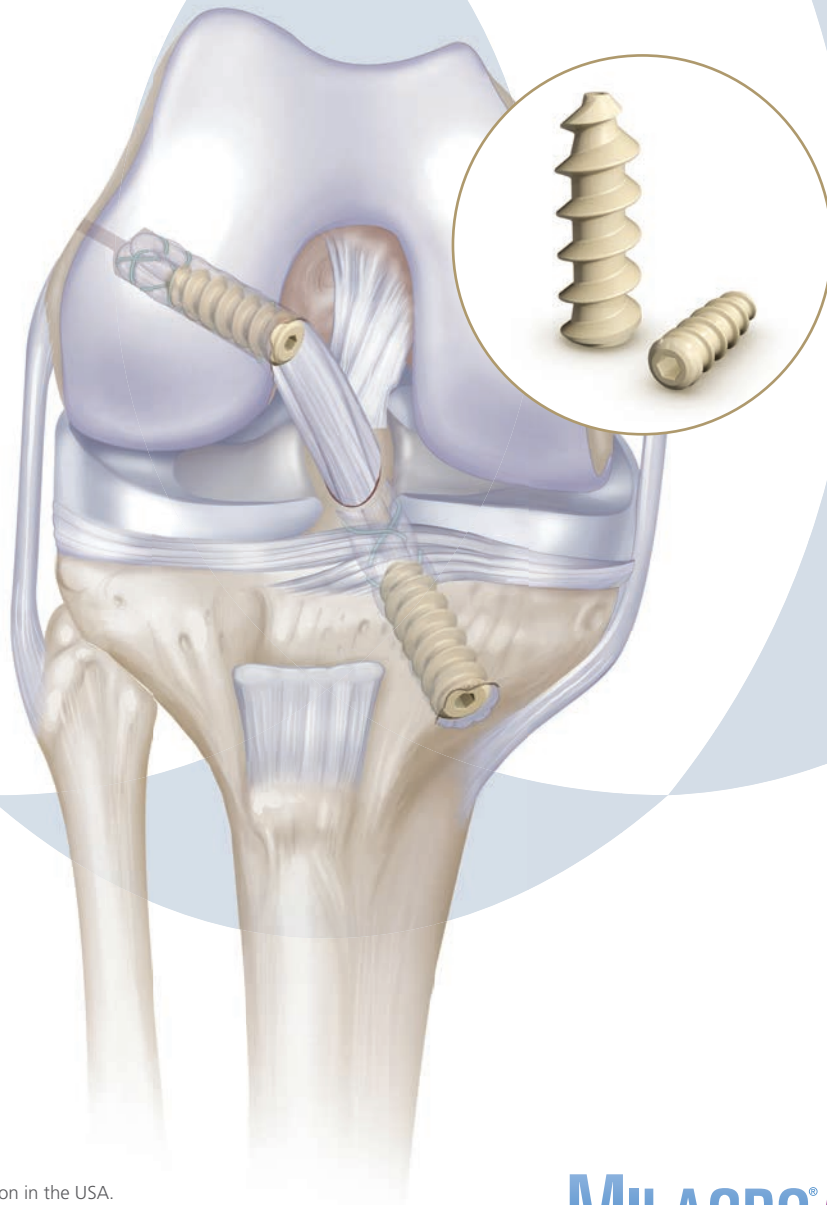


# ANTEROMEDIAL ACL RECONSTRUCTION

## FOR SOFT TISSUE GRAFTS



This publication is not intended for distribution in the USA.

### SURGICAL TECHNIQUE

**MILAGRO**<sup>®</sup>ADVANCE



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## MILAGRO® ADVANCE Interference Screw Anteromedial ACL Reconstruction for Soft Tissue Grafts

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## ADVANCING ACL RECONSTRUCTION WITH IMPLANT ABSORPTION AND OSSIFICATION OF THE IMPLANT SITE<sup>2,3</sup>

The MILAGRO ADVANCE Interference Screw is a second generation Biocomposite comprised of BIOCRYL<sup>®</sup> RAPIDE<sup>®</sup> Biocomposite Material. MILAGRO ADVANCE Interference Screw combines osteoconductive  $\beta$ -TriCalcium Phosphate and a faster absorbing Polylactide co-glycolide polymer to promote bone formation within the implant profile.<sup>2,3</sup>

### Material Benefits

- 30% Osteoconductive  $\beta$ -TriCalcium Phosphate
- 70% PLGA co-polymer offers improved absorption time relative to PLA polymers.<sup>2</sup>
- In long-term human imaging studies BIOCRYL RAPIDE Biocomposite Material has been shown to absorb and promote bone formation within the implant profile.<sup>2,3</sup>
- $\beta$ -TCP has been shown to buffer PLGA as it undergoes the degradation process.<sup>4</sup>
- Proprietary Micro Particle Dispersion (MPD) Technology ensures a homogenous blend of  $\beta$ -TCP and PLGA particles eliminating material related stress concentrations.<sup>1</sup>



# GRAFT PREPARATION

**Technical note on positioning – it is important to ensure the patient is positioned in a manner which allows adequate range of motion for the knee joint. In order to achieve anatomic placement of the femoral tunnel, the knee must be able to achieve a range of motion from full extension to 120° of flexion. A leg holder is also helpful in maintaining flexion angle during the procedure.**

## Graft Preparation

For a semitendinosus-gracilis autograft or an allograft fold the graft in half. Place the graft in tension on the graft board. Whip stitch a distance of 30 mm from each end of the graft with #0 Vicryl or #0 ETHIBOND suture.

Once graft has been tensioned to remove creep and whip stitching is complete, measure the graft diameter in advance of tunnel preparation.

Place one strand of #2 ORTHOCORD® Suture through the graft within the whip stitch region. This will be used later with a passing suture to introduce the graft through the tibia and into the femoral tunnel. (Figure 1)

Keep the graft under tension and moist with saline until ready for use.



Figure 1

# CREATE FEMORAL AM PORTAL AND MARK FEMORAL TUNNEL LOCATION

## Create Femoral AM Portal

**Technical note – alternatively, the tibial tunnel can be created before the femoral tunnel, which may allow debris to drain from the site allowing a clear view of the desired ACL insertion site.**

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. (Figure 2)

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.

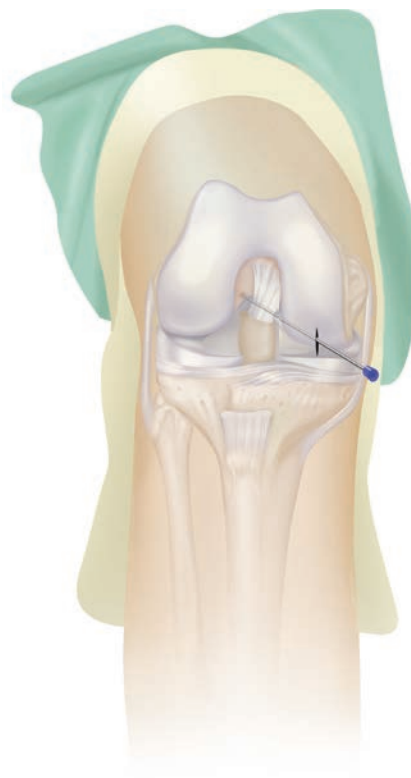


Figure 2

## Mark Femoral Tunnel Location

Next, an 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 6 mm to 8 mm anterior to the posterior cortex at the 2 o'clock position for a left knee or 10 o'clock position for a right knee. (Figure 3)

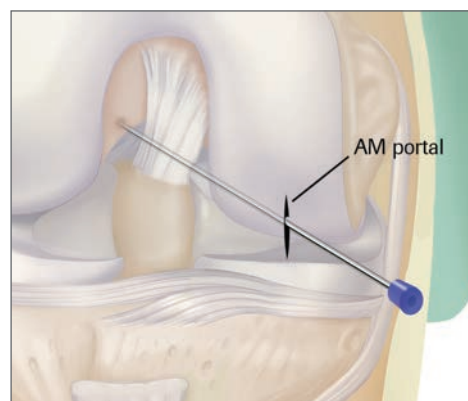


Figure 3

# PREPARE FEMORAL TUNNEL LOCATION WITH ANTEROMEDIAL FEMORAL AIMER

## Prepare Femoral Tunnel Location with Anteromedial Femoral Aimer

Select the desired AM Femoral Aimer based on the proposed tunnel diameter and desired backwall using table 1.

Tunnel Diameter	Desired Backwall	AM Femoral Aimer
5.0 mm	2.0 mm	4.5 mm
5.5 mm	1.75 mm	4.5 mm
6.0 mm	2.0 mm	5.0 mm
6.5 mm	1.75 mm	5.0 mm
7.0 mm	2.0 mm	5.5 mm
7.5 mm	1.75 mm	5.5 mm
8.0 mm	2.5 mm	6.5 mm
8.5 mm	2.25 mm	6.5 mm
9.0 mm	2.0 mm	6.5 mm
9.5 mm	1.75 mm	6.5 mm
10.0 mm	2.5 mm	7.5 mm
10.5 mm	2.25 mm	7.5 mm
11.0 mm	2.0 mm	7.5 mm

**Table 1**

AM Femoral Aimer Offset = (Tunnel Diameter/2) + Desired Backwall

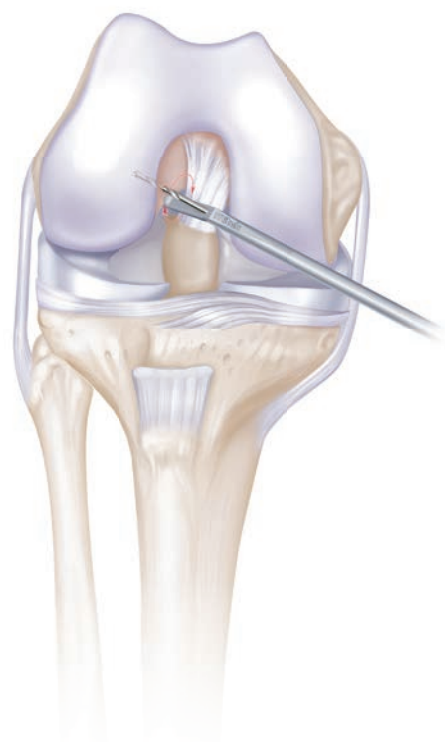
With the knee at 90° of flexion, the selected AM Femoral Aimer is placed through the AM portal with the tip placed posterior to the marked position for the femoral tunnel.

The knee is then hyperflexed between 110 and 120° allowing the 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. (Figure 4)

An Eyelet Drill Pin is placed through the AM Femoral Aimer and advanced through the AM portal. The Drill Pin should exit the femur anterior to its midline. Hyperflexion allows better access to the medial portion of the lateral femoral condyle and the AM Femoral Aimers ensure approximately 2 mm of backwall (when using sizing guidelines) to avoid compromising the posterior aspect of the tunnel. The Femoral Aimers are specifically contoured to fit the AM portal hyperflexion technique. (Figure 5)



**Figure 4**



**Figure 5**

# DRILL FEMORAL TUNNEL WITH ACORN REAMER AND TIBIAL TUNNEL PREPARATION

## Drill Femoral Tunnel with Acorn Reamer

Using the graft diameter measurements obtained during graft preparation select a comparable sized Acorn Reamer.

Place the Acorn Reamer through the AM portal and over the guidewire. Initially it is important to advance the reamer by hand to atraumatically pass by the articular surface of the medial femoral condyle.

The femoral tunnel is drilled to a depth of approximately 25-30mm. In small femurs, the femoral tunnel length may have to be adjusted to avoid violation of the lateral femoral cortex. (Figure 6)

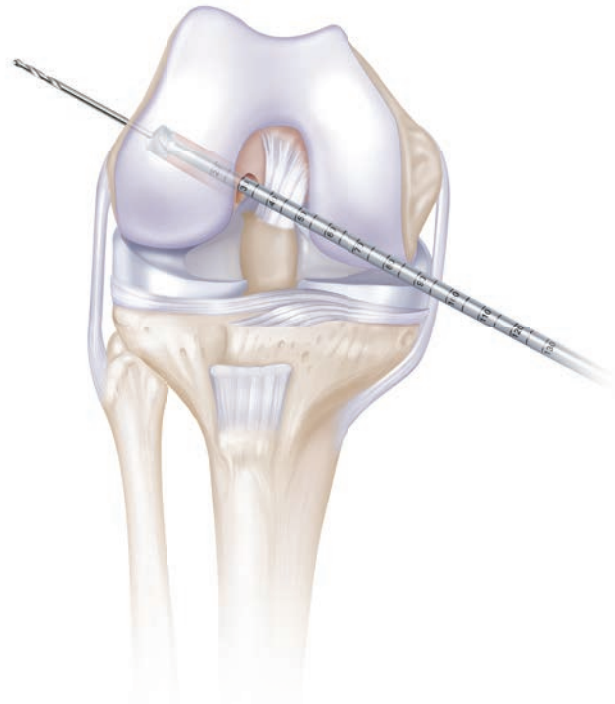


Figure 6

## Tibial Tunnel Preparation

**Technical note – it is the choice of surgeon of which tunnel to create first.**

The angle for the adjustable tibial guide setting is typically 50-55°. At this angle, the tibial tunnel length is typically 35-45 mm.

An Eyelet Drill pin is placed into the tibial guide and advanced until it exits on the tibial plateau. (Figure 7)

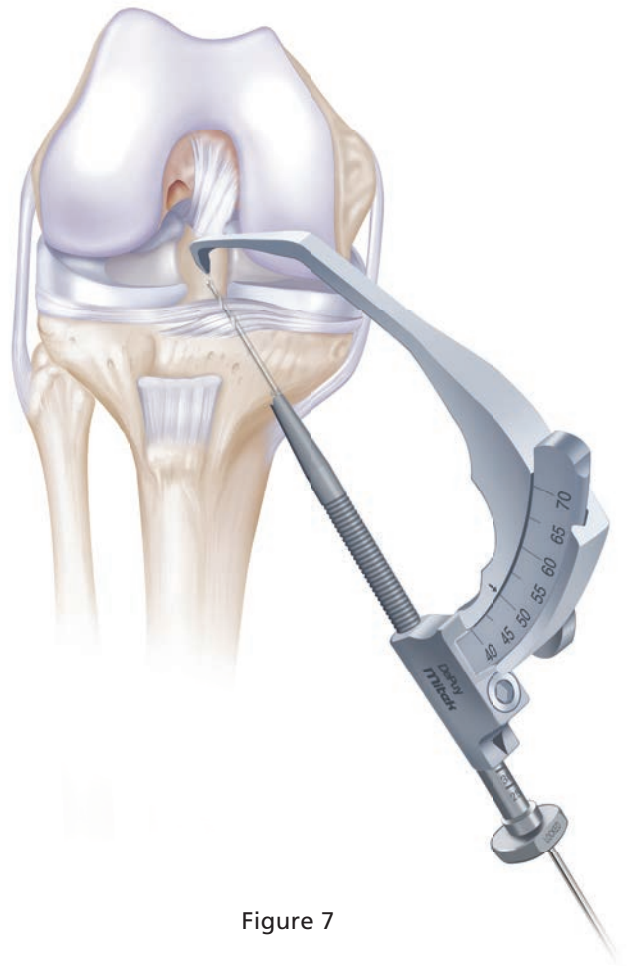


Figure 7



# TIBIAL TUNNEL PREPARATION

## Tibial Tunnel Preparation

Next remove the tibial guide. Using the graft diameter measurements obtained during graft preparation select a comparable sized Fully Fluted Reamer and ream over the Drill Pin until it exits at the tibial plateau. A curette or other instrument may be used inside the joint to prevent the drill pin from advancing while reaming the tunnel. (Figure 8 and 9)

Begin by clearing the soft tissue away from the tunnel edge to improve visualization.

**Technical note – Tibial Tunnel Dilation is recommended. To allow easier passage of the dilators, the tunnel dilation process should begin by first decorticating the anterior tibia with a fluted drill bit sized to match the final tunnel diameter. Drill 1mm less than the ultimate diameter and dilate the remainder of the difference. In older patients, or in those with softer bone, under-drilling by 2 mm is preferred. Dilation should be performed over a guidewire. This helps the dilator follow the tunnel axis and prevents divergence of the dilator as it is driven into bone. The final tunnel diameter should be the same as the graft diameter.**

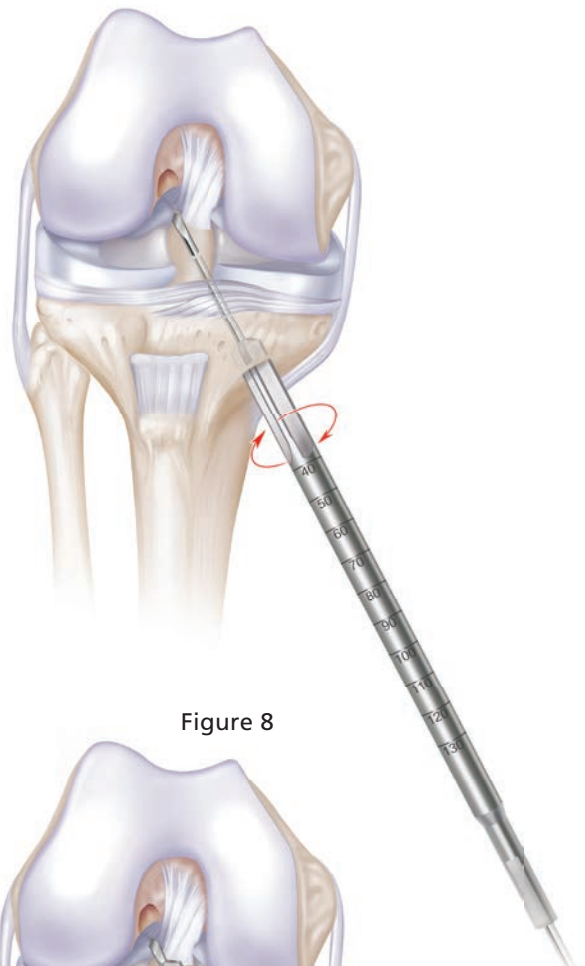


Figure 8



Figure 9

# INTRODUCE GRAFT INTO THE FEMORAL TUNNEL

## Choose Graft Passing Method

### Introduce Graft into the Femoral Tunnel

Introduce the passing suture attached to a Drill Pin through the AM portal (Figure 10) and retrieve the passing suture through the tibial tunnel with a grasping instrument. (Figure 11)

Pass the two limbs of #2 ORTHOCORD Suture from graft through the suture loop exiting the tibial tunnel. (Figure 12)

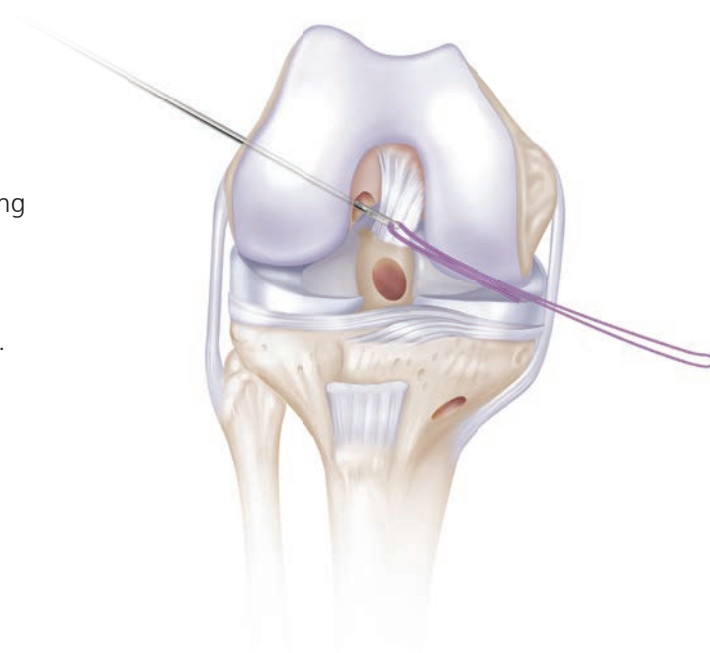


Figure 10

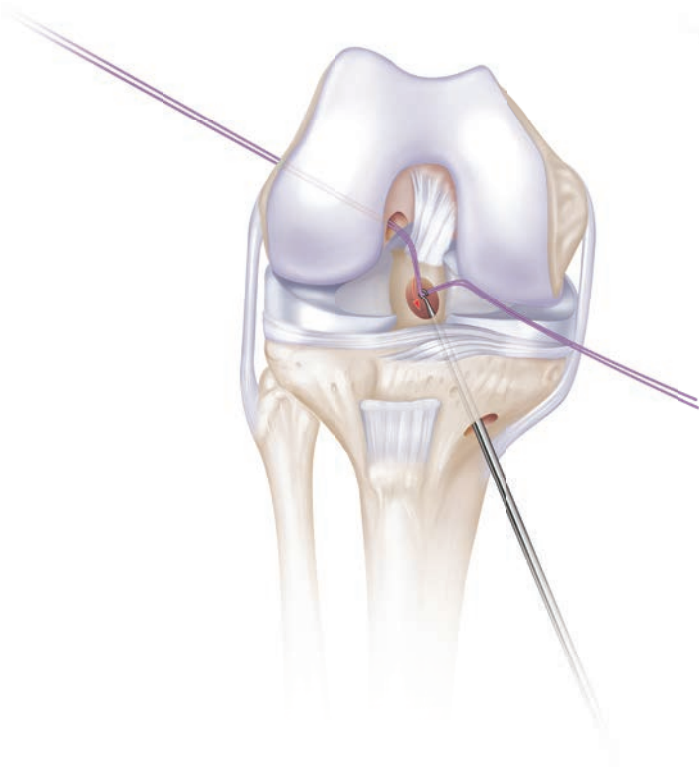


Figure 11

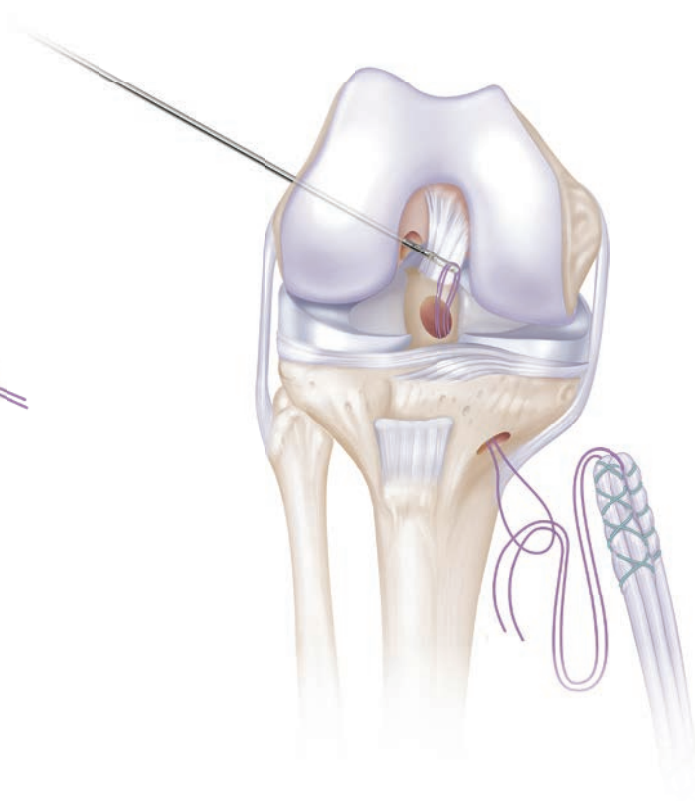


Figure 12

# INTRODUCE GRAFT INTO THE FEMORAL TUNNEL

## **Introduce Graft into the Femoral Tunnel**

With the knee between 110 and 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. (Figure 13 and 14)

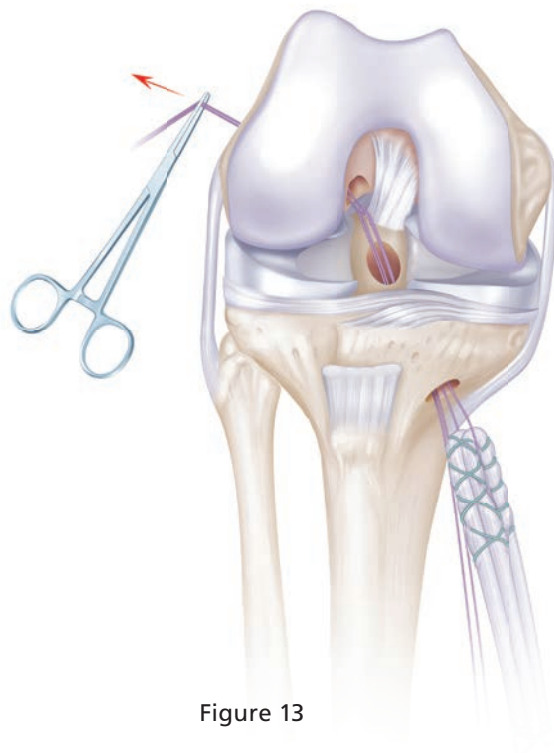


Figure 13

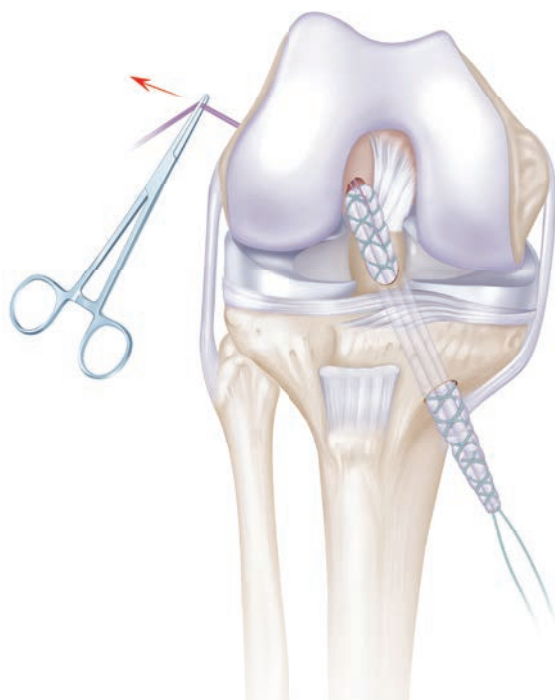


Figure 14

# IMPLANTING THE MILAGRO SCREW IN THE FEMUR

## Implanting the MILAGRO Screw in the Femur

Place a guidewire between the tunnel wall and graft at the desired location of the screw. Insert the Tunnel Notcher over the guidewire and notch the femoral tunnel to a depth that matches the screw length. This will create a path for the screw to follow and prevent the graft from twisting as the screw is inserted. (Figure 15)

Select the appropriate size MILAGRO screw. Typically, the femoral screw diameter is the same size as the tunnel diameter and the length is 23 mm. If dense bone is encountered it may be appropriate to undersize the screw by 1 mm with respect to the tunnel diameter.

With the knee flexed between 110 and 120°, maintain tension on the suture pulling the graft fully into the tunnel.

Place the desired MILAGRO screw on the modular hex driver and insert the screw and driver over the guidewire through the AM portal to the entrance of the femoral tunnel. In addition to the guidewire, the Malleable Graft Retractor can be used as a barrier between the graft and screw to prevent screw threads from contacting the graft as it exits the femoral tunnel. (Figure 16)

Drive the screw into the femoral tunnel until it is flush with the joint line and remove the guidewire and driver. (Figure 17)

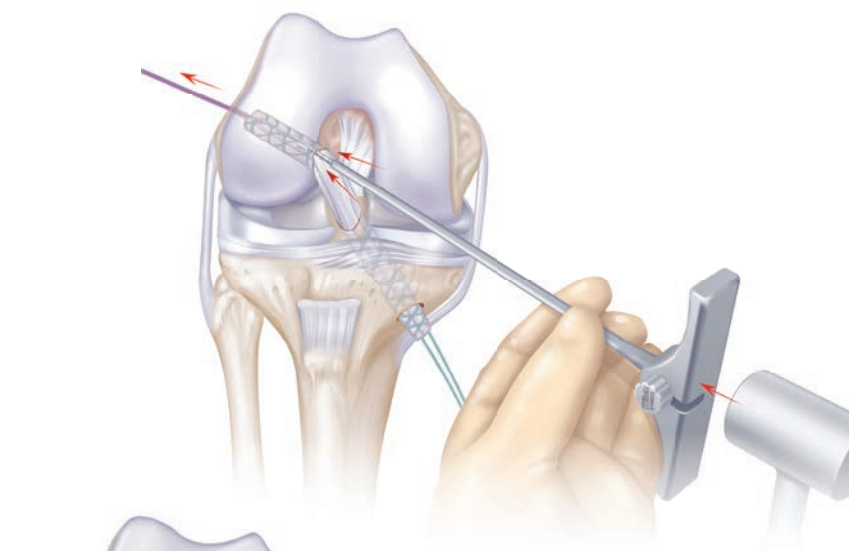


Figure 15

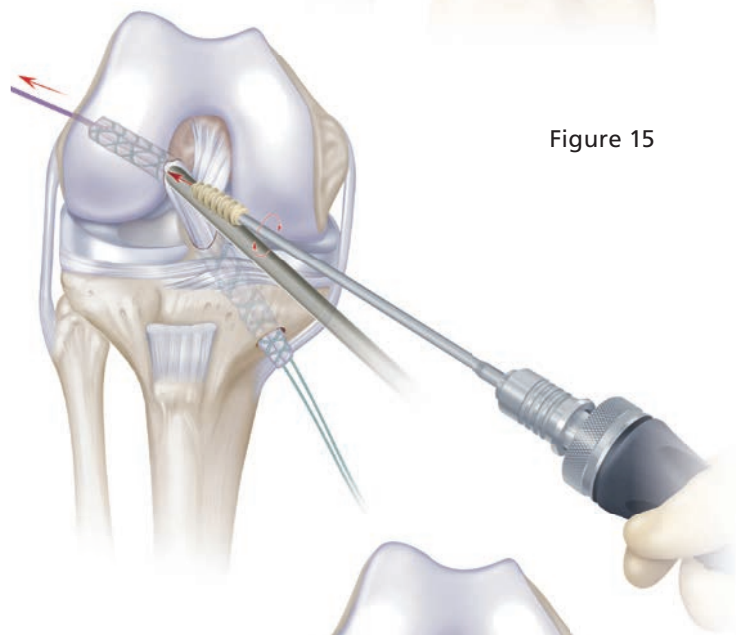


Figure 16

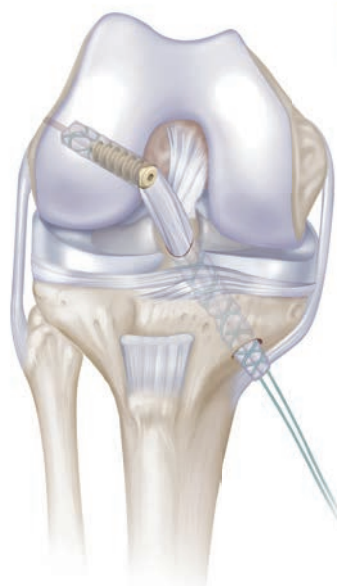


Figure 17

# IMPLANTING THE MILAGRO SCREW ON THE TIBIA

## Implanting the MILAGRO Screw on the Tibia

Select the appropriate sized screw. Typically, the screw diameter is 1 mm greater than the tibial tunnel diameter and the length is 30 to 35 mm depending on the length of tunnel. If dense bone is encountered it may be appropriate to use a screw of equivalent diameter.

Apply approximately 10-15lbs of tension distally on the whip-stitched sutures exiting the tibial cortex. Cycle the knee approximately 20 times in flexion and extension to eliminate graft creep. (Figure 18)

Maintain tension on the graft. Place a guidewire between the tunnel wall and graft at the desired location of the screw. Insert the notcher over the guidewire and notch the tibial tunnel to a depth that matches the screw length. This will create a path for the screw to follow and prevent the graft from twisting as the screw is inserted. (Figure 19)

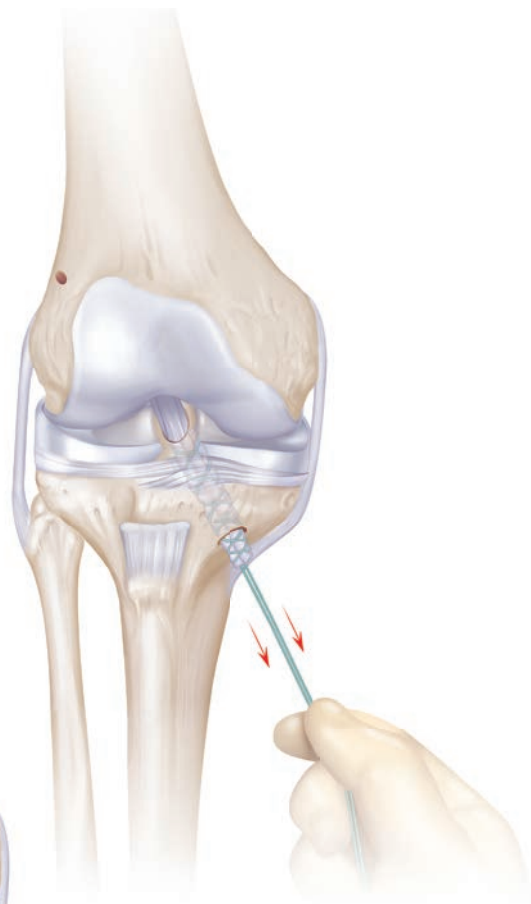


Figure 18

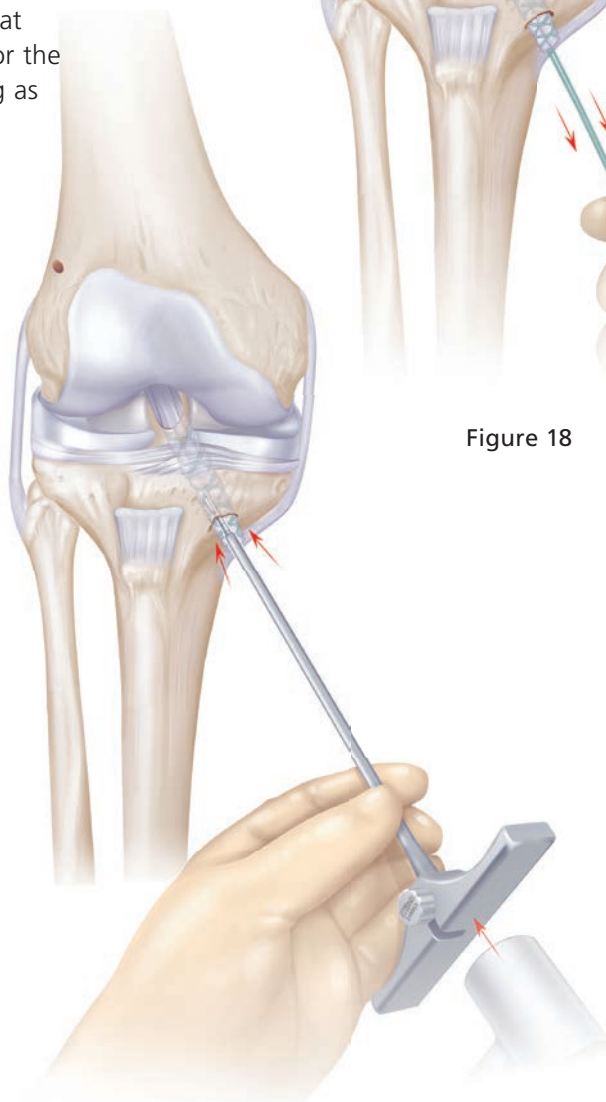


Figure 19



# IMPLANTING THE MILAGRO SCREW ON THE TIBIA

Extend the knee, maintain tension on the graft. Place the MILAGRO screw on the modular hex driver. Maintain approximately 10-15lbs of tension on the graft and with the knee fully extended or slightly flexed insert a screw over the guidewire. Maintain orientation to the tunnel axis as the screw is fully advanced until it is recessed relative to the tibial cortex. It is advantageous to insert the screw as close to the joint line as possible. (Figure 20) Trim any excess suture and graft as needed. (Figure 21)

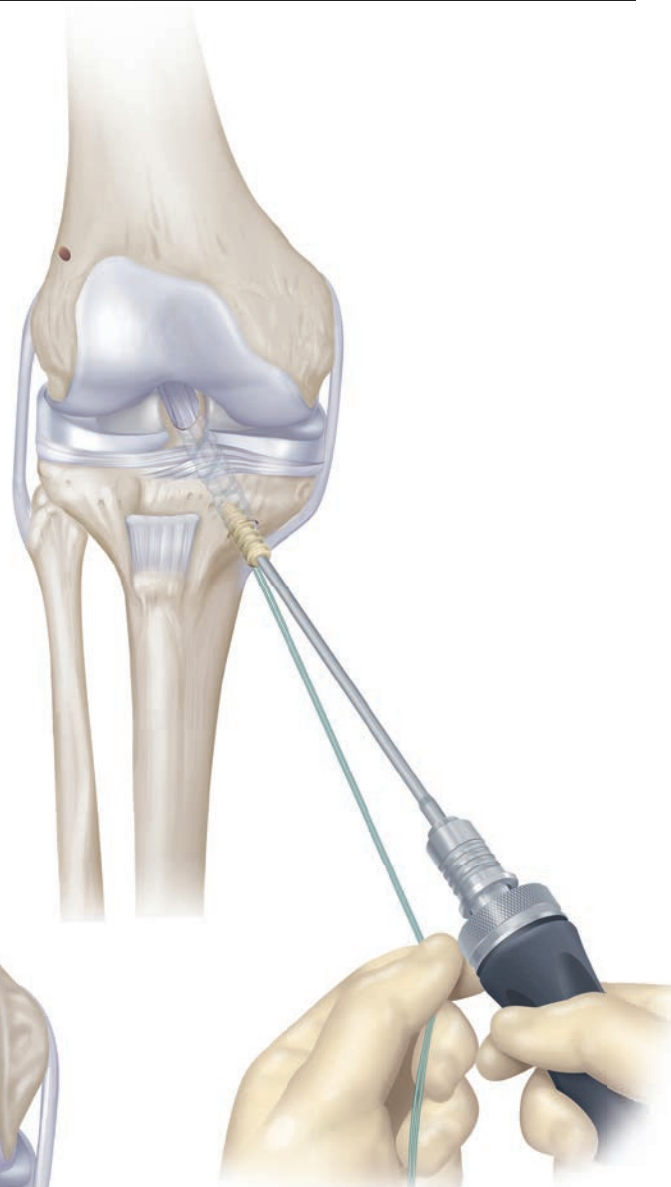


Figure 20

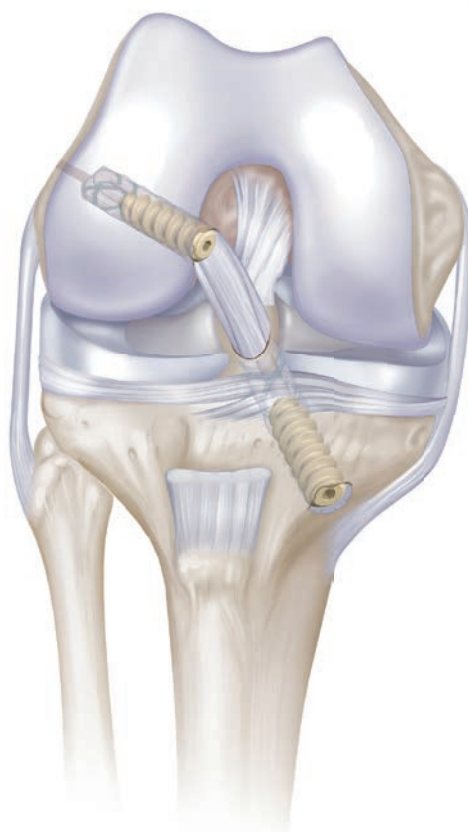


Figure 21

# ORDERING INFORMATION

## Description

## Cat No.

### MILAGRO ADVANCE Biocomposite Interference Screws

MILAGRO ADVANCE Screw, 7 mm x 23 mm	231816
MILAGRO ADVANCE Screw, 8 mm x 23 mm	231817
MILAGRO ADVANCE Screw, 9 mm x 23 mm	231818
MILAGRO ADVANCE Screw, 10 mm x 23 mm	231819
MILAGRO ADVANCE Screw, 7 mm x 30 mm	231831
MILAGRO ADVANCE Screw, 8 mm x 30 mm	231821
MILAGRO ADVANCE Screw, 9 mm x 30 mm	231822
MILAGRO ADVANCE Screw, 10 mm x 30 mm	231823
MILAGRO ADVANCE Screw, 11 mm x 30 mm	231824
MILAGRO ADVANCE Screw, 12 mm x 30 mm	231832
MILAGRO ADVANCE Screw, 9 mm x 35 mm	231826
MILAGRO ADVANCE Screw, 10 mm x 35 mm	231827
MILAGRO ADVANCE Screw, 11 mm x 35 mm	231828
MILAGRO ADVANCE Screw, 12 mm x 35 mm	231829

### MILAGRO Biocomposite Interference Screws

MILAGRO BR Interference Screw, 5 mm x 23 mm	231803
MILAGRO BR Interference Screw, 5 mm x 30 mm	231804
MILAGRO BR Interference Screw, 6 mm x 23 mm	231807
MILAGRO BR Interference Screw, 6 mm x 30 mm	231809
MILAGRO BR Interference Screw, 7 mm x 23 mm	231800
MILAGRO BR Interference Screw, 7 mm x 30 mm	231805
MILAGRO BR Interference Screw, 8 mm x 23 mm	231810
MILAGRO BR Interference Screw, 8 mm x 30 mm	231815
MILAGRO BR Interference Screw, 9 mm x 23 mm	231820
MILAGRO BR Interference Screw, 9 mm x 30 mm	231825
MILAGRO BR Interference Screw, 9 mm x 35 mm	231830
MILAGRO BR Interference Screw, 10 mm x 23 mm	231835
MILAGRO BR Interference Screw, 10 mm x 30 mm	231840
MILAGRO BR Interference Screw, 10 mm x 35 mm	231845
MILAGRO BR Interference Screw, 11 mm x 30 mm	231850
MILAGRO BR Interference Screw, 11 mm x 35 mm	231855
MILAGRO BR Interference Screw, 12 mm x 30 mm	231860
MILAGRO BR Interference Screw, 12 mm x 35 mm	231865

# ORDERING INFORMATION

## Description

## Cat No.

### MILAGRO ADVANCE Handles, Driver Shafts and Taps

Universal MILAGRO ADVANCE Driver*	219500
Quick-Connect Handle	219970
7-8 mm Starter Tap	219496
9-10 mm Starter Tap	219497
11-12 mm Starter Tap	219498

\*all predicate MILAGRO screwdrivers can also be used with the respective size MILAGRO screws (219960, 219957, 219958, 219959) but the new UNIVERSAL screwdriver is indicated for MILAGRO ADVANCE screws only.

### MILAGRO Handles, Driver Shafts and Taps

Quick-Connect Handle*	219970
7 mm MILAGRO Starter Tap	270106
8 mm MILAGRO Starter Tap	270107
9 mm MILAGRO Starter Tap	270108
10 mm MILAGRO Starter Tap	270109

\*indicated for all screwdrivers: codes 219446, 219438, 219960, 219957, 219958 and 219959

### Anteromedial ACL Reconstruction Aimers

Anteromedial Femoral Aimer, 4.5 mm	219435
Anteromedial Femoral Aimer, 5.0 mm	219434
Anteromedial Femoral Aimer, 5.5 mm	254672
Anteromedial Femoral Aimer, 6.5 mm	254686
Anteromedial Femoral Aimer, 7.5 mm	254687

### Tibial Guide System

Tibial Guide and Ratchet	219301
Bullet	219390
Guide Rail	219391
Elbow Aiming Arm	219392
Tip Aiming Arm	219393
Tibial Guide Tray	215100



# ORDERING INFORMATION

Description	Cat No.
<b>Reamers</b>	
Fully Fluted Reamer, 5 mm	219442
Fully Fluted Reamer, 5.5 mm	219443
Fully Fluted Reamer, 6 mm	219346
Fully Fluted Reamer, 6.5 mm	219553
Fully Fluted Reamer, 7 mm	219347
Fully Fluted Reamer, 7.5 mm	219554
Fully Fluted Reamer, 8 mm	219348
Fully Fluted Reamer, 8.5 mm	219555
Fully Fluted Reamer, 9 mm	219349
Fully Fluted Reamer, 9.5 mm	219556
Fully Fluted Reamer, 10 mm	219340
Fully Fluted Reamer, 10.5 mm	219557
Fully Fluted Reamer, 11 mm	219341
Fully Fluted Reamer, 11.5 mm	219558
Fully Fluted Reamer, 12 mm	219342
Fully Fluted Reamer, 13 mm	219343
Acorn Reamer, 5 mm	219440
Acorn Reamer, 5.5 mm	219441
Acorn Reamer, 6 mm	219336
Acorn Reamer, 6.5 mm	219547
Acorn Reamer, 7 mm	219337
Acorn Reamer, 7.5 mm	219548
Acorn Reamer, 8 mm	219338
Acorn Reamer, 8.5 mm	219549
Acorn Reamer, 9 mm	219339
Acorn Reamer, 9.5 mm	219550
Acorn Reamer, 10 mm	219335
Acorn Reamer, 10.5 mm	219551
Acorn Reamer, 11 mm	219331
Acorn Reamer, 11.5 mm	219552
Acorn Reamer, 12 mm	219332
Acorn Reamer, 13 mm	219333

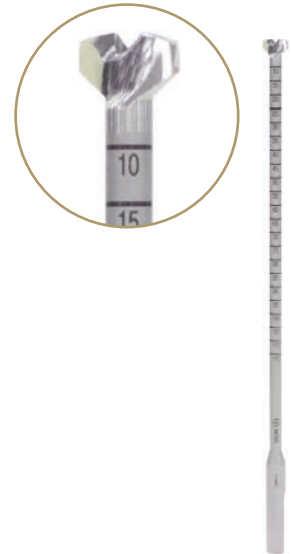
# ORDERING INFORMATION

## Description

## Cat No.

### Low Profile Reamers:

Low Profile Reamer (Non-Sterile), 6 mm	219624
Low Profile Reamer (Non-Sterile), 6.5 mm	219625
Low Profile Reamer (Non-Sterile), 7 mm	219626
Low Profile Reamer (Non-Sterile), 7.5 mm	219627
Low Profile Reamer (Non-Sterile), 8 mm	219628
Low Profile Reamer (Non-Sterile), 8.5 mm	219629
Low Profile Reamer (Non-Sterile), 9 mm	219630
Low Profile Reamer (Non-Sterile), 9.5 mm	219631
Low Profile Reamer (Non-Sterile), 10 mm	219632
Low Profile Reamer (Non-Sterile), 10.5 mm	219633
Low Profile Reamer (Non-Sterile), 11 mm	219634
Low Profile Reamer (Non-Sterile), 11.5 mm	219635
Low Profile Reamer (Non-Sterile), 12 mm	219636
Low Profile Reamer (Non-Sterile), 13 mm	219637



### Tunnel Dilator Instrumentation

Tunnel Dilator, 6 mm	219403
Tunnel Dilator, 6.5 mm	219404
Tunnel Dilator, 7 mm	219405
Tunnel Dilator, 7.5 mm	219406
Tunnel Dilator, 8 mm	219407
Tunnel Dilator, 8.5 mm	219408
Tunnel Dilator, 9 mm	219409
Tunnel Dilator, 9.5 mm	219410
Tunnel Dilator, 10 mm	219411
Tunnel Dilator, 10.5 mm	219412
Tunnel Dilator, 11 mm	219413
Tunnel Dilator, 11.5mm	219414
Tunnel Dilator, 12mm	219415
Tunnel Dilator Sterilization Tray	215700
Tunnel Dilator, 11.5 mm	219414
Tunnel Dilator, 12 mm	219415
Tunnel Dilator Sterilization Tray	215700

# ORDERING INFORMATION

## Description

## Cat No.

### Graft Preparation System

Graft Preparation System (Single code Includes all items below)	280039
Graft Preparation System Tray	215810
Graft Preparation Board	219961
Slider Unit (Requires 2 each for system)	219962
Tensioning Clamp	219963
Graft Clamp (Requires 2 each for system)	219964
Suture Clamp	219965
BTB Graft Drill Guide	219967
Cutting Board	219968
Tendon Graft Sizer	219444

### ACL Reconstruction Accessories

ACL Disposable Kit (Sterile)	232300
Guidewire, 1.1 mm (.042") x 15" (Nitinol), 6 per box	254514
Knee Cannula (Sterile), 5 per box	219377
Tunnel Notcher	219952
Malleable Graft Retractor, 5 per box	232024
Beath Pin w/Eyelet, 2.4 mm (.094") x 14"	219321
Bayonet Point Pin w/Eyelet, 2.4 mm (.094") x 18"	219328
Thin Shaft Trocar Pin, 2.4 mm (.094") x 14"	219323
Calibrated Passing Pin w/Trocar Tip, 2.4 mm (.094") x 15"	254728
Calibrated Passing Pin w/Drill Tip, 2.4 mm (.094") x 15"	254729
Trocar Point Guide Pin, 2.4 mm (.094") x 15"	211311
Pigtail Tendon Peeler	232002
Tendon Stripper Closed	254730
Pin Puller	219352

## References

1. TenHuisen, KS. B-Tricalcium Phosphate (B-TCP) and Absorbable Composites Properties, Synthesis and Use in the Medical Industry. Johnson & Johnson Corporate Biomaterials Center a Division of Ethicon Inc. P/N 900655 Rev A 2001.
2. Barber et al. Long-Term Degradation of a Poly-Lactide Co-Glycolide/ $\beta$ -Tricalcium Phosphate Biocomposite Interference Screw, Arthroscopy Journal: The Journal of Arthroscopic and Related Surgery, Vol.27, No. 5, 2011, pp. 637-643.
3. Information from "Clinical Update: Imaging and in vivo Absorption of  $\beta$ -TCP/PLGA Interference Screws Used in ACL Reconstruction." Barber et al. DePuy Mitek White Paper, 2009.
4. Suchenski, Maureen et al. Material Properties and Composition of Soft Tissue Fixation, Arthroscopy: The Journal of Arthroscopic and Related Surgery, Vol. 26, No. 6, 2010: pp 821-831.

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