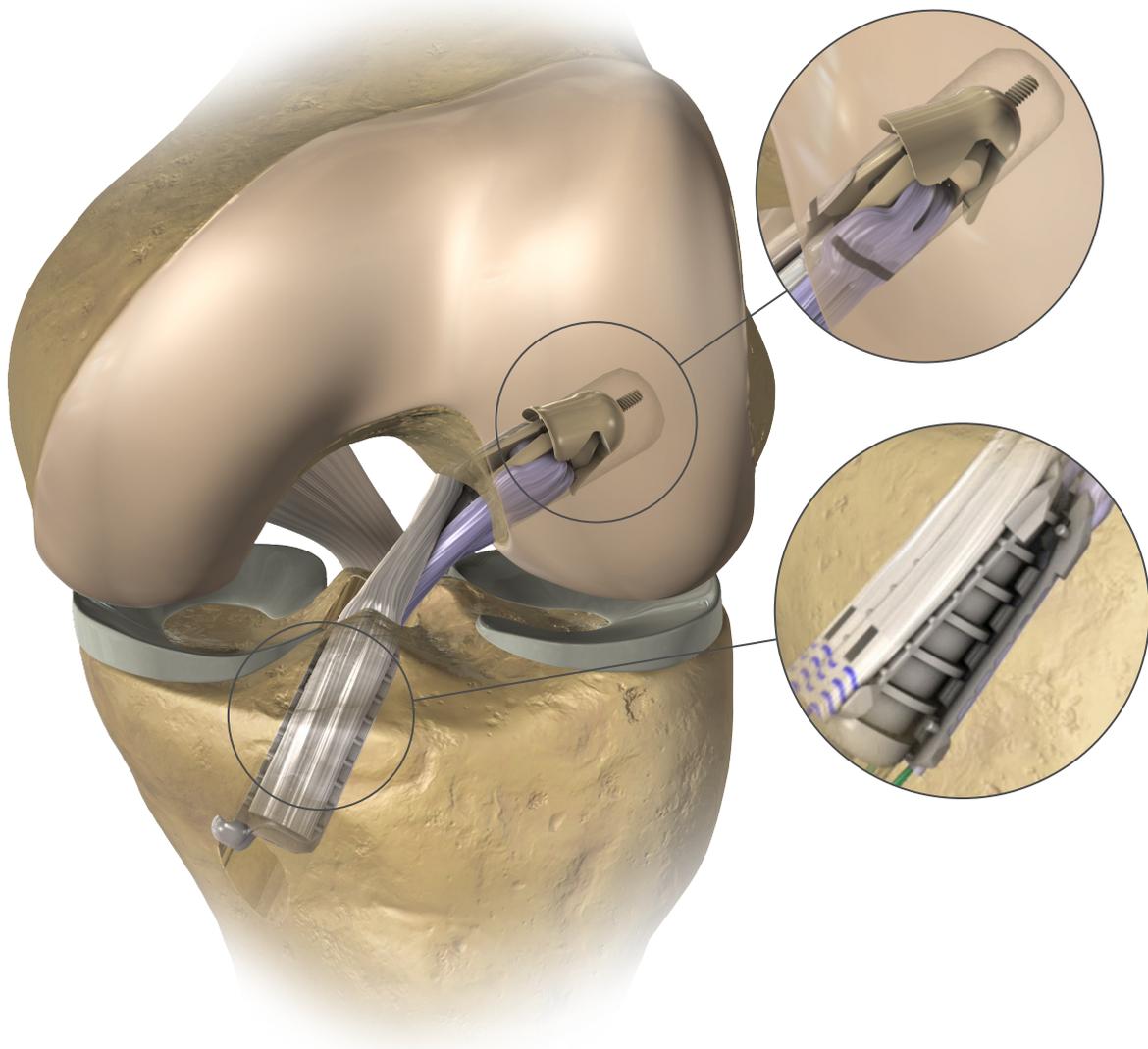
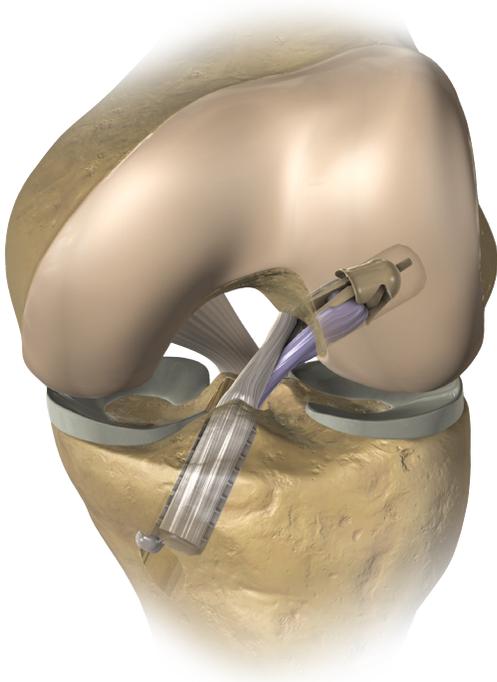


# The AperFix<sup>®</sup> System

The Anatomic Implant

AM Portal Surgical Technique





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 1

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

Figure 2

## A Complete Anatomic Solution

The Cayenne Medical AperFix System introduces an innovative, anatomic approach to soft tissue multi-ligament reconstruction of the knee for enhanced performance, strength, and simplicity. The AperFix System was designed to offer surgeons strong aperture fixation with circumferential graft compression at the native footprint through an easy, reproducible technique.

The AperFix System Anteromedial Portal Technique provides a simplified solution to reconstruct the ACL and restore native knee kinematics. This technique showcases the versatility of the AperFix System, allowing surgeons to practice their preferred method of tunnel delivery to achieve a strong, reliable, and anatomic reconstruction.

The Cayenne Medical AperFix II 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.

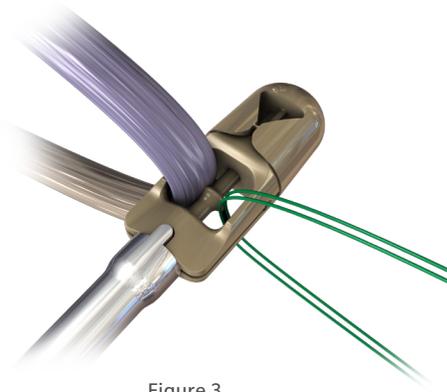


Figure 3

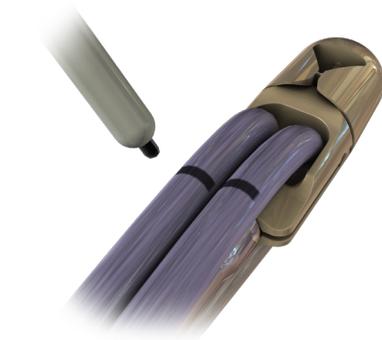


Figure 4



Figure 5

## 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.

- Do not open the sterile AperFix Femoral Implant packaging until proper sizing has been completed. Please refer to the sizing table (Figure 1).

### Step 3

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

- Cayenne's low profile drill is available in the Accessory Portal Kit (Figure 2).

### Step 4

Pass the prepared soft tissue grafts through the eyelets of the AperFix Femoral Implant (Figure 3).

### Step 5

Wrap the sutures of the prepared tendons around the suture cleats of the Femoral Inserter Handle.

### 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).

### Step 7

With the safety pin facing up, pass one end of the suture loop through the eyelet that will be closest to the tibial tunnel during insertion (Figure 5).

- Hold the suture that runs along the femoral inserter.

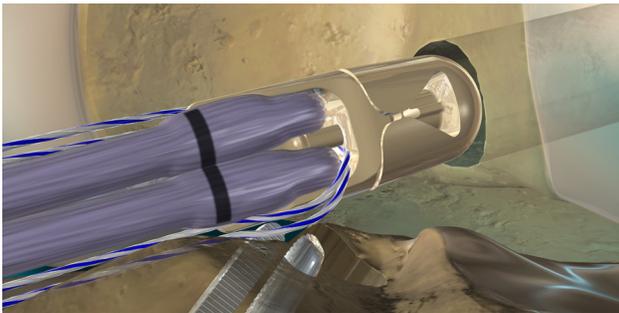
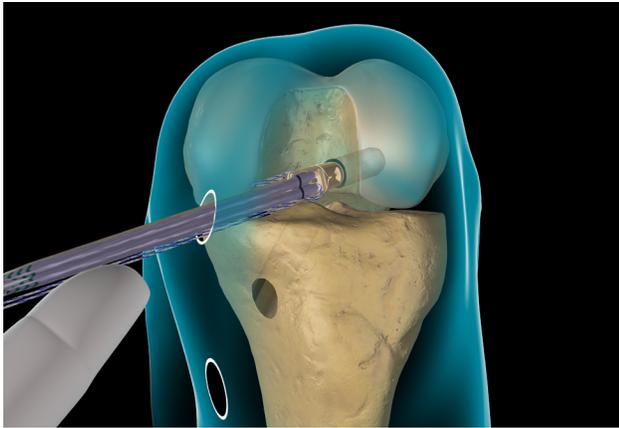


Figure 6

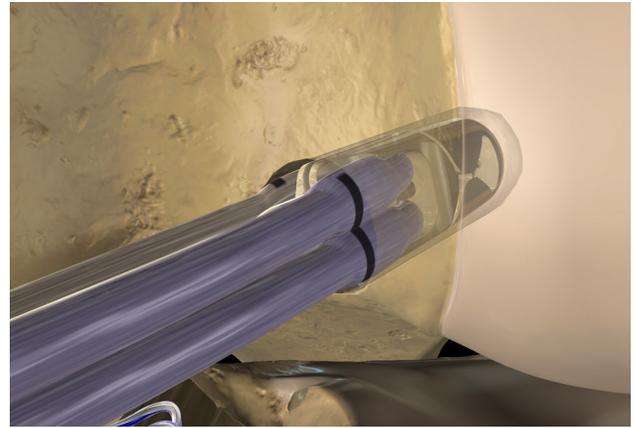


Figure 7



Figure 8

## Femoral Fixation

### Step 1

Insert the AperFix 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 (Figure 6).

### Step 2

Insert the AperFix Femoral Implant into the femoral socket to the marked depth location (Figure 7).

- Maintain the same knee hyperflexion angle that was positioned during femoral socket drilling.

### Step 3

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



Pre-Deployed

Deployed

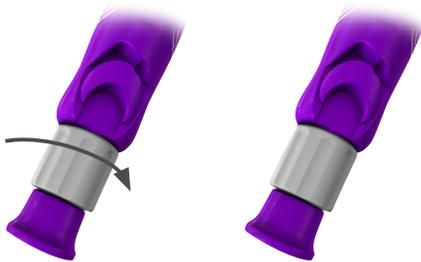


Figure 9



Figure 10

## Femoral Fixation (cont.)

### Step 4

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 9).

### Step 5

Disengage the tendon sutures from the suture cleats.

### Step 6

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 10).

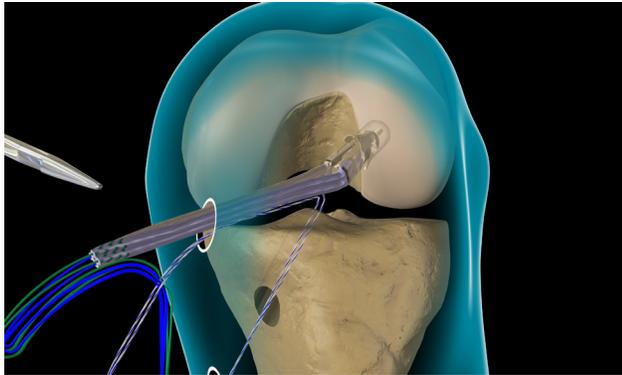


Figure 11

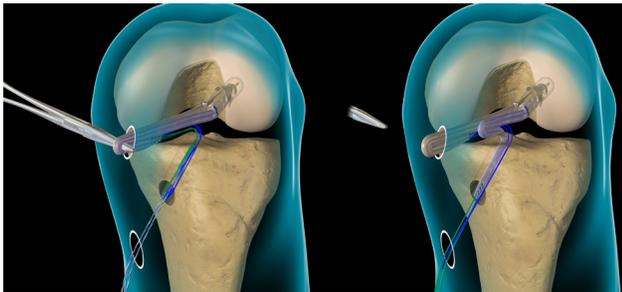


Figure 12

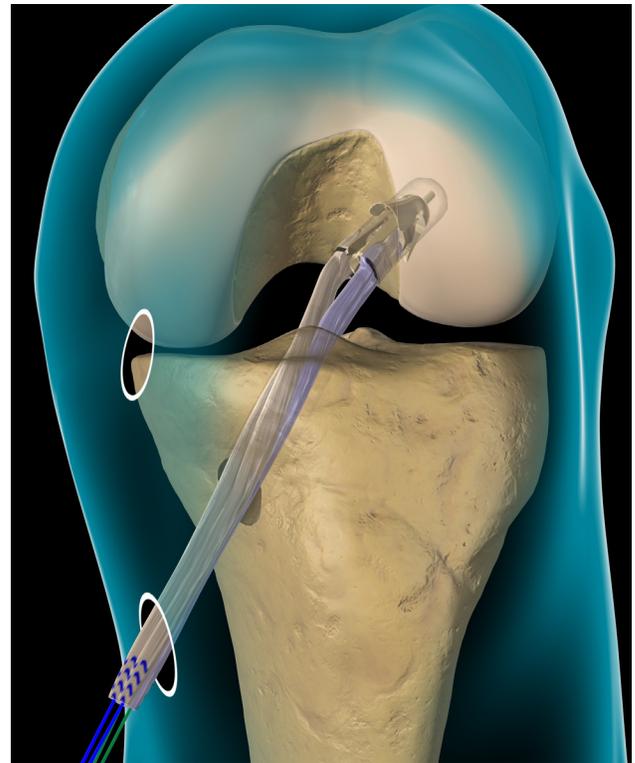


Figure 13

## Passing the Tendon

### Step 1

Feed the tendon sutures through the retrieval suture loop and gently pull the suture from the AM portal down the tibial tunnel (Figure 11).

- 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.

### Step 2

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 (Figure 12).

### Step 3

Once the graft ends have been pulled through the tibial tunnel, the knee may be cycled and traction applied (Figure 13).

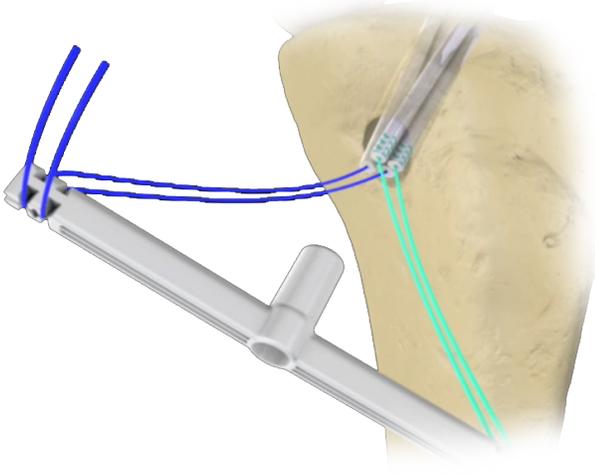


Figure 14

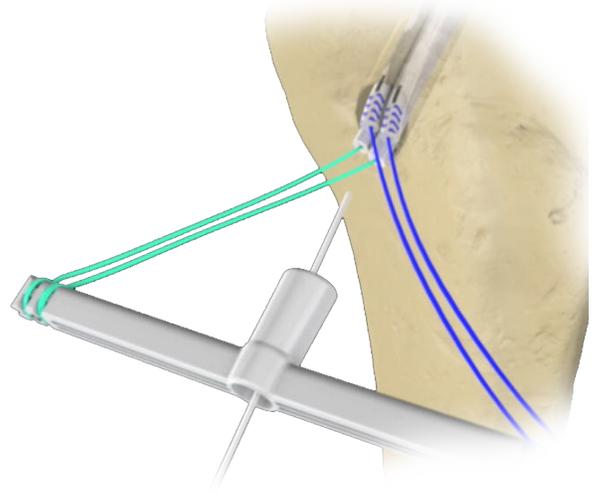


Figure 15

## 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 14).

### 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 15).

- Confirm the Guide Wire is in the joint space.

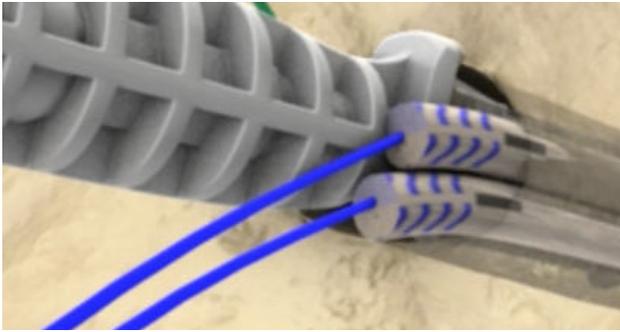


Figure 16



Figure 17

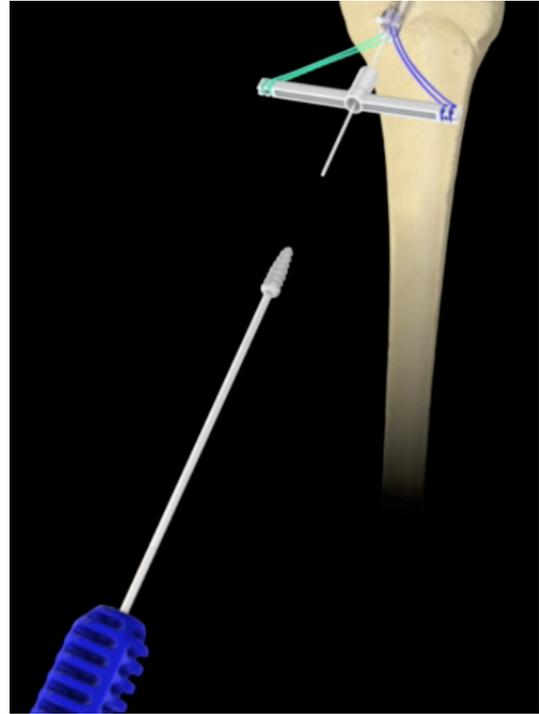


Figure 18

## Tibial Fixation (cont.)

### Step 4

Place the knee in full 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.

- The Tibial Sheaths should be positioned such that the tabs are fully seated against the tibia (Figure 16).

### 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 17).

- 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 18).



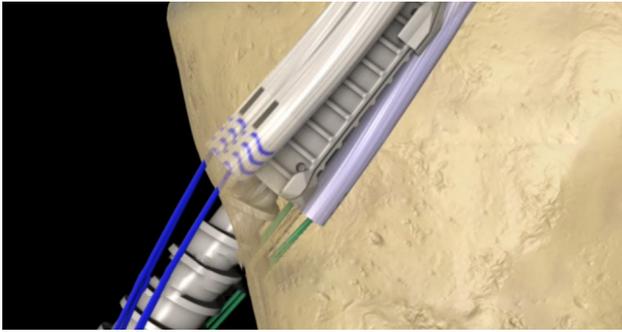


Figure 19

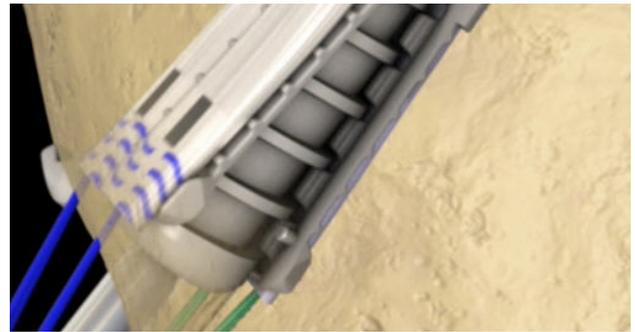
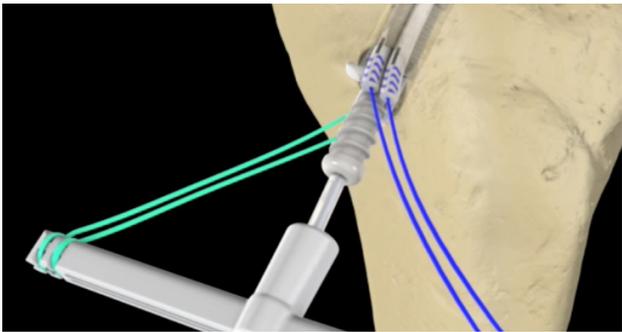


Figure 20

## Tibial Fixation (cont.)

### Step 7

Insert the Tibial Screw over the Guide Wire until the tip of the screw engages the Sheaths (Figure 19).

- 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 20).

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

## Ordering Information

### AperFix Femoral Implant with Inserter

Description	Size	Part Number
AperFix AM Femoral Implant with Inserter	9 mm x 24 mm	CM-2409
	10 mm x 24 mm	CM-2410
AperFix Femoral Implant with Inserter	9 mm x 29 mm	CM-2909
	10 mm x 29 mm	CM-2910
	11 mm x 29 mm	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	CM-3009C
	10 mm x 30 mm	CM-3010C
	11 mm x 30 mm	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	CM-7609
	10 mm	CM-7610
	11 mm	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.
- 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.

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