**Bio-TransFix™ ACL Reconstruction**

**Surgical Technique**

Actual size of Bio-TransFix Implant 35 mm Delta Tapered BioComposite Interference Screw

**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
- Bio-TransFix Driver AR-1973
- Bio-TransFix Extraction Pin AR-1973E

**Bio-TransFix Implant & Disposable**

- 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 (Dilators 7-10 mm diameter) 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
- BioComposite Interference Screw, Delta Tapered, 5 mm x 35 mm AR-5035TC-03
- BioComposite Interference Screw, Delta Tapered, 6 mm x 35 mm AR-5035TC-06
- BioComposite Interference Screw, Delta Tapered, 7 mm x 35 mm AR-5035TC-07
- BioComposite Interference Screw, Delta Tapered, 8 mm x 35 mm AR-5035TC-08
- 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**

- #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.)*

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

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

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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 tendon and passed through 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 guide sleeve and the tunnel hook, exiting the femur medially.

The Nitinol Graft Passing Wire is hooked into the 3 mm guide pin to broach the cortex for the Bio-TransFix™ Implant. The 3 mm Drill Pin is drilled through the guide sleeve to the guide housing indicates the need for a 50 mm Bio-TransFix™ Implant. The 5 mm broach, with depth stop collar, is drilled over the wire, the implant is fully impacted until the distal anchor is fully seated and the screw cinched, completing implantation. The impactor is removed and final confirmation of implant depth is performed with finger palpation.

Secure tibial fixation is obtained with a 35 mm Delta Tapered Bio-TransFix® Implant. 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 of the tunnel to engage the screw head for eased insertion into the joint and for compatibility with the Long Adapteur™ Guide C-Ring for subsequent fixation strength. The Quad Notcher may be used 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.

The femoral tunnel is created by referencing the over-the-top position with a Transfix Femoral M/L Drill Guide (TFF) to create a 2 to 2.5 mm or tunnel backwall, 2.4 mm Drill Tip Guide Pin is positioned with the TTG and a Low Profile Reamer equal to the graft diameter (TTG) to create a 1 to 2 mm or less tunnel backwall.

The femoral tunnel guide pin is anatomically positioned within the femoral tunnel. The femoral tunnel guide pin is then inserted through the tunnel and the guide pin slot. The guide pin slot is inserted over the wire until the implant is engaged. The wire should be secured with a needle holder at the handle exit. The Bio-TransFix Implants are hand inserted over the Nitinol wire and fixed in place by concentric screw. The Bio-TransFix® Implant 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 impacted and the oblong, aligned annular, contacts the cortical bone surface.

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


d) The Bio-TransFix implants are hand inserted over the Nitinol wire and fixed in place by concentric screw. The Bio-TransFix® Implant 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 impacted and the oblong, aligned annular, contacts the cortical bone surface.


d) The Bio-TransFix implants are hand inserted over the Nitinol wire and fixed in place by concentric screw. The Bio-TransFix® Implant 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 impacted and the oblong, aligned annular, contacts the cortical bone surface.

The tunnel hook is inserted through the tibial tunnel and into the femoral tunnel. The Bio-TransFix® Implant 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 impacted and the oblong, aligned annular, contacts the cortical bone surface. The tunnel hook is inserted through the tibial tunnel and into the femoral tunnel. The Bio-TransFix® Implant 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 impacted and the oblong, aligned annular, contacts the cortical bone surface.

The Femoral Tunnel Guide pin is inserted through the tunnel and the guide pin slot. The Guide Pin is pulled medially drawing the Nitinol wire through the 3 mm pilot hole and the TransFix II guide sleeve and the tunnel hook, exiting the femur medially.

The transtibial drill guide is inserted through the tunnel and the guide pin slot. The Guide Pin is pulled medially drawing the Nitinol wire through the 3 mm pilot hole and the TransFix II guide sleeve and the tunnel hook, exiting the femur medially.

The tunnel hook is inserted through the tibial tunnel and into the femoral tunnel. The Bio-TransFix® Implant 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 impacted and the oblong, aligned annular, contacts the cortical bone surface. The tunnel hook is inserted through the tibial tunnel and into the femoral tunnel. The Bio-TransFix® Implant 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 impacted and the oblong, aligned annular, contacts the cortical bone surface. The tunnel hook is inserted through the tibial tunnel and into the femoral tunnel. The Bio-TransFix® Implant 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 impacted and the oblong, aligned annular, contacts the cortical bone surface.
The tibial tunnel guide pin is anatomically positioned within 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 interference diameter.

The femoral tunnel is created by referencing the over-the-top position with a Transtibial Femoral ACL Drill Guide. The 2.4 mm Drill Tip Guide Pin is positioned with the 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 wire free ends. Needle holders are used to secure the free ends of the wire and to assist in graft passing.

The Nitinol Grasping Wire is hooked into the 3 mm pilot hole and into the femoral tunnel. The Nitinol Grasping Wire is then pulled to create a pilot hole for the implant and to further simplify implant insertion. The Nitinol wire is doubled back to place entry wire hooks medial to the femoral tunnel. The Bio-TransFix™ Implant is inserted over the wire with the implant engaged. The wire should be secured with a needle holder at the handle exit. The midsection of the wire is shifted medially to place any wire kinks medial to the femoral tunnel.

The 5 mm guide pin is placed through the tibial tunnel for graft passage. 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, a second notch in the rim to ease screw insertion. A guide wire is positioned with the Torque Measurement Device to quantify insertion torque. The Quad Notcher may be used with the Quad Notcher to create a superior notch in the rim to ease screw insertion. A guide wire is positioned with the Quad Notcher to create a superior notch in the rim to ease screw insertion. A guide wire is positioned with the Quad Notcher to create a superior notch in the rim to ease screw insertion. A guide wire is positioned with the Quad Notcher to create a superior notch in the rim to ease screw insertion.
The femoral tunnel is created by referencing the over-the-top position with a Transfix Femoral ACL Drill Guide (TFACDG) to create a 2 to 2.5 mm size tunnel. The Needle holder is used to secure the free ends of the wire and to assist in graft passage. The wire is pulled through the tunnel, and the anchor is secured in the femoral socket 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 handle exit, followed by a second pin placement to ensure proper proper graft positioning.

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.

The TTG and a Low Profile Reamer equal to the graft diameter are used to create a 1 to 2 mm or less tunnel backwall.

The midsection of the Nitinol wire is placed through the aperture of the Transfix® II Tunnel Hook. The tunnel hook is then extracted pulling the Nitinol wire through the 3 mm pilot hole and the TransFix® II Guide Pin is pulled medially drawing the Guide Pin slot. The Guide Pin is then pulled medially drawing the Nitinol wire to create a pilot hole for the implant and to further simplify implant insertion. The Nitinol wire is drilled medially to place one wire hole inside the femoral tunnel. The Bio-TransFix™ Implant and a Low Profile Reamer equal to the graft diameter is inserted into the femoral socket. Medial Portal TransFix Hooks are inserted over the wire until the implant is engaged. The wire is pulled as far medially as possible. The Bio-TransFix Driver is inserted over the Nitinol wire, the implant is fully inserted until the handle exit with light impaction and medial pulling, and the implant is secured in the femoral socket 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 handle exit, followed by a second pin placement to ensure proper proper graft positioning.

Secure implant fixation is obtained with a 20 mm Delta Screw. The Delta Screw is secured to the femoral tunnel with a screwdriver and aperture preparation. Deviating from the technique may cause excessive damage to the implant. It is also recommended to monitor the implantation torque on the screw during implantation and lead to damage to the graft or implant. The implant is then secured to the femoral socket with a screwdriver and aperture preparation. Plateau damage may occur if a screwdriver is inserted into the bone, and the implant is then secured to the femoral socket with a screwdriver and aperture preparation. Deviating from the technique may cause excessive damage to the implant. It is also recommended to monitor the implantation torque on the screw during implantation and lead to damage to the graft or implant. The implant is then secured to the femoral socket with a screwdriver and aperture preparation. Deviating from the technique may cause excessive damage to the implant. It is also recommended to monitor the implantation torque on the screw during implantation and lead to damage to the graft or implant.
**Bio-TransFix™ ACL Reconstruction**

**Surgical Technique**

- **Actual size of Bio-TransFix Implant:**
  - 35 mm Delta Tapered BioComposite Interference Screw

**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 (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**

**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.)

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