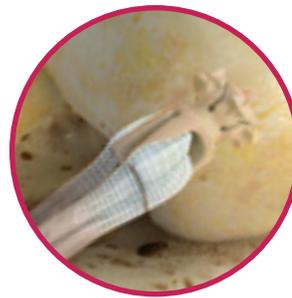


# The AperFix® System with the AFX™ Femoral Implant

## AM Portal Surgical Technique Guide

The Cayenne Medical AperFix® system with the AFX™ Femoral Implant is the only anatomic system for soft tissue ACL reconstruction that offers:

- A simple, fast, and reproducible technique
- An all PEEK-OPTIMA® construct
- 360° active fixation
- Active graft compression at aperture mimics native ACL kinematics and optimizes graft healing<sup>1,2</sup>



AFX™ Femoral Implant



AperFix® II Tibial  
Sheath & Screw System



The AperFix® System with  
the AFX™ Femoral Implant

The Cayenne Medical AperFix® II Tibial Sheath & Screw System and AFX™ 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.

## GRAFT PREPARATION

**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.
- AFX™ can be used with hamstring autograft or various allografts.

**2** Double the grafts over a loose suture and pull the 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.

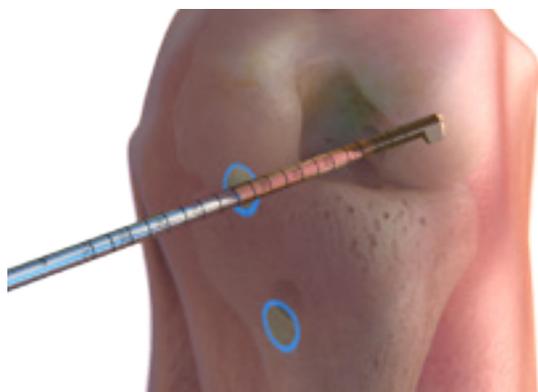
- Do not open the sterile AFX™ Femoral Implant packaging until proper sizing has been completed. Please refer to the sizing table below:

If the graft bundle diameter is:	Use Femoral & Tibial:
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>8mm AperFix Tibial Implants with 8mm Tibial Drill can be used with the 9mm AFX Femoral Implant and 9mm Femoral Drills when following the AM portal technique. <b>Note.</b> If Tendon Diameter is 9mm to 10mm, use CM-9211 AperFix II Femoral Implant with Inserter, 11mm x 29mm.</i>	

**3** Create the tibial tunnel and femoral socket. Drill the femoral socket with the knee hyperflexed at 120° or more. Hyperflexion of the knee will help achieve optimal anatomic positioning.

- Cayenne's low profile drill is available in the Accessory Portal Kit

Femoral Implant:	Femoral Socket Length:
AFX™ 24mm	25mm minimum
AperFix® 29mm	30mm minimum



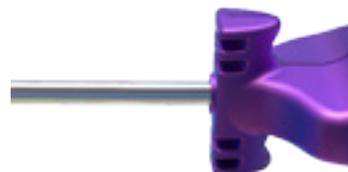
**4** Grasp the inserter shaft and pull away from the body of the inserter until it clicks into place. The inserter is now in load mode.



Pass the prepared soft tissue grafts through the open eyelet of the AFX™ Femoral Implant.



Grasp the whipstitched ends of the graft construct and pull toward the body of the inserter until the inserter shaft clicks into place. The inserter is now in drive mode.



- This will pass the deployment driver's dilating tip through the graft bundles and into the top of the AFX™ Femoral Implant.

**Note:** Testing has demonstrated that splitting the graft bundles will not effect their mechanical strength.<sup>3</sup>

**5** Tightly wrap the sutures of the prepared tendons around the suture cleats of the Femoral Inserter Handle.

**6** Make a horizontal mark across the top of the tendon bundles at the inferior edge of the implant to serve as the aperture depth indicator.



**7** With the safety pin facing up, pass one end of the EZ Shuttle™ Suture Loop through the eyelet that will be closest to the tibial tunnel during insertion.

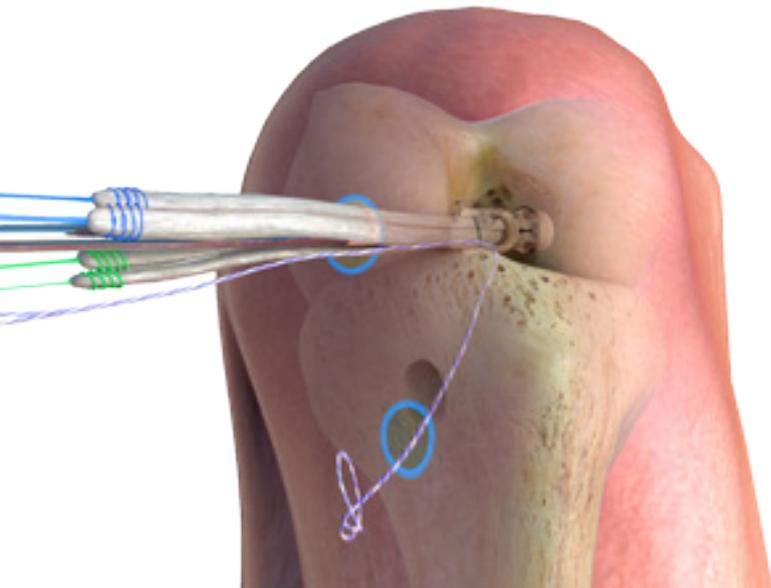
- Hold the suture that runs along the femoral inserter.



## FEMORAL FIXATION

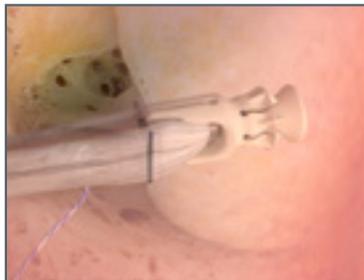
**8** Discard the deployment driver clip. Insert the AFX™ Femoral Implant and suture loop through the AM Portal and STOP in the joint space. **DO NOT** insert the implant into the femoral socket until the suture loop has been passed down the tibial tunnel.

- Insert graspers through the tibial tunnel and grab the suture that is anterior of the implant (closest to tibial tunnel). Pull the loop out of the eyelet and down the tibial tunnel. The suture loop will no longer be through the implant.
- Clamp both ends of the suture loop outside the knee.



**9** Insert the AFX™ Femoral Implant into the femoral socket to the marked depth location.

- Maintain the same knee hyperflexion angle that was positioned during femoral socket drilling. Lightly mallet if necessary.



### Optional: Rotating the Tendons

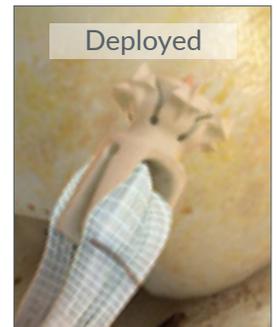
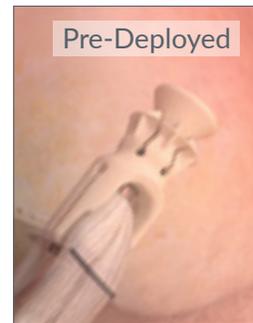
For orientation of the graft bundles at the femoral footprint, rotate the femoral inserter until the tendons representing the AM bundle are positioned in the posterior portion of the femoral socket and the PL bundle in the anterior portion.

**10** Ensure the implant is in the proper position, then pull the safety pin out of the Inserter Handle.



**11** With the Inserter Handle held firmly in place, rotate the white implant deployment knob clockwise until the deployment knob comes into contact with the purple handle.

- Over torquing the deployment knob may damage the femoral implant.



**12** Disengage the tendon sutures from the suture cleats.

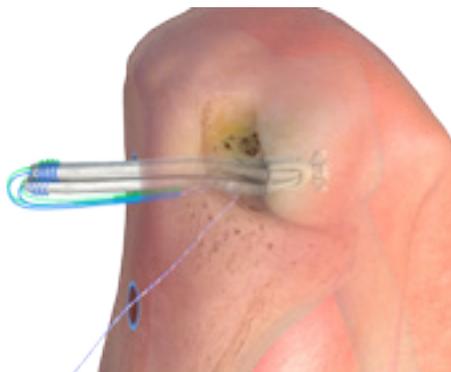
**13** Pull back on the Inserter Handle to release it from the implant. Remove the Inserter Handle from the operating site and discard.

**Note:** To ease release of the Inserter Handle, lightly mallet the suture cleats in the direction in which the Inserter Handle is being retracted.

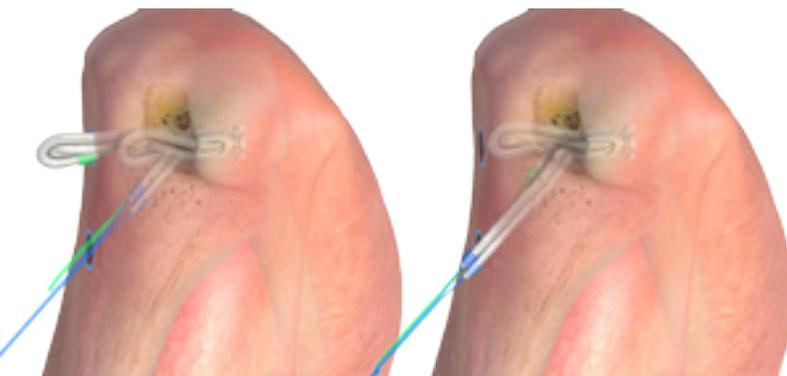
## PASSING THE TENDONS

**14** Feed the tendon sutures through the retrieval suture loop and gently pull the suture from the AM Portal down the tibial tunnel.

- Care should be taken to allow the sutures to pass through the AM Portal first and exit the tibial tunnel prior to allowing the grafts to pass into the knee.



**15** Place a probe or hemostats between the tendons and the knee to maintain tension on the grafts as they begin to enter the AM Portal. Once the graft ends have been pulled in, release tension and allow the tendons to pass through the tibial tunnel one at a time.



**16** Once the graft ends have been pulled through the tibial tunnel, the knee may be cycled and traction applied.

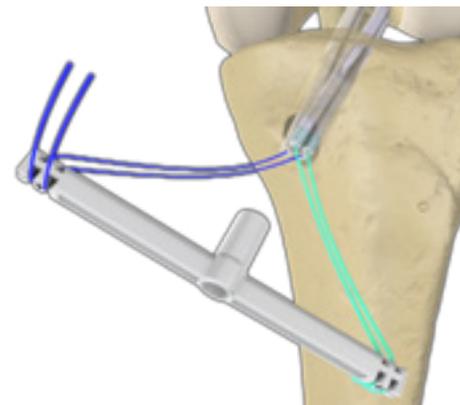


## TIBIAL FIXATION

**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 Sheath Holder and Tibial Sheaths.

**2** Hold the Tendon Expander arms approximately a fist's length away at a perpendicular angle 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.

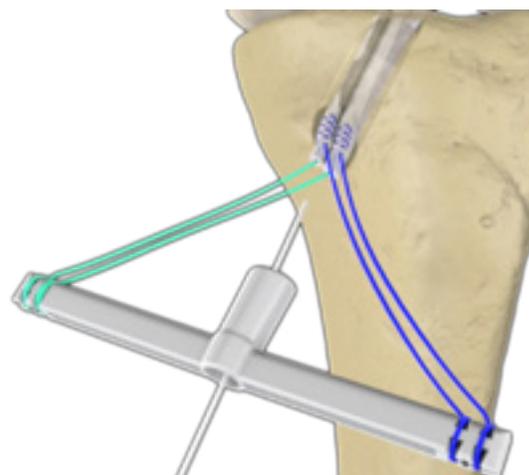


### Optional: Rotating the Tendons

*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.*

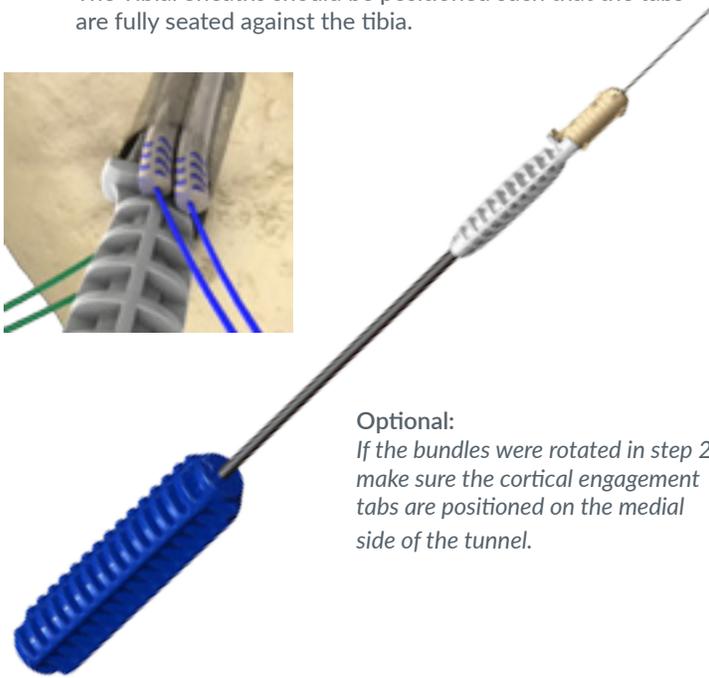
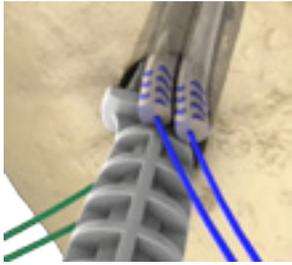
**3** Insert the Guide Wire through the Tendon Expander, into the tibial tunnel (between the tendons), and into the joint space.

- Confirm the Guide Wire is in the joint space.



- 4 Per surgeon's preference, place the knee anywhere between 0° and 30° of flexion and maintain a constant tension on the graft. 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.

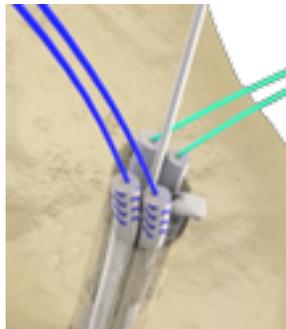
- The Tibial Sheaths should be positioned such that the tabs are fully seated against the tibia.



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

- 5 Pull the Driver back along the Guide Wire to disengage from the Tibial Sheaths.

- Verify the tabs are fully seated against the cortex.

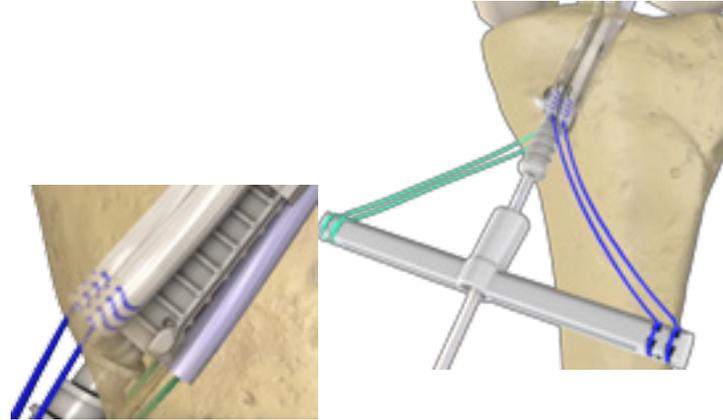


- 6 Remove the Sheath Holder from the Driver and securely place the Tibial Screw on the end.



- 7 Insert the Tibial Screw over the Guide Wire until the tip of the screw engages the Sheaths.

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

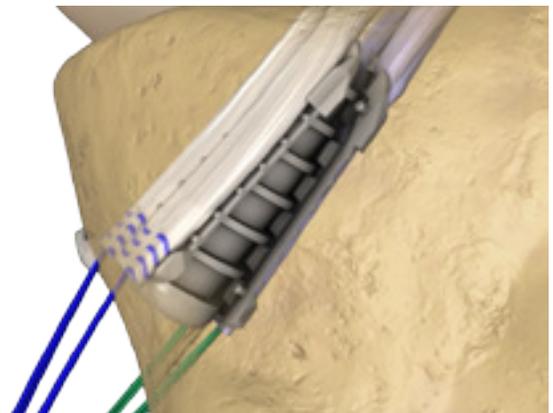


- 8 With forward pressure, turn the Driver clockwise until the screw head is flush with the superior rim of the cortical wall. Maintain tension on the graft to prevent loss of graft stiffness.

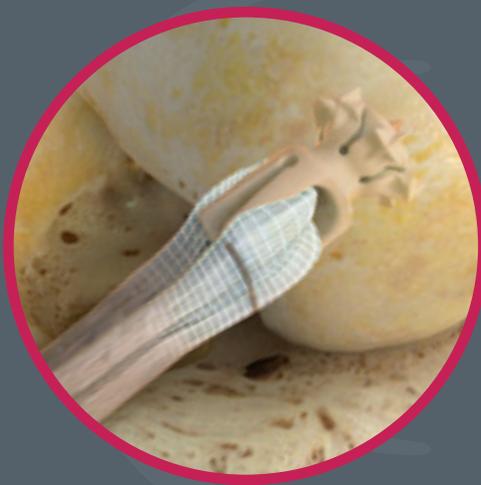
- The Tibial Screw threads match that of the Sheath, therefore excessive torque is not needed to engage and insert the screw.

- 9 Once the Tibial Screw is completely seated between the Sheaths, remove the Driver by pulling the handle straight back. Remove the Guide Wire.

- 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.



## Ordering Information

### AFX™ Femoral Implant with Inserter

CM-2409AP	9 mm x 24 mm AFX™ Femoral Implant with Inserter
CM-2410AP	10 mm x 24 mm AFX™ Femoral Implant with Inserter

### AperFix® II Femoral Implant with Inserter

CM-2911	11 mm x 29 mm AperFix® Femoral Implant with Inserter
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### AperFix® II Tibial Implant with Driver

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

### AperFix® Disposable Instruments

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

### References

1. Weiler A, Hoffman RFG, Bail HJ, et al: Tendon healing in a bone tunnel. Histological analysis after biodegradable interference fit fixation. *Arthroscopy*. 1999; 15: 548-549.
2. Gadikota, HR et al. Biomechanical Comparison of Single-Tunnel–Double- Bundle and Single-Bundle Anterior Cruciate Ligament Reconstructions. *Am J Sports Med*. 2009; 37 (5): 962-969.
3. Cayenne Medical Whitepaper, 11093 - Rev A

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Contact Cayenne Medical for order information

This description of technique is an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Cayenne Medical products. The medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature as well as the product's Instructions For Use.