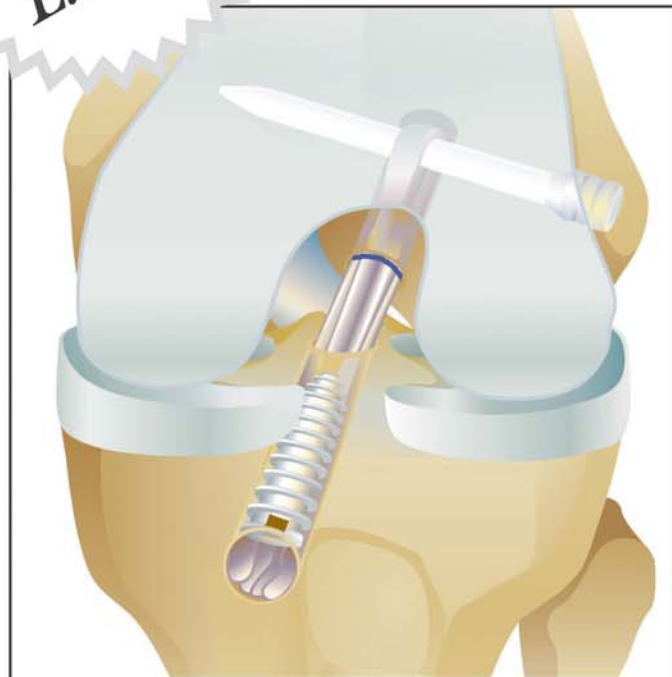




Bio-TransFix® ACL Reconstruction

Surgical Technique

2003
Updated
Edition



Bio-TransFix® ACL Reconstruction

Bio-TransFix® II ACL Reconstruction Instrumentation:

Bio-TransFix Driver	AR-1973DB
5.0 mm Drill for TransFix Implant, for 3 mm Guide Pin	AR-1974
Drill Guide Assembly for TransFix II	AR-1975
TransFix Guide Pin Sleeve, 3 mm	AR-1976
TransFix II Tunnel Hook, 7 mm	AR-1977-07P
TransFix II Tunnel Hook, 8 mm	AR-1977-08P
TransFix II Tunnel Hook, 9 mm	AR-1977-09P
TransFix II Tunnel Hook, 10 mm	AR-1977-10P
TransFix II Tunnel Hook, 11 mm	AR-1977-11P
TransFix II Tunnel Hook, 12 mm	AR-1977-12P
Bio-TransFix Dilator	AR-1373
Bio-TransFix Extractor	AR-1973E
TransFix II Sterilization Case	AR-1972

Bio-TransFix Implants & Disposables:

Bio-TransFix Implant, 5 mm x 40 mm	AR-135IB
Bio-TransFix Implant, 5 mm x 50 mm	AR-135ILB
TransFix II Pin & Graft Passing Wire Set	AR-1978S
Transtibial ACL Disposables Kit, w/o Saw Blade, box of 5 each	AR-1898S

Delta Screw Tibial Fixation Instrumentation:

ACL Tunnel Preparation Instrumentation Set (<i>Dilators 7-10 mm diameter</i>)	AR-1856S
Ratcheting Screwdriver Handle	AR-1999
Canulated Screwdriver Shaft for Delta Screws	AR-1997D
Torque Measurement Device	AR-1990
Quad Notcher Set	AR-1842S

Tibial Fixation Implants & Disposables:

Delta Tapered Bio-Interference Screw, 7.5 mm - 9 mm x 35 mm	AR-5035TB-09
Delta Tapered Bio-Interference Screw, 8.5 mm - 10 mm x 35 mm	AR-5035TB-10
Delta Tapered Bio-Interference Screw, 9.5 mm - 11 mm x 35 mm	AR-5035TB-11
Delta Tapered Bio-Interference Screw, 10.5 mm - 12 mm x 35 mm	AR-5035TB-12

Tibial Fixation Backup:

Bio-Tenodesis Screw System Instrumentation Set	AR-1675S
Bio-Tenodesis Disposable Kit	AR-1675DS
Bio-Tenodesis Screw, 5.5 mm (<i>FiberWire fixation option</i>)	AR-1555B
Bio-Tenodesis Screw, 7 mm	AR-1570B
Bio-Tenodesis Screw, 8 mm	AR-1580B
Bio-Tenodesis Screw, 9 mm	AR-1590B

Femoral and Tibial Tunnel Placement Instrumentation:

Transtibial ACL Reconstruction Basic Set	AR-1817S
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Tendon Stripping:

Semitendinosus Stripper, closed end, 5 mm diameter	AR-1278
Semitendinosus Stripper, closed end, 7 mm diameter	AR-1278L
Pigtail Hamstring Tendon Stripper, open end, 5 mm diameter	AR-1278P

Graft Preparation:

Graft Prep Station Basic Set for Soft Tissue Grafts	AR-2950S
#2 FiberWire, box of 12 each	AR-7200

(All implants and disposables are sterile packed and single use.)

U.S. PATENT NOS. 5,918,604; 5,895,425; 6,132,433; 6,371,124 and PATENTS PENDING

*A study "In Vitro Biomechanical Evaluation of Tenodesis Bioscrew Efficacy for Secondary Fixation in ACL Reconstruction" by David Caborn, M.D., is available upon request.



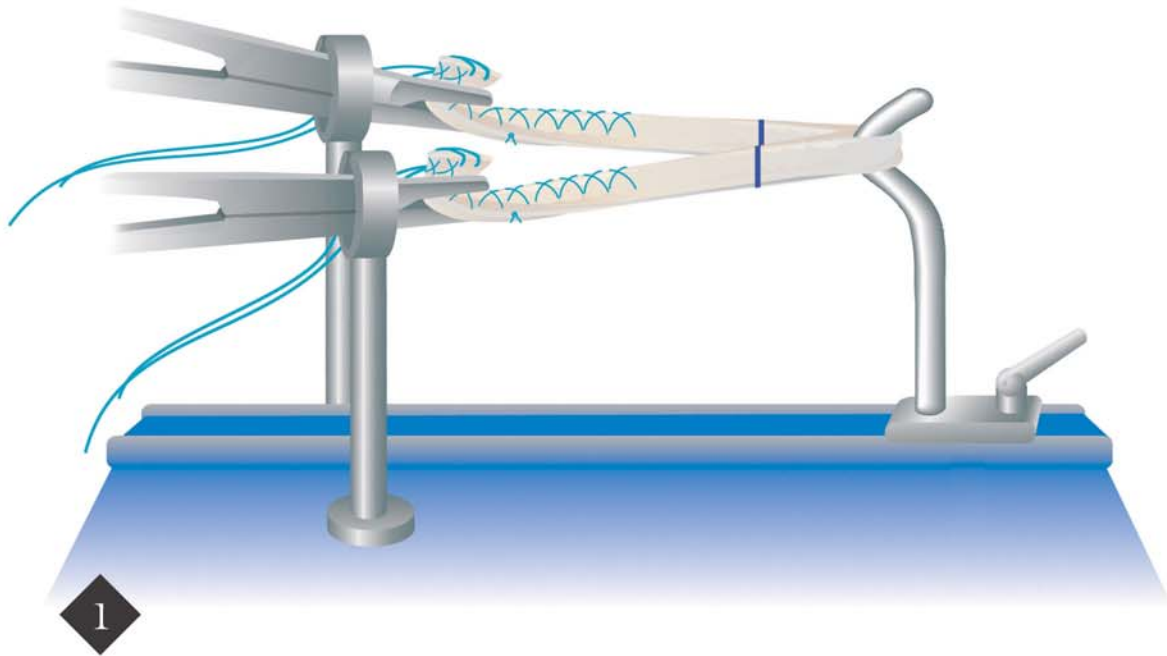
Actual size of Bio-TransFix Implant



*Actual size of 8.5 mm - 10 mm
Delta Tapered Bio-Interference Screw*



*Actual size of 5.5, 7, 8 and 9 mm
Bio-Tenodesis Screws*



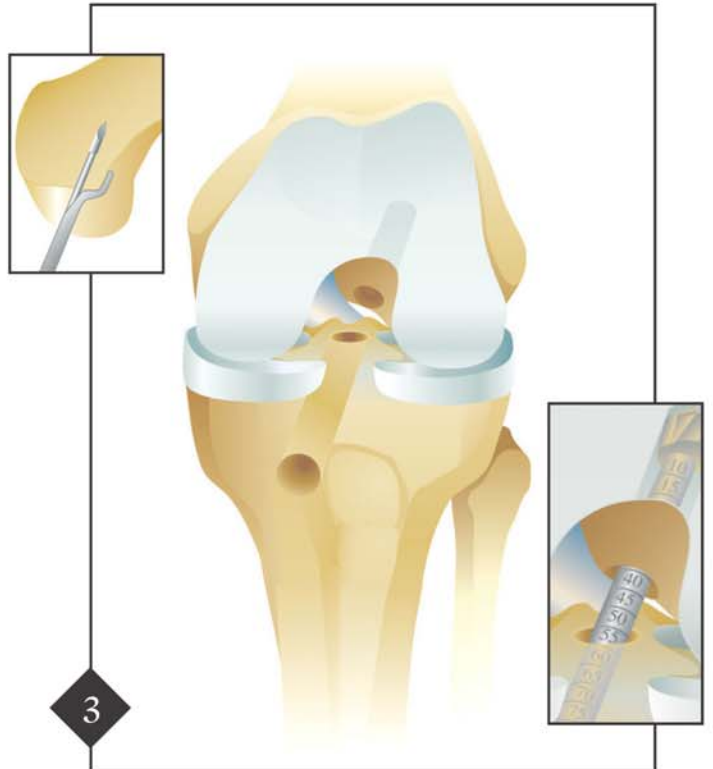
1

Semitendinosus and gracilis tendon autografts or tibialis tendon allografts are mounted on the Graft Prep Station. The tendons are placed around the adjustable post and the free ends secured in dual stationary posts with Kocher clamps. A spring Tensioning Device may be added to the prep station for graft pretensioning if desired. A methylene blue mark is made 30 mm from the proximal end of the graft. Whipstitches with #2 FiberWire suture are placed beginning 30 mm distal of the methylene blue mark. The completed graft should be sized to the nearest half millimeter diameter. Overall graft length should be between 100 and 120 mm of length.



2

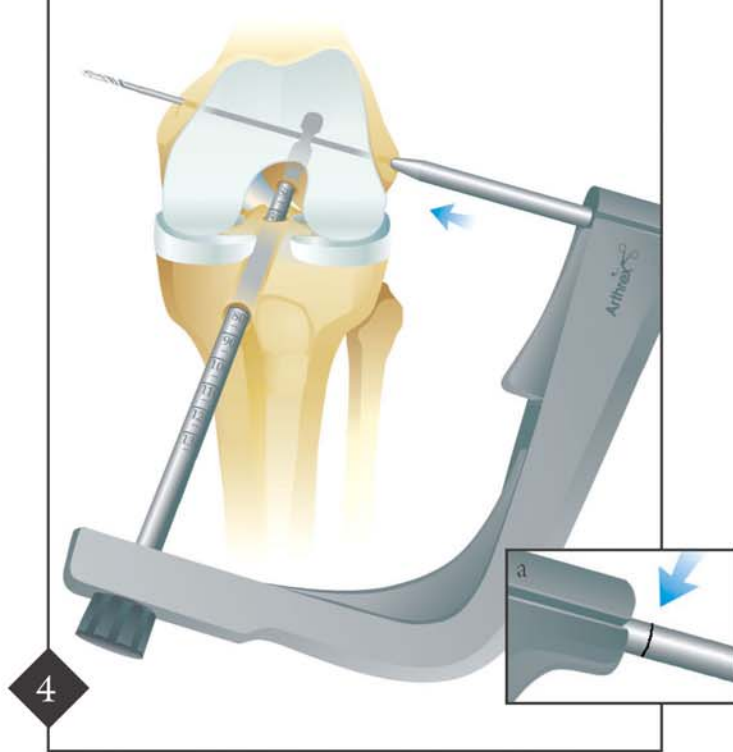
The tibial tunnel guide pin is anatomically positioned by referencing a point 7 mm anterior of the PCL base with the PCL referencing tibial guide marking hook. The tibial tunnel length of at least 40 mm can be determined prior to guide pin placement with the calibrated guide sleeve. The tibial tunnel is drilled to a diameter 1 to 2 mm less than the graft diameter and dilators impacted to create the final tunnel diameter equal to the graft diameter.



3

The femoral tunnel is created by referencing the over-the-top position with a Trans tibial Femoral ACL Drill Guide (TTG) to create a 1 to 2 mm or less tunnel backwall.

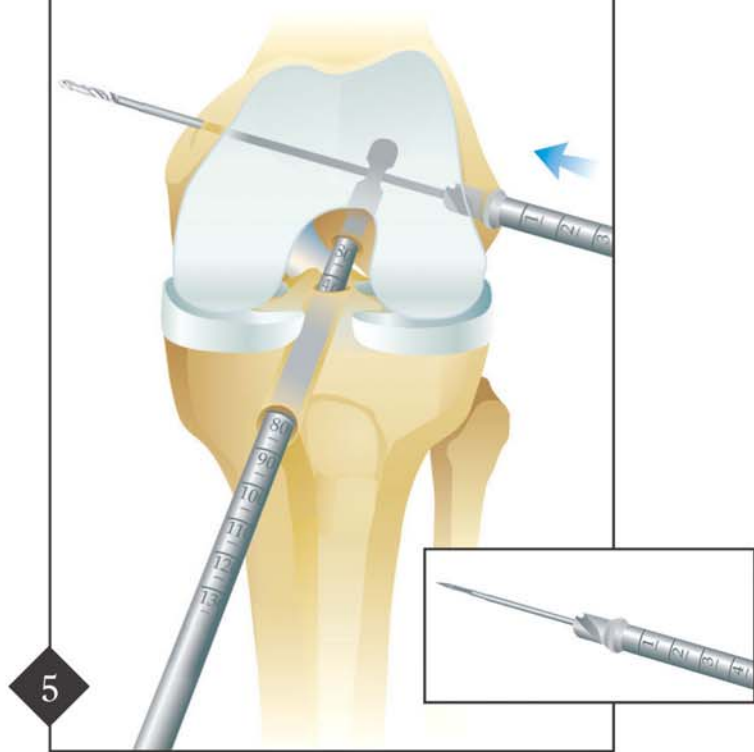
A 2.4 mm Drill Tip Guide Pin is positioned with the TTG and a Cannulated Headed Reamer equal to the graft diameter is drilled to a depth of 40 mm. The drill and guide pin are removed.



4

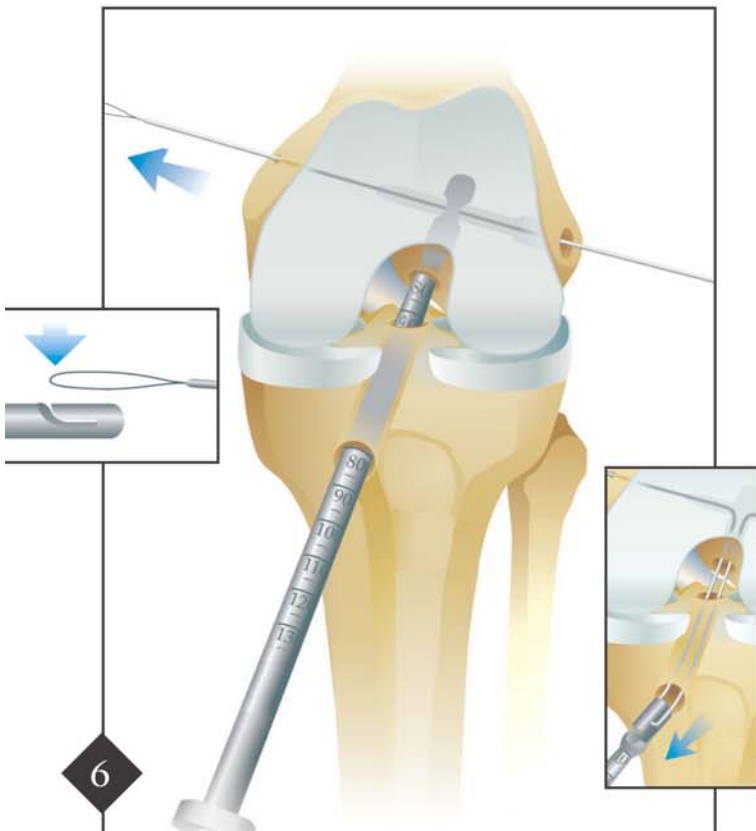
The TransFix II Tunnel Hook that matches the tunnel diameter is assembled with the TransFix II Drill Guide. The tunnel hook is inserted through the tibial tunnel and positioned into the femoral socket. The Guide Pin Sleeve is positioned on the skin of the lateral thigh, a small incision is made and the sleeve advanced to bone.

Exposure of the guide sleeve's marking (a) external to the guide housing indicates the need for a 50 mm Bio-TransFix Implant. The 3 mm Drill Pin is drilled through the guide sleeve and the tunnel hook, exiting the femur medially.



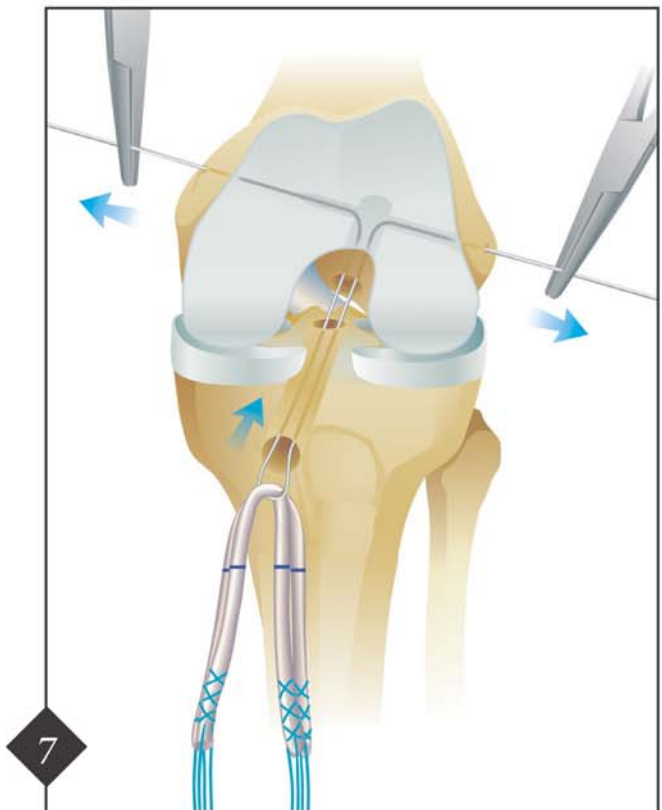
5

The 5 mm broach, with depth stop collar, is drilled over the 3 mm guide pin to broach the cortex for the Bio-TransFix Implant. The depth of the soft tissue is measured with the calibration on the drill shaft as a secondary control of subsequent implant insertion depth.



6

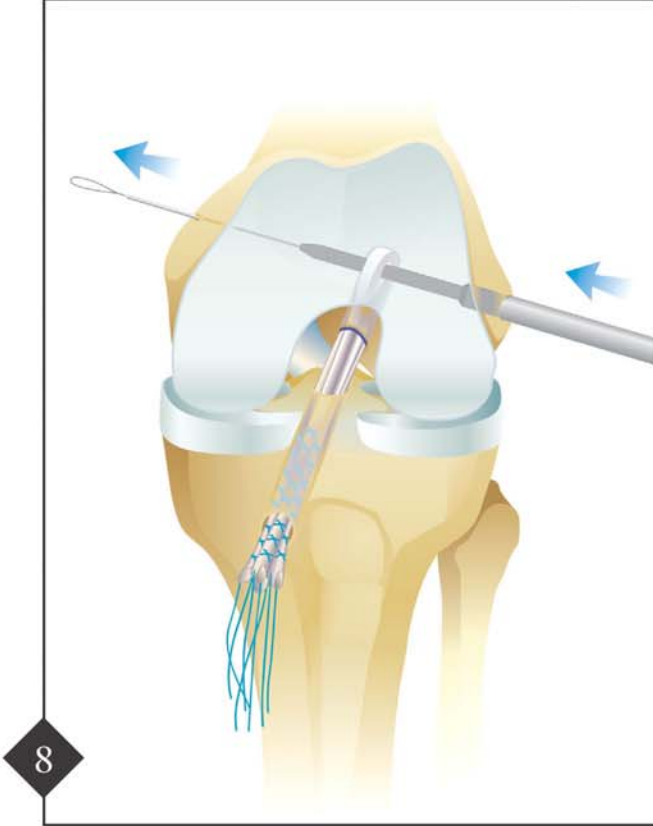
The Nitinol Graft Passing Wire is hooked into the 3 mm guide pin slot. The Guide Pin is pulled medially drawing the Nitinol wire through the 3 mm pilot hole and the TransFix II Tunnel Hook. The tunnel hook is then extracted pulling the midsection of the Nitinol wire out the tibial tunnel for graft passing.



7

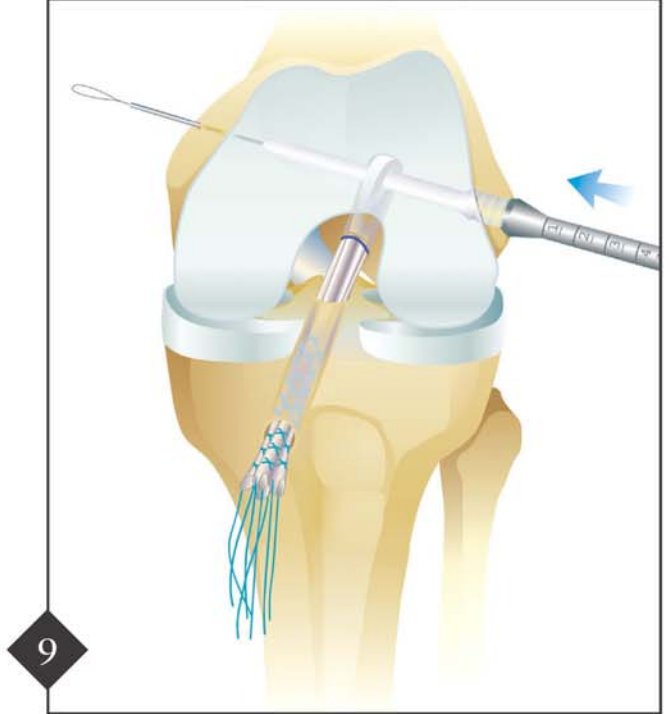
The midsection of the graft is positioned over the Nitinol wire with the graft end lengths equalized. Needle holders are used to secure the free ends of the wire and to assist in graft passing. The wire free ends are simultaneously pulled away from the knee advancing the graft through the tibial tunnel and into the femoral tunnel.

After graft passage, unrestricted back and forth motion of the wire confirms full proximal insertion of the graft.



8

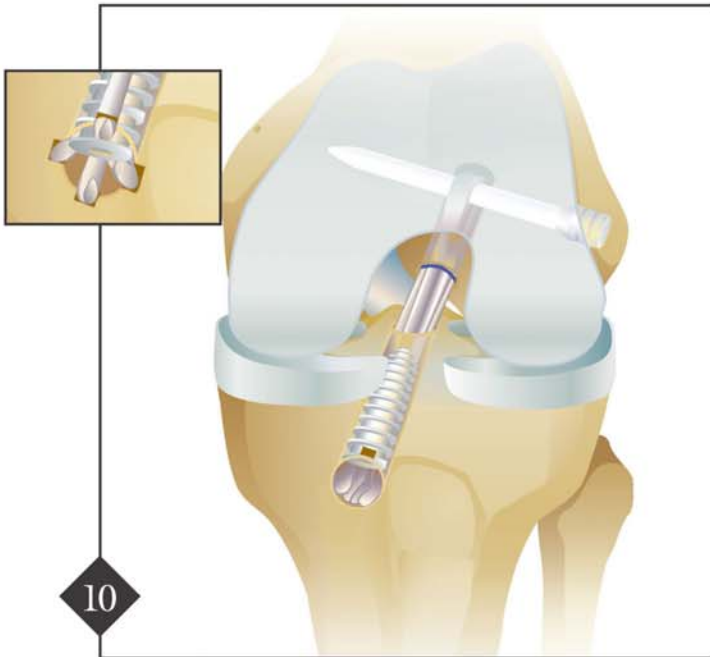
To further simplify implant insertion, the Nitinol wire is shifted medially to place any wire kinks medial to the femoral tunnel. The Bio-TransFix Dilator may be inserted over the wire to create a pilot hole for the implant and to further ensure proper graft positioning.



9

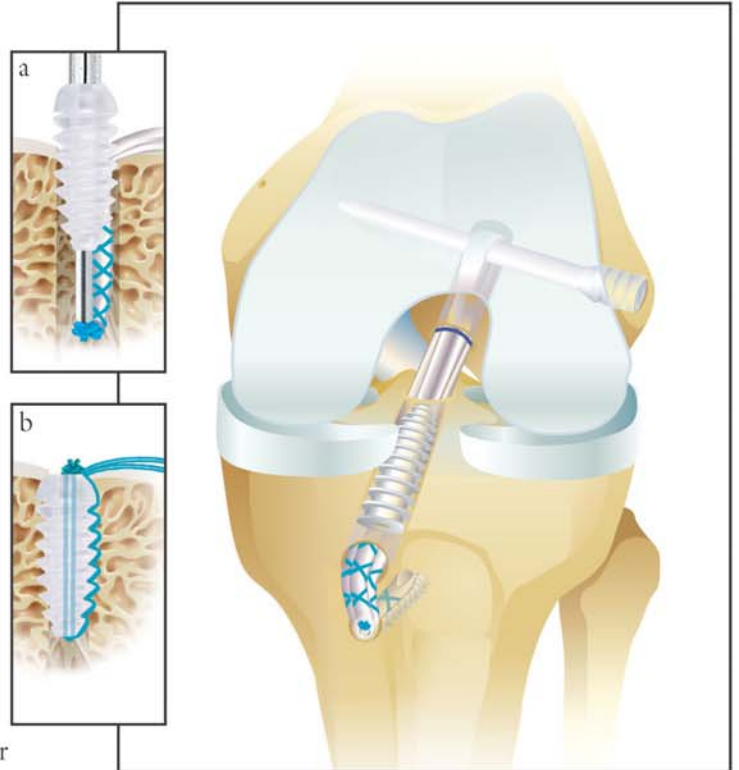
The 40 or 50 mm Bio-TransFix Implant is hand-inserted over the Nitinol wire as far medially as possible. The Bio-TransFix Driver is inserted over the wire until the implant is engaged. The wire should be secured with a needle holder at the handle exit. With combined light impaction and medial pulling of the wire, the implant is fully inserted until the impactor flange, aligned anteriorly, contacts the cortical bone surface.

Depth markings on the impactor should match the prior broach depth mark to secondarily confirm proper implant insertion depth. The impactor is removed and final confirmation of implant depth is performed with finger palpation.



10

Secure tibial fixation is obtained with a 35 mm Delta Tapered Bio-Interference Screw. The Delta Screw tapers 1.5 mm from proximal to distal (i.e. 8.5 mm to 10 mm diameter). A distal screw diameter that is 1 mm greater than the tunnel diameter should be selected. A tunnel notcher should be used to create a superior notch in the rim to ease screw insertion. A guide wire is positioned anterior to the graft and secured in the joint with a clamp to control screw migration during insertion. The screw may be inserted with the torque measuring screwdriver to quantify insertion torque and subsequent fixation strength. The Quad Notcher may be used if concentric screw insertion is desired to secure four quadrant graft positioning (a).



Backup fixation (*insets*) using the Bio-Tenodesis Screw System should be considered in situations of poor metaphyseal bone or when less than 15 in./lbs of insertion torque is quantified during Delta Screw insertion. Bio-Tenodesis Screw fixation with FiberWire suture doubles tibial fixation strength* without soft tissue implant irritation. The Bio-Tenodesis Screw may be used to secure the graft end directly (a) or FiberWire suture alone (b) under tension in a 1 cm distally placed tibial socket.



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*The Bio-TransFix® ACL Reconstruction System has been developed in cooperation
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Illustrations by Siri Mills*

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