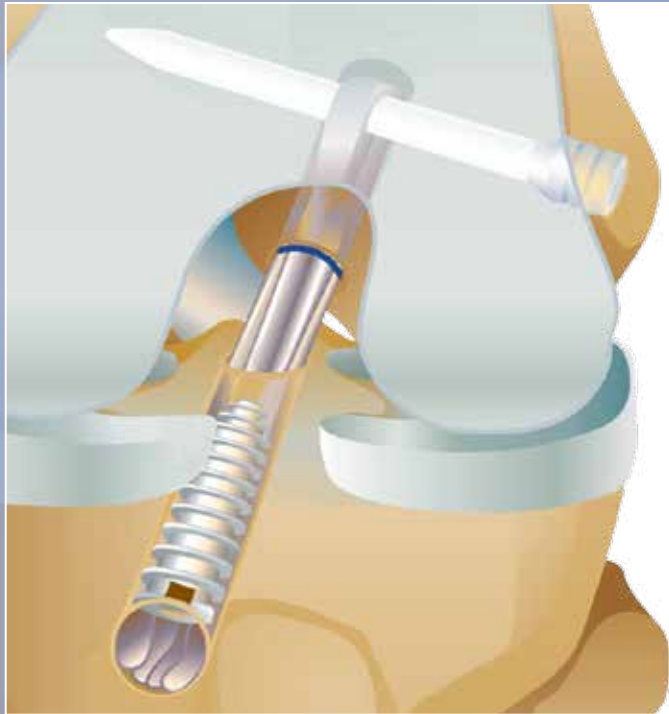


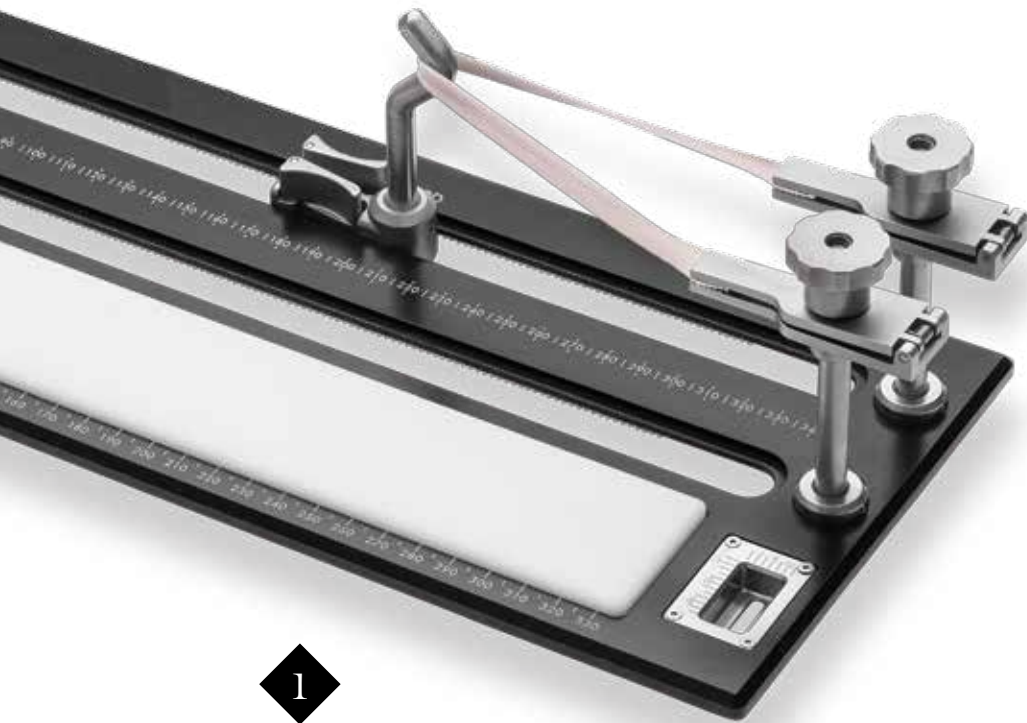


Bio-TransFix™ ACL Reconstruction

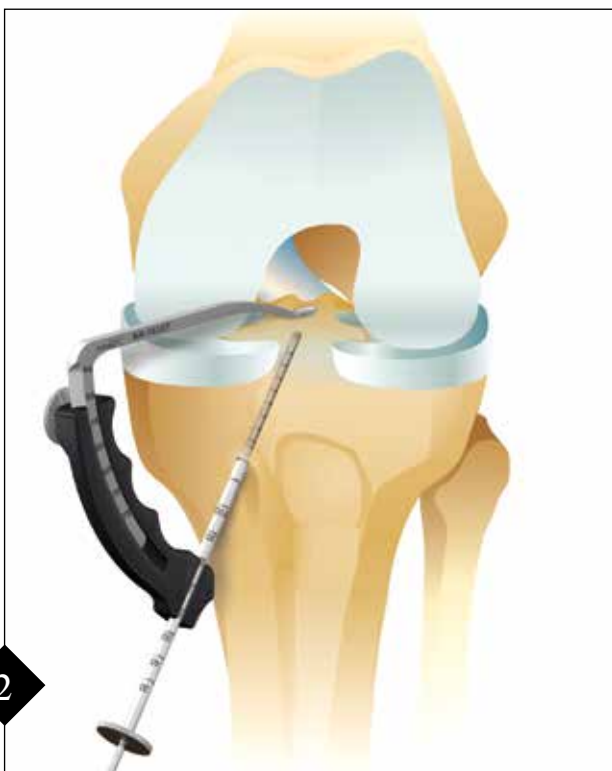
Surgical Technique



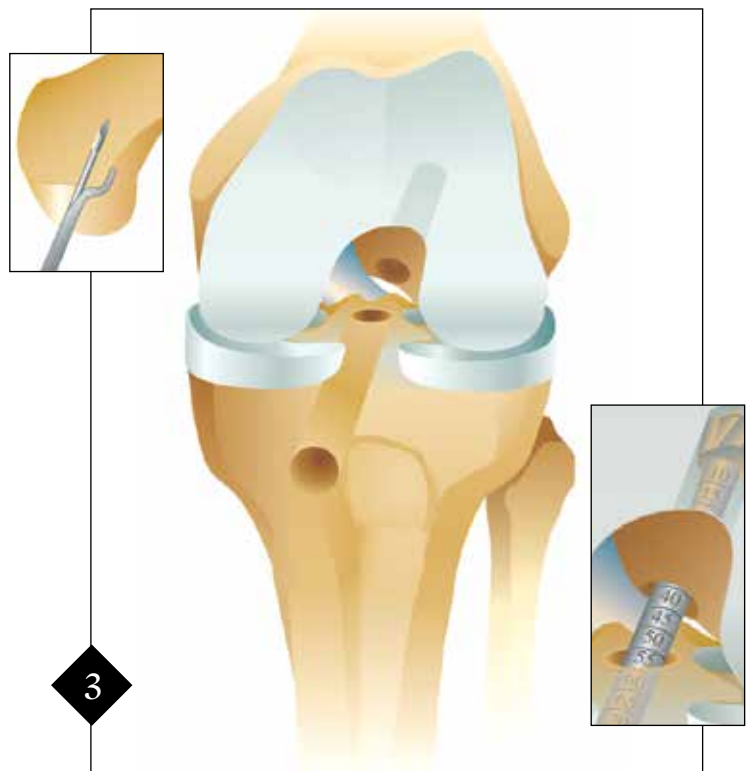
Bio-TransFix ACL Reconstruction



Semitendinosus and gracilis tendon autografts or tibialis tendon allografts are mounted on the GraftPro™ workstation. The tendons are placed around the adjustable post and the free ends secured in the Tissue Clamps. Whipstitches are placed in the tibial ends of the graft with #2 FiberLoop® suture. The completed graft should be sized to the nearest half millimeter diameter.

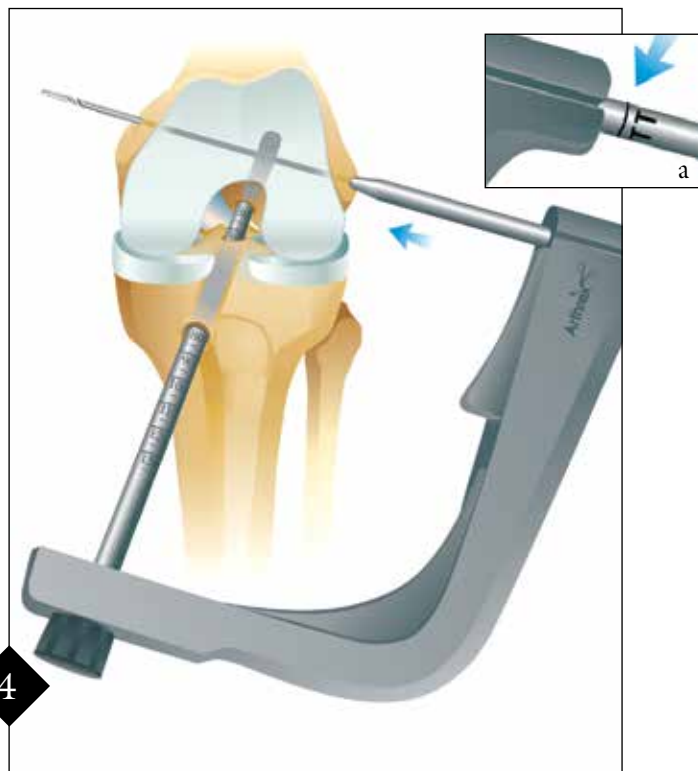


The tibial tunnel guide pin is anatomically positioned within the ACL footprint. The tibial tunnel length of at least 40 mm can be determined prior to guide pin placement with the graduated guide sleeve. The tibial tunnel is then created equal to the size of the graft.



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

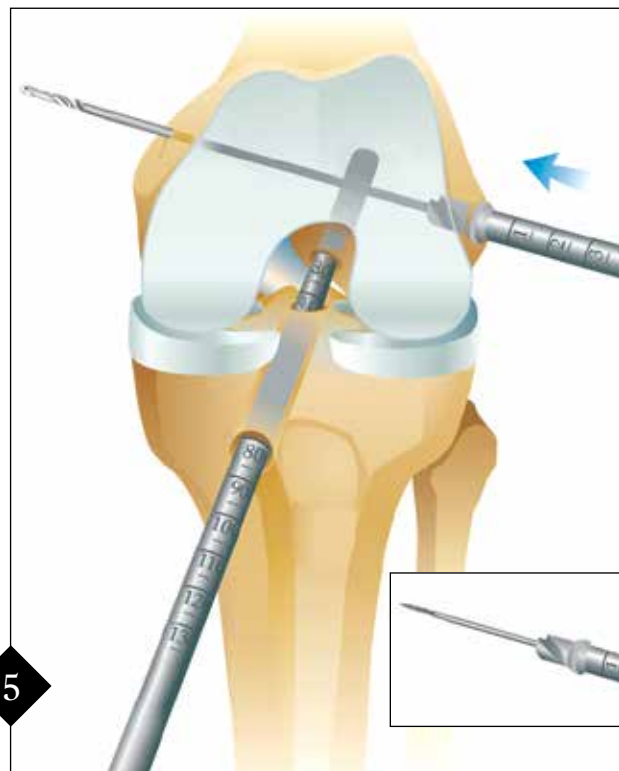
A 2.4 mm Drill Tip Guide Pin is positioned with the TTG and a Low Profile Reamer equal to the graft diameter is drilled to a depth of 35-40 mm. The drill and guide pin are removed.



4

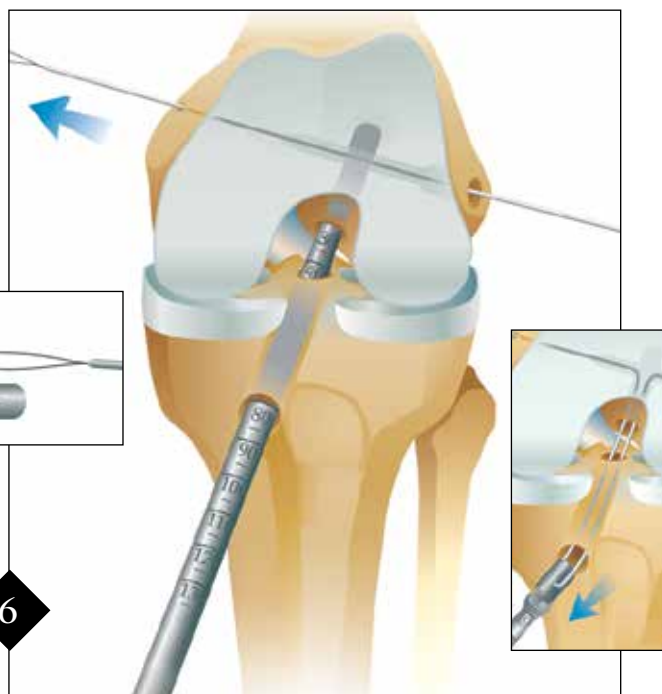
The TransFix® II Tunnel Hook that matches the tunnel diameter is assembled with the TransFix II Drill Guide. The tunnel hook is inserted through the tibial tunnel and positioned into the femoral socket. The Guide Pin Sleeve is positioned on the skin of the lateral thigh, a small incision is made and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

Exposure of the guide sleeve's "TT" 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.



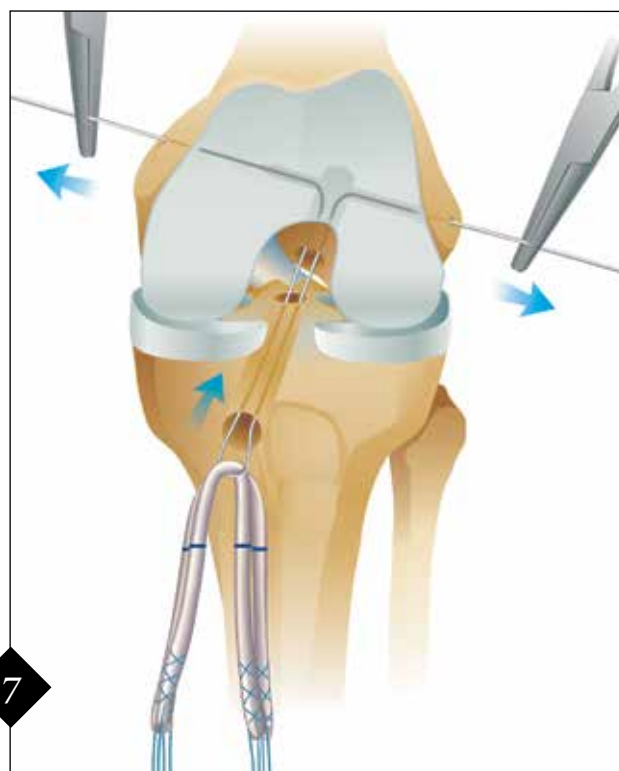
5

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 laser marks on the drill shaft as a secondary control of subsequent implant insertion depth.



6

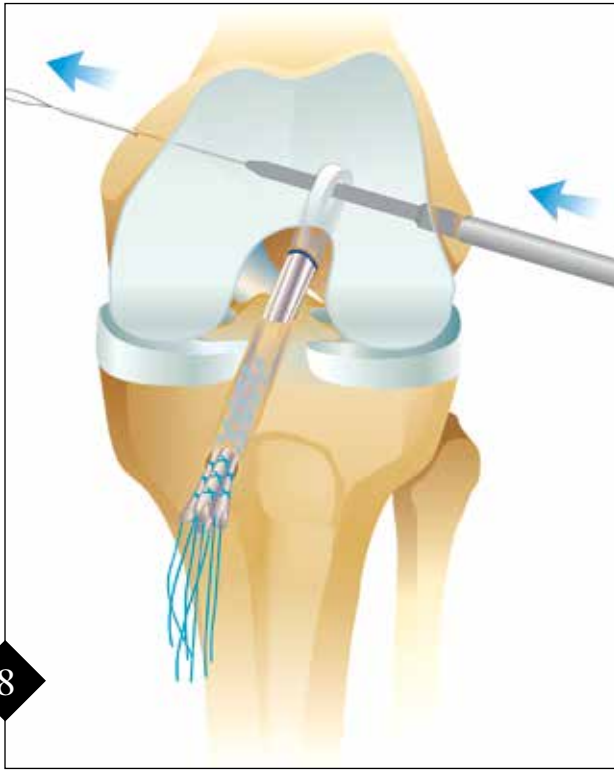
The Nitinol Graft Passing Wire is hooked into the 3 mm guide pin slot. The Guide Pin is pulled medially drawing the Nitinol wire through the 3 mm pilot hole and the TransFix II Tunnel Hook. The tunnel hook is then extracted pulling the midsection of the Nitinol wire out the tibial tunnel for graft passing.



7

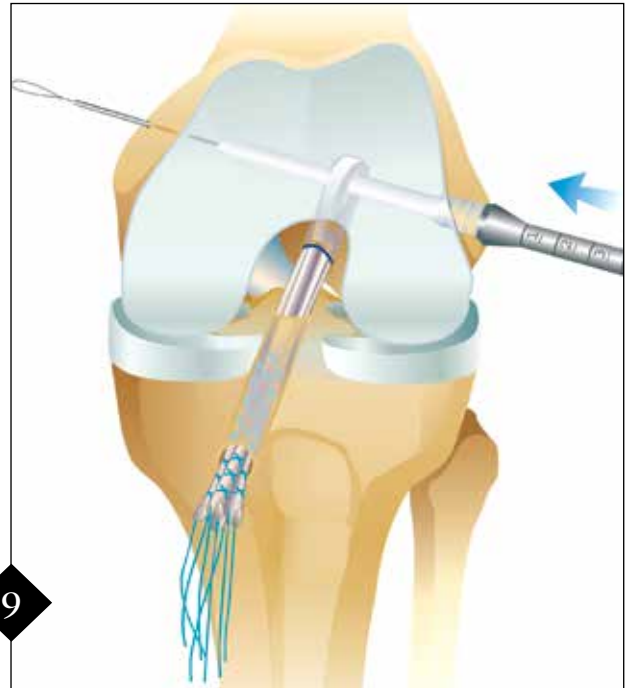
The midsection of the graft is positioned over the Nitinol wire with the graft end lengths equalized. Needle holders are used to secure the free ends of the wire and to assist in graft passing. The wire free ends are simultaneously pulled away from the knee advancing the graft through the tibial tunnel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

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



8

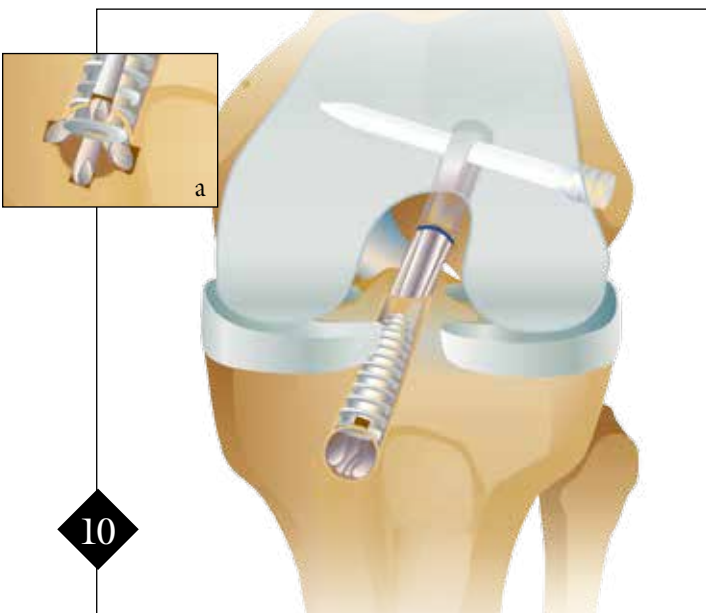
To further simplify implant insertion, the Nitinol wire is shifted medially to place any wire kinks medial to the femoral tunnel. The Bio-TransFix Dilator may be inserted over the wire to create a pilot hole for the implant and to further ensure proper graft positioning.



9

The Bio-TransFix Implants are 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-Composite 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 Measurement Device 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).



Alternatively, Medial Portal TransFix Hooks may be used to facilitate insertion into femoral sockets that are not colinear with the tibial tunnel. Low Profile Reamers are used through the medial portal. Medial Portal TransFix Hooks are compatible with the Long Adaptur™ Guide C-Ring for increased flexibility in pin placement. They have a low profile head for eased insertion into the joint and for compatibility with shorter femoral sockets. (see technique - LTI-0130-EN)

Note: Proper technique must be followed to ensure adequate tunnel/socket and aperture preparation. Deviating from the technique may cause excessive torque on the screw during implantation and lead to damage to the graft or damage to the implant. It is also recommended to monitor the implantation depth of the screw to ensure that the tip of the screw inserted into the tibial tunnel is not protruding into joint.

ORDERING INFORMATION

Bio-TransFix II ACL Reconstruction Set (AR-1817TS)

TransFix II Implant Impactor on Handle	AR-1973
Bio-TransFix Driver	AR-1973BD
TransFix Screw Driver	AR-1364
Drill for TransFix II, 5 mm, for 3 mm Drill Pin	AR-1974
Drill for TransFix II, 5 mm, for 3 mm Drill Pin, long	AR-1974L
Drill Guide Assembly for TransFix II	AR-1975
TransFix II 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
Semitendinosus Stripper, 5 mm	AR-1278
TransFix II Instrumentation Case	AR-1817TC
Bio-TransFix Dilator	AR-1373
Bio-TransFix Extraction Pin	AR-1973E

Bio-TransFix Implants & Disposables

Bio-TransFix Implant, 5 mm x 40 mm	AR-1351B
Bio-TransFix Implant, 5 mm x 50 mm	AR-1351LB
TransFix II Drill Set, 3 mm, qty. 5	AR-1978S
Transtibial ACL Disposables Kit, w/o Saw Blade, qty. 5	AR-1898S
Metal TransFix Convenience Pack, 40 mm	AR-1351K-CP
Metal TransFix Convenience Pack, 50 mm	AR-1351LK-CP
Bio-TransFix Convenience Pack, 40 mm	AR-1351BK-CP
Bio-TransFix Convenience Pack, 50 mm	AR-1351BLK-CP

Delta Screw Tibial Fixation Instrumentation

ACL Tunnel Preparation Instrumentation Set (<i>Dilators 7-10 mm diameter</i>)	AR-1856S
Ratcheting Screwdriver Handle	AR-1999
Driver, BioComposite Interference Screw, quick connect	AR-1996CD-1
Torque Measurement Device	AR-1990
Quad Notcher Set	AR-1842S

Tibial Fixation Implants

BioComposite Interference Screw, Delta Tapered, 9 mm x 35 mm	AR-5035TC-09
BioComposite Interference Screw, Delta Tapered, 10 mm x 35 mm	AR-5035TC-10
BioComposite Interference Screw, Delta Tapered, 11 mm x 35 mm	AR-5035TC-11
BioComposite Interference Screw, Delta Tapered, 12 mm x 35 mm	AR-5035TC-12

Medial Portal TransFix Set

AR-1978MPS

ACL ToolBox Instrumentation Set

AR-1900S

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

GraftPro Graft Preparation System

AR-2950D

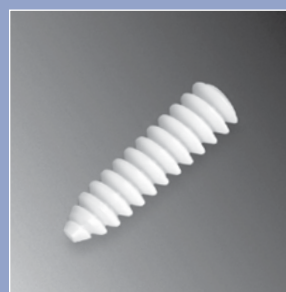
Disposables

#2 FiberLoop w/Straight Needle, 15 inches (blue), 76 mm needle w/7 mm loop	AR-7234
#2 TigerLoop w/Straight Needle, 15 inches w/TigerWire (white/green), 76 mm needle w/7 mm loop	AR-7234T

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



*Actual size of
Bio-TransFix Implant*



*Actual size of 35 mm
Delta Tapered BioComposite
Interference Screw*

This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature and the product's Directions For Use.



The Bio-TransFix™ ACL Reconstruction System has been developed in cooperation with Eugene M. Wolf, M.D., San Francisco, CA, and Jeffery Whelan, M.D., Houston, TX.

View U.S. patent information at www.arthrex.com/corporate/virtual-patent-marking

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