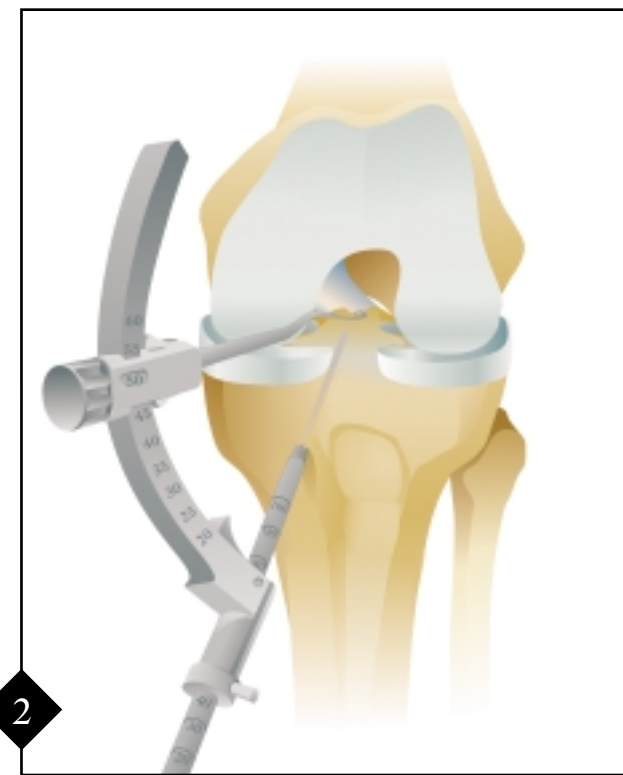
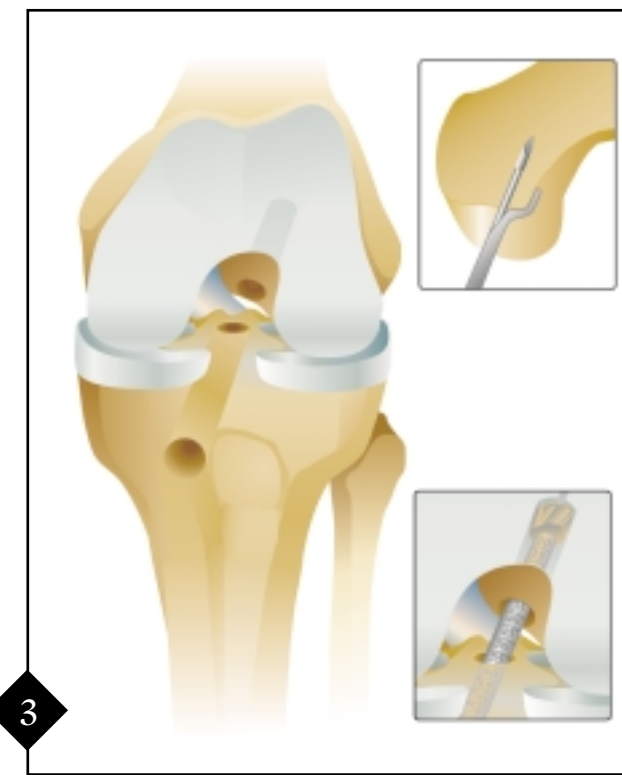


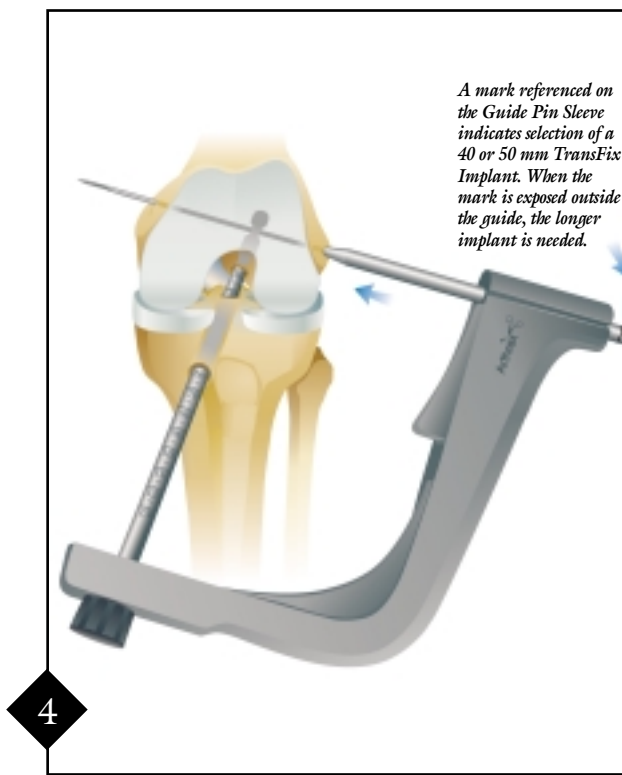
1 Through a three to four centimeter incision the graecilis and semitendinosus tendons are harvested with either a closed-end Semitendinosus Stripper or Pigtail Hamstring Tendon Stripper. Both strands of the semitendinosus and graecilis tendons are mounted on the Graft Workstation Base. The tendons are placed around the adjustable post at their midpoint and the free ends are clamped together with a Kocher clamp. Pretensioning of the graft to 15 lbs is recommended. The free ends are whip-stitched to a length of 30 mm. The graft is then sized to the nearest half millimeter. A mark is made 30 mm from the proximal end of the graft.



2 The tibial and femoral tunnels are located and prepared using transtibial instrumentation which references intra-articular constants for reproducible tunnel placement. Once the guide pin determines the center of the tibial tunnel a Cannulated Drill 2 mm smaller than the measured graft's diameter is drilled to create the tibial tunnel. In half millimeter sizes, smooth tunnel dilators are used to expand the tunnel walls until the graft diameter is matched. The edges of the tibial tunnel opening are smoothed with a Tunnel/Notchplasty Rasp.



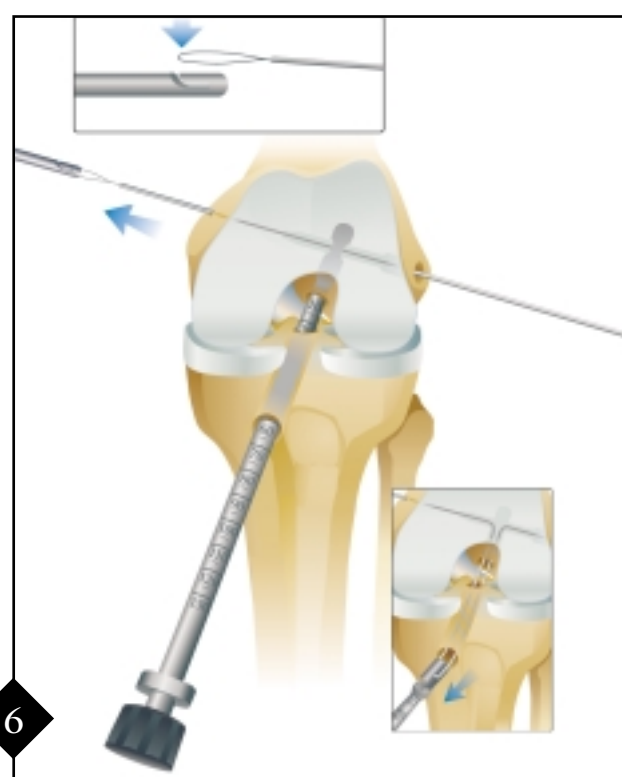
3 The Transtibial Femoral ACL Drill Guide is placed in the over-the-top position (10:30-11:00 for a right knee and 1:30-2:00 for a left knee). A 2.4 mm guide pin is then drilled until it reaches the anterior lateral femoral cortex. A Cannulated Headed Reamer corresponding to the graft's diameter is placed over the guide pin and advanced through the tibial tunnel and PCL until rested against bone. As the femoral socket is created, the depth appropriate to the femoral portion of the graft is overdrilled by 7-10 mm. The headed reamer and guide pin are removed.



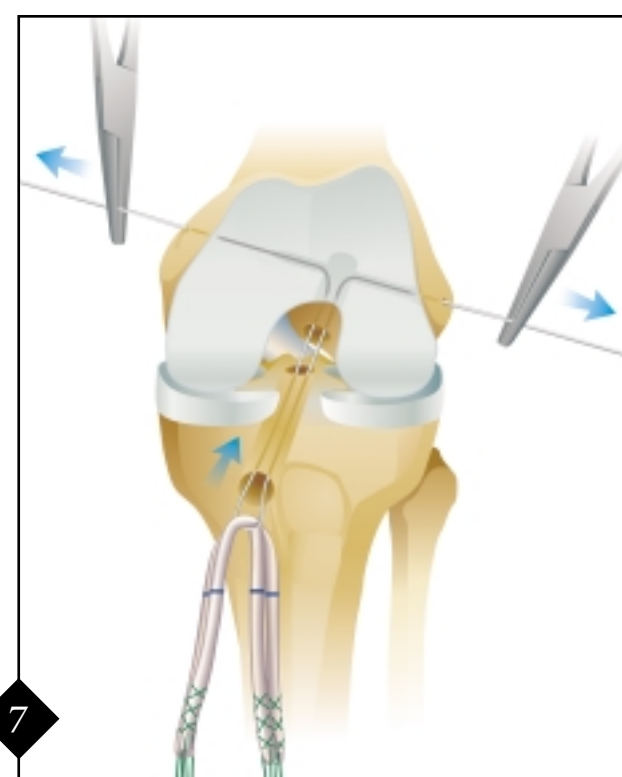
4 The TransFix II Tunnel Hook corresponding to the tunnel diameter is placed through the tibial tunnel and seated into the femoral tunnel until the 30 mm mark is flush with the exit of the femoral tunnel. The 3 mm TransFix Guide Pin Sleeve is positioned firmly against the skin of the lateral thigh, dimpling the skin where an incision will be made and the sleeve advanced to bone. The 3 mm Drill Pin is placed through the guide sleeve and advanced across the knee. The pin will capture the center of the tunnel hook and exit the anterior medial aspect of the knee.



5 The 5 mm Drill for the TransFix Implant is then introduced over the guide pin and drilled until the collar is flush with the lateral cortex. The drill is designed to create a pilot hole for the TransFix Implant. The depth of the drill is recorded. The depth noted is referenced when the TransFix Implant is seated. The Reamer Handle is loaded onto the medial aspect of the guide pin.



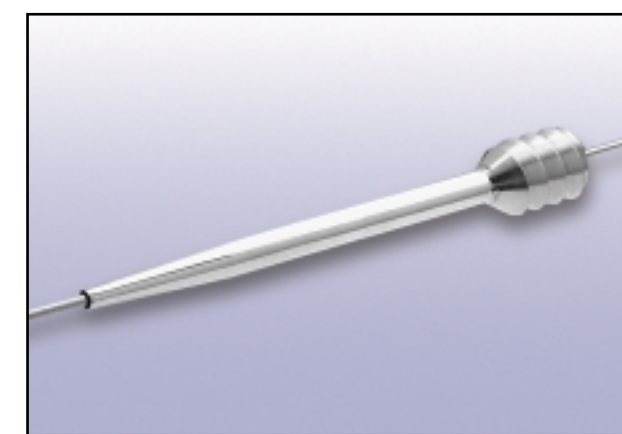
6 The Nitinol Graft Passing Wire is hooked onto the guide pin and held taut. The guide pin is then pulled from the medial side in one continuous motion, leading the wire through the 3 mm pilot hole. Once the guide wire exits the medial aspect of the knee, clamps are placed on each end of the wire to hold its position. Without twisting, the tunnel hook is removed, delivering the wire loop out the tibial tunnel.



7 The graft is placed through the Nitinol wire loop and the marked position aligned. A clamp may be secured to the base of the graft to ensure that equal length is maintained. While avoiding any distal tensioning of the graft, the medial and lateral sides of the graft passing wire are equally pulled delivering the graft through the tibial tunnel and joint until the graft is fully seated into the femoral tunnel.



8 Prior to inserting the TransFix Implant, it is important to advance the Graft Passing Wire medially in order to clear any kinks in the wire created during graft passing. The TransFix Implant in either 40 mm or 50 mm lengths is loaded over the Graft Passing Wire. The implant is designed to be impacted until flush with the lateral cortex of the femur.



If necessary the reverse cutting threads on the TransFix Implant allow it to be removed by unscrewing the implant with the TransFix II Implant Impactor or a 3 mm hex driver.

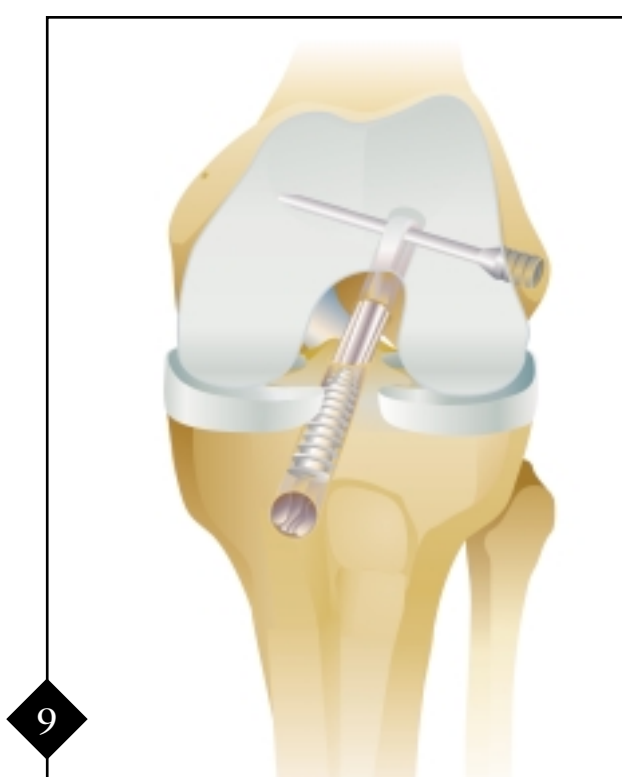
Advance the implant by hand prior to loading the impactor over the Graft Passing Wire.

Once the impactor is secured to the implant, a clamp is placed on the Graft Passing Wire as it exits the side of the impactor.

Pull the graft wire taut from the medial side of the knee prior to advancing the TransFix Implant. The Graft Passing Wire is continuously pulled medially which helps pass the implant and avoids kinking of the wire.

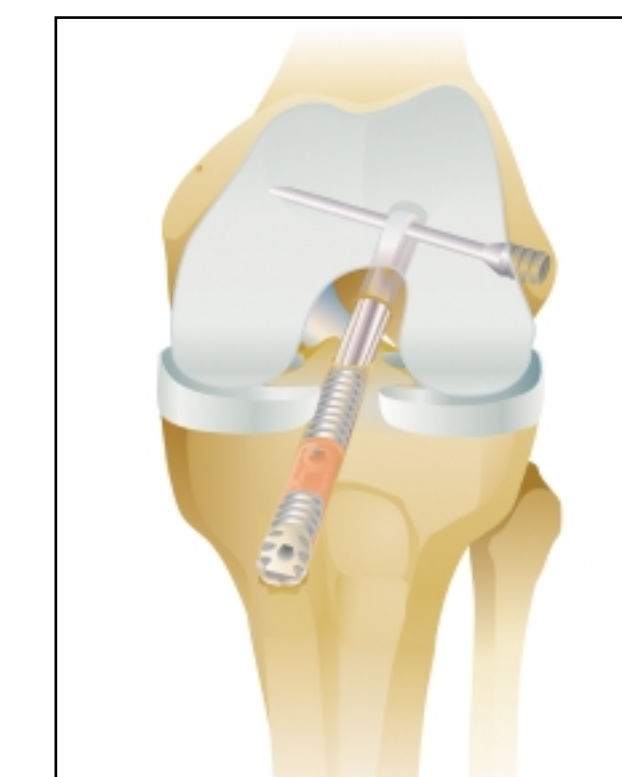
The driver and implant are further impacted by a mallet. Confirm the implant is fully seated laterally in addition to assuring solid femoral fixation by pulling on the graft prior to removing the Graft Passing Wire.

Cycle the knee repeatedly prior to placing the tibial Bio-Interference Screw.



9 Selection of an 8.5 to 10 mm or 9.5 to 11 mm Delta Tapered Bio-Interference Screw is made based on the size of the tunnel prepared and quality of bone at the time of the procedure. While maintaining tension on the graft the knee is placed in a slight amount of flexion.

The 35 mm Delta Tapered Bio-Interference Screw is placed anterior to the graft and advanced until optimal fixation of the graft is achieved.



In situations of poor metaphyseal bone quality, fixation with two Bio-Cortical Interference Screws should be considered. The Bio-Cortical screws are specifically designed for placement at each tunnel orifice providing greater apposition in cortical bone for maximum fixation strength.

TransFix™ II ACL Reconstruction Set (AR-1972S) * includes:

TransFix Instrumentation:

TransFix II Implant Impactor on Handle	AR-1973
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
Semitendinous Stripper, 5 mm	AR-1278
TransFix II Sterilization Case	AR-1972

TransFix Implants & Disposables:

TransFix Implant, 3 mm x 40 mm	AR-1351**
TransFix Implant, 3 mm x 50 mm	AR-1351L**
TransFix Drill Pin, 3 mm & Graft Passing Wire Set	AR-1978S
1.1 mm Nitinol Guide Pin for Bio-Interference Screw, qty. 6	AR-1249

Tibial Fixation Implants:

8 mm x 20 mm Bio-Cortical Interference Screw, proximal	AR-5080BB
9 mm x 20 mm Bio-Cortical Interference Screw, proximal	AR-5090BB
10 mm x 20 mm Bio-Cortical Interference Screw, proximal	AR-5010BB
8 mm x 17 mm Bio-Cortical Interference Screw, angled, distal	AR-5080AB
9 mm x 17 mm Bio-Cortical Interference Screw, angled, distal	AR-5090AB
10 mm x 17 mm Bio-Cortical Interference Screw, angled, distal	AR-5010AB
11 mm x 17 mm Bio-Cortical Interference Screw, angled, distal	AR-5011AB
8.5 mm - 10 mm x 35 mm Delta Tapered Bio-Interference Screw	AR-5035TB-10
9.5 mm - 11 mm x 35 mm Delta Tapered Bio-Interference Screw	AR-5035TB-11

*U.S. PATENT NO. 5,918,604

**U.S. PATENT NO. 5,895,425

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



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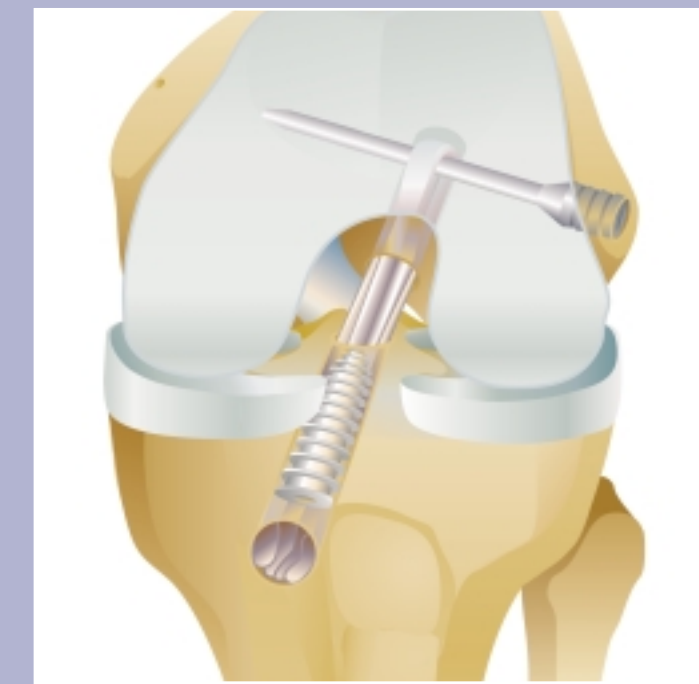
The TransFix™ ACL Reconstruction System has been developed in cooperation with Eugene M. Wolf, M.D., San Francisco, CA and Jeffery Whelan, M.D., Houston, TX. Illustrations by Siri Mills

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TransFix™ II ACL Reconstruction

Surgical Technique



TransFix II ACL Reconstruction