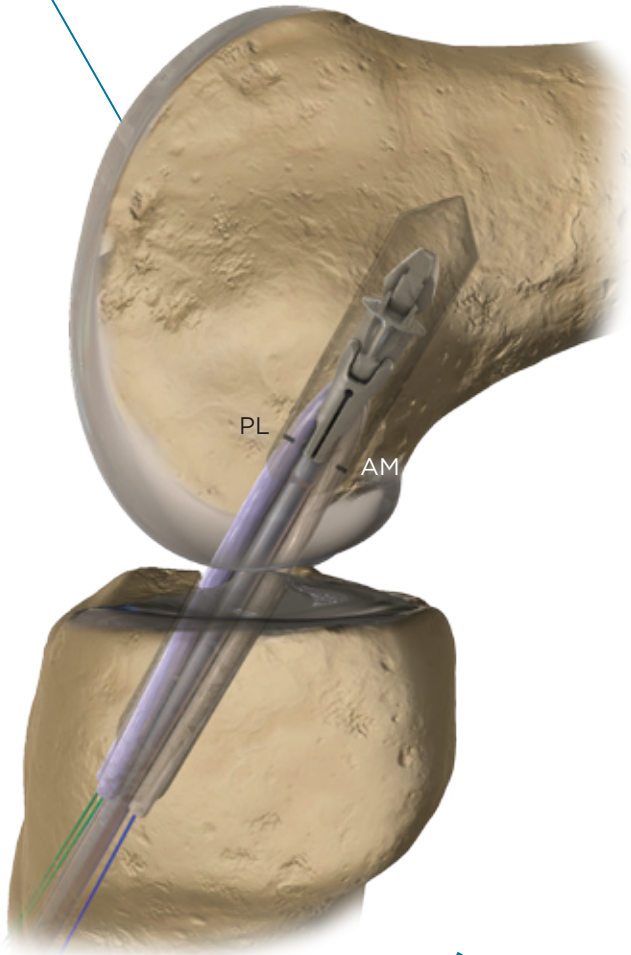
PL



Inserting AperFix® Femoral Implant

7

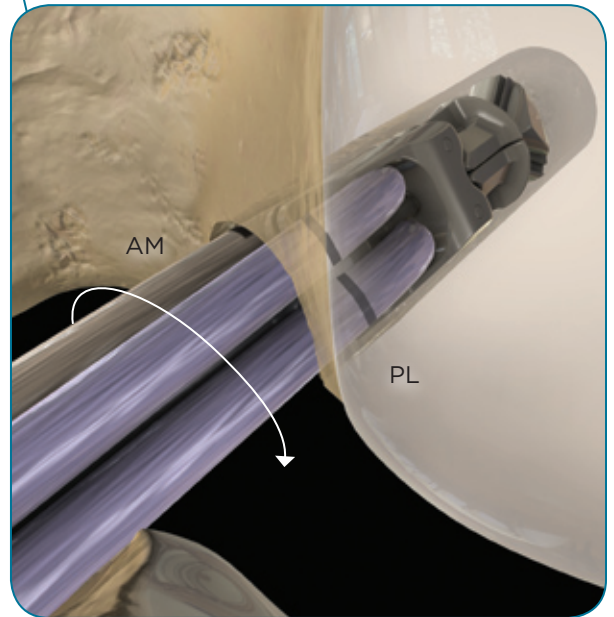
Holding the Implant Inserter Handle with the safety pin facing upward, insert the implant through the tibial tunnel and into the femoral socket to the marked depth location.



8

To achieve optimal anatomic femoral placement of the bundles, flex the knee to 90 degrees and rotate the inserter until the marked grafts representing the AM bundle are placed in the postero-superior position and the PL bundles are placed in the antero-inferior position.

- Orientation of the suture cleats, located on the inserter handle, will be approximately 10 and 4 o'clock for a left knee.



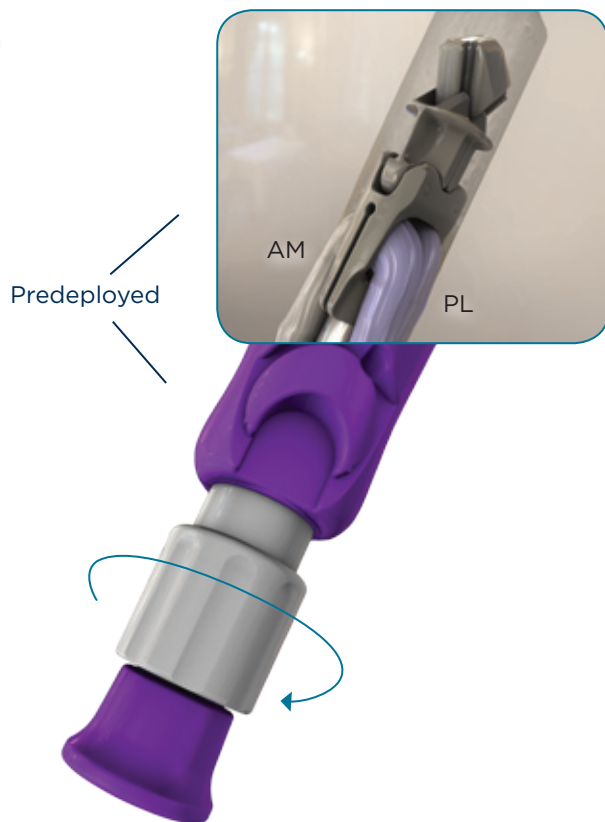
9

Ensure the implant is in proper position and pull the safety pin completely out.

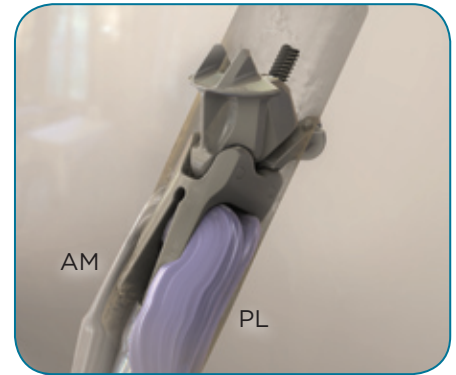
Deploying AperFix® Femoral Implant

10

With the inserter handle held firmly in place, rotate the white implant deployment knob clockwise until the deployment knob can no longer be turned and comes into contact with the purple inserter handle.

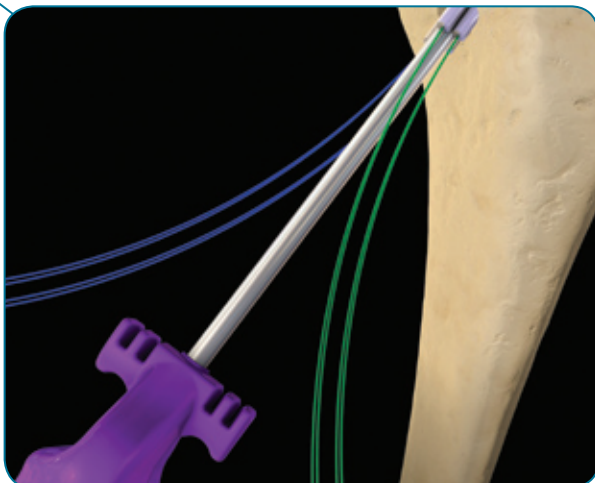


Deployed



11

Disengage the sutures from the suture cleats.



12

Release the inserter from the implant by pulling and holding the implant release knob, then drawing back the inserter handle. Remove the inserter from the operating site and discard.



Positioning the Graft Bundles

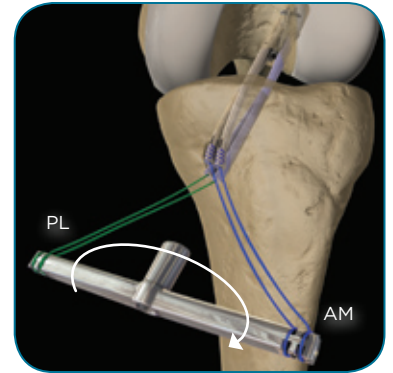
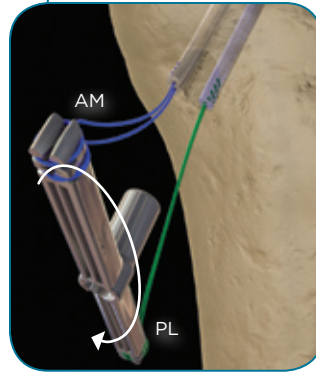
13

Select the AperFix Tibial Screw to match the drilled tunnel diameter. Securely place the Tibial Screw onto the Tibial Inserter Handle.



15a

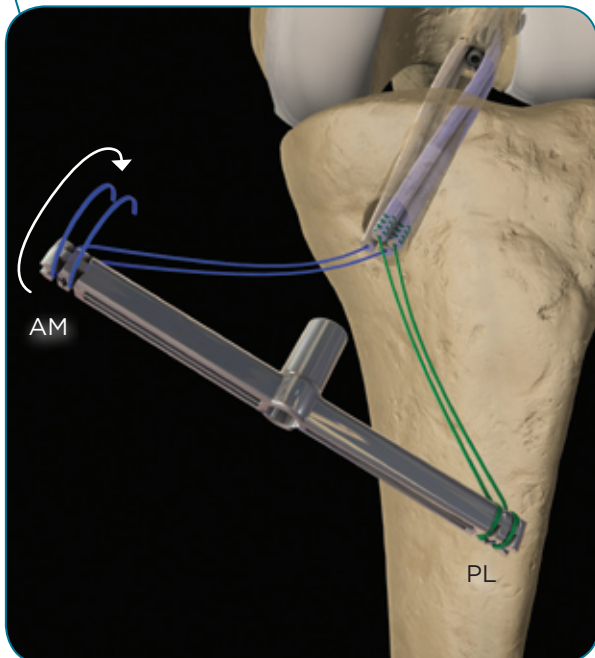
For proper orientation of the graft bundles at the tibial aperture, position the Tendon Expander until the tendons representing the AM bundle are positioned in the anteromedial portion of the tunnel and the PL bundle in the posterolateral portion.



14

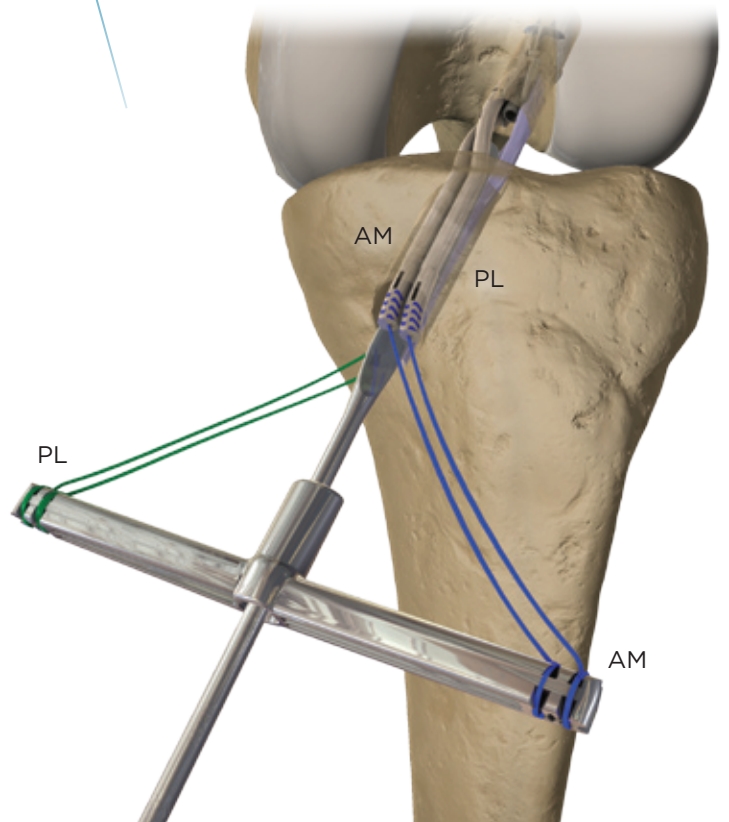
Hold the Tendon Expander perpendicular to the tibial tunnel and wrap the sutured ends of the tendon bundles around the suture cleats of the Tendon Expander, such that the sutures are first inserted in the lateral slits, then wrapped around the vertical cleats.

- Holding the bundles in the desired orientation, cycle the knee with applied tension to the graft.



15b

Positioning of the bundles can be facilitated by inserting a flat device, such as a freer elevator, into the tibial tunnel (between the bundles) to rotate the graft at the internal aperture.

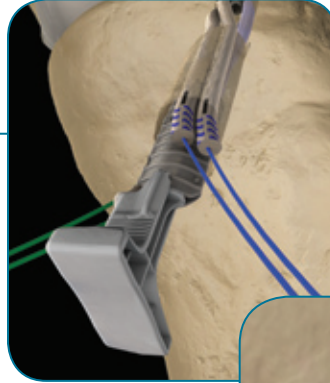


Inserting AperFix® Tibial Sheaths and Screw

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Place the knee in full extension and with the graft under tension, insert the Tibial Sheaths (in between the tendon bundles) into the tibial tunnel such that the cortical engagement tabs are in the 9 o'clock position for a left knee and 3 o'clock for a right knee.

- The sheaths should be positioned such that the tabs are fully seated against the tibia. Snap off the white Sheath Inserter to disengage from sheaths and discard.



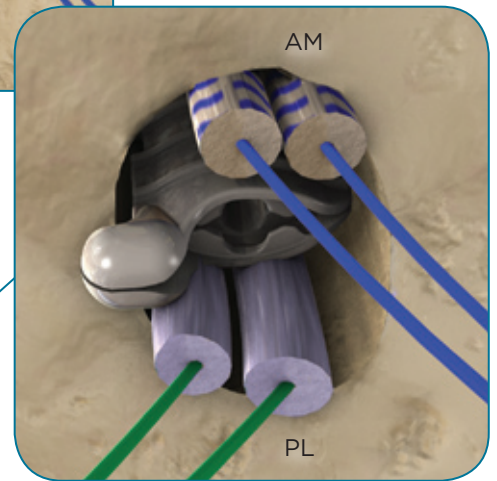
17

Insert the Tibial Screw in the center of the sheaths, so that the tip of the screw engages the sheaths.

18

Turn the Tibial Screw Driver clockwise until the screw head is flush with the superior rim of the cortical wall. Take care to maintain tension on the graft to prevent loss of graft stiffness.

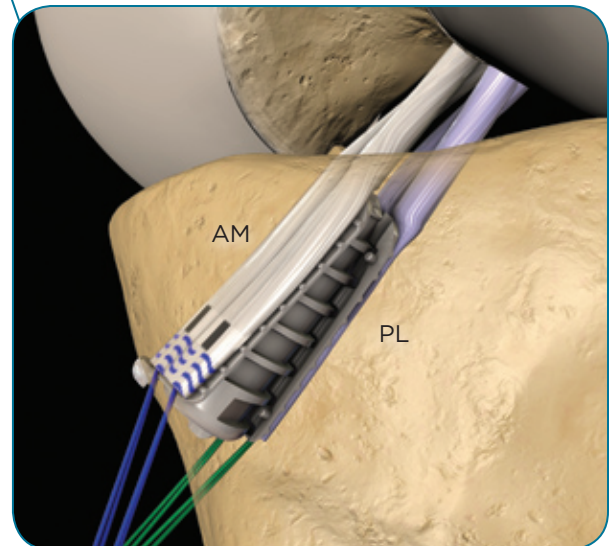
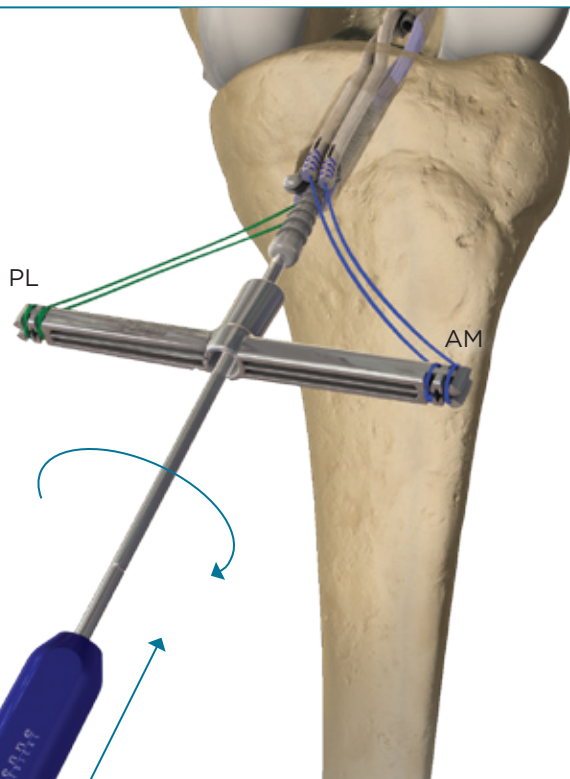
- Tibial Screw threads match that of the sheaths, therefore excess torque is not needed to engage and insert the screw.



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Once the Tibial Screw is completely seated to the cortical wall, remove the screw driver by pulling the handle straight back.

- Check the integrity of the repair. Trim the excess suture and tendon flush with the tibial tunnel.



Ordering Information

AperFix® Femoral Implant with Inserter

Model No.	Description
CM-2909	9mm x 29mm Femoral Implant with Inserter
CM-2910	10mm x 29mm Femoral Implant with Inserter
CM-2911	11mm x 29mm Femoral Implant with Inserter
CM-3509	9mm x 35mm Femoral Implant with Inserter
CM-3510	10mm x 35mm Femoral Implant with Inserter
CM-3511	11mm x 35mm Femoral Implant with Inserter

AperFix® Tibial Implant with Inserter

Model No.	Description
CM-3008	8mm x 30mm Tibial Implant with Inserter
CM-3009	9mm x 30mm Tibial Implant with Inserter
CM-3010	10mm x 30mm Tibial Implant with Inserter
CM-3011	11mm x 30mm Tibial Implant with Inserter

AperFix® Disposable Instruments

Model No.	Description
CM-7014	Calibrated Drill Tipped Guide Wire, 14" x 2.4mm

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AperFix® Femoral Implant with Inserter



AperFix® Tibial Implant with Inserter

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