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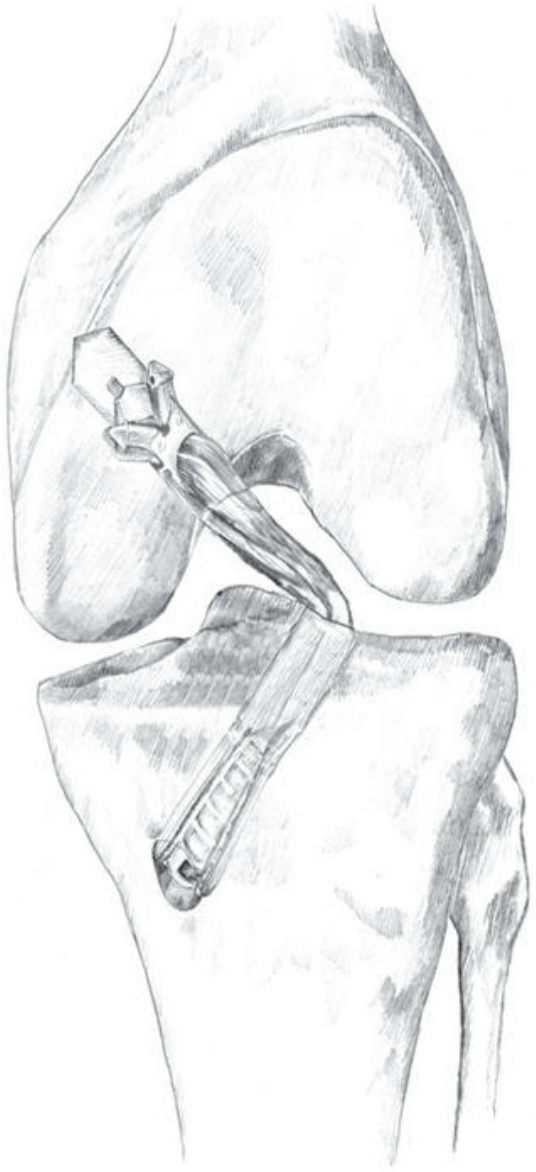
The AperFix® System

The Anatomic Implant

PCL Surgical Technique



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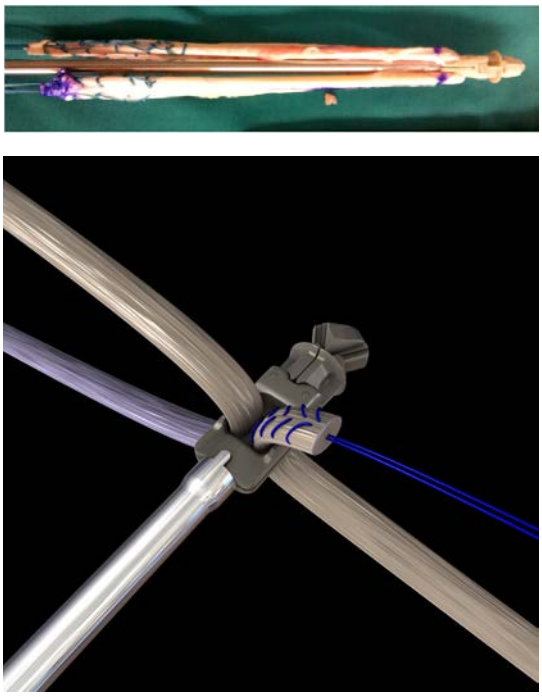


Figure 1

Posterior Cruciate Ligament Review

Primary restraint to posterior tibial translation:

- Larger anterolateral (AL) bundle tight in 90° flexion
- Posteromedial (PM) bundle tight in extension

Origin:

- Femur: 8-10 mm posterior to the anterior articular surface of the medial femoral condyle
- Tibia: 15 mm distal to the posterior tibial plateau

Graft Preparation and Tunnel Placement

Step 1

The recommended graft choice is an anterior or posterior allograft tendon at least 240 mm in length (when doubled over, graft should ideally fit an 11 mm implant to maximally fill the PCL footprint). Split the graft longitudinally to half of its length (pant leg).

Note: Autograft hamstring tendon may also be used.

Step 2

Whip stitch approximately 20 mm of the graft ends 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 3

Double the graft over at its mid length, then 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. Please refer to the sizing table above.

Step 4

Pass the prepared soft tissue grafts through the eyelets of the AperFix Femoral Implant (AperFix 29 mm shown) (Figure 1).

Note: Taper graft ends for easier graft loading through the implant.

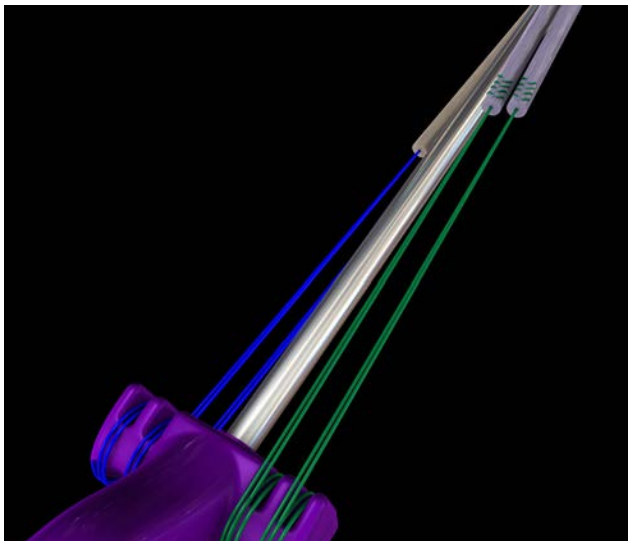


Figure 2

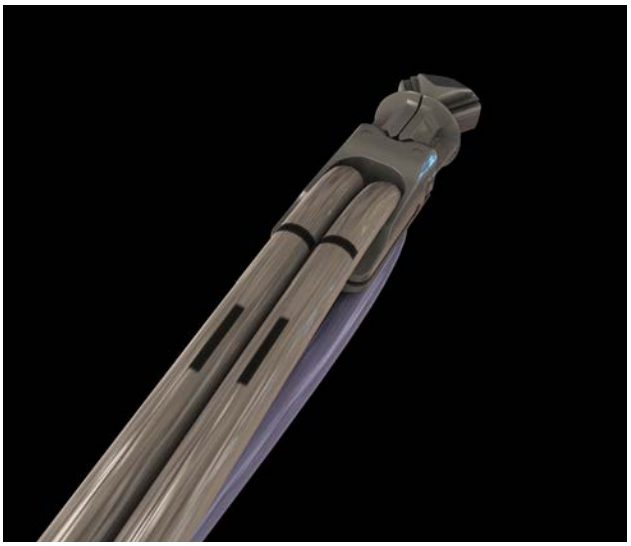


Figure 3

Graft Preparation and Tunnel Placement (cont.)

Step 5

Wrap the sutures of the prepared tendons around the suture cleats of the Femoral Inserter Handle to pre-tension the graft (Figure 2).

Note: To achieve optimal anatomic placement of the bundles, it is recommended to wrap the AL graft bundles on one suture cleat and PM graft bundles on the opposite suture cleat.

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 3).

Note: It is recommended to make a second mark on the grafts that will represent the AL bundle, at both the implant end and sutured end to help orient the bundles in the joint space.

Step 7

Anterolateral scope portal should be made 10-12 mm from the patellar tendon to facilitate femoral drilling.

Figure 4

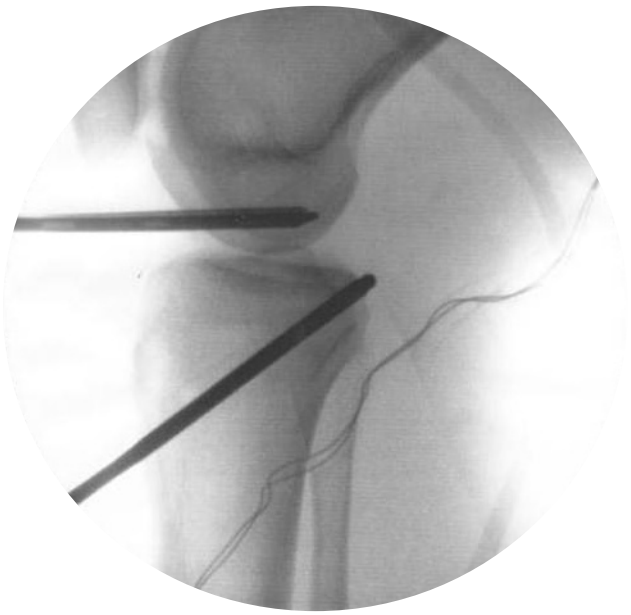


Figure 5

Graft Preparation and Tunnel Placement (cont.)

Step 8

Drill the femoral tunnel first to avoid fluid outflow through the tibial tunnel.

- With the knee flexed between 90° and 120° (Figure 4), insert a guide wire through the lateral portal to the center of the PCL footprint (approximately 6-8 mm posterior to the articular surface of the medial femoral condyle). Create the femoral socket using the sizing table below:

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

Step 9

Flex the knee to 45° and place a transtibial PCL guide through the medial portal to the PCL insertion location (approximately 1.5 cm distal to the tibial articular surface and slightly lateral to midline).

Note: A posteromedial portal is recommended to fully debride the posterior tibia for tunnel positioning, suture management, and graft passage.

Step 10

Use a curette posteriorly to protect the neurovascular structures and place the PCL guide parallel to the tibial plateau. Pass the drill tipped guide wire through the PCL guide to the posterior tibial cortex (Figure 5).

Note: Use fluoroscopic imaging to confirm proper pin placement.

Step 11

Using the appropriate size tibial drill, carefully ream the tibial tunnel.

Note: Fluoroscopic and direct visualization should be used as guidance.

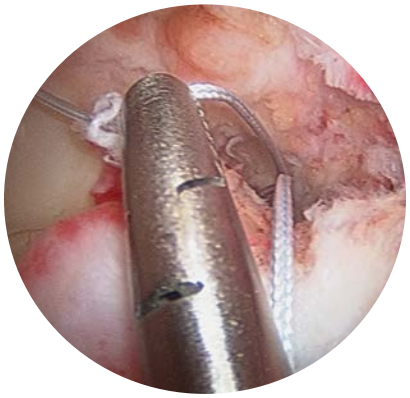


Figure 6

Figure 8

Figure 7

Figure 9

Femoral Fixation and Graft Passage

Step 1

Load a looped, high tensile strength suture through the tibial tunnel; retrieve through the intercondylar notch and out of the anterolateral portal. Suture loop will be used to shuttle the graft bundles independently through the "killer turn" (Figure 6).

Note: Place hemostats on the ends of the retrieval suture loops to keep the sutures in position while inserting the AperFix femoral implant.

Step 2

Insert the prepared AperFix device through the lateral portal and into the femoral socket to the marked depth location. Confirm the implant is fully seated into the socket (Figure 7).

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

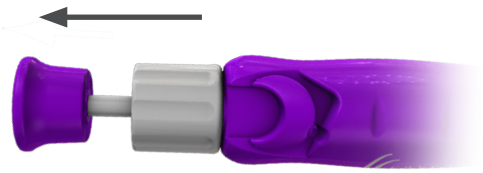
Step 3

To optimize anatomic femoral placement of the graft bundles, rotate the AperFix inserter until the AL bundle is positioned anterior and the PM bundle is positioned posterior in the femur (Figure 8).

Step 4

Ensure the implant is in proper position, then pull the safety pin out of the Inserter Handle (Figure 9).

Figure 10



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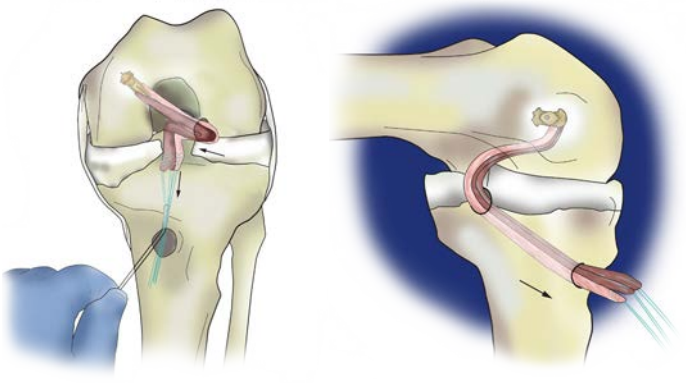


Figure 12

Femoral Fixation and Graft Passage (cont.)

Step 5

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 10).

Step 6

Disengage the tendon sutures from the suture cleats.

Step 7

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 11).

Step 8

Feed the sutures of the tendon bundles through the retrieval suture loop. Shuttle the tails of the AL and PM bundles through the tibial tunnel by pulling gently on the suture loop from the tibial tunnel end.

Note: Care should be taken to allow the sutures to pass through the AL portal first and exit the tibial tunnel prior to allowing the grafts to pass into the knee.

Step 9

Place a probe or hemostats between the tendons and the knee to maintain tension on the grafts as they begin to enter the lateral portal. Once the graft ends have been pulled in, release tension and allow the AL and PL bundles to pass through the tibial tunnel independently (Figure 12).

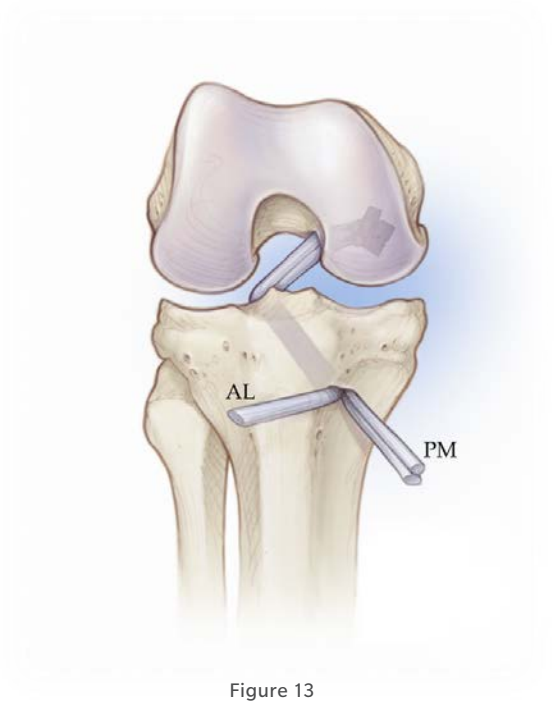


Figure 13

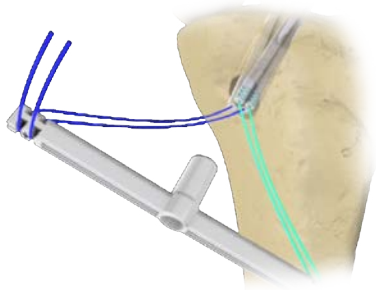


Figure 14

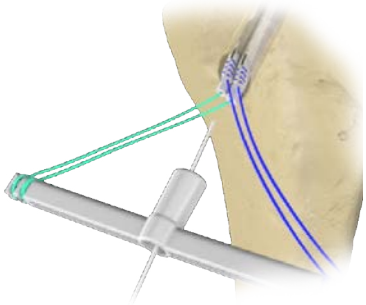


Figure 15

Tibial Fixation

Step 1

With the AL and PM bundles anatomically separated, select the Tibial Implant size to match the drilled tunnel diameter (Figure 13).

Note: 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).

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.

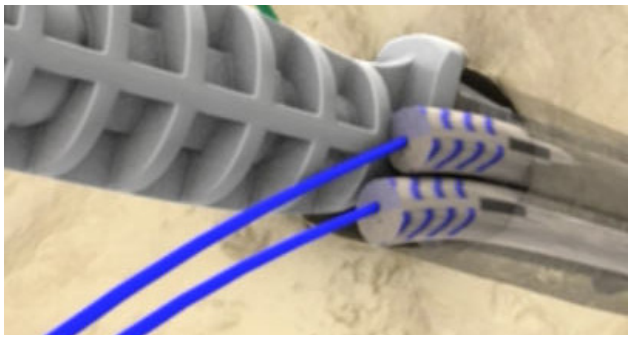


Figure 16

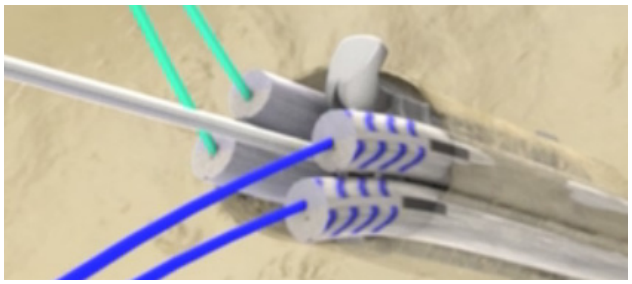


Figure 17

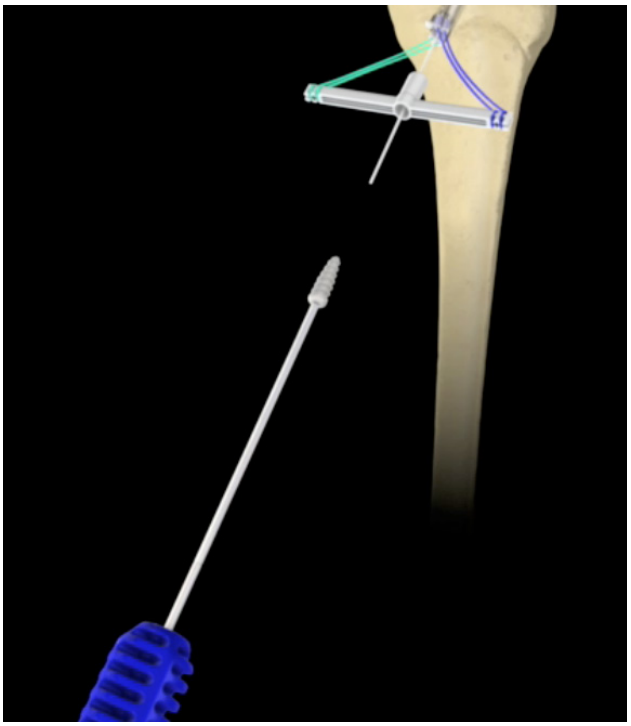


Figure 18

Tibial Fixation (cont.)

Step 4

With the knee held at 90° and under an anterior tibial force, and with the graft under tension (to simulate the larger AL bundle), 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 16).

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

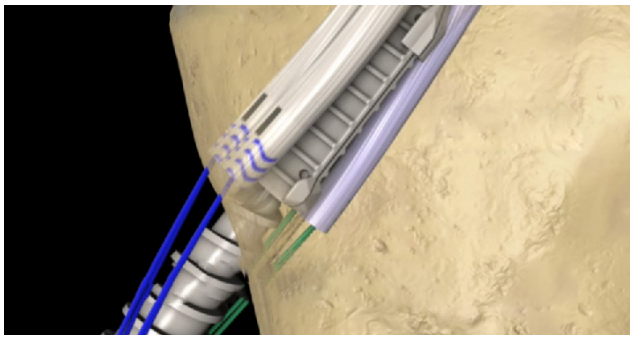
Step 5

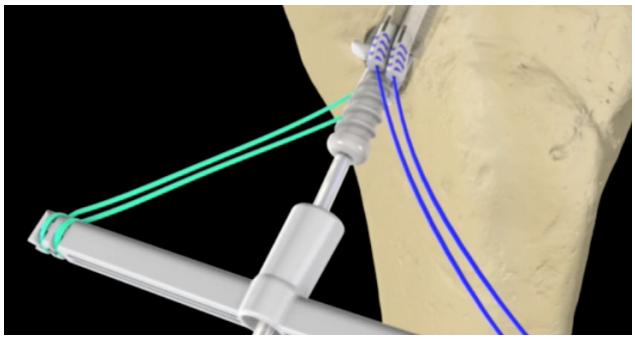
Pull the Driver back along the Guide Wire to disengage from the Tibial Sheaths (Figure 17).

- 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).





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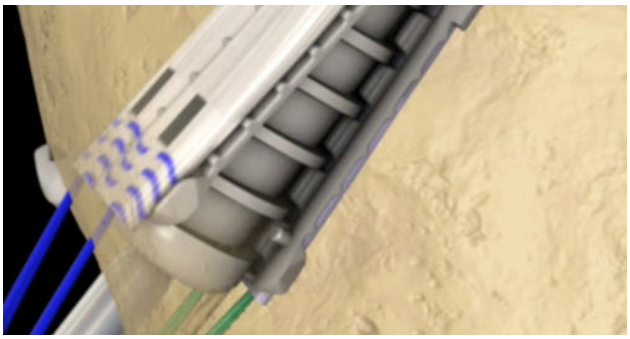

Figure 20

Tibial Fixation (cont.)

Step 7

Keep the knee in 90° of flexion and 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.

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

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.

Notes

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.

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