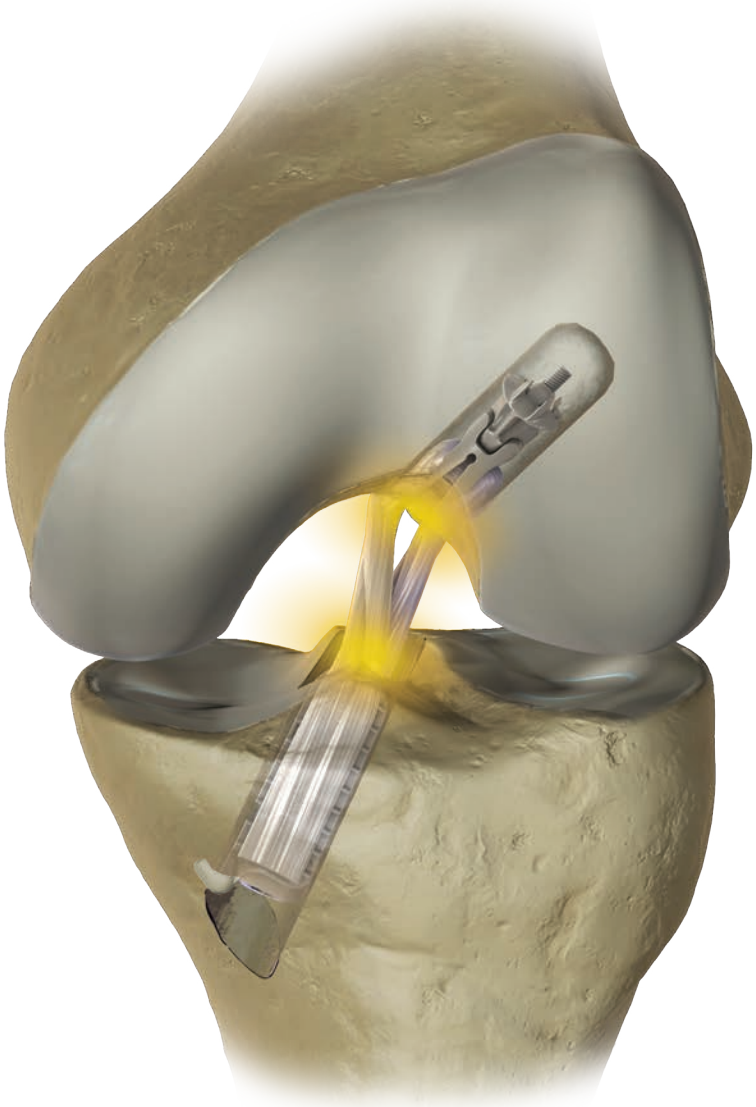
The AperFix® II System

A Complete Anatomic Solution

Transtibial Surgical Technique



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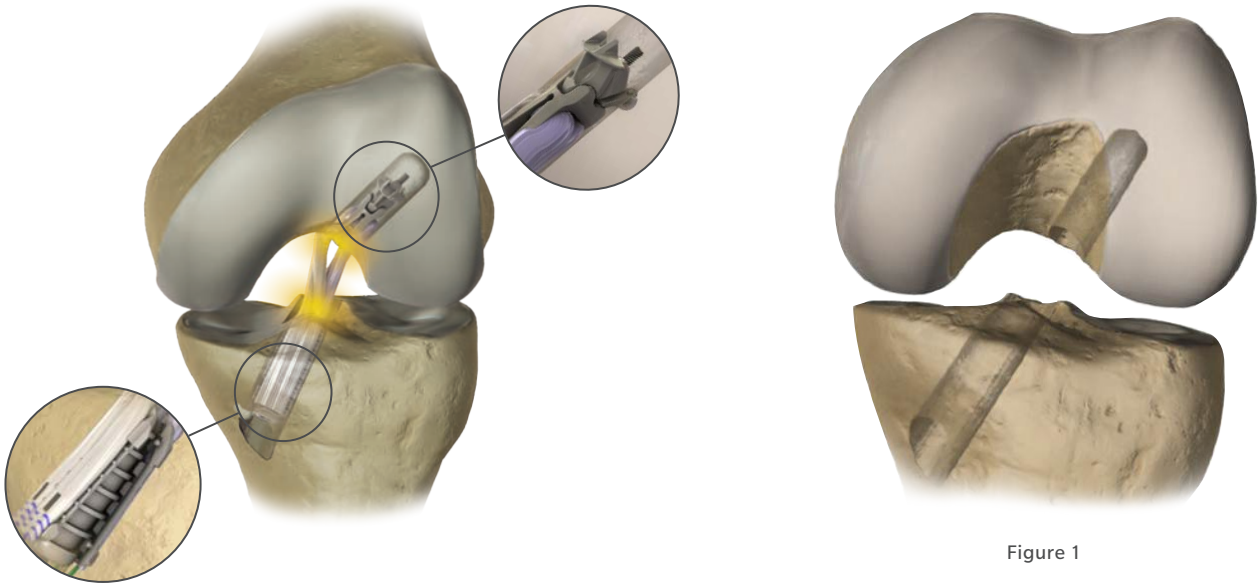


Figure 1

A Complete Anatomic Solution

The Cayenne Medical AperFix and AperFix AM Femoral Implants (referred to as "AperFix Femoral Implant") are intended for use in tenodesis procedures with soft tissue grafts, utilizing either arthroscopic or open techniques during Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Collateral Ligament (MCL), Lateral Collateral Ligament (LCL), and Medial Patellofemoral Ligament (MPFL) reconstruction.

The AperFix II soft tissue system can be used with hamstring autografts or various allografts such as: the Anterior Tibialis or the Gracilis and Semitendinosis tendons.

Graft Preparation

Step 1

Whip stitch grafts with a sturdy suture (#2 non-absorbable) in the standard fashion.

- It is recommended to use two different colored sutures to distinguish between the graft bundles.

Step 2

Pull the graft bundles through the Graft Sizing Block to determine the diameter of the implant to be used. Select a diameter which the graft bundle passes tightly through (Figure 1).

- Do not open the sterile AperFix Femoral Implant packaging until proper sizing has been established. Please refer to the sizing table below:

If the graft bundle diameter is:	Use Femoral & Tibial
Less than 7.5 mm	9 mm Implants with 9 mm Drills
7.5 mm to 9 mm	10 mm Implants with 10 mm Drills
9 mm to 10 mm	11 mm Implants with 11 mm Drills
8 mm AperFix Tibial Implants with 8 mm Tibial Drill can be used with the 9 mm AperFix Femoral Implant and 9 mm Femoral Drills when following the AM portal technique.	

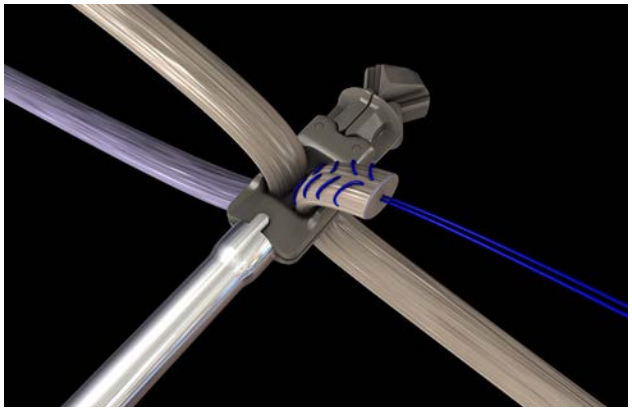


Figure 2

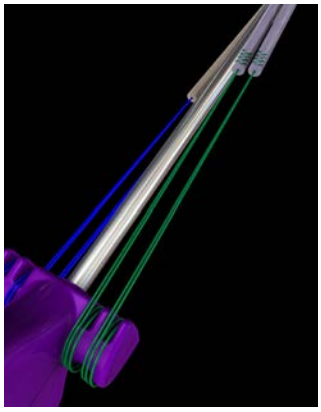


Figure 3

Figure 4

Graft Preparation (cont.)

Step 3

Create the tibial tunnel in the standard fashion. For femoral socket length, please refer to the sizing table below:

Femoral Implant	Femoral Socket Length
AperFix AM 24 mm	25 mm minimum
AperFix 29 mm	30 mm minimum

Step 4

Pass the prepared soft tissue grafts through the eyelets of the AperFix Femoral Implant (Figure 2).

Step 5

Wrap the sutures of the prepared tendons around the suture cleats of the Femoral Inserter Handle (Figure 3).

Step 6

Make a horizontal mark on the top of the tendon bundles at the inferior edge of the implant to serve as the aperture depth indicator (Figure 4).

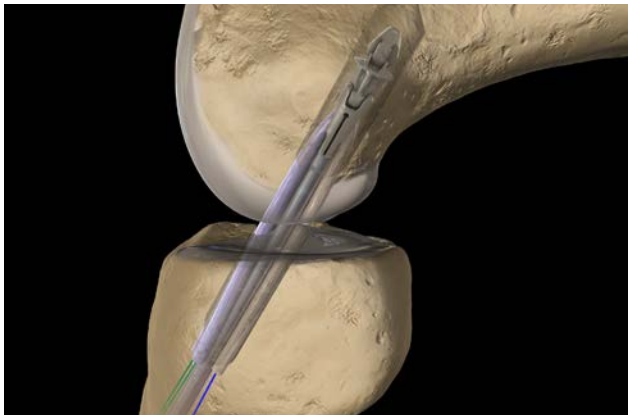
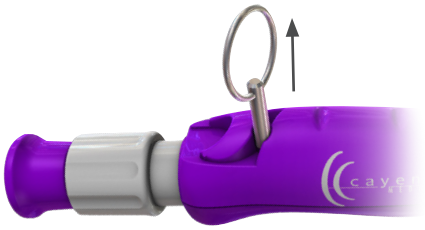


Figure 5



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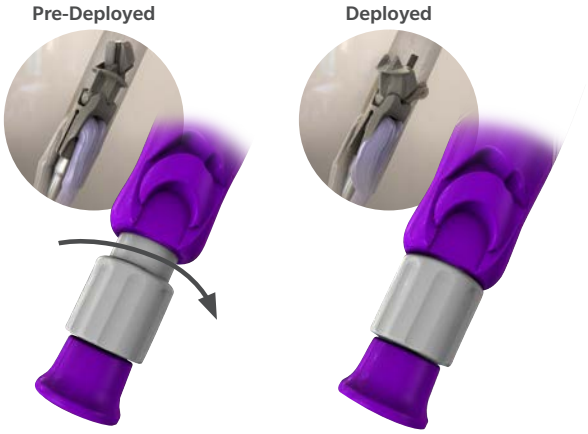


Figure 7

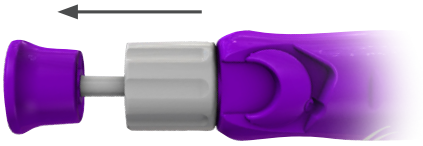


Figure 8

Femoral Fixation

Step 7

Holding the Inserter Handle with the safety pin facing upward, insert the AperFix Femoral Implant through the tibial tunnel and into the femoral socket to the marked depth location (Figure 5).

- Confirm the implant is fully seated into the femoral socket.

Step 8

Ensure the implant is in the proper position, then pull the safety pin out of the Inserter Handle (Figure 6).

Step 9

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 handle (Figure 7).

Step 10

Disengage the tendon sutures from the suture cleats.

Step 11

Release the Inserter Handle from the implant by pulling back on the Implant Release Knob. Remove the Inserter Handle from the operating site and discard (Figure 8).

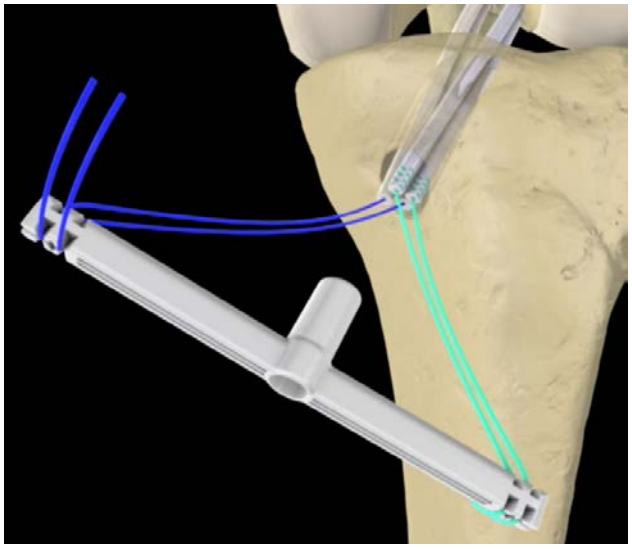


Figure 9

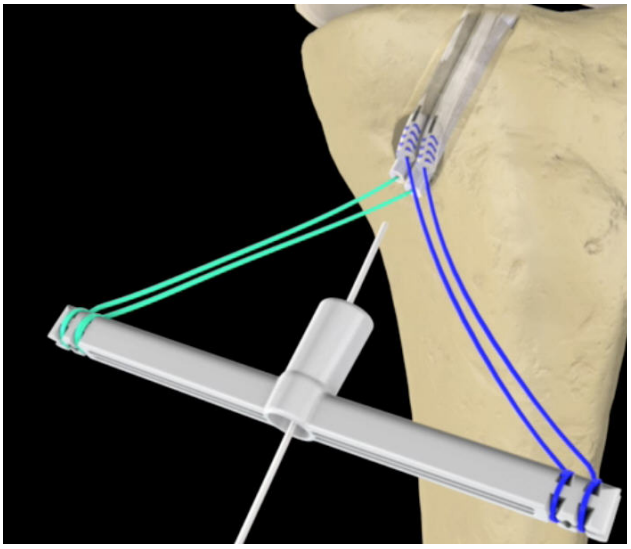


Figure 10

Tibial Fixation

Step 1

Select the Tibial Implant size to match the drilled tunnel diameter.

- The Tibial Implant will come with a Tendon Expander, Guide Wire, Cannulated Screw, and a Driver pre-loaded with the Tibial Sheaths and Sheath Holder.

Step 2

Hold the Tendon Expander arms perpendicular to the tibial tunnel and wrap the sutures from the tendon bundles around the suture cleats, such that the sutures are first inserted in the lateral slits and then wrapped around the vertical cleats (Figure 9).

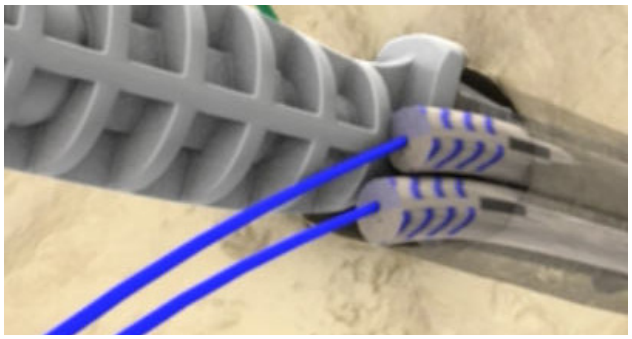
Optional: Rotating the Tendons

For orientation of the graft bundles at the tibial aperture, rotate 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.

Step 3

Insert the Guide Wire through the Tendon Expander, into the tibial tunnel (between the tendons), and into the joint space (Figure 10).

- Confirm the Guide Wire is in the joint space.



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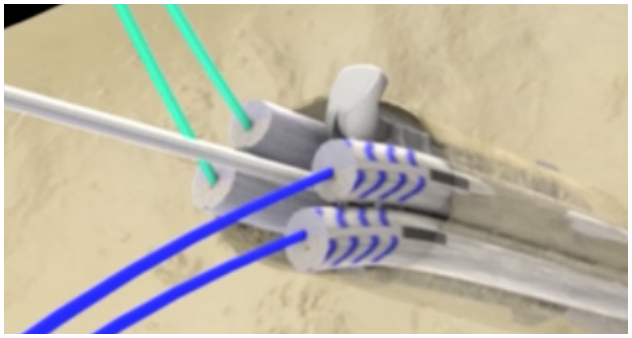

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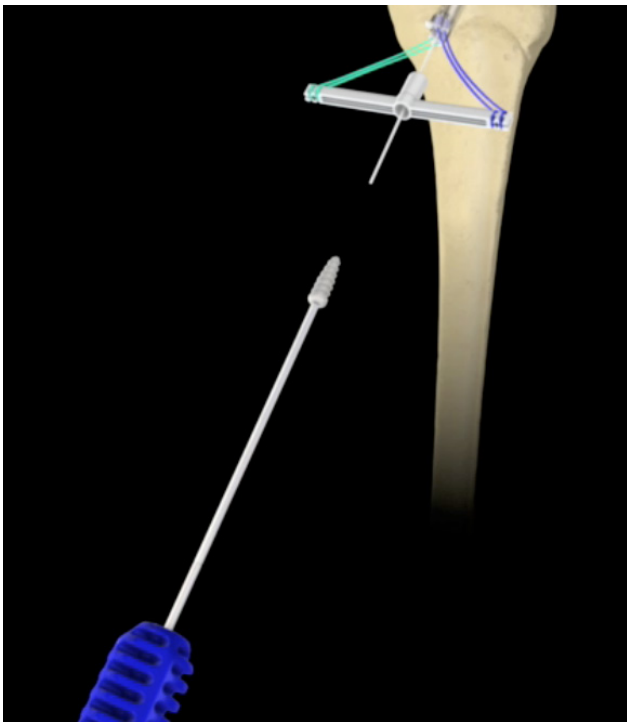


Figure 13

Tibial Fixation (cont.)

Step 4

Place the knee in extension and maintain the graft under tension. Insert the Tibial Sheaths over the Guide Wire and into the tibial tunnel such that the cortical engagement tabs are in the 12 o'clock position (Figure 11).

- The Tibial Sheaths should be positioned with the tabs fully seated against the tibia.

Optional

If the bundles were rotated in step 2, make sure the cortical engagement tabs are positioned on the medial side of the tunnel.

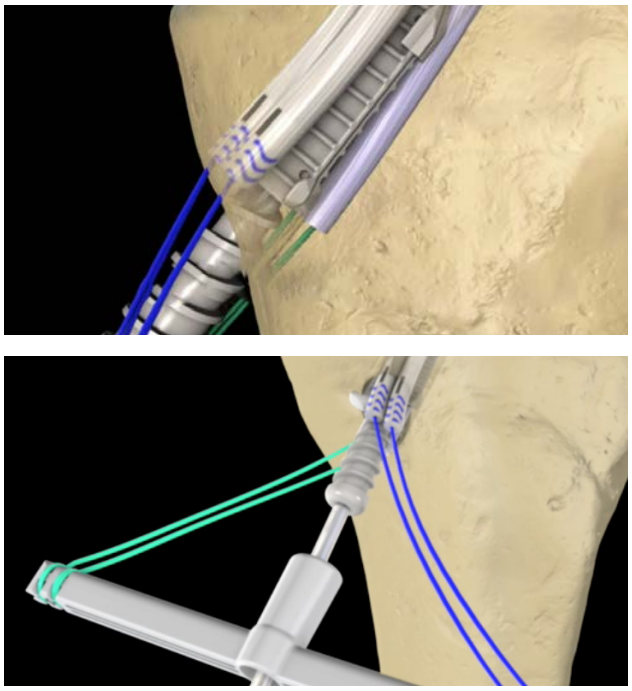
Step 5

Pull the Driver back along the Guide Wire to disengage from the Tibial Sheaths (Figure 12).

- Verify the tabs are fully seated against the cortex.

Step 6

Remove the Sheath Holder from the Driver and securely place the Tibial Screw on the end (Figure 13).



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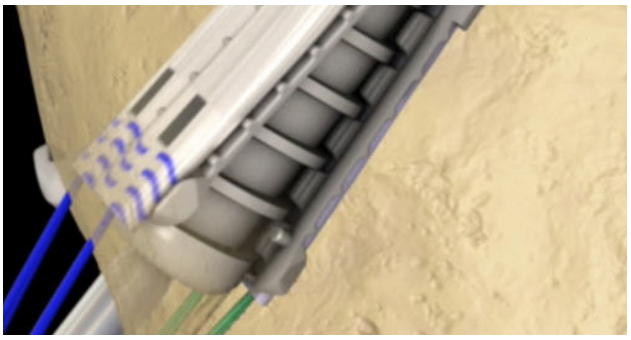

Figure 15

Tibial Fixation (cont.)

Step 7

Insert the Tibial Screw over the Guide Wire until the tip of the Screw engages the Sheaths (Figure 14).

- Use the "Easy Start" feature of the Tibial Screw by aligning the flat tip parallel with the Sheaths prior to deployment.

Step 8

With forward pressure, turn the Driver clockwise until the screw head is flush with the superior rim of the cortical wall. Maintain tension on the graft to prevent loss of graft stiffness.

- The Tibial Screw threads match that of the Sheath, therefore excessive torque is not needed to engage and insert the Screw.

Step 9

Once the Tibial Screw is completely seated between the Sheaths, remove the Driver by pulling the handle straight back. Remove the Guide Wire (Figure 15).

- Confirm the integrity of the repair.
- Trim the excess suture and tendon flush with the tibial surface.

*Refer to the product Instructions For Use (IFU) insert for a list of contraindications, warnings, and precautions.

AperFix II Removal

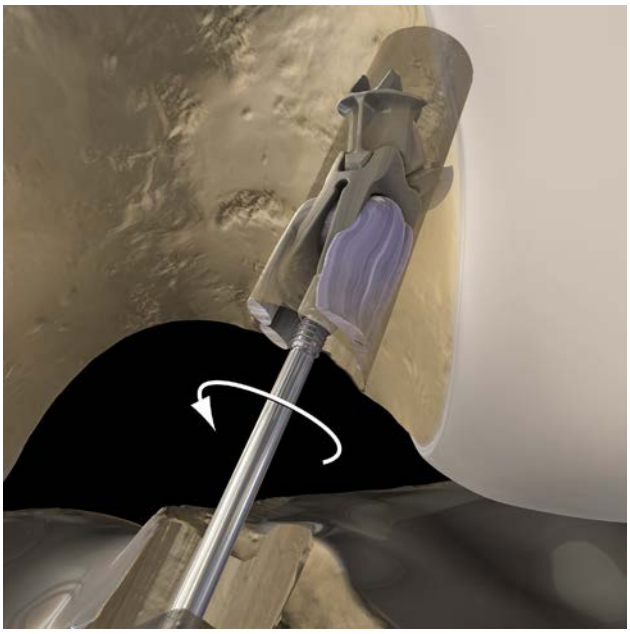

Figure 16

Figure 17

Tibial Removal Steps

Step 1

Use the Tibial Removal Tool to disengage the Screw from the Sheaths by rotating counterclockwise.

Step 2

Using a standard grasping instrument, remove the Tibial Sheaths from the tunnel one at a time.

Step 3

Clean the tibial tunnel and joint space to expose the Femoral Implant. Tibial tunnel diameter must match Coring Reamer Diameter for Femoral Removal Option 2.

Femoral Removal Steps

Option 1 - Femoral Removal Tool

To be used intra-operatively or post surgery when there is no bony ingrowth around the implant.

Step 1

Using the reverse threaded Femoral Removal Tool, remove the Central Screw.

Step 2

Turn counter clockwise while pulling axially (Figure 16).

Step 3

Remove the implant from the femoral socket once it has returned to its pre-deployed formation (Figure 17).

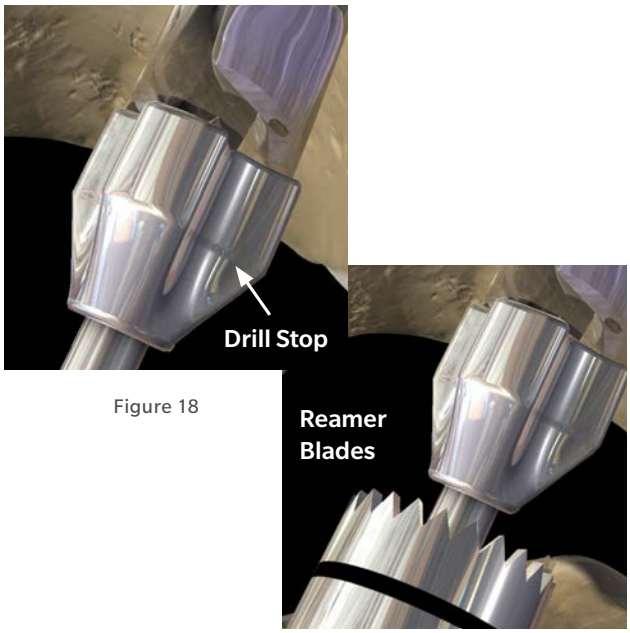

Figure 18

Figure 19

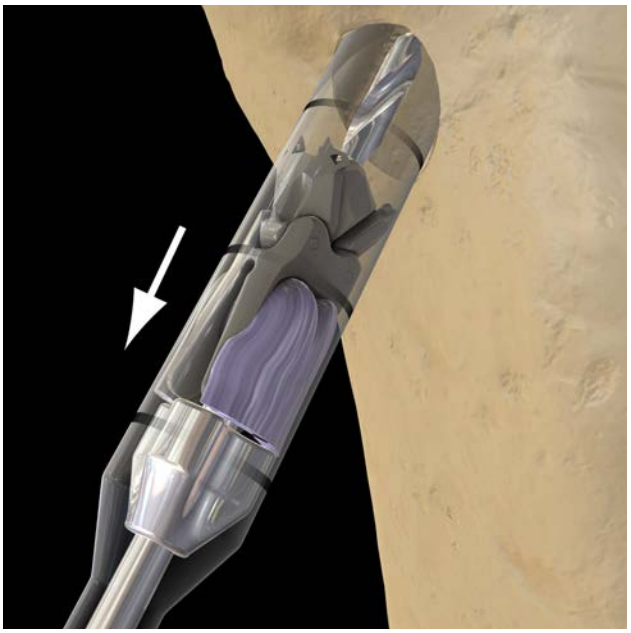

Figure 19

Femoral Removal Steps

Option 2 - Coring Reamer System

To be used post-surgery when bony ingrowth prevents the implant from being undeployed and removed.

Step 1

Use the reverse threaded Femoral Removal Tool to remove the Central Screw by turning counterclockwise and pulling axially.

Step 2

Insert the Alignment Guide Wire up through the center of the Femoral Implant.

Step 3

Make sure the Drill Stop is positioned just outside of the femoral tunnel (Figure 18).

Step 4

Manually walk the Coring Reamer over the Alignment Guide Wire. Ensure the Coring Reamer blades are completely over the Drill Stop before using power (Figure 19).

Step 5

Core at least 30 mm.

Step 6

Using power, back the coring reamer out of the socket. It now holds the encased Femoral Implant (Figure 20).

- Remaining PEEK-Optima® material can be removed from the tunnel

**For more detailed removal techniques, please see our Removal Technique Guide located on our website: www.cayennemedical.com

Ordering Information

AperFix Femoral Implant with Inserter

Description	Size	Part Number
AperFix AM Femoral Implant with Inserter	9 mm x 24 mm 10 mm x 24 mm	CM-2409 CM-2410
AperFix Femoral Implant with Inserter	9 mm x 29 mm 10 mm x 29 mm 11 mm x 29 mm	CM-2909 CM-2910 CM-2911

Aperfix II Tibial Implant with Driver

Description	Size	Part Number
Tibial Implant with Driver	8 mm x 30 mm	CM-3008
Cannulated Tibial Implant with Driver	9 mm x 30 mm 10 mm x 30 mm 11 mm x 30 mm	CM-3009C CM-3010C CM-3011C

AperFix Disposable Instruments

Description	Size	Part Number
Calibrated Drill Tipped Guide Wire	2.4 mm x 14”	CM-7014
ACL Disposable Procedure Kit		CM-1501
Accessory Portal Kit with Low Profile Drill and EZ Shuttle® Suture Loop	9 mm 10 mm 11 mm	CM-7609 CM-7610 CM-7611

APERFIX / APERFIX AM FEMORAL IMPLANT

INDICATIONS FOR USE

The AperFix® Femoral Implant is intended for use in tenodesis procedures with soft tissue grafts, utilizing either arthroscopic or open techniques during Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Collateral Ligament (MCL), Lateral Collateral Ligament (LCL), and Medial Patellofemoral Ligament (MPFL) reconstruction.

CONTRAINDICATIONS

1) Fixation using Bone-Patella Tendon-Bone or Quads Tendon grafts.
2) Surgical procedures other than those listed in the INDICATIONS section.
3) Presence of infection.
4) Patient conditions including insufficient quantity or quality of bone or soft tissue.
5) Insufficient blood supply or previous infections which may hinder the healing process.
6) Foreign body sensitivity. If material sensitivity is suspected, testing should be completed prior to device implantation.
7) The use of this device may not be suitable for patients with immature bone. The physician should carefully assess the status of the physes of the distal femur and proximal tibia before performing ACL reconstruction surgery on patients who are skeletally immature.
8) Conditions which may limit the patient's ability or willingness to follow postoperative care instructions.

APERFIX TIBIAL IMPLANT

INDICATIONS FOR USE

The Cayenne Medical AperFix Tibial Implant with Inserter is intended for use in tenodesis procedures with soft tissue grafts, utilizing either arthroscopic or open techniques during Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Collateral Ligament (MCL), Lateral Collateral Ligament (LCL), and Medial Patellofemoral Ligament (MPFL) reconstruction.

CONTRAINDICATIONS

1) Fixation using Bone-Patella Tendon-Bone grafts.
2) Surgical procedures other than those listed in the INDICATIONS section.
3) Presence of infection.
4) Patient conditions including insufficient quantity or quality of bone or soft tissue.
5) Insufficient blood supply or previous infections which may hinder the healing process.
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8) Conditions which may limit the patient's ability or willingness to follow postoperative care instructions.

For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counselling information, see the package insert and www.zimmerbiomet.com. Check for country product clearances and reference product specific instructions for use.

Zimmer Biomet does not practice medicine. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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