INTRAFIX® ADVANCE
Tibial Fastener System

ACL Reconstruction with INTRAFIX® ADVANCE Tibial Fastener System

Surgical Technique

DePuy Synthes
MITEK SPORTS MEDICINE
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

INTRAFIX® ADVANCE Tibial Fastener System

INTRAFIX® ADVANCE Tibial Fastener System is a tibial fixation device designed to maximize the strength and stiffness of an ACL reconstruction using soft tissue grafts.

Based on the original INTRAFIX® System which has been used clinically since 1999, the INTRAFIX ADVANCE System has optimized the implants and instruments for reliability, simplicity, and speed while maintaining the biomechanical performance that surgeons expect.

- High fixation strength and low displacement
- Sheath protects soft tissue graft and provides 360° of graft to bone compression
- Simplified implant sizing scheme

Redesigned Implants for Improved Reliability and Speed

- Thread pitch is approximately twice that of "traditional interference screws"
- Screw insertion in approximately half the time
- Non-tapered screw design offers consistent graft compression throughout entire length of implant
- Available in BIOCRYL RAPIDE® Biocomposite Material for screw and sheath or PEEK screw and polypropylene sheath
- Same screw and sheath design for both materials to simplify sizing guidelines
- Additional sizes in 23 mm lengths and extra-large sizes in PEEK for revision cases

Redesigned Instrumentation for Improved Ergonomics and Simplicity

- Color-coded to correspond to implant size
- Simplified, reliable tie-tensioner
- Slotted mallet to easily disengage instrument
- Cannulation to accommodate use of guidewire

Graft Harvest and Preparation

An incision is made over the insertion site of the semitendinosis and gracilis tendons. The tendons are identified and whip-stitched (Figure 1). Care is taken to free the tendons of any distal attachments that might cause early truncation of the tendons during harvesting.

A tendon stripper is placed over each tendon and carefully advanced towards the musculotendinous junction. Firm counter-pressure is maintained while advancing the tendon stripper until the tendon is released from its muscular attachment (Figure 2).

Strip the tendons of any remaining muscle. Whip-stitch the ends of the grafts approximately 30mm using high-strength 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. Optionally, pre-tension the graft on a graft preparation board until ready for use.

Note on Suturing: **Different colored sutures allow you to differentiate the gracilis from the semi-tendinous tendons. The SPEEDTRAP™ Graft Prep System prepares the graft quickly and is available in two colors and two lengths (20 mm and 30 mm).**

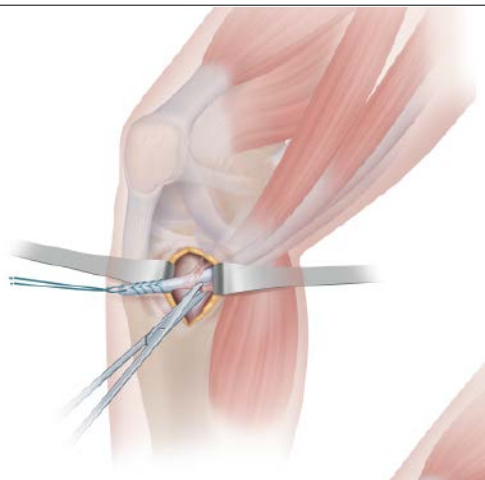

Figure 1

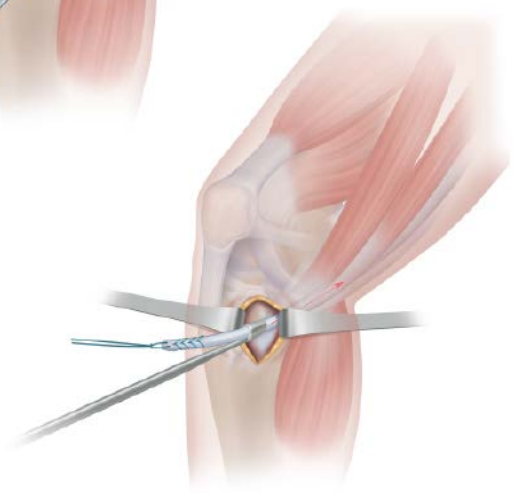

Figure 2

Size the Graft
Use a graft sizing block to measure the graft diameter. Refer to the sizing guideline to determine the appropriate tunnel, trial (dilator), and sheath and screw size.

Graft/Tunnel Size (mm)	Screw Size (mm)	Sheath Size/Sheath Inserter (mm)	Trial (Dilator)
7.0 – 7.5	7 x 23	Small/Small 23mm	Small
	7 x 30	Small/Small 30mm	
8.0 – 8.5	8 x 23	Small/Small 23mm	
	8 x 30	Small/Small 30mm	
9.0 – 9.5	9 x 23	Large/Large 23mm	Large
	9 x 30	Large/Large 30mm	
10.0 – 10.5	10 x 23	Large/Large 23mm	
	10 x 30	Large/Large 30mm	
11.0 – 11.5	11 x 30*	Extra Large/XL 30mm*	Extra Large*
12.0 – 12.5	12 x 30*	Extra Large/XL 30mm*	

*Available in PEEK screw and polypropylene sheath only.

Femoral and Tibial Tunnel Drilling

Femoral Tunnel Drilling
Drill the femoral tunnel per the surgeon's preferred technique (Figure 3).

Tibial Tunnel Drilling
Per standard technique, use a beath pin and a tibial aiming guide to create an anatomic tibial tunnel. Remnants of the tibial attachment of the ACL can be used as a reference as well as the anterior horn of the lateral meniscus. Once the beath pin has been placed, over-ream with the appropriate sized reamer to match the graft diameter.

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.

Femoral Fixation
Securely fix the graft into the femoral tunnel using any of Mitek Sports Medicine's femoral fixation systems (RIGIDLOOP® Adjustable Cortical Fixation System is a reliable, easy-to-use, adjustable loop implant that offers high strength and low displacement.) (Figure 4).

Attach Graft to the Tensioner
Mark the whip-stitch sutures approximately 4.5"– 5.0" (11.4 cm – 12.7 cm) 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 5).

Loop each pair of knotted sutures over the arms or pegs of the tensioner. Pull tension to the 30 mark on the tensioner and cycle the knee to eliminate graft creep (Figure 6). The tensioner will equally tension and separate each strand of the graft.

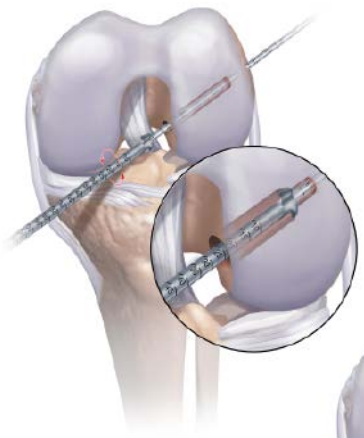

Figure 3

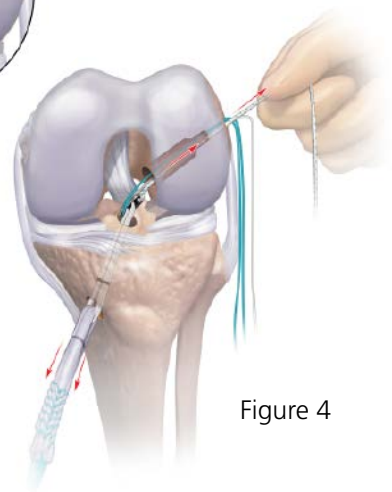

Figure 4

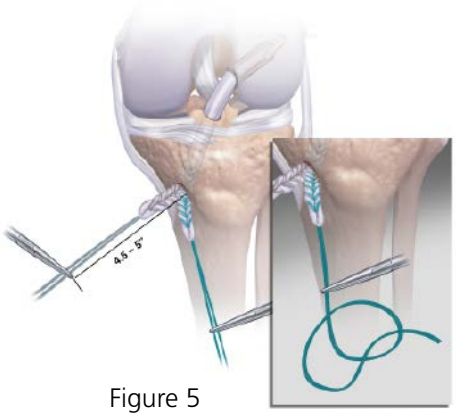

Figure 5

Figure 6

Trial, Sheath, and Screw Insertion

Insert the Trial

Find the axis of the tibial tunnel and insert the INTRAFIX® ADVANCE Guidewire (12.0"). Select the proper size trial and slide over the guidewire. Orient the trial so that each graft strand sits in its own channel. Using the slotted mallet, tap the trial into the tibial tunnel to a depth that is equal or greater than the sheath length. The trial will separate and compress the tendons while preparing the bony tunnel for the sheath (Figure 7). Remove the trial and keep guidewire in place.

Insert the Sheath

Select the appropriate sized sheath and place on the corresponding sheath inserter. Slide the inserter onto the guidewire. Pull to approximately the 15 mark on the tensioner. Slowly and steadily advance the sheath into the tunnel, with the derotational tab at the 12 o'clock position until the tab is flush with the cortex (Figure 8). This may require the use of a mallet.

Insert Screw Into the Sheath

Place the INTRAFIX ADVANCE Screw on the modular hex driver. With the knee fully extended or slightly flexed in accordance with surgeon preference, insert the screw along the guidewire into the sheath (Figure 9). Maintain approximately 10-15 units of tension on the tendons during screw insertion. Trim any excess sheath material with a rongeur.

Figure 7

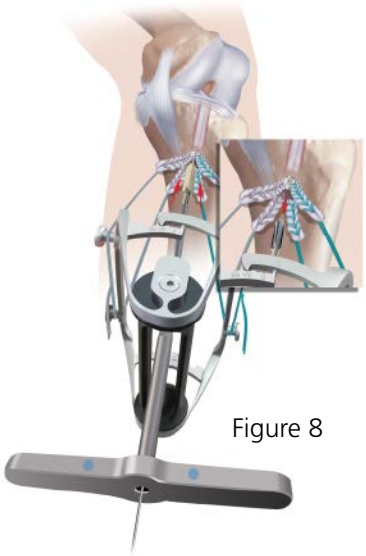

Figure 8

Figure 9

Product #	UOM	Instruments
254828	EA	Trial/Dilator - Small
254829	EA	Trial/Dilator - Large
254830	EA	Trial/Dilator - Extra Large
254831	EA	Sheath Inserter - Small 23 mm
254832	EA	Sheath Inserter - Large 23 mm
254833	EA	Sheath Inserter - Small 30 mm
254834	EA	Sheath Inserter - Large 30 mm
254835	EA	Sheath Inserter - Extra Large 30 mm
254836	EA	Hex Head Screw Driver

Product #	UOM	Instruments
254847	EA	Ratchet Handle
254838	EA	Tensioner
254842	EA	Slap Hammer
254839	EA	Sterilization Case (Outer)
254845	EA	Sterilization (Inner) Tray 1
254846	EA	Sterilization (Inner) Tray 2
254848	EA	Sterilization Lid
254844	EA	Guidewire 12" Sterile
254843	PK	Guidewire 12" (6 pack) Sterile

Product #	UOM	Implants BIOCRYL RAPIDE (Screw & Sheath)
254800	EA	INTRAFIX ADVANCE BR Screw, 7 x 23 mm & Small 23 mm Sheath
254801	EA	INTRAFIX ADVANCE BR Screw, 8 x 23 mm & Small 23 mm Sheath
254802	EA	INTRAFIX ADVANCE BR Screw, 9 x 23 mm & Large 23 mm Sheath
254803	EA	INTRAFIX ADVANCE BR Screw, 10 x 23 mm & Large 23 mm Sheath
254806	EA	INTRAFIX ADVANCE BR Screw, 7 x 30 mm & Small 30 mm Sheath
254807	EA	INTRAFIX ADVANCE BR Screw, 8 x 30 mm & Small 30 mm Sheath
254808	EA	INTRAFIX ADVANCE BR Screw, 9 x 30 mm & Large 30 mm Sheath
254809	EA	INTRAFIX ADVANCE BR Screw, 10 x 30 mm & Large 30 mm Sheath
		Implants PEEK (Screw only)
254814	EA	INTRAFIX ADVANCE PEEK Screw, 7 x 23 mm
254815	EA	INTRAFIX ADVANCE PEEK Screw, 8 x 23 mm
254816	EA	INTRAFIX ADVANCE PEEK Screw, 9 x 23 mm
254817	EA	INTRAFIX ADVANCE PEEK Screw, 10 x 23 mm
254820	EA	INTRAFIX ADVANCE PEEK Screw, 7 x 30 mm
254821	EA	INTRAFIX ADVANCE PEEK Screw, 8 x 30 mm
254822	EA	INTRAFIX ADVANCE PEEK Screw, 9 x 30 mm
254823	EA	INTRAFIX ADVANCE PEEK Screw, 10 x 30 mm
254824	EA	INTRAFIX ADVANCE PEEK Screw, 11 x 30 mm
254841	EA	INTRAFIX ADVANCE PEEK Screw, 12 x 30 mm
		Implants Polypropylene (Sheath only)
254818	EA	INTRAFIX ADVANCE PP Sheath, Small 23 mm
254819	EA	INTRAFIX ADVANCE PP Sheath, Large 23 mm
254825	EA	INTRAFIX ADVANCE PP Sheath, Small 30 mm
254826	EA	INTRAFIX ADVANCE PP Sheath, Large 30 mm
254827	EA	INTRAFIX ADVANCE PP Sheath, Extra Large 30 mm

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