

# [ rigidfix™ cross pin system ]

The Mitek Rigidfix ACL Cross Pin System is an innovative fixation method for ST grafts on both, the femoral and tibial sides during ACL reconstruction. The absorbable Cross Pins provide a secure graft fixation and facilitate a 360 degree bone-to-graft interface.



■ **High fixation stability**

High pull out strengths. The Cross Pin fixation facilitates a 100% bone-to-graft interface which leads to a quick and safe 360 degree in healing process of the graft.

■ **Easy to use system – improved handling**

The operative technique ensures a higher level of reproducibility and reduces the risk of complications.

■ **Secure location of the cross pins**

Cross Pin fixation is performed accurately in the bone tunnels – always positioned at the same location. This virtually eliminates fixation tolerances, injuries to the graft and potential loosening of the fixation device.

■ **Improved biomechanics**

The ability to achieve ‘close to the joint’ fixation, minimises any graft elongation and tunnel widening.

■ **Absorbable implants**

No artificial material will remain permanently in the bone. Secure fixation performance is also ensured during the absorption period.

MITEK HOTLINE:

<http://www.jnjgateway.com>

**INDICATIONS**  
The MITEK RIGIDfix 3,3 mm ST Cross Pin Kit is intended for femoral and tibial fixation of autograft or allograft ACL soft tissue grafts (semitendinosus and gracilis).

**CONTRAINDICATIONS**

1. Pathological conditions of bone, such as cystic changes or severe osteopenia, which would compromise secure cross pin fixation.
2. Pathological conditions in the soft tissue graft to be attached that would impair secure fixation with the cross pins.
3. Physical conditions that would impair, eliminate, or tend to eliminate adequate implant support or retard healing; i.e. blood supply limitations, infection, etc.
4. Conditions which tend to preempt the patient's ability to heal during the healing period, such as senility, mental illness or alcoholism.

**PRECAUTIONS**

1. Surgeons should not attempt clinical use of MITEK RIGIDfix 3,3 mm ST Cross Pins before reviewing the instructions for use and rehearsing the installation procedure in skills laboratory.
2. Discard used sleeve assemblies and interlocking trocars in sharps container.
3. Mitek RIGIDfix Cross pin instruments should be only used with the Mitek RIGIDfix 3,3mm ST Cross Pin Kit.

**WARNINGS**  
Inspect all instruments for damage before use. DO NOT attempt to repair a damaged instrument. Polylactic acid (PLA) implants have shown to cause some tissue reaction in a small percentage of patients.

MITEK RIGIDfix 3,3 mm ST Cross Pin Kits must never be reused. DO NOT re-sterilize. Discard opened and unused RIGIDfix Cross Pins, Sleeve Assemblies and Interlocking Trocar.

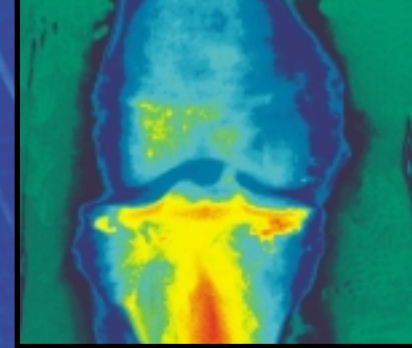
**CAUTION**  
Federal law (USA) restricts this device to sale by or on the order of a physician.

For detailed information concerning appropriate handling and application please refer to the relevant instructions for use.



For more information, call your Mitek representative at 1-800-382-4682 or visit us at [www.mitek.com](http://www.mitek.com). Mitek Worldwide, a Division of ETHICON, Inc., 60 Glacier Drive, Westwood, Massachusetts 02090

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[ the art of fixation ]

femoral + tibial

**RIGIDFIX™**  
**ABSORBABLE**  
**CROSS-PINS**  
**FOR**  
**SOFT TISSUE ACL-**  
**RECONSTRUCTION**

[ rigidfix femoral fixation ]

[ rigidfix tibial fixation ]



m i t e k 1 0 / 2 0 0 1

m i t e k k n e e - t e c h n o l o g i e s

# [ ST basics ]



Fig. A

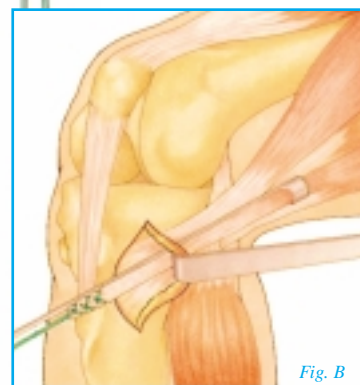


Fig. B

## ■ Tendon harvest

To harvest the soft tissue graft for ACL reconstruction, slightly different techniques for different type of tendon are common practice. The following describes one way to harvest semitendinosus (semi-t) and gracilis tendons.

Fig. C

Make a longitudinal or oblique incision approximately 2 cm medial to the tibial tubercle, almost directly beneath the medial arthroscopic portal. The top part of the incision is used for tibial tunnel drilling. The bottom part is used to harvest the semitendinosus (semi-t) and gracilis tendon. After the incision is made, the fat and gossamer-like tissue are dissected from the sartorius fascia, which is flat and overlies the tendons. A #15 blade is used to incise the sartorius tendon along its fiber. Note that only the sartorius is incised. A window is completed to view the gracilis and semi-t tendons,

Fig. D

which can be seen overlying the insertion of the MCL (Fig. A). The gracilis is narrower in width and is more superior and apparent than the semi-t. Unlike the semi-t, the gracilis generally has no inferior connections at its insertion.

It is essential to ensure that the stripper is not sharp and that all connections to the tendon have been severed. After one or both tendons are harvested, they are prepared on the preparation board.

## ■ Graft preparation

The semi-t and gracilis tendons can be prepared for implantation, on the graft board. Whip stitch the ends of the grafts. A #2 suture should hold adequately. Fold the two grafts over a #5 ETHIBOND® Suture (Fig. C). To prepare the femoral portion of the graft, whip stitch the looped-over part of the graft (Fig. D). Specifically, whip stitch the semi-t to semi-t, the gracilis to gracilis, and, finally, the semi-t to the gracilis, across the front and back to create a secure bundle. This bundle is the part of the graft that will be inserted into the femoral bone tunnel. Mark the graft at 30 mm from the distal end for later reference when placing it into the bone tunnel.

To prepare the tibial portion of the graft, the distance from the top of the femoral tunnel to the top of the tibial plateau is required to be measured, as described later in the procedure. Refer to this recorded measurement and whip stitch the graft beginning at this measurement and stitch distally for a total of 30mm. Use the same technique and type of suture as for the femoral preparation. (Fig. E).

It is not necessary to loop the graft over the pins. The whip stitched tendon strands form a tight bundle that is placed snugly in the bone tunnel.

Fig. E

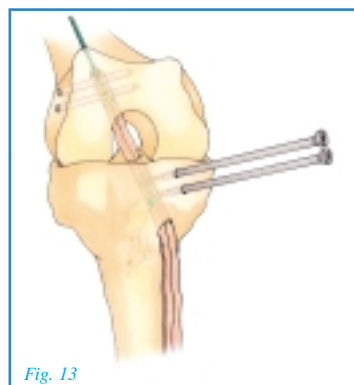


Fig. 13

Now the graft is securely fixed in the femoral tunnel with two parallel pins (Fig. 13).

Tension the graft on the tibial side using 90 to 130 N of force to verify solid femoral fixation. Make sure that the 30 mm line does not move while applying the force.

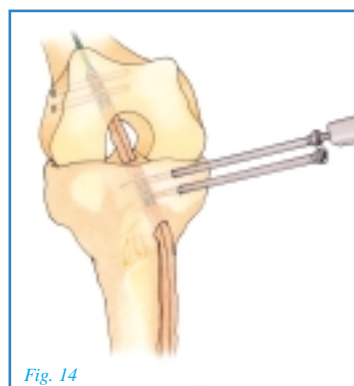


Fig. 14

While tensioning the graft and flexing the knee appropriately, insert a tibial cross pin into the top tibial sleeve using the tibial pin insertion rod and a mallet. Advance until the stepped portion of the rod meets the sleeve hub (Fig. 14).

Repeat this step, advancing the second tibial pin in the bottom sleeve, to complete the repair.

If you should encounter excessive resistance while inserting the pin, before the stepped portion of the rod meets the sleeve hub, do not advance any further. Using the sleeve removal tool, remove the sleeves from the tibia.

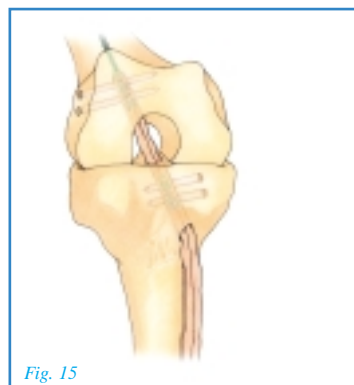


Fig. 15

Test for notch impingement and verify a full range of motion of the knee.

The tibial fixation is now complete, and the graft is securely fixed (Fig. 15).

- RIGIDFIX ST FEMORAL
- 210 133 RIGIDFIX ST 3,3 mm Femoral Cross Pin Kit
- 213 701 RIGIDFIX ST Femoral Guide Frame
- 213 707 RIGIDFIX ST Femoral Rod, 7 mm
- 213 708 RIGIDFIX ST Femoral Rod, 8 mm
- 213 709 RIGIDFIX ST Femoral Rod, 9 mm
- 213 710 RIGIDFIX ST Femoral Rod, 10 mm
- 213 704 RIGIDFIX ST Femoral Pin Insertion Rod
- 215 701 RIGIDFIX ST Femoral Instrument Case

- RIGIDFIX ST TIBIAL
- 210 333 RIGIDFIX ST 3,3 mm Tibial Cross Pin Kit
- 213 800 RIGIDFIX ST Tibial Guide Frame
- 213 801 RIGIDFIX ST Tibial Guide Block
- 213 807 RIGIDFIX ST Tibial Rod, 7 mm
- 213 808 RIGIDFIX ST Tibial Rod, 8 mm
- 213 809 RIGIDFIX ST Tibial Rod, 9 mm
- 213 810 RIGIDFIX ST Tibial Rod, 10 mm
- 213 604 RIGIDFIX ST Tibial Pin Insertion Rod
- 213 630 RIGIDFIX ST Tibial Trial
- 213 625 RIGIDFIX ST Tibial Probe

- 210 033 RIGIDFIX ST 3,3 mm Femoral and Tibial Cross Pin Kit **[new]**
- 213 705 RIGIDFIX ST Mallet
- 213 706 RIGIDFIX ST Sleeve Removal Tool

