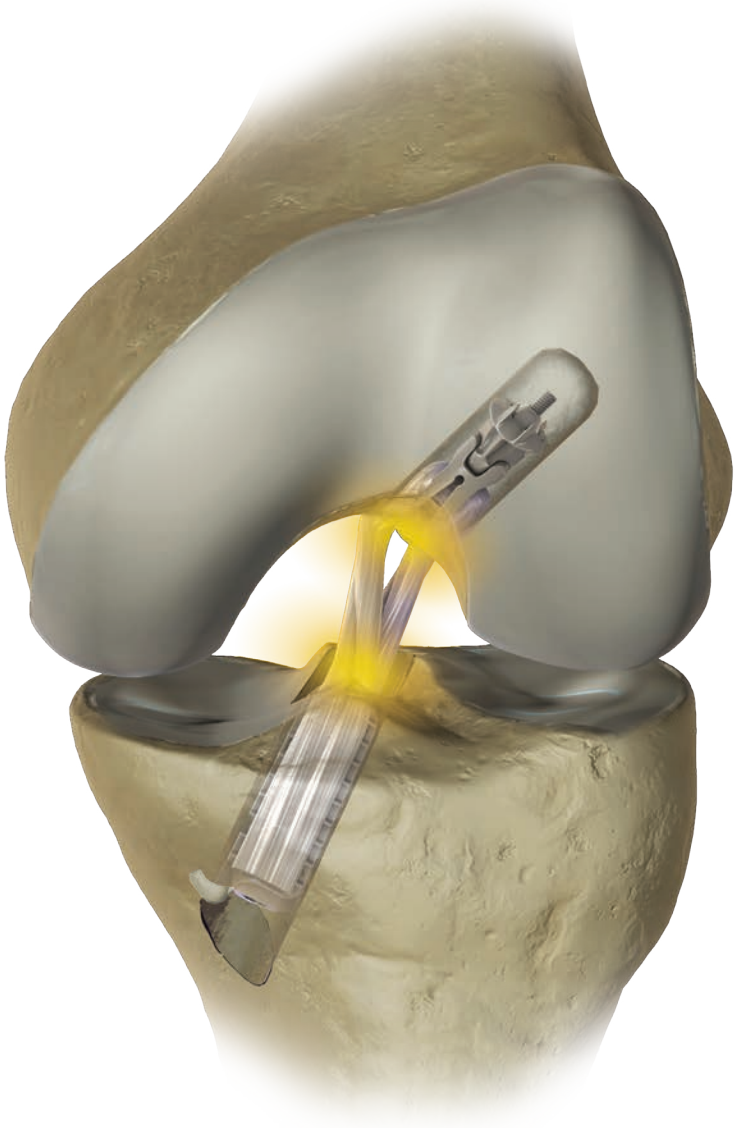
The AperFix® System

The Anatomic Implant

Removal Technique Guide



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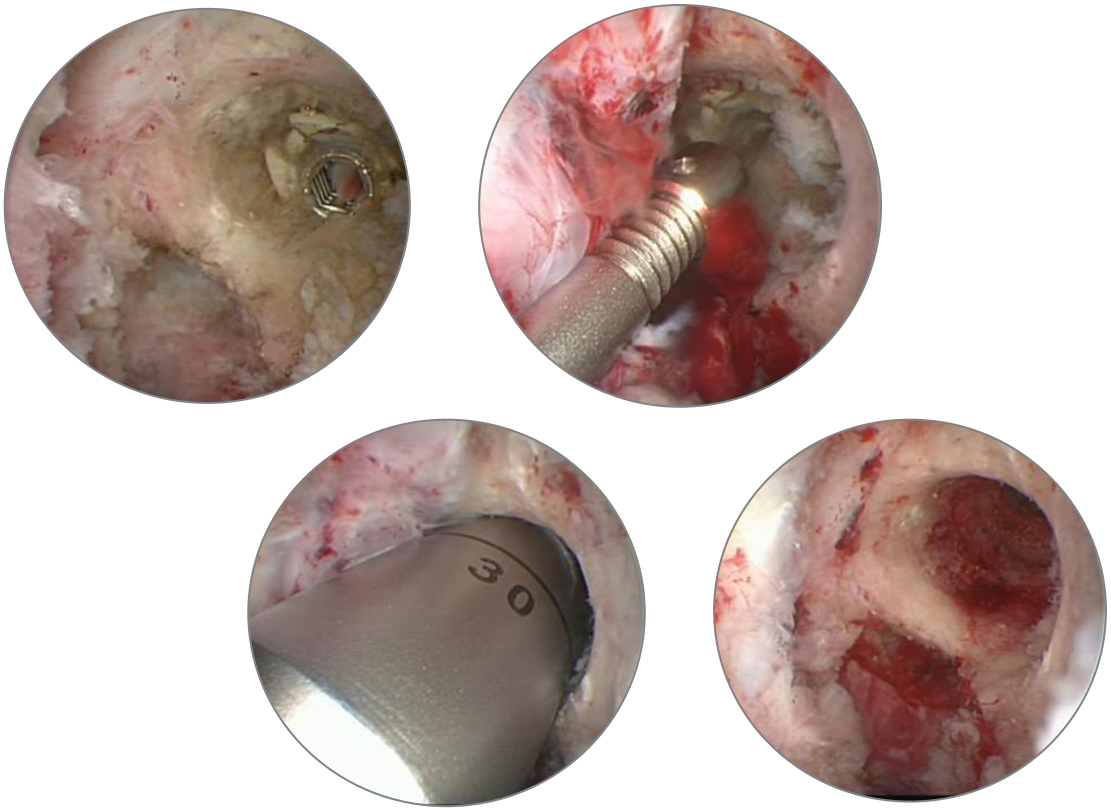


The AperFix System for soft tissue multi-ligament reconstruction of the knee was designed to create a strong, anatomic construct through aperture fixation and circumferential graft compression. The device is designed to restore the native ACL footprint through a simple and reproducible technique.

If a revision is required, Cayenne Medical offers surgeons a simple revision technique and instruments for removal.

The following guide demonstrates the steps for removal of the tibial implant and two options for removing the femoral implant.

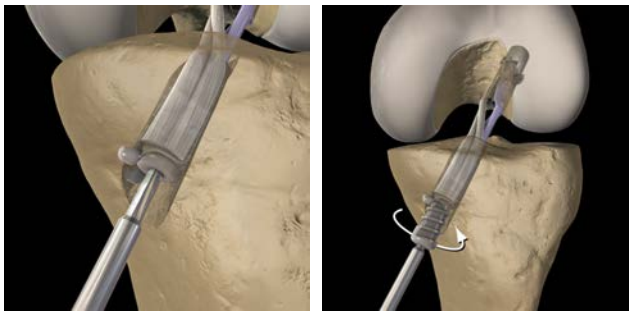


Figure 1

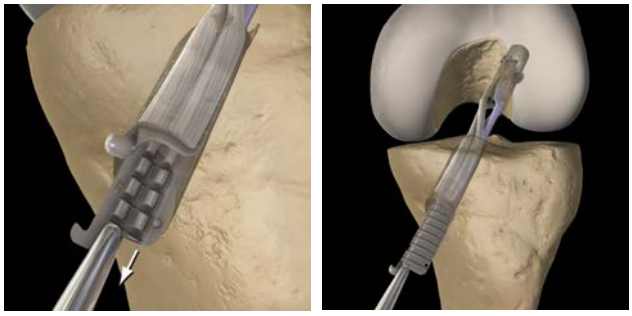


Figure 2

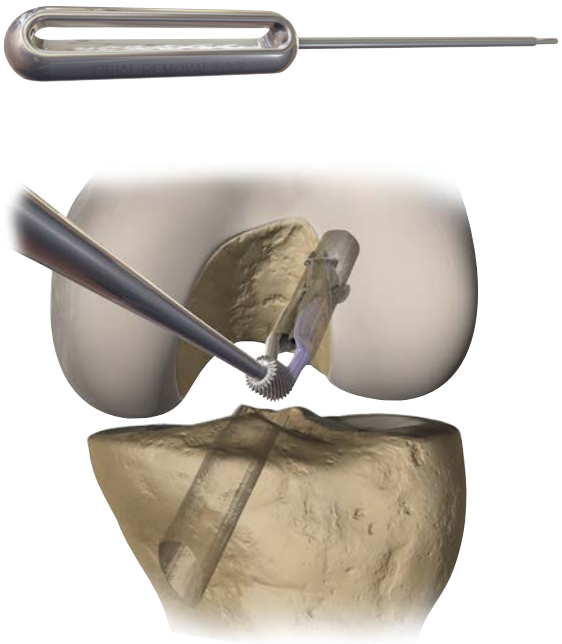


Figure 3

Tibial Removal Steps

Step 1

Clear soft tissue from tibial tunnel to reveal the distal end of the Tibial Screw.

Step 2

Engage the Tibial Removal Tool with the Screw and rotate counterclockwise (to disengage Screw from Sheaths) (Figure 1).

Once disengaged, remove the Screw from the tunnel.

In the absence of the Tibial Removal Tool, a 2.7 – 3.0 mm hex driver may also be used.

Step 3

Grasp the first Tibial Sheath with a standard grasping instrument and remove from the tunnel.

Step 4

Grasp the second Tibial Sheath and remove from the tunnel (Figure 2).

Step 5

Clean the tibial tunnel of all integrated soft tissue and remove remnants of the ACL graft to expose the Femoral Implant (Figure 3).

Figure 4

Figure 5

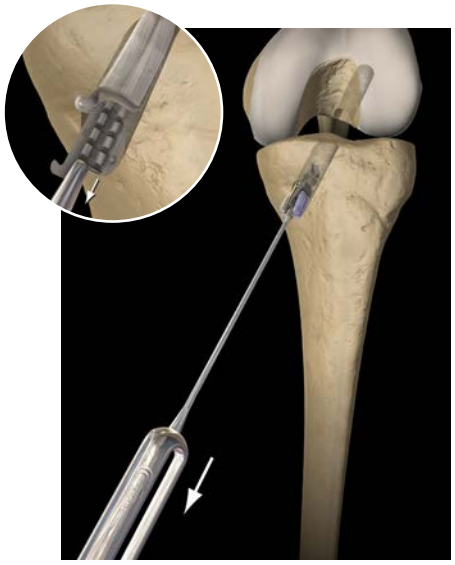


Figure 6

Option 1 – Femoral Implant Removal

Femoral Reverse Threaded Removal Tool

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

Step 1

Insert the AperFix Femoral Implant Removal Tool into the knee joint and locate the distal end of the Femoral Center Screw. This can be accomplished transtibially or using the anteromedial portal (Figure 4).

Step 2

Engage the reverse threaded Removal Tool with the Femoral Central Screw by turning counterclockwise.

Step 3

Once engaged, pull axially while continuing to rotate (Figure 5).

It is important to pull axially while rotating (approximately 7 to 8 full turns) to allow the implant to return to its pre-deployed formation.

Step 4

Remove the Femoral Implant from the femoral socket once it has completely transformed back into its pre-deployed formation (Figure 6).

Step 5

If removed during primary procedure, the graft may be removed from the implant and reused if still intact.

To remove the implant from the removal tool, rotate the removal tool in a clockwise fashion to disengage the left-handed threads from the Femoral Center Screw.

Discard the implant.

Coring Reamer

Alignment Guide Wire

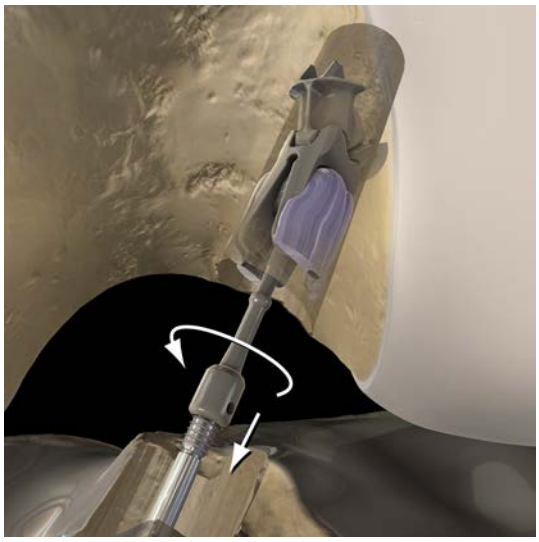


Figure 7

Option 2 – Femoral Implant Removal

Coring Reamer System

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

Pre-Surgery

It is important to determine the technique that was used in the patient's primary procedure prior to revision. To determine whether the AperFix Femoral Implant was implanted transtibially or through the anteromedial portal, it is best to take two X-rays: one from the lateral view with the knee flexed at 90 degrees; the second from the transverse view, taken along the axis of the femur.

Step 1

Engage the reverse threaded Removal Tool with the Femoral Center Screw and turn counterclockwise while pulling axially until the Femoral Center Screw has been completely removed from the implant (Figure 7).

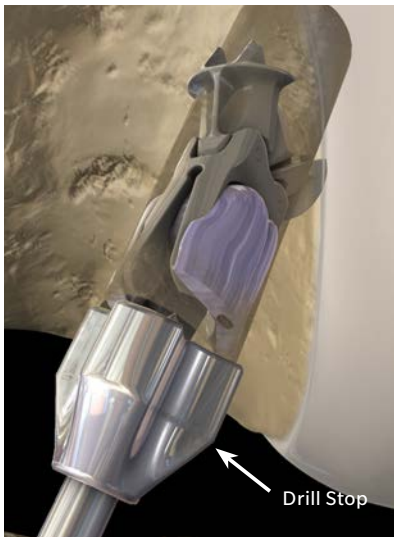


Figure 8

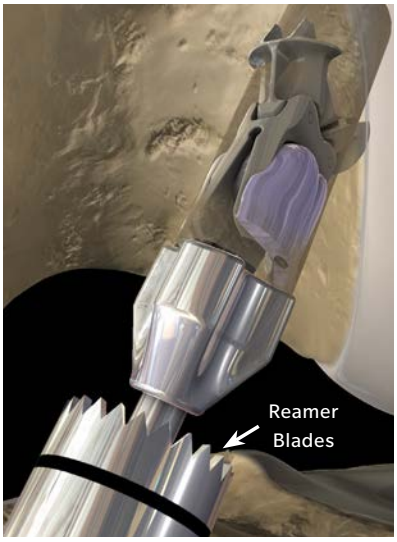


Figure 9

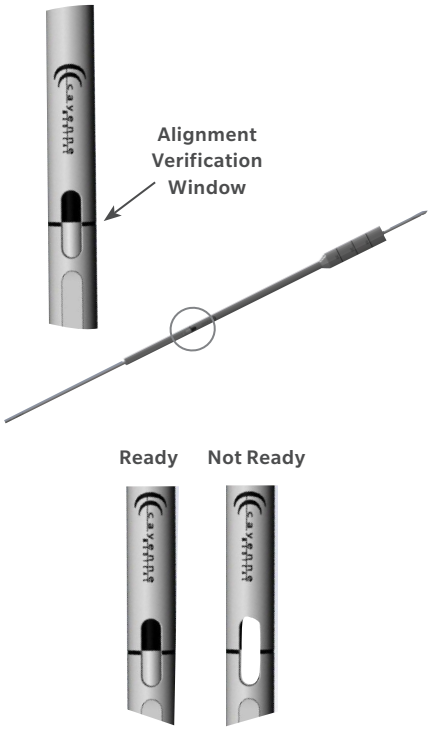


Figure 10

Step 2

Insert the Alignment Guide Wire up into the center of the AperFix Femoral Implant. Stop advancement once the Drill Stop is positioned just outside femoral aperture (Figure 8).

Internal Alignment Verification: Drill Stop must remain in joint space, not inside the femoral socket.

Intended Use: The Sterile AperFix Femoral Implant Coring Removal Drill is intended for use during surgical procedures associated with removal of the AperFix Femoral Implant.

Step 3

Manually insert (walk) the AperFix Femoral Removal Coring Reamer over the Alignment Guide Wire ensuring it rides easily over the Drill Stop. To confirm alignment, use the external verification window.

It is critical to confirm the blades of the Coring Reamer are entirely over the Drill Stop before proceeding with power (Figure 9).

Ensure that the Coring Reamer did not accumulate bone or tissue during passage through the tibial tunnel.

External Alignment Verification: Ensure the Coring Reamer is correctly seated over the Drill Stop (Figure 10).

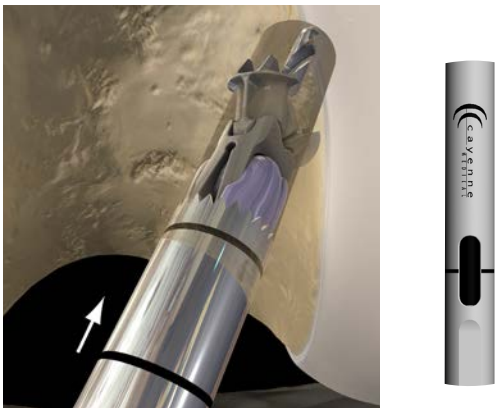
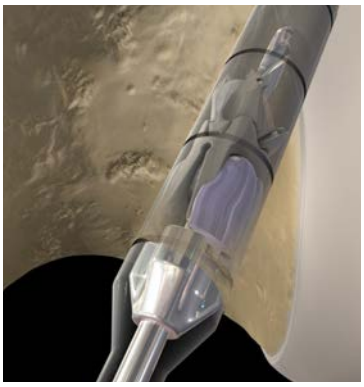


Figure 11



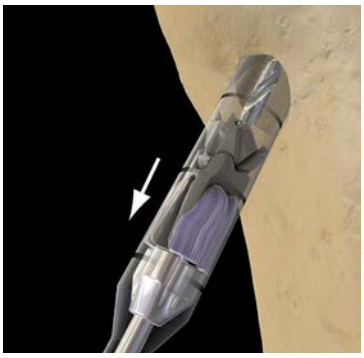


Figure 12

Step 4a

Core at least 30 mm until the Coring Reamer bottoms out against the Drill Stop (Figure 11).

External Alignment Verification: The Alignment Verification Window will be fully shaded during drilling.

Step 4b

Once the Coring Reamer bottoms out against the Drill Stop, the laser band will be visible on the proximal edge of the Alignment Verification Window (Figure 12).

Step 5

Using power, back the Coring Reamer out of the socket to ensure proper encapsulation of the implant.

The Coring Reamer will now hold the encased AperFix Femoral Implant. If not, advance the Coring Reamer back into position and continue reaming.

Any remaining PEEK material can be cleaned out of the tunnel using standard graspers.

The size of the remaining femoral socket will be the same diameter of the Coring Reamer.

Ordering Information

AperFix Removal Instruments

Description	Size	Part Number
Femoral Removal Coring Reamer, Sterile	9 mm 10 mm 11 mm	CM-7109ST CM-7110ST CM-7111ST
Femoral Implant Removal Tool		CM-7200
Tibial Implant Removal Tool		CM-7300

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

INDICATIONS

The Sterile AperFix Femoral Implant Coring Removal Drill is intended for use during surgical procedures associated with removal of the AperFix Femoral Implant.

- CM-7109ST Removal Coring Reamer 9mm, Sterile
- CM-7110ST Removal Coring Reamer 10mm, Sterile
- CM-7111ST Removal Coring Reamer 11mm, Sterile

WARNINGS AND PRECAUTIONS:

AperFix Femoral Implant Coring Removal Drill

WARNINGS

- This instrument is provided STERILE and is a single patient use device. Do not reuse or re-sterilize. The Instruments should be checked for proper function, prior to each use.
- All safety caps and other packaging materials must be removed prior to use.
- The Instruments should be checked for proper function, prior to each use.
- If the instrument does not function properly and smoothly, immediately discontinue use and contact a Cayenne Medical Customer Service Representative.
- As with any surgical instrument, careful attention should be made to assure that excessive force is not placed on this instrument. Excessive force can result in failure.
- The AperFix Coring Removal Drill is designed to be used for removal of the AperFix Femoral Implants. Do not use this drill for other surgical purposes or use with other implants.
- The proper alignment of the Coring Removal Drill and Guide Wire is critical in successful operation of this tool. Misalignment could cause Coring Removal Drill damage.
- Ensure the drill stop is fully recessed inside the AperFix Coring Removal Drill prior to advancing the drill under power.

PRECAUTIONS

- A surgeon should not begin clinical use of the instrument without reviewing the instructions for use and practicing the procedure in a skills laboratory.
- Additional precautions include those applicable to any surgical procedure. In general, careful attention must be paid to avoid all hazards.
- Precautions must be taken when handling some of the instruments since they have sharp points and edges.
- This surgical instrument should only be used with associated Cayenne Medical devices and accessories.
- Ensure axial alignment with all surgical instruments during use.
- Reference the Cayenne Medical Surgical Technique Guide for the instrument to be used.

Notes

For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counselling information, see the package insert and www.zimmerbiomet.com.

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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