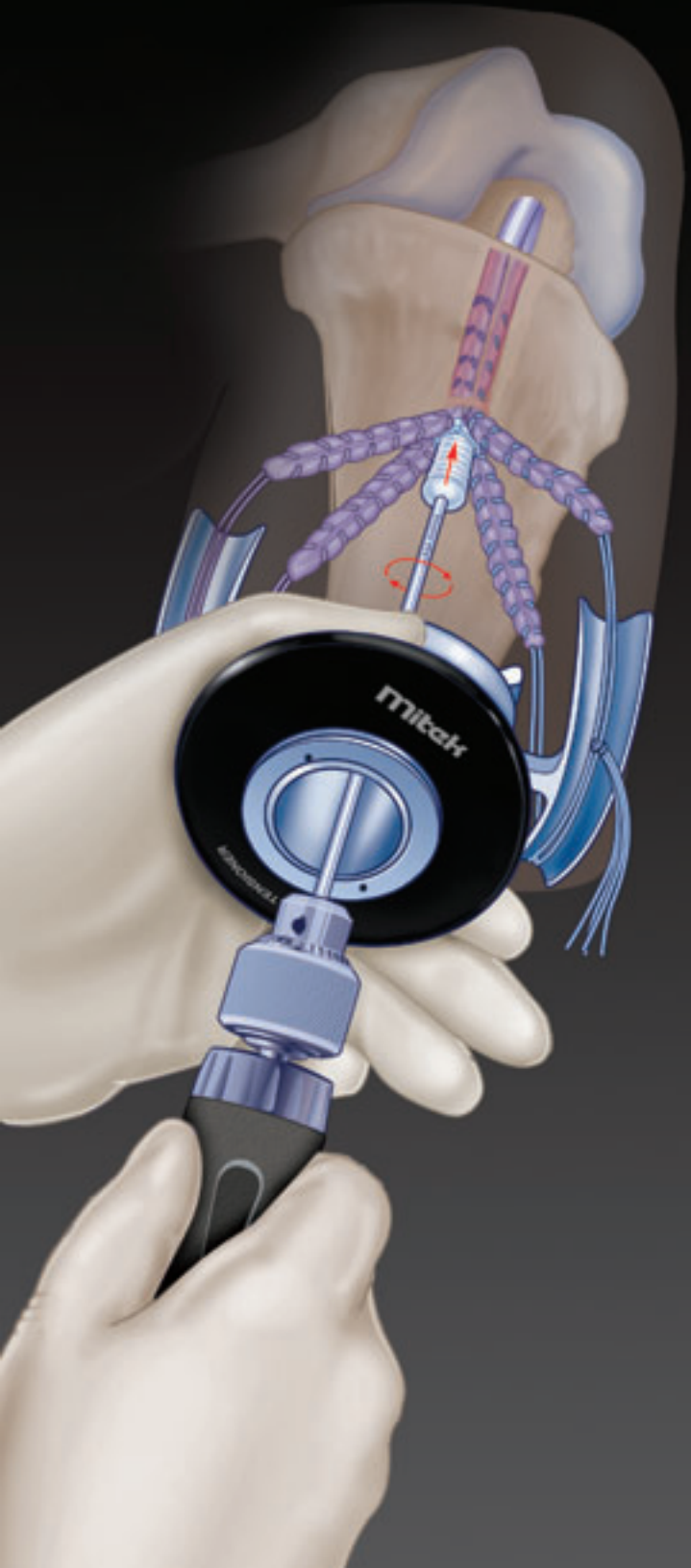
Tibial Soft Tissue Fasteners

BIO-INTRAFIX™



Building on the Legacy of INTRAFIX

- **Expanded size selection & enhanced design** - for optimal engagement and fixation
- **Bioabsorbable** - contains osteoconductive TCP (known to promote bone growth)
- **360° of graft-to-bone contact** - maximizes intra-tunnel graft compression

DePuy Mitek
a Johnson & Johnson company

Bio-INTRAFIX & INTRAFIX Surgical Technique

BIOCRYL Material & Bio-INTRAFIX System

MATERIAL

The Bio-INTRAFIX screw and sheath are molded from a composite of PLA and osteoconductive TCP (Tricalcium Phosphate).[1] **TCP provides the osteoconductive bioceramic material necessary to promote bone growth into the sheath and screw.** ß-TCP has been shown to dissolve and reabsorb more quickly than HAp (Hydroxyapatite). In-vivo studies show that ß-TCP forms a strong bone-implant interface, bonding to bone and exhibiting osteoconductive characteristics.[1]

PROVEN[1] QUALITY

DePuy Mitek developed a process for molding a TCP/PLA screw and sheath that can withstand the insertion forces imposed during soft tissue ACL reconstruction. **Using proprietary Micro Particle Dispersion (MPD) technology, DePuy Mitek creates a uniformly strong implant with a homogeneous blend of TCP and PLA throughout the implants, increasing their strength and stiffness.**

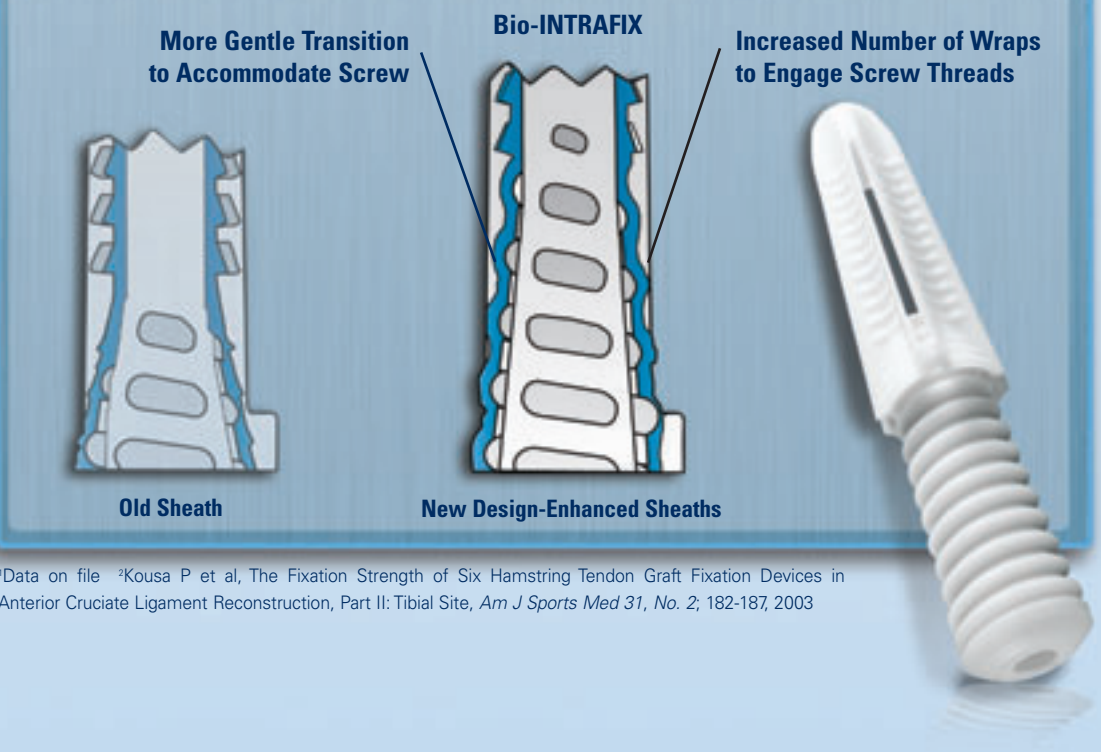
NEW DESIGN

The Bio-INTRAFIX fastener now offers an expanded size selection and line-to-line sizing. It also features a patented screw and sheath design that enhances bone-to-graft contact and strength through:

- Concentric screw placement
- 360° graft placement
- Improved engagement

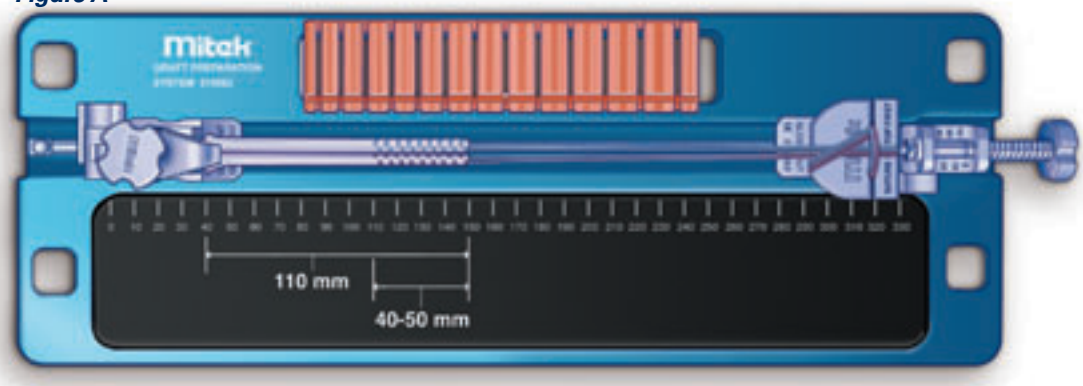
STRENGTH

Tested in human cadaver bone, the Bio-INTRAFIX system demonstrated excellent fixation, with >1000N pull-out strength[1], and allows rigid absorbable material to perform like a flexible plastic sheath. Tested in an independent study (against five other tibial soft tissue fixation systems), INTRAFIX demonstrated the highest strength and stiffness with the lowest graft displacement.[2]



[1]Data on file [2]Kousa P et al, The Fixation Strength of Six Hamstring Tendon Graft Fixation Devices in Anterior Cruciate Ligament Reconstruction, Part II: Tibial Site, *Am J Sports Med 31, No. 2*; 182-187, 2003

Figure A



1. Prepare the Graft

Whip-stitch the ends of the soft tissue grafts for 4-5cm using a #2 ORTHOCORD™ high-strength braided polyester suture. If possible, plan graft preparation so that the sutured portion of the graft is placed in the tibial tunnel alongside the sheath. This may increase pull-out strength. Once the graft is prepared, the graft strands should be pre-tensioned on a graft preparation board until ready for use ***(Figure A).***

Note on Suturing: *Different colored sutures allow you to label the gracilis separately from the semitendinous (ORTHOCORD is available in two colors). Alternatively, use a marking pen to color the suture on the gracilis or semitendinous in order to make it easier to identify the graft strands after the graft has been pulled into the tunnel.*

2. Size the Graft

Use a sizing block to measure the graft diameter. Refer to the sizing guideline below to determine the appropriate tunnel, sheath trial, sheath and screw size.

Bio-INTRAFIX Sizing Guidelines (mm)*

Graft	Tunnel	Trial	Sheath	Screw**
7	7	Small (7-8)	Small	6-7
7.5	7.5	Small (7-8)	Small	6-7
8	8	Small (7-8)	Small	6-8
8.5	8.5	Small (7-8)	Small	6-8
9	9	Large (9)	Large	7-9
9.5	9.5	Large (9)	Large	7-9
10	10	Large (9)	Large	8-10
10.5	10.5	Large (9)	Large	8-10

*The sizing guideline above is recommended for 4-strand ST graft

INTRAFIX Sizing Guidelines (mm)

Graft	Tunnel	Screw**
7	7	6-8
8	8	7-9
9	9	8-10
10	10	8-10

**Screw size is ultimately the decision of the surgeon

Figure B - Pass the Graft

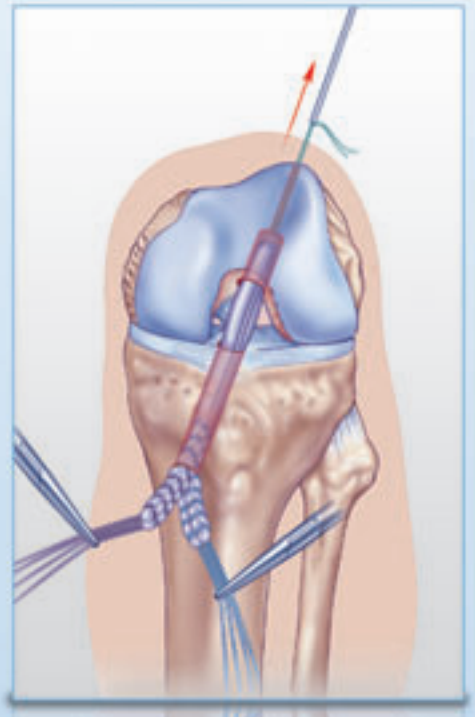
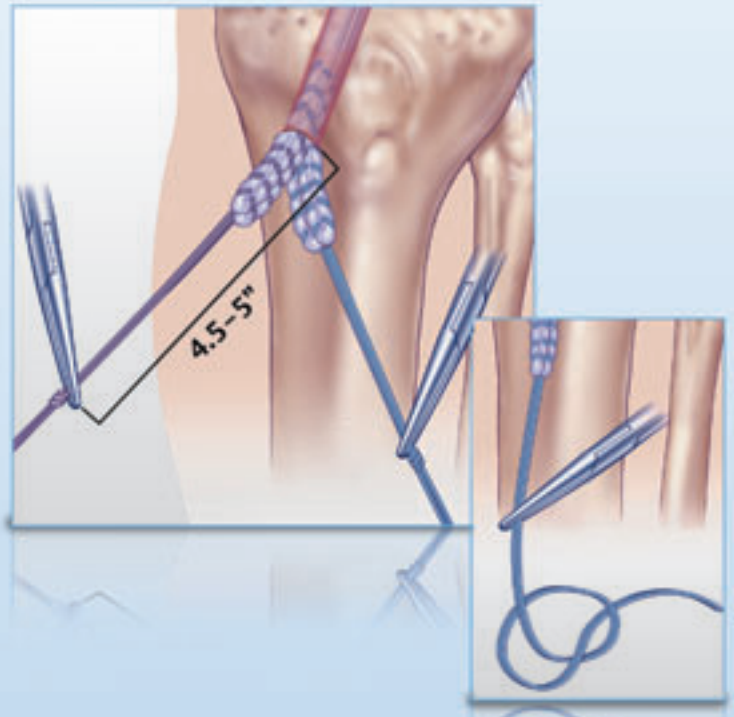


Figure C - Tie the Sutures



3. Drill & Dilate Tibial Tunnel

The ideal angle for the adjustable tibial guide setting is 40-45˚. At this angle, the tibial tunnel length is typically 35-45mm. Drilling 1.5-2cm medial to the medial edge of the tibial tubercle allows for a more advantageous angle of approach to the anatomical insertion of the ACL on the femur.

Begin by clearing the soft tissue away from the tunnel edge to improve visualization. **Tunnel dilation is strongly recommended.**

Note on dilating: *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, underdrilling by 2mm is preferred.* ***The final diameter should be the same as the graft diameter.*** *Make sure that dilation is done with a guidewire, confirming the tunnel axis, as the dilators may wander off the central axis as they are driven in.*

4. Pre-Notch / Trial

Use the appropriate sheath trial to pre-notch the tibial tunnel prior to pulling the graft into the tunnel. Insert the trial into the tibial tunnel to a depth that matches the sheath length (30-35mm). This will aid the insertion of the trial after the graft has been pulled into place.

5. Passing the Graft

The four strands of the graft should be paired and straight as you draw them into the tunnel. This makes separation of the tendons much easier when the sheath is inserted ***(Figure B)***.

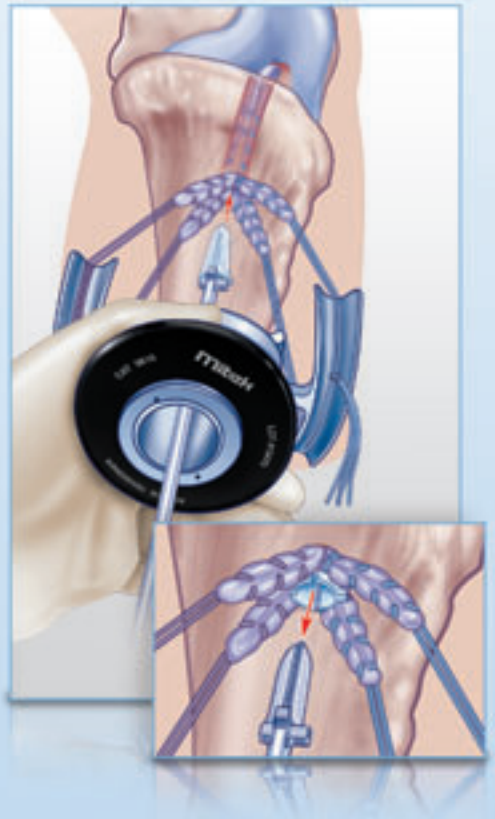
6. Femoral Fixation

Securely fix the graft into the femoral tunnel. (RIGIDFIX™ works well to approximate joint line fixation.)

Figure D - Apply Tension for Orientation

Figure E - Insert Sheath Trial

Figure F - Sheath Following Insertion



SURGICAL TECHNIQUE

7. Attach Graft to the Tie Tensioner

Mark the sutures between 4.5" and 5" from the tibial tunnel edge and knot the gracilis suture limbs together (A hemostat can be used to hold the location during knot tying). Repeat for the semitendinosus sutures ***(Figure C)***. Loop each pair of knotted sutures over the arms of the tie tensioner. Apply approximately 40 lbs. of tension distally on the whip-stitched sutures and cycle the knee to eliminate graft creep. The tensioner will equally tension and separate each strand of the graft.

8. Compress Tendons with the Sheath Trial

Find the axis of the tunnel again with a guidewire ***(Figure D)***. Position the tensioner to hold this angle of orientation, then remove the guidewire and insert the proper size sheath trial along this axis. Orient the sheath trial so that each graft strand sits in its own channel. The trial will separate and compress the tendons, while preparing the bony tunnel for the sheath ***(Figure E)***. Gentle tapping with a mallet may be necessary to advance the trial, especially when dealing with smaller tunnel sizes or tightly fitting grafts.

9. Insert the Sheath

Select the appropriate sheath and place on the sheath inserter. Direct the sheath inserter along the axis of the tibial tunnel while applying approximately 10 lbs. of tension to the tie tensioner. Slowly and steadily advance the sheath into the tunnel, with the derotational tab at the 3 or 9 o'clock position, until the tab is flush with the cortex ***(Figure F)***. This may require the use of a mallet.

10. Insert Screw into the Sheath*

Place the Bio-INTRAFIX screw on the modular hex driver (#254641) or place the INTRAFIX screw on the fixed handle driver (#254604). Maintain firm tension on the tendons during this step (approximately 10-15 lbs. of tension). With the knee fully extended or slightly flexed in accordance with surgeon preference, insert a tapered screw along a 0.042" guidewire into the sheath ***(Figure G)***. Maintain orientation to the tunnel axis as the screw is advanced to the tibial cortex ***(Figure H)***. Trim any excess sheath material with a rongeur.

Figure G - Insert Screw

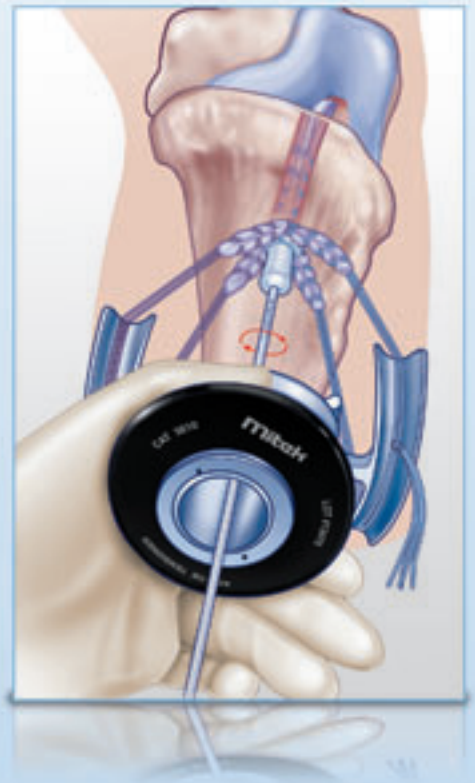
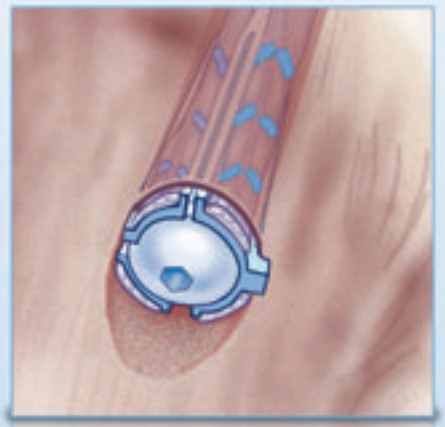


Figure H - Screw Following Insertion



*Use the Bio-INTRAFIX screw with the Bio-INTRAFIX sheath, and use the INTRAFIX screw with the INTRAFIX sheath.

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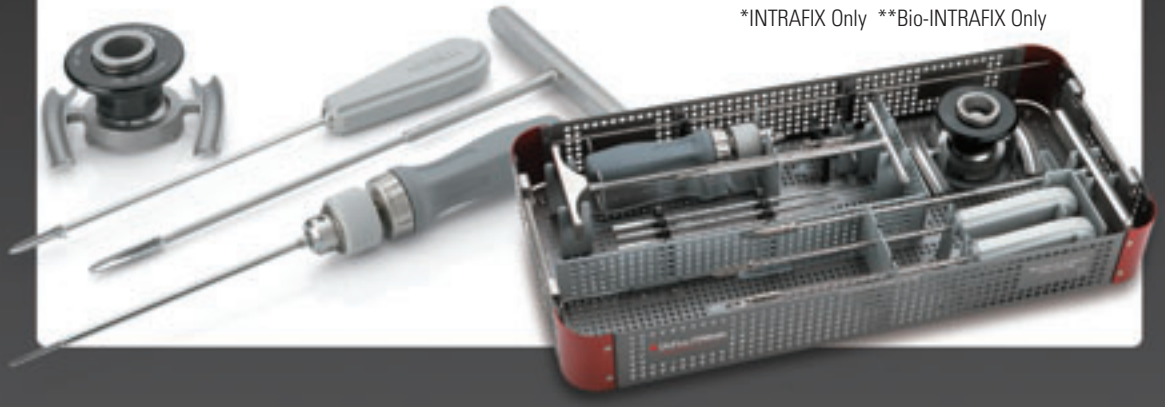
BIO-INTRAFIX™

ORDERING INFORMATION

Catalog #	Description
Bio-INTRAFIX Implants - Bioabsorbable TCP/PLA	
254629	Bio-INTRAFIX Sheath, Small
254628	Bio-INTRAFIX Sheath, Large
254622	Bio-INTRAFIX Screw, 6-7 x 30mm
254660	Bio-INTRAFIX Screw, 6-8 x 30mm
254624	Bio-INTRAFIX Screw, 7-9 x 30mm
254625	Bio-INTRAFIX Screw, 8-10 x 30mm
Bio-INTRAFIX Instruments	
254605	Tie Tensioner
254650	Bio-INTRAFIX Sheath Trial, Small (7-8mm)**
254651	Bio-INTRAFIX Sheath Trial, Large (9mm)**
254618	INTRAFIX Family Sheath Inserter
254641	30mm Modular Hex Driver
219215	Ratchet Handle w/ Jacobs Chuck
INTRAFIX Implants - Non-absorbable	
254601	Sheath, 9 x 30mm
254602	Screw, 6-8 x 30mm
254609	Screw, 7-9 x 30mm
254603	Screw, 8-10 x 30mm
INTRAFIX Instruments	
254605	Tie Tensioner
254643	Sheath Trial w/ T-handle*
254618	INTRAFIX Family Sheath Inserter
254604	30mm Fixed Handle Hex Driver*
254641	30mm Modular Hex Driver
219215	Ratchet Handle w/ Jacobs Chuck

*INTRAFIX Only **Bio-INTRAFIX Only



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