

# FEMORAL INTRAFIX

ACL Reconstruction System

*RESTORING THE ANATOMIC ACL FOOTPRINT*

## **ANATOMIC ACL RECONSTRUCTION USING A SINGLE TUNNEL THROUGH AN ANTEROMEDIAL APPROACH**

*SURGICAL TECHNIQUE BY DAVID LINTNER, MD*

### **IMPROVED ACL FOOTPRINT PLACEMENT & COVERAGE\***

- By utilizing a patented sheath and screw design that spreads the graft around the perimeter of a single tunnel.

### **CONTROLLED AM & PL BUNDLE POSITIONING**

- Offers distinct bundle separation in a single tunnel.

### **SOFT TISSUE INTERFERENCE APERTURE FIXATION**

- Provides average pullout strength of 804N with less than 1 mm elongation.\*\*

 **DePuy Mitek**  
a *Johnson & Johnson* company



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## INTRODUCTION

The new Femoral INTRAFIX® ACL Fixation System from DePuy Mitek, Inc. is designed to provide soft tissue femoral fixation for ACL reconstruction surgery using a single tunnel through an anteromedial approach with the use of either allograft or autograft. Femoral INTRAFIX, with its unique patented polypropylene sheath and PEEK screw implant design offers a new technique to achieve a more anatomic ACL reconstruction with improved femoral footprint placement and coverage, controlled anteromedial (AM) and posterolateral (PL) bundle positioning, and strong, stiff soft tissue aperture fixation\*.

The current trend in ACL reconstruction techniques is to more closely restore the anatomical footprint and kinematics of the ACL through a more laterally (“lower”) positioned femoral tunnel, which replaces portions of both the AM and PL bundles<sup>\*\*</sup>.<sup>1,2,5,10,11</sup> Femoral INTRAFIX achieves this result using an anteromedial portal to accurately position a single tunnel in the center of the femoral ACL footprint. Femoral INTRAFIX also creates an hourglass shaped footprint by separating and controlling the positioning of the graft strands toward the native location of the AM and PL bundles. The anteromedial approach allows flexibility in placing the femoral tunnel independent of the tibial tunnel and eliminates a preventable error of an excessively vertical tunnel position commonly seen with a transtibial approach.<sup>1,4</sup>

It has been reported that kinematics of the reconstructed knee are strongly affected by the location of the tibial and femoral tunnels. Biomechanical tests of cadaveric reconstructions demonstrate nearly normal knee kinematics when the tibial tunnel is close to the center of the tibial footprint and the femoral tunnel is placed in the center of the femoral footprint.<sup>4-9</sup> In addition, studies have reported that a lateralized tunnel placed lower in the notch and drilled in the center of the ACL femoral footprint can effectively replace approximately half of the AM bundle and PL bundle footprints.<sup>10</sup>

To further address all the components of an anatomic ACL reconstruction, the shape of the footprint also needs to be evaluated. The native ACL footprint is not circular, and has two distinct regions for the AM and PL bundles. In contrast to other femoral fixation devices, Femoral INTRAFIX allows the strands of a soft tissue graft to be clustered into an hourglass configuration rather than a cylinder.<sup>2</sup> Harner et al<sup>3</sup> reported insertional areas up to 3.5 times larger than the midsubstance of the ligament indicating that the collagen is spread around the perimeter of the insertion. To achieve the goal of anatomic reconstruction, Femoral INTRAFIX fixates the AM and PL bundles in the shape of an hourglass, closely resembling the shape of the native ACL footprint with the collagen segregated into two bundles around the perimeter of the single tunnel.

Finally, Femoral INTRAFIX offers the advantages of strong, stiff aperture fixation. With its unique patented screw and sheath design, Femoral INTRAFIX eliminates problems associated with graft rotation and damage as seen during the insertion of interference screws. In addition, results from a cadaveric comparative study show Femoral INTRAFIX provides an average pullout strength of 800N vs. an interference screw average of 452N after a 1000 cycles loaded between 50 – 200N.<sup>\*\*\*</sup> Femoral INTRAFIX also experienced an average displacement of less than 1 mm compared to the interference screw at approximately 3mm.<sup>\*\*\*</sup>

## **DAVID LINTNER, MD**

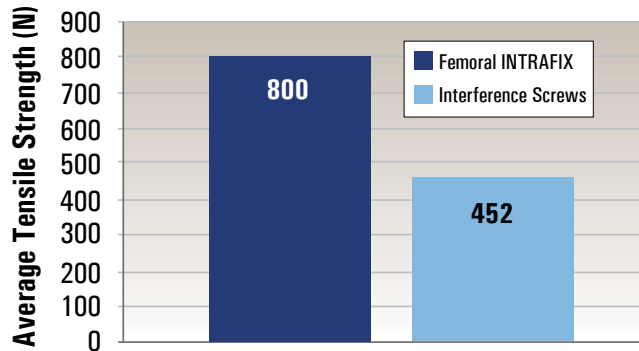
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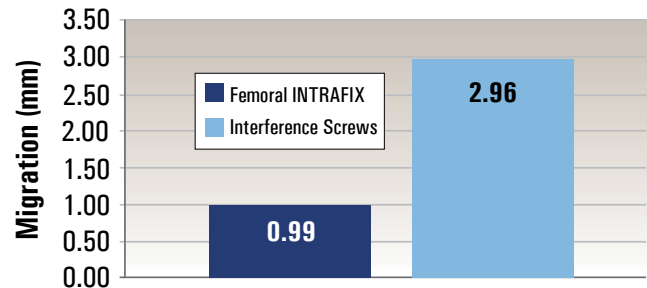
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- \* Compared to existing techniques for single tunnel ACL reconstruction
- \*\* Compared to existing transtibial techniques for single tunnel ACL reconstruction
- \*\*\*Data on File, DePuy Mitek, Inc. April, 2007. MILAGRO® Interference Screw was used in the testing to represent the family of all interference screws

## I. FEMORAL INTRAFIX VS. INTERFERENCE SCREWS COMPARISON STUDY

### ACL Tensile Pull-out (Post-cycling)



### ACL Graft Migration: Femoral INTRAFIX vs. Interference Screw



A strength and stiffness comparison study was conducted in cadaver knees to evaluate the effects of cyclic loading on Hamstring ACL reconstruction. The results showed a significant improvement in both strength and stiffness of Femoral INTRAFIX vs. Interference Screws, reducing elongation from 3mm to 1mm and increasing pullout from 452N to 800N with the test knees cycled 1000 times under loading of 50N to 200N at a frequency of 1/2 Hz.\*\*\*

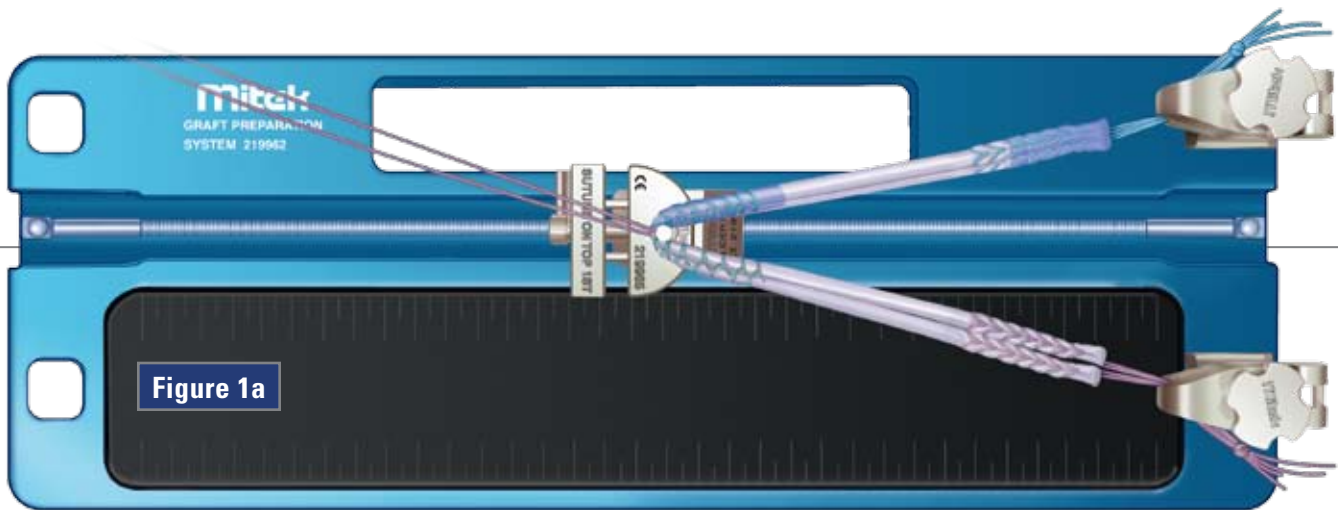


Figure 1a

## II. PREPARE GRAFT

### A. CREATE A TWO BUNDLE GRAFT (Figure 1a)

- **For a semitendinosus gracilis autograft**, fold the graft in half over a single strand of #2 ORTHOCORD® suture and mark 33 mm from the proximal end. Create two bundles by whip stitching each side separately (#0 Vicryl® or #0 Ethibond® is recommended) to 30 mm from fold.

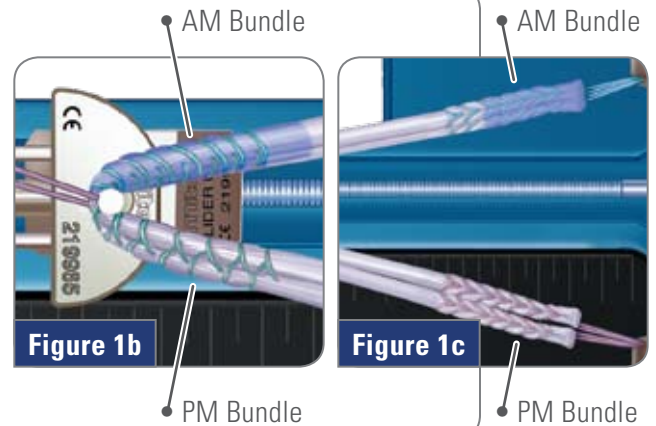
- **For anterior/posterior tibialis allograft**, fold the graft in half over a single strand of #2 ORTHOCORD suture and mark 33mm from the proximal end. Tighten the independent fibers of the allograft by whip stitching each bundle separately onto itself (#0 Vicryl or #0 Ethibond® recommended) to 30mm from fold.

*Note: Suturing the posterior edge of both strands together may help control bundle positioning during screw placement. In addition, Suturing the proximal bundles 2mm – 3mm past the entrance of the femoral tunnel also helps to control bundle positioning during screw placement.*



## B. MARK THE GRAFT

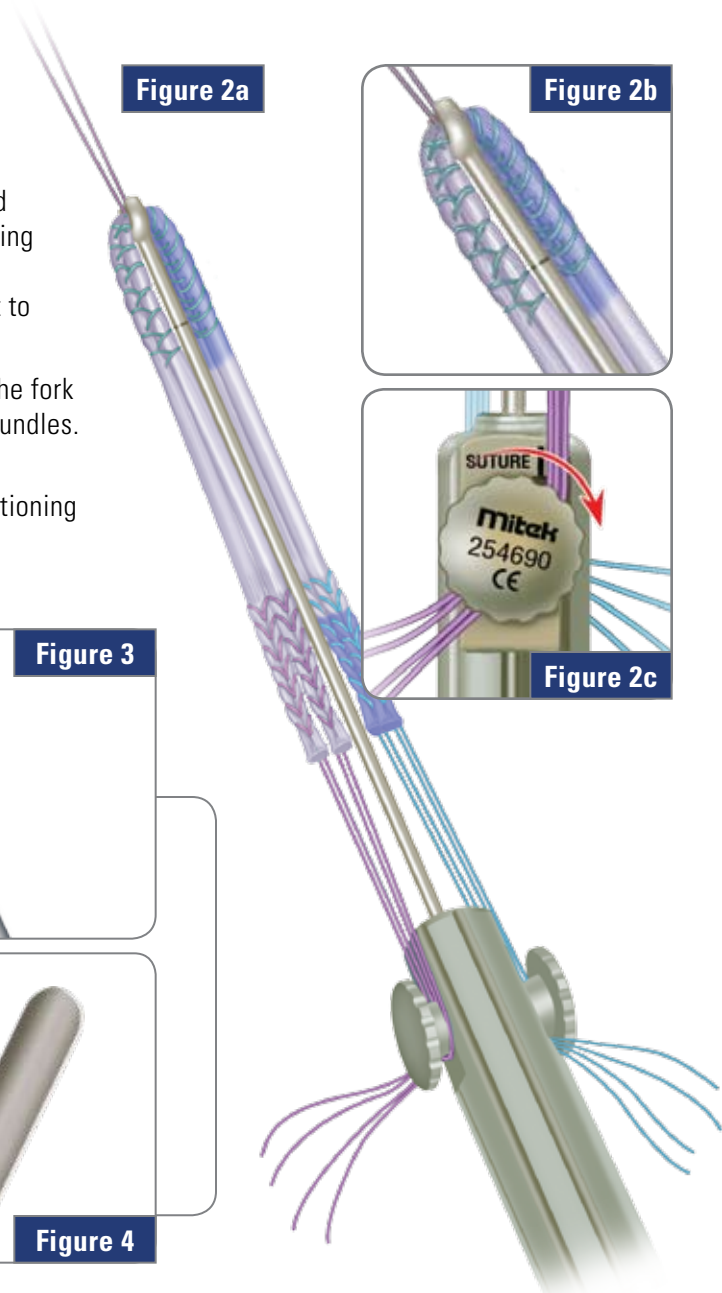
- **Femoral graft side** – Mark each strand at 30 mm. Then, color a portion of the AM bundle and leave the PL bundle unmarked. (**Figure 1b**)
- **Tibial graft side** – whipstitch based on current technique for desired fixation. It is recommended to use two different color sutures for easier identification of the AM and PL bundles and to mark the AM bundle to match the marking on the proximal side. (**Figure 1c**)



## III. PREPARE GRAFT FOR DELIVERY

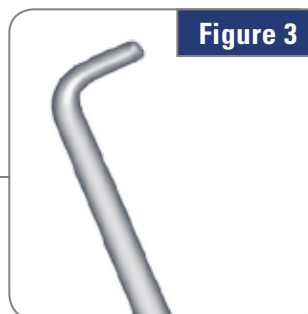
### A. USING THE GRAFT POSITIONING TOOL (Figure 2a)

- The Graft Positioning Tool can be used to facilitate desired AM and PL positioning of the two bundle strands in the Femoral Tunnel during graft passage. Note: When using the Graft Positioning Tool, it is recommended to upsize the tibial tunnel 1mm larger than the graft to facilitate easy graft passage and rotation.
- With #2 ORTHOCORD looped through the graft, place the graft in the fork on the positioning instrument, thus separating the graft into two bundles. (**Figure 2b**)
- Secure the graft sutures around the suture cleats on the Graft Positioning Tool to maintain tension in both bundle strands. (**Figure 2c**)
- Wrap graft in damp gauze and store for later steps.

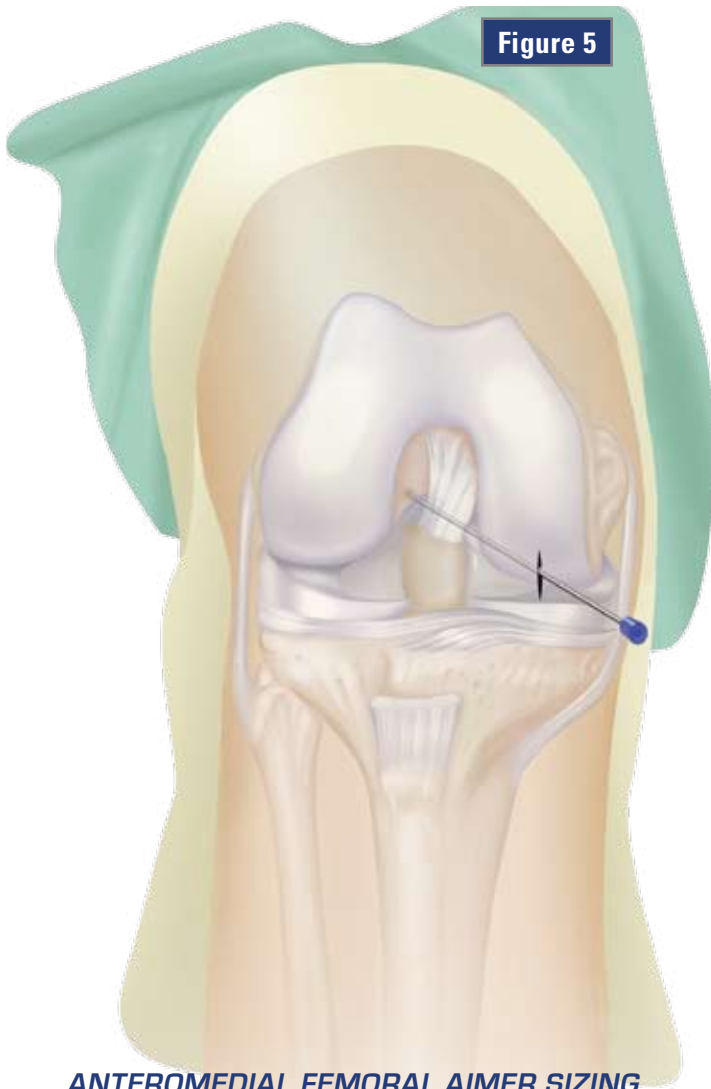


### B. USING A PROBE AND/OR MALLEABLE GRAFT RETRACTOR

- Alternatively, a probe (**Figure 3**) and/or DePuy Mitek Malleable Graft Retractor (**Figure 4**) can be used to control bundle rotation and positioning during graft insertion into the femoral tunnel.
- Wrap graft in damp gauze and store for later steps.



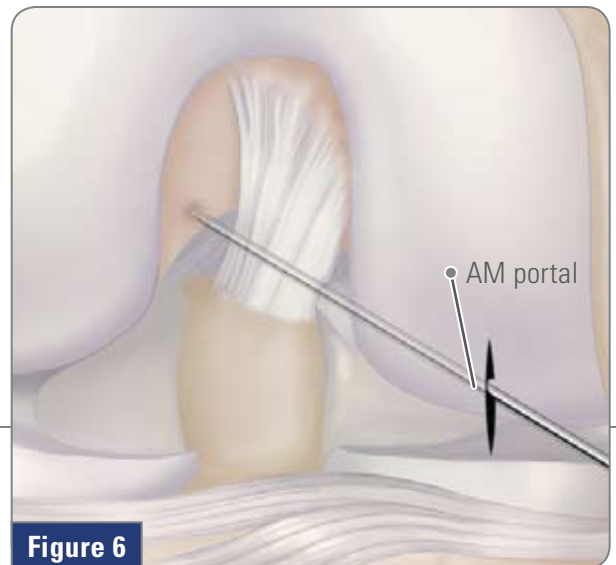
**IV. ANTEROMEDIAL (AM) PORTAL APPROACH FOR CREATING THE FEMORAL TUNNEL**



**Figure 5**

**A. CREATE FEMORAL AM PORTAL**

- Standard arthroscopy portals are marked and incised.
- The “working” AM arthroscopy portal is placed 1cm medial to the patellar tendon and just distal to the inferior pole of the patella (assuming no patella baja).<sup>12</sup> **(Figure 5)**
- The AM Portal can also be located while under direct visualization with the scope in the anterolateral portal by inserting a spinal needle just above the tibial plateau and anterior horn of the medial meniscus.



**Figure 6**

**B. MARK FEMORAL TUNNEL LOCATION**

- A small notchplasty is performed in most cases and the over-the-top position is identified.
- Next, a 30 Awl or spinal needle is placed through the AM portal with the knee at 90 of flexion. The awl or spinal needle is used to identify the ACL insertion site on the femur and to mark the center of the proposed tunnel roughly 6mm to 8mm anterior to the posterior cortex at the 2-o’clock position for the left knee or 10-o’clock position for a right knee.<sup>12</sup> **(Figure 6)**

**ANTEROMEDIAL FEMORAL AIMER SIZING**

Tunnel	AM Femoral Aimer	Back Wall
8 mm	6.5 mm	2.5 mm
8.5 mm	6.5 mm	2.25 mm
9 mm	6.5 mm	2 mm
9.5 mm	6.5 mm	1.75 mm
10 mm	7.5 mm	2.5 mm
10.5 mm	7.5 mm	2.25 mm
11 mm	7.5 mm	2 mm

*Note: Posteriorization of fixated graft makes a thicker back wall more desirable*

## C. PREPARE FEMORAL TUNNEL LOCATION WITH AM FEMORAL AIMER (SEE FEMORAL AIMER SIZING CHART)

- With the knee at 90° of flexion, the DePuy Mitek AM Femoral Aimer is placed through the AM portal with the tip placed posterior to the marked position for the femoral tunnel. **It is essential that the knee be at 90° of flexion when marking the notch at the drilling site to ensure correct femoral tunnel placement. (Figure 7a)**
- The knee is then hyperflexed to 110 to 120° allowing aimer to move with the rotating condyle. Changing the knee's position by hyperflexing during drilling will allow for a more anterior directed tunnel and avoids posterior wall blowout.<sup>12</sup>
- An Eyelet Drill Pin is placed through the AM Femoral Aimer and advanced through the AM portal (Figure 7b). The Drill Pin should exit the femur anterior to its midline (Figure 7c). Hyperflexion allows better access to the medial portion of the lateral femoral condyle and the AM Femoral Aimers ensure approximately a 2mm back wall to avoid compromising the posterior aspect of the tunnel. The Femoral Aimers are specifically contoured to fit the AM portal hyperflexion technique.

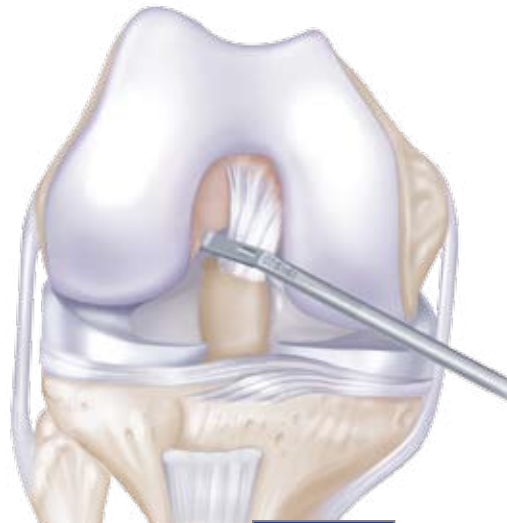


Figure 7a

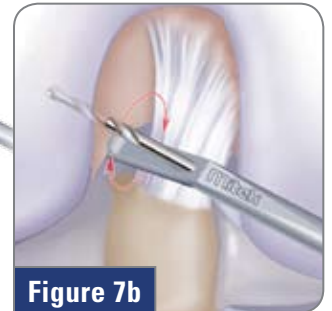


Figure 7b

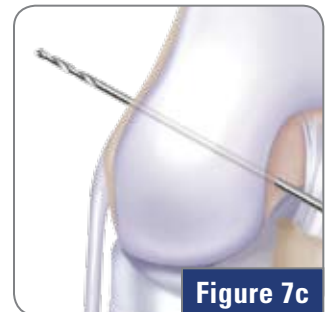


Figure 7c

## D. DRILL FEMORAL TUNNEL WITH ACORN REAMER

- An Acorn Reamer 1mm larger than graft size is passed over the guidewire and initially advanced by hand to atraumatically pass by the articular surface of the medial femoral condyle.<sup>12</sup>
- The femoral tunnel is drilled to a depth of 30mm. In small femurs, the femoral tunnel length may have to be adjusted to avoid violation of the lateral femoral cortex. It is important to note that drill depths of less than 27mm may result in difficulties with trial and sheath insertion. (Figure 8a and 8b).
- A shaver is used to remove excess bone debris.

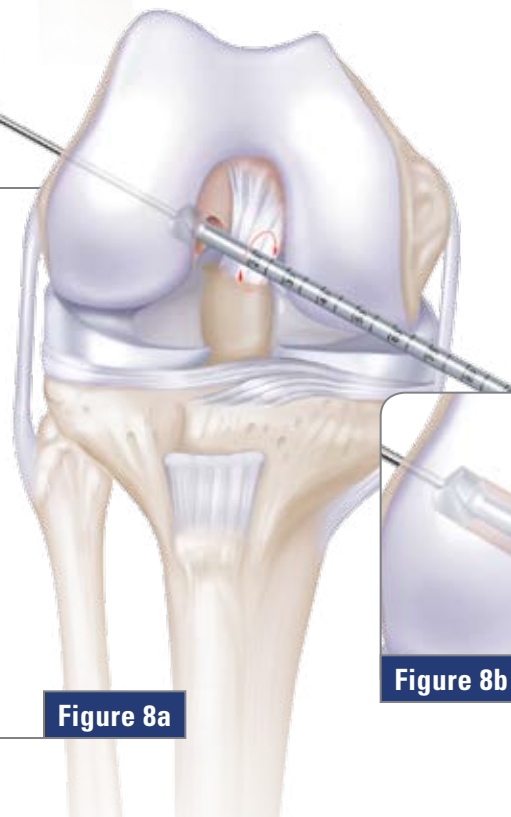


Figure 8a



Figure 8b



## V. INTRODUCE GRAFT

### A. TIBIAL TUNNEL PREPARATION

- Use the DePuy Mitek Tip to Tip or Elbow Aiming Tibial Guide to drill the tibial tunnel.

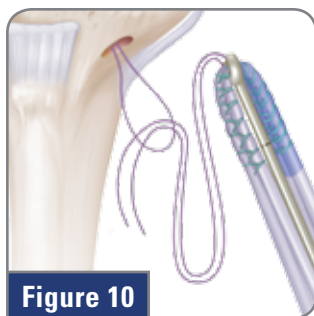
*Note: When using the Graft Positioning Tool, it is recommended to upsize the tibial tunnel 1mm larger than the graft to facilitate easy graft passage and rotation.*

### B. CHOOSE GRAFT PASSING METHOD

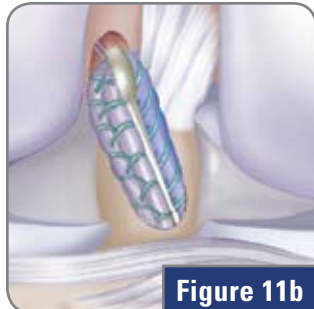
- The Graft Positioning Tool or probe and/or DePuy Mitek Malleable Graft Retractor can also be used for graft passage to and facilitate graft positioning.

### C. INTRODUCE GRAFT AND POSITION IN FEMORAL TUNNEL

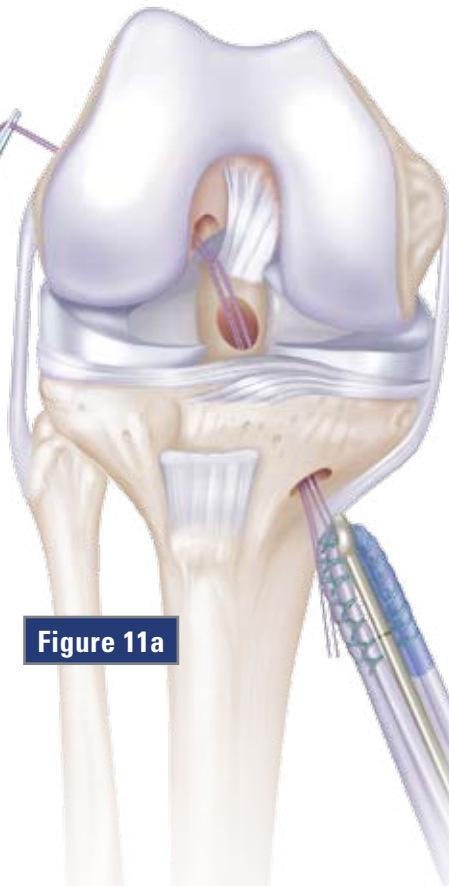
- Introduce the passing suture attached to a Drill Pin through the AM portal and Retrieve the passing suture through the tibial tunnel with a grasping instrument. **(Figures 9a and 9b)**
- Pass the two limbs of #2 ORTHOCORD from the apex of the graft through the suture loop exiting the tibial tunnel. **(Figure 10)**



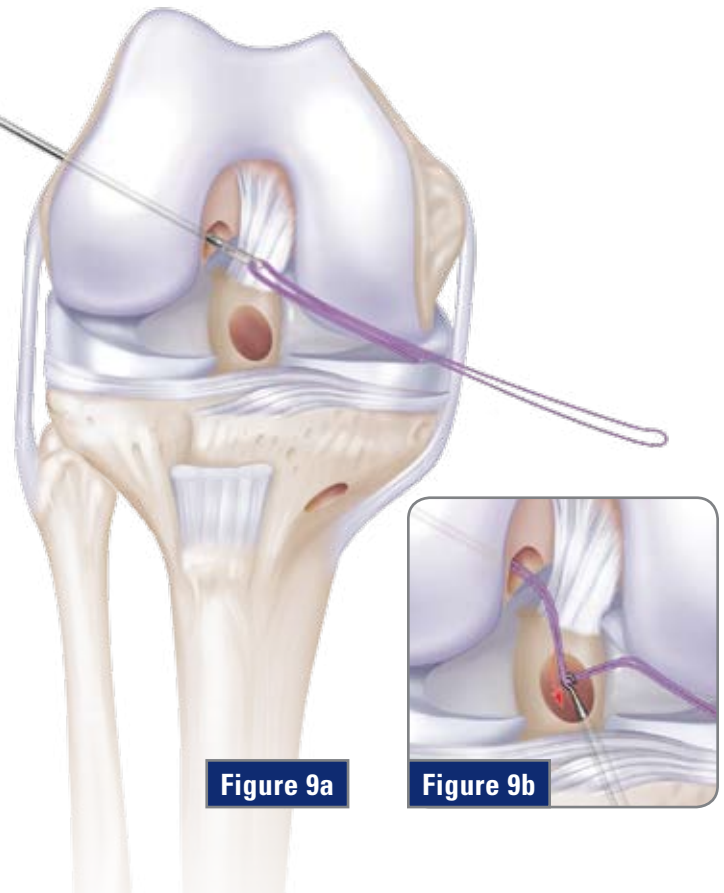
**Figure 10**



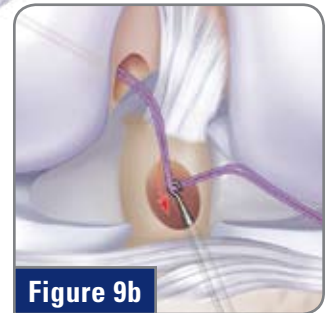
**Figure 11b**



**Figure 11a**

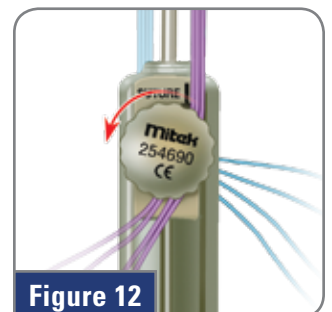


**Figure 9a**



**Figure 9b**

- With the knee at 110 to 120 of flexion, the graft sutures are then shuttled through the knee via the suture loop and passed through the femoral tunnel and out the anterolateral thigh. Pull the graft sutures while advancing the Graft Positioning Tool through the tibial tunnel to the aperture of the femoral tunnel. Before advancing the graft into the femoral tunnel, the AM and PL bundles are rotated to the desired position. **(Figures 11a and 11b)**
- Release the sutures from the Graft Positioning Tool by loosening both wheels when the graft is at the entrance of the femoral tunnel. While maintaining the orientation of the Graft Positioning Tool, pull the graft into the femoral tunnel using the fork on the instrument to guide the graft in. **(Figure 12)**
- Alternatively, in place of using the Graft Positioning Tool, a probe and/or Malleable Graft Retractor can be used through the AM portal to position the AM and PL strands into the desired locations.



**Figure 12**



## VI. TRIAL FEMORAL TUNNEL

### A. INTRODUCE SHEATH TRIAL INTO FEMORAL TUNNEL

- **Do not select and open implant size until the trial fit has been determined.**
- With the knee flexed at the same angle as when the femoral tunnel was drilled, introduce the Sheath Trial of a size equal to the size of the graft via the AM portal. **(Figure 13)**
- Place the keel of the Sheath Trial between the AM & PL strands to create bundle separation. Rotate to obtain desired positioning before trial insertion (i.e. one strand posterior, the other inferior within the single tunnel). This can also be facilitated using a Malleable Graft Retractor. **(Figure 14)**
- Rotate the Sheath Trial to orient its broader convex surface (laser marked) to an anterior distal position in the femoral tunnel and manually insert trial tip between graft bundles until snug. **(Figure 14)**

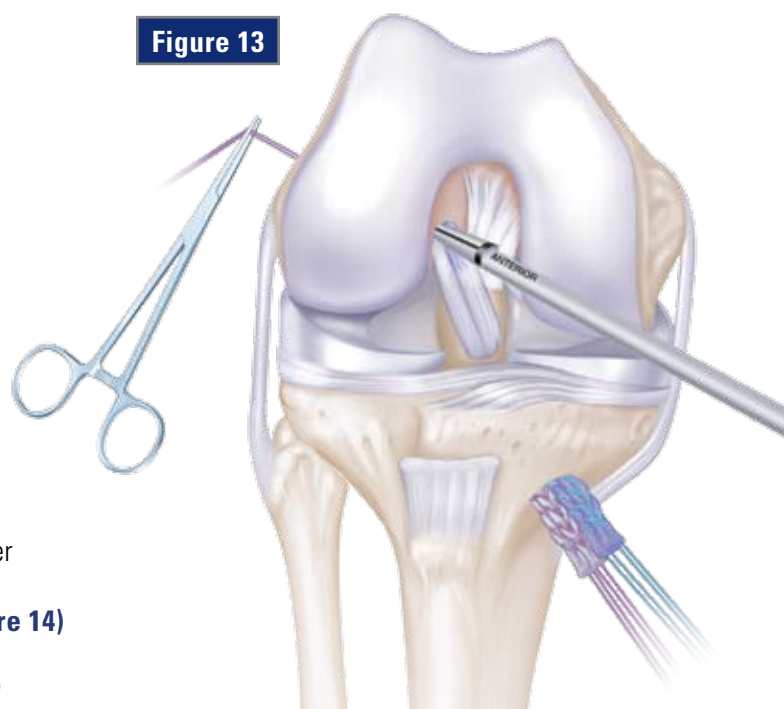


Figure 13

### B. SELECT IMPLANT SIZE (SEE IMPLANT SIZING CHART)

- Femoral INTRAFIX comes packaged in two implant systems called Hard (for hard bone) and standard. The surgeon will select the appropriate system based on assessment of bone quality.
- Drive the Sheath Trial between graft and tunnel using a mallet until fully seated to the back shoulder of the trial. The laser mark on the inserter should not be visible when the trial is completely inserted. In addition, **it is very important for the shoulder of the trial to be flush or slightly recessed to create the dilation needed to properly insert the Femoral Intrafix Sheath Implant with the Sheath Inserter.** **(Figure 15)**
- The Sheath Trial should seat completely with moderate force. If comfortable with trial fit, select Femoral INTRAFIX Standard System equal to trial size. If the bone is hard, use the “hard” system as indicated by the sizing guidelines (undersize the screw 1 mm).
- If the Sheath Trial seats easily (i.e., without malleting) proceed with the next larger Sheath Trial size. If the larger Sheath Trial completely seats, use the “standard” sizing guideline.
- If the Sheath Trial cannot be fully seated, it is removed and the system corresponding to the sizing guidelines for the previous Sheath Trial is used.
- Remove the Sheath Trial from femoral tunnel (may require malleting) leaving the graft compressed posteriorly in the femoral tunnel.



Figure 14

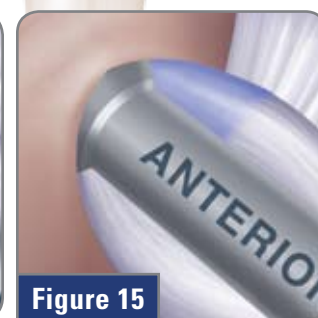


Figure 15

### FEMORAL INTRAFIX SIZING GUIDELINES (mm)

Graft	Tunnel	Trial	System**	System Includes
7	8	7-7.5	7-7.5 Hard	7mm Sheath, 6mm Screw
7.5	8.5		7-7.5 Standard	7mm Sheath, 7mm Screw
8	9	8-8.5	8-8.5 Hard	8mm Sheath, 7mm Screw
8.5	9.5		8-8.5 Standard	8mm Sheath, 8mm Screw
9	10	9-10	9-10 Hard	9mm sheath, 8mm screw
9.5	10.5		9-10 Standard	9mm sheath, 9mm screw
10	11		9-10 Standard	9mm sheath, 9mm screw

\*\* Screw size is ultimately the decision of the Surgeon. If the Trial is difficult to insert, use a smaller screw implant system that corresponds to the trial size.

## VIII. IMPLANTING THE FEMORAL INTRAFIX SYSTEM

### A. IMPLANTING THE FEMORAL INTRAFIX SHEATH

- Once the Femoral INTRAFIX System size has been selected, place the Femoral INTRAFIX Sheath on same size Sheath Inserter shaft tip.
- With the knee flexed at the same angle as when the tunnel was drilled, insert the Sheath and Sheath Inserter through the AM portal with the wide convex ribbed surface of the Sheath oriented anteriorly in the femoral tunnel.

(Figure 16)

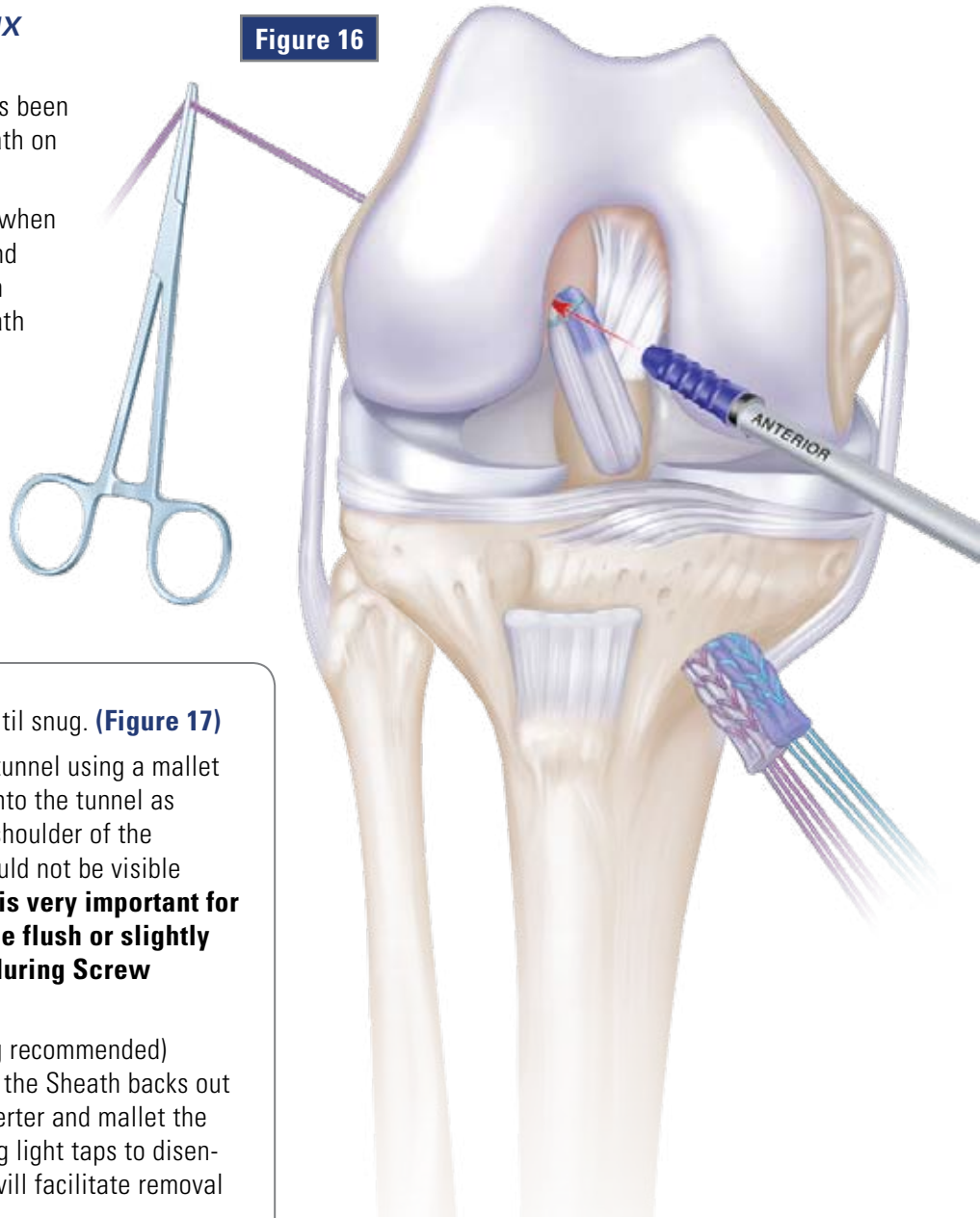


Figure 16

- Insert the Sheath between graft bundles until snug. (Figure 17)
- Drive Sheath between graft strands in the tunnel using a mallet until fully seated to a depth of 2mm-3mm into the tunnel as indicated by the laser marking on the rear shoulder of the inserter. The laser mark on the inserter should not be visible when the Sheath is completely inserted. **It is very important for the shoulder of the Sheath Inserter to be flush or slightly recessed to prevent Sheath extrusion during Screw insertion.** (Figure 18)
- Remove the Sheath Inserter (light malleting recommended) leaving the Sheath in the femoral tunnel. If the Sheath backs out during instrument removal, reinsert the inserter and mallet the Sheath back to the appropriate depth. Using light taps to disengage the Sheath Inserter from the Sheath will facilitate removal while maintaining Sheath placement within the femoral tunnel. (Figure 19)

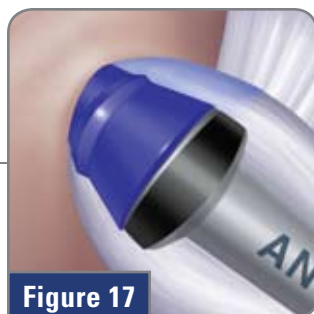


Figure 17



Figure 18

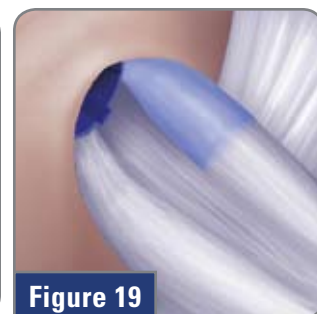
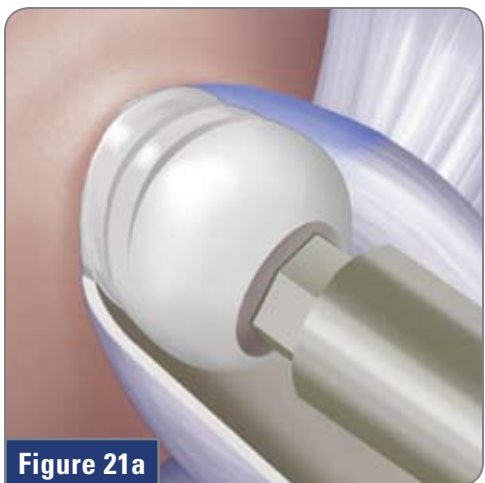
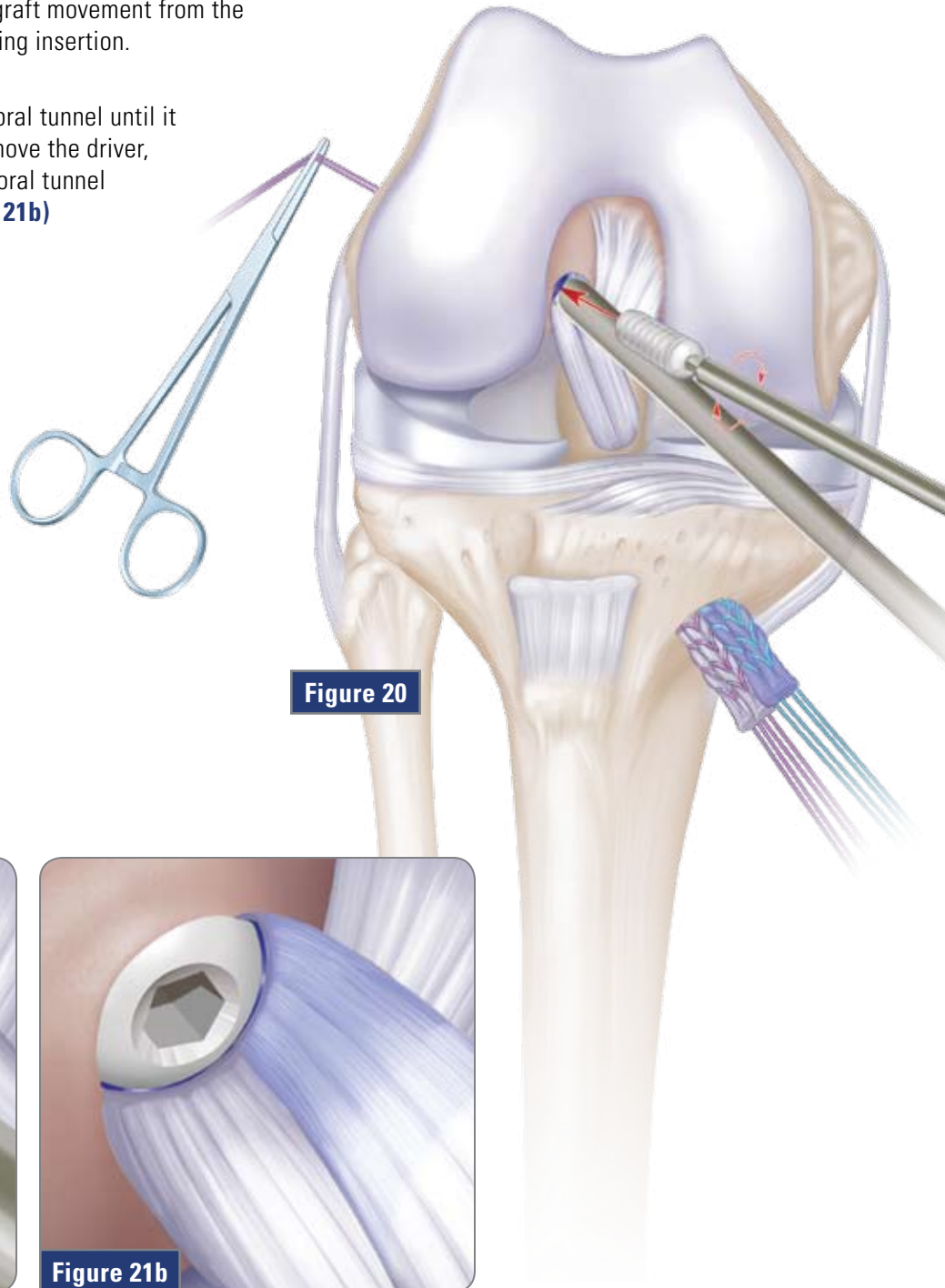


Figure 19

## B. IMPLANTING THE FEMORAL INTRAFIX SCREW

- Screw size is determined by the system chosen per the sizing guideline (in general, the Screw size is the same size as the Sheath size, unless the bone is hard, then it is undersized 1 mm).
- With the knee flexed at the same angle, introduce the Femoral INTRAFIX Screw through the AM portal to the entrance of the femoral tunnel. A Malleable Graft Retractor can be used as a barrier between the graft and screw to prevent graft movement from the screw threads contacting graft fibers during insertion. **(Figure 20)**
- Drive the Screw into the Sheath and femoral tunnel until it is flush with the cortical surface and Remove the driver, leaving the Screw and Sheath in the femoral tunnel with the graft fixated. **(Figures 21a and 21b)**





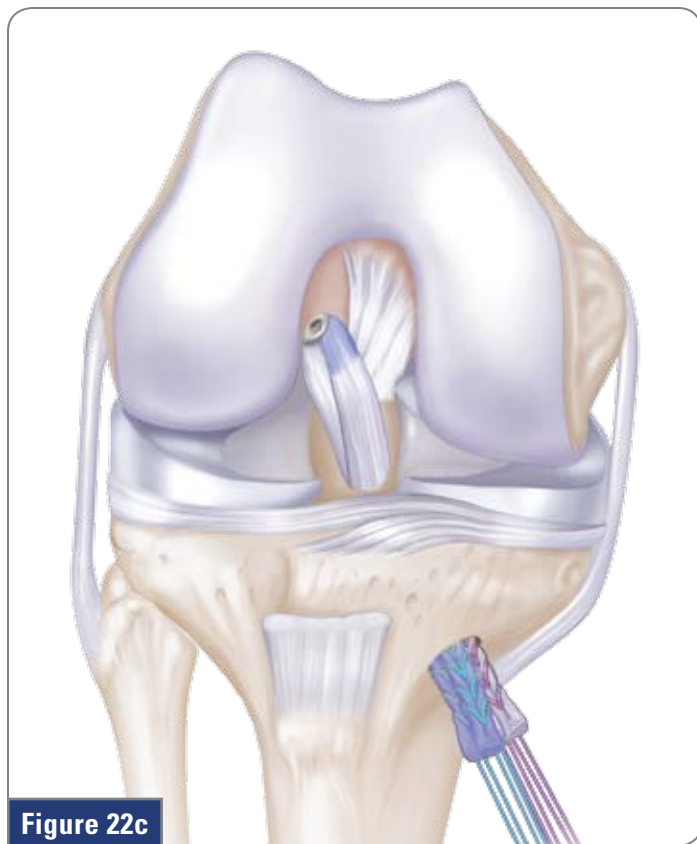
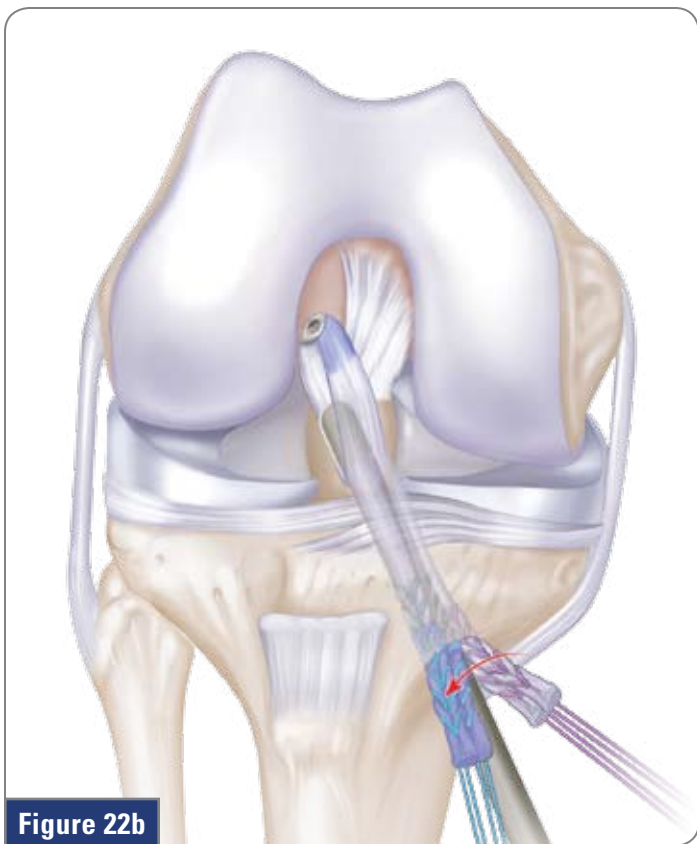
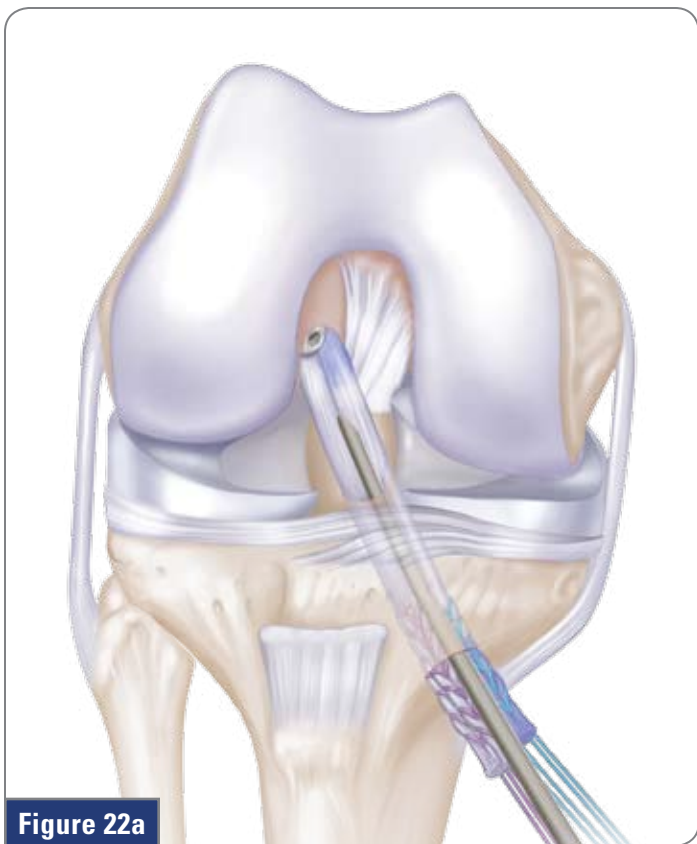
## **IX. AM AND PL BUNDLE POSITIONING FOR TIBIAL FIXATION**

### **A. AM & PL POSITIONING FOR TIBIAL FIXATION**

- Introduce the Malleable Graft Retractor into the tibial tunnel between the AM and PL bundle. **(Figure 22a)**
- With the concavity of the Malleable Graft Retractor cupping the AM bundle, rotate the AM bundle so its position is anterior to the PL bundle. **(Figure 22b)**
- Remove the Malleable Graft Retractor leaving the AM and PL bundles in their desired positions and complete the ACL reconstruction with either DePuy Mitek's Tibial INTRAFIX or MILAGRO Interference Screw. **(Figure 22c)**

### **B. TIBIAL TUNNEL FIXATION**

- See INTRAFIX or MILAGRO Surgical Techniques for instructions for use.



**Figure 22a**

**Figure 22b**

**Figure 22c**



**X. COMPLETED FEMORAL INTRAFIX ACL RECONSTRUCTION**

**A. FEMORAL INTRAFIX ACL RECONSTRUCTION WITH TIBIAL INTRAFIX (Figures 23a, 23b and 23c)**

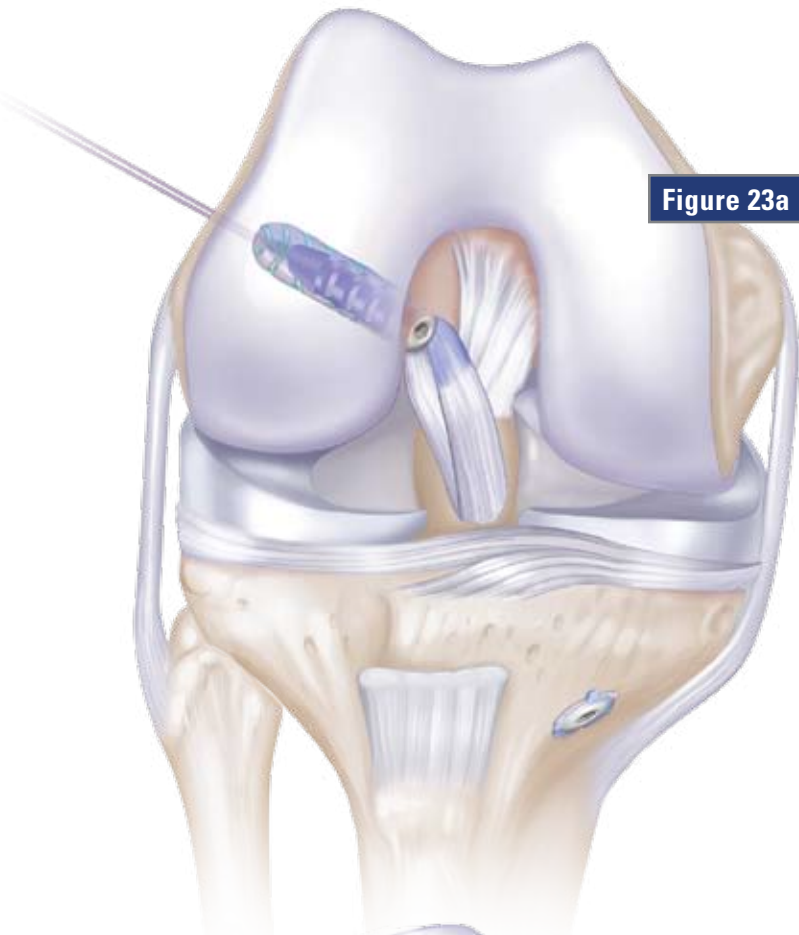


Figure 23a



Figure 23b



Figure 23c

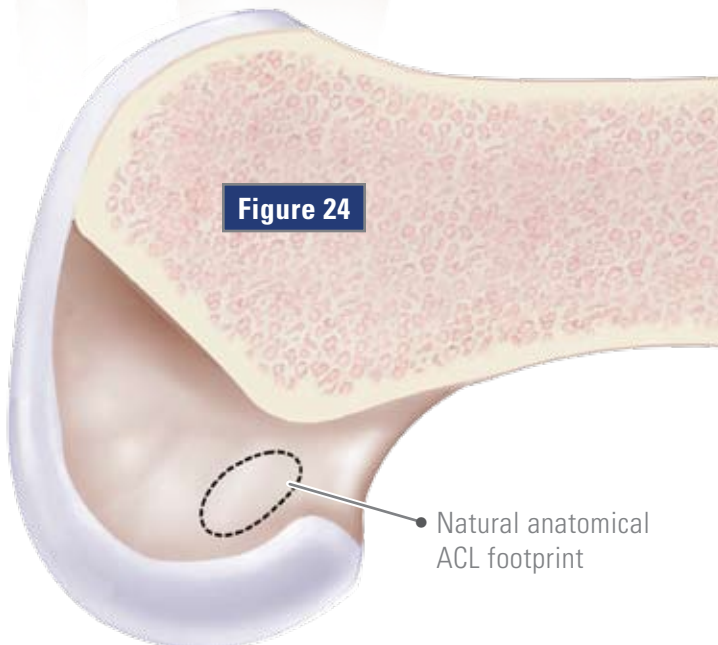


Figure 24

Natural anatomical ACL footprint

**B. RESTORING THE ANATOMIC ACL FOOTPRINT (Figures 24 and 25)**

- Improved ACL Footprint Placement & Coverage\*
- Controlled AM & PL bundle positioning
- Soft Tissue Interference Aperture Fixation

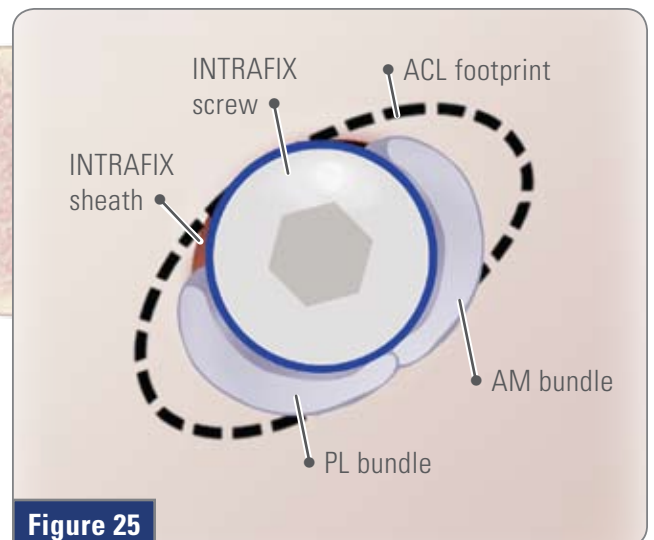


Figure 25

# FEMORAL INTRAFIX

ACL Reconstruction System



## RESTORING THE ANATOMIC ACL FOOTPRINT

### ORDERING INFORMATION

#### FEMORAL INTRAFIX IMPLANT SYSTEMS

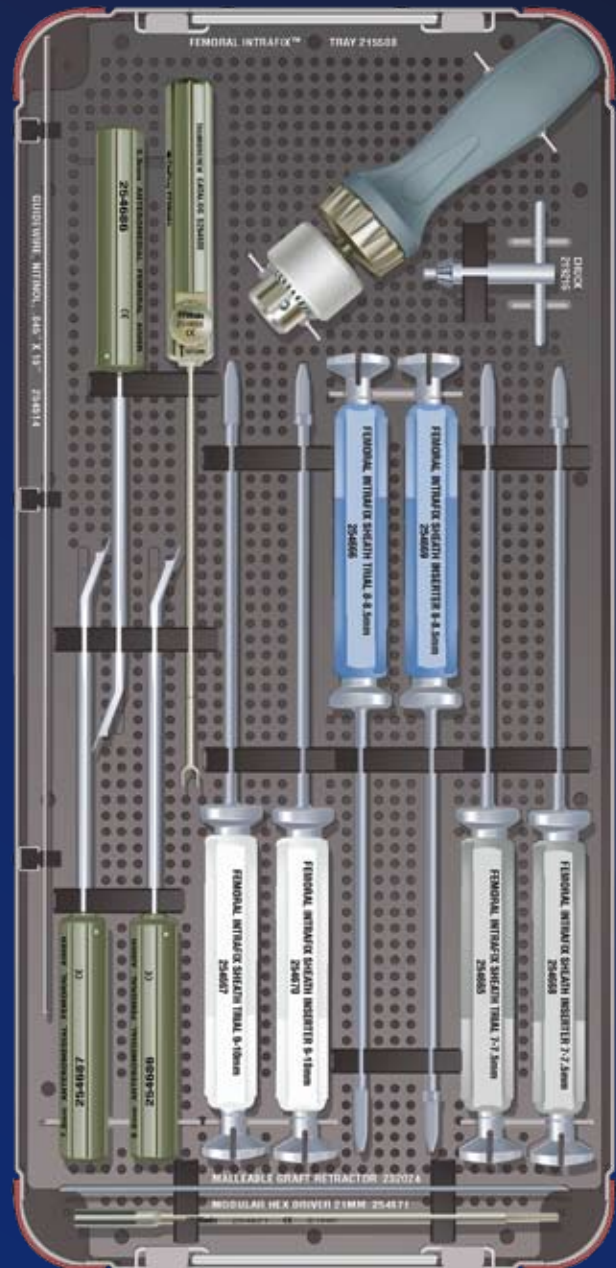
- 254680 Femoral INTRAFIX System 7-7.5mm Hard
- 254681 Femoral INTRAFIX System 7-7.5mm Standard
- 254682 Femoral INTRAFIX System 8-8.5mm Hard
- 254683 Femoral INTRAFIX System 8-8.5mm Standard
- 254684 Femoral INTRAFIX System 9-10mm Hard
- 254685 Femoral INTRAFIX System 9-10mm Standard

#### FEMORAL INTRAFIX INSTRUMENTS & ACCESSORIES

- 254665 Femoral INTRAFIX Sheath Trial 7-7.5mm
- 254666 Femoral INTRAFIX Sheath Trial 8-8.5mm
- 254667 Femoral INTRAFIX Sheath Trial 9-10mm
- 254668 Femoral INTRAFIX Sheath Inserter 7-7.5mm
- 254669 Femoral INTRAFIX Sheath Inserter 8-8.5mm
- 254670 Femoral INTRAFIX Sheath Inserter 9-10mm
- 254671 Modular Hex Driver 21mm
- 252762 Anteromedial Femoral Aimer 5.5mm
- 254686 Anteromedial Femoral Aimer 6.5mm
- 254687 Anteromedial Femoral Aimer 7.5mm
- 254677 Femoral INTRAFIX Graft Positioner
- 254690 Graft Positioner Replacement Screw
- 232024 Malleable Graft Retractor
- 232300 ACL Disposable Kit

#### FEMORAL INTRAFIX TRAY SYSTEM

- 215000 Femoral INTRAFIX ACL Fixation Tray
- 215451 Large Sterilization Tray Lid



For more information, call your DePuy Mitek representative at 1-800-382-4682 or visit us at [www.depuymittek.com](http://www.depuymittek.com). DePuy Mitek, Inc., 325 Paramount Drive, Raynham, MA 02767.

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