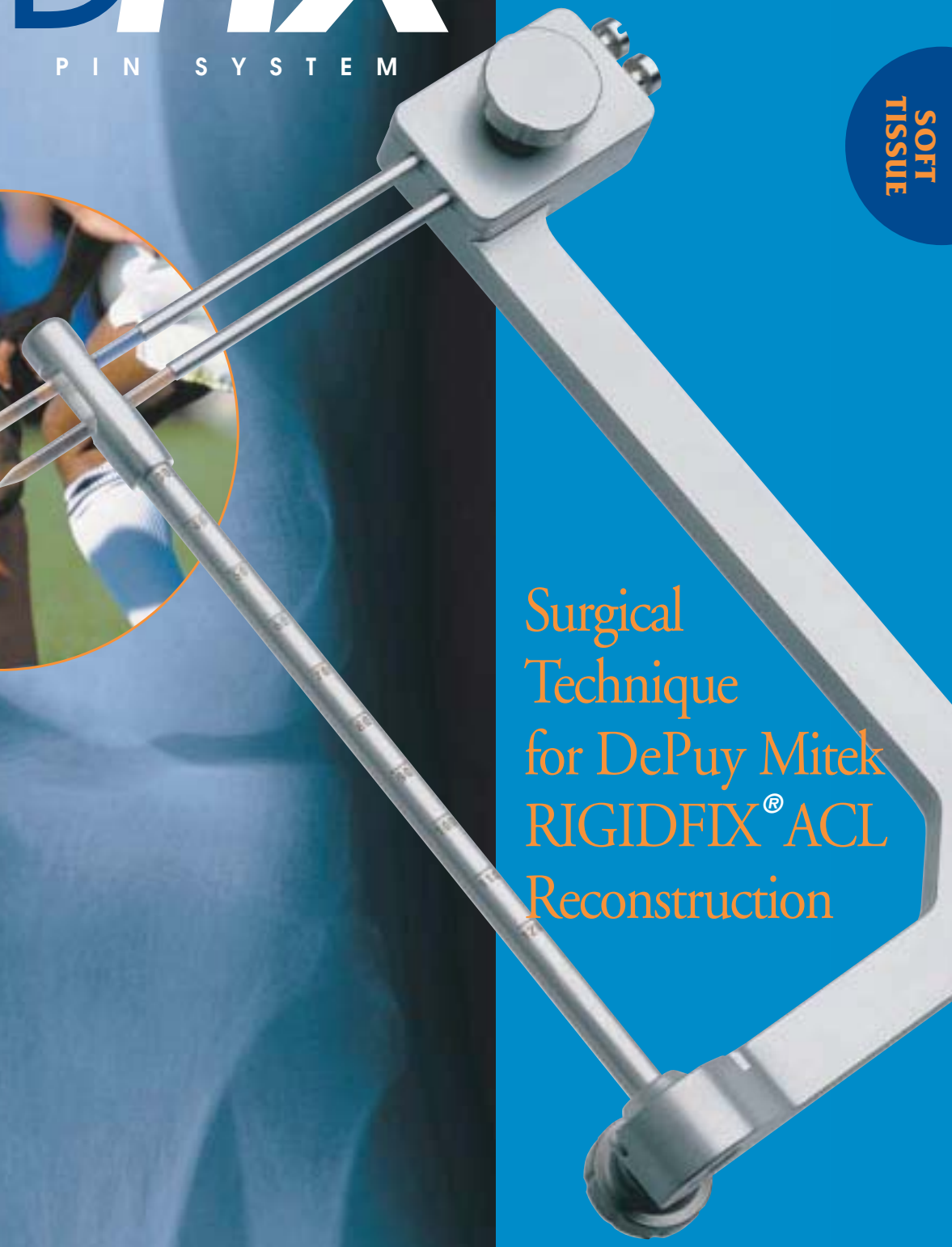
RIGIDFIX®

ACL CROSS PIN SYSTEM

Daniel J. McKernan, M.D.
Toledo, Ohio

SOFT TISSUE



Surgical Technique for DePuy Mitek RIGIDFIX® ACL Reconstruction

Soft Tissue

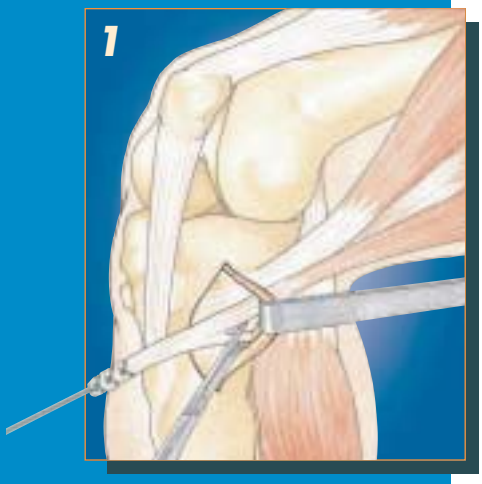
DePuy Mitek
a Johnson&Johnson company

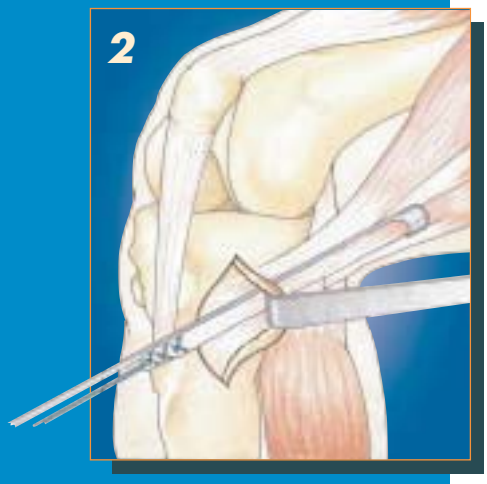
SURGICAL TECHNIQUE

RIGIDFIX®
ACL CROSS PIN SYSTEM

SOFT TISSUE

Daniel J. McKernan, M.D.





Tendon Harvest

Make a longitudinal or oblique incision approximately 2cm 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 semi-tendinosus (semi-t) and gracilis tendons.

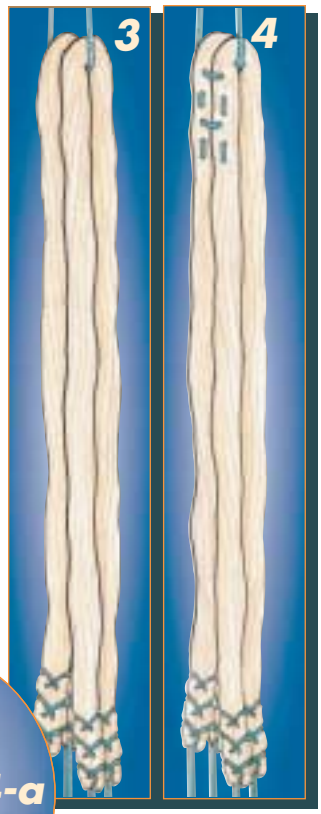
After the incision is made, the fat and gossamer-like tissue are dissected away from the sartorius fascia, which is flat and overlies the tendons. A #15 blade is used to incise the sartorius tendon along its fiber. Note that only the sartorius is incised. A window is completed to view the gracilis and semi-t tendons, which can be seen overlying the insertion of the MCL (Fig. 1). 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. The semi-t can be identified by its generally robust nature and its attachments. These attachments must be separated prior to harvesting or the graft may be prematurely cut during harvesting.

A finger run around the graft can assure that all connections have been severed before the tendon is stripped. Run a tendon stripper toward the origin of the muscle (Fig. 2). 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 back table while the notch is prepared.

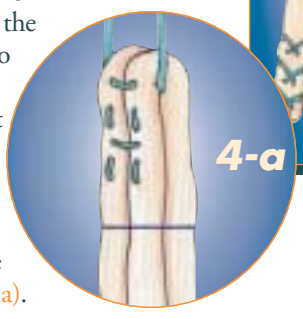
Graft Preparation

The semi-t and gracilis tendons can be prepared on the back table for implantation. A key advantage of soft-tissue grafts is that the best part of the graft can be steered to the area between the bone tunnels.

Whip stitch the ends of the grafts. A #2 suture should hold adequately. Fold the two grafts over a #5 ETHIBOND® Suture (Fig. 3). Whip stitch the looped-over part of the graft with either an absorbable or nonabsorbable suture as shown (Fig. 4). 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.



In the unlikely event that during final placement, the cross pins pass between the tendon graft and not through them, whip stitching the tendon into a bundle ensures fixation. In most cases the tendons loop over the pins. In some cases, it may pierce the tendons in which case the loops are held in place by the tendons' cross fibers. However, should a pin hit the seam exactly, the whip stitching, combined with the compression generated by the two 3.3mm pins, will ensure that the pin remains securely in place. The two 3.3mm pins not only suspend the graft, they compress the graft in two areas (Fig. 4-b), thus giving two types of fixation, compression and suspension. This allows RIGIDFIX Pins to cross the graft in any plane and still provide rigid fixation. (Even though correct orientation of the graft is accomplished, it is not imperative for fixation.)



Mark the graft at 30mm for later reference when placing it into the bone tunnel (Fig. 4-a).

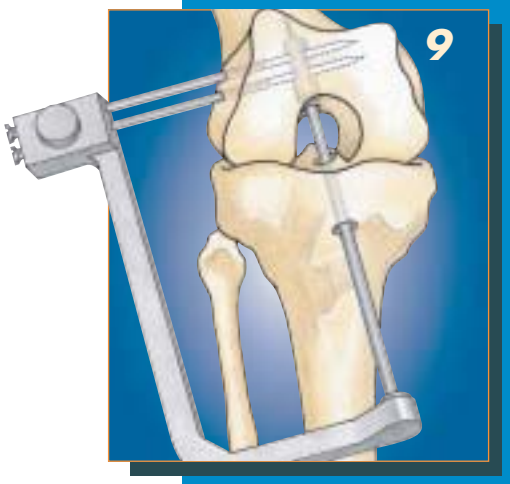
Guide should be relatively parallel to the floor. With large patients, care must be taken not to damage the skin that overlies the lateral side of the femur.

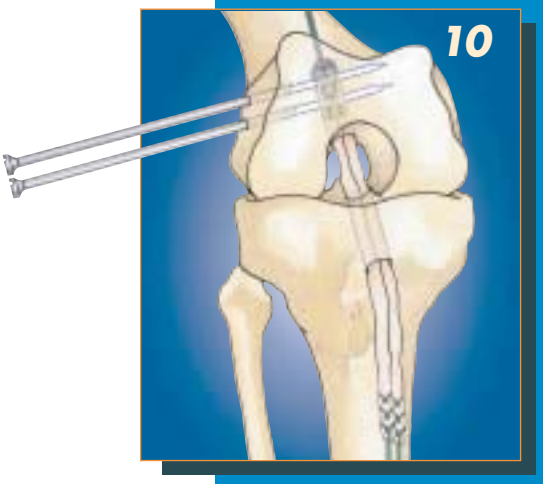
Assemble the RIGIDFIX Cross Pin Sleeve over the Interlocking Trocar (Fig. 6). Drill the Sleeve-Trocar assembly through the bottom hole of the guide into the lateral side of the femur until the Sleeve hub meets the guide (Fig. 7). As the sleeve-trocar assembly is spinning, make sure it stays engaged and that both are spinning. In young patients this bone can be particularly hard. Remove the Trocar by *pulling* it from the Sleeve, leaving the Sleeve in the guide/femur (Fig. 8). It may be necessary to gently tap the drill chuck with a mallet to disengage the Trocar. Note: *do not* drill or spin the trocar when removing it from the sleeve. If water is flowing into the knee, you may have a flow of water out of the sleeves at this point. Later, after removal of the femoral rod, with water flow into the knee the flow will increase.

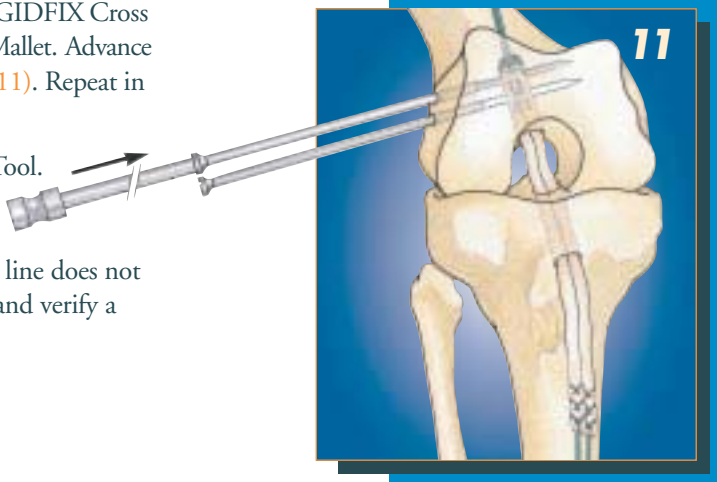
Drill the second Sleeve-Trocar assembly through the top hole of the guide (Fig. 9). Note that the Sleeves remain outside of the femoral tunnel. Place the guide pin back into the femur through the cannulation of the femoral rod. Detach the guide plate and remove the guide from the knee, leaving only the two sleeves in the lateral femur and the guide pin placed through the knee.

As the graft is pulled into the tunnel, it is recommended that the alignment be kept anterior to posterior (Fig. 10). The marking at 30 mm should be visible at the edge of the femoral tunnel. Insert a DePuy Mitek RIGIDFIX Cross Pin into the Sleeve using the Stepped Pin Insertion Rod and Mallet. Advance until the stepped portion of the Rod meets the Sleeve hub (Fig. 11). Repeat in the other sleeve to complete the repair.

Remove the Sleeves from the femur using the Sleeve Removal Tool. The graft is fixed in the femoral tunnel with two parallel pins (Fig. 12). Tension the graft on the tibial side using 20 to 30 lbs. of force to ensure fixation. Watch to see that the 30mm line does not move with the 20 to 30 lb. force. Test for notch impingement and verify a full range of motion of the knee.







Tibial Fixation

Presently, there are a number of options available to fix the graft on the tibia. The author currently uses a screw and washer, such as the GEOFIT™ Football Screw and DePuy Mitek Washer. Other fixation devices such as the INTRAFIX™ Tibial Fastener provides excellent tibial fixation.

Rehabilitative Protocol

The postoperative rehabilitation are being used successfully. However, with this fixation full weight bearing and an accelerated rehabilitation can be considered.

Graft Diameter

Using a graft-sizing block, select the diameter through which the graft bundle fits tightly but still passes. A tightly fitting graft not only ensures better initial fixation, but also allows ingrowth directly into the graft and not into a dead space. This measurement determines the diameter of the tibial and femoral tunnels to be drilled.

Notchplasty

During preparation of the graft, the intra-articular tibial drill site can be chosen and prepared. Some of the ACL stump can be debrided. Prepare the lateral and posterior part of the notch to measure a site for the femoral tunnel. Place the femoral tunnel as close to the posterior aspect of the notch as possible. Should you blow out the back, it is not problematic because fixation is achieved several millimeters into the tunnel and does not depend upon an intact cortical rim.

Tibial Tunnel

Using a DePuy Mitek Tibial Drill Guide, choose a point above the ACL tibial footprint for emergence of the guide pin. After guide pin placement, check the direction and possible impingement to reconfirm a satisfactory position. Remove the drill guide.

Drill a tibial tunnel to accommodate your graft diameter. The drill hole should be small enough to accommodate a tight fit of the graft and thus facilitate subsequent rapid ingrowth of bone but big enough to allow the graft to pass through. Clear the tunnel of bone debris and chamfer the edges using a rasp.

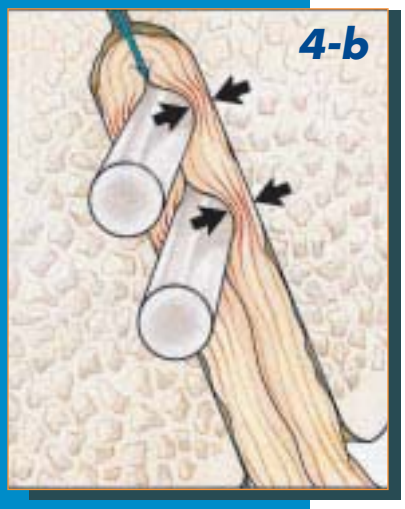
Femoral Tunnel

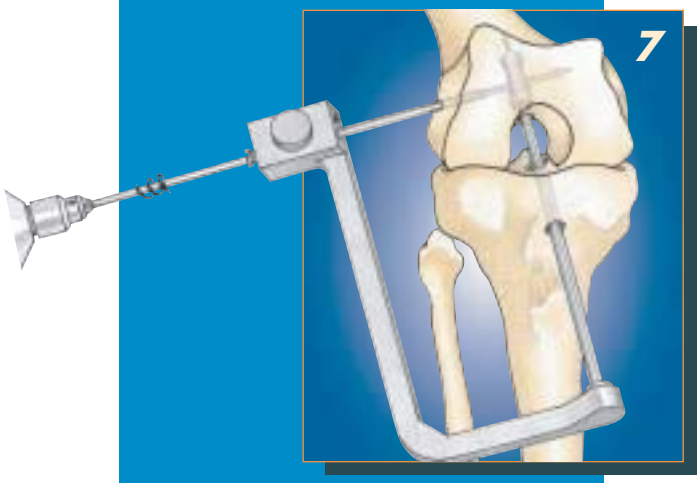
Using an offset guide, place the guide pin at the appropriate position on the superior rim of the notch. Once this position is satisfactory, the guide pin can be drilled up through the notch and out the anterior cortex of the femur.

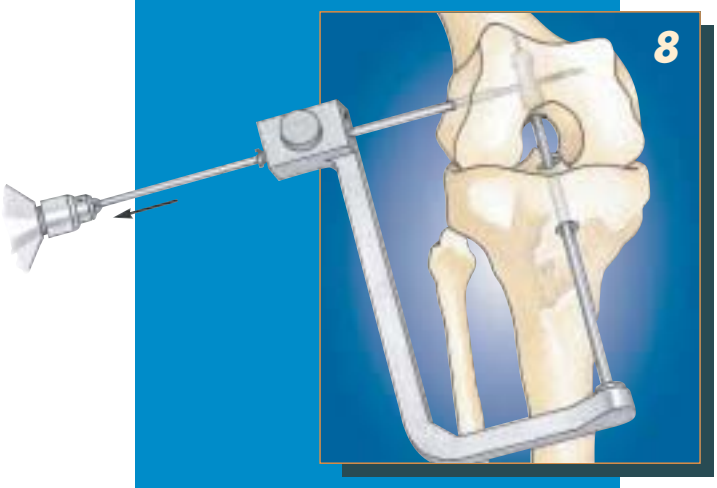
Drill the femoral tunnel to the diameter of your graft and to a depth of 30 mm. Make sure the tunnel is clear of debris for easy passage of the graft and device.

Femoral Fixation

Attach the appropriate size femoral rod (i.e., a 9mm femoral rod for a 9-mm femoral tunnel) to the RIGIDFIX Cross Pin Guide frame and insert the cannulated rod over the guide pin into the femoral tunnel (Fig. 5). This frequently requires tapping with a small mallet. The RIGIDFIX Cross Pin Guide should be advanced, so that the shoulder of the femoral rod can easily be seen at the femoral tunnel edge. Remove the guide pin. The RIGIDFIX Cross Pin







Introduction

The RIGIDFIX® ACL Cross Pin System for Mitek is an innovative method for fixing soft-tissue grafts during ACL reconstruction. The RIGIDFIX Cross Pin System was developedwith three goals in mind:

1. To provide bioabsorbable (PLA) fixation, compression and suspension at the graft-tunnel interface.
2. To deliver 360° of bone-to-graft contact.*
3. To expedite surgery.

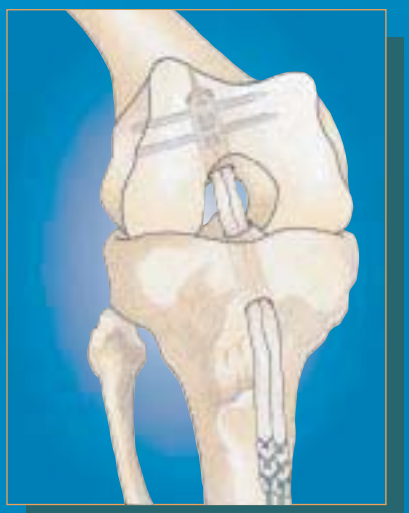
** A study of bone-to-bone grafts showed 100% circumferential ingrowth at 12 weeks. Study on file at DePuy Mitek, conducted by Steven Arnoczky et al.: The healing of cortiocancellous bone plugs fixed with Mitek BTB cross-pins or an absorbable interference fit screw (BIOSCREW™) – an experimental study in dogs. Laboratory for Comparative Orthopaedics College of Veterinary Medicine, Michigan State University.*

DePuy Mitek
a Johnson&Johnson company

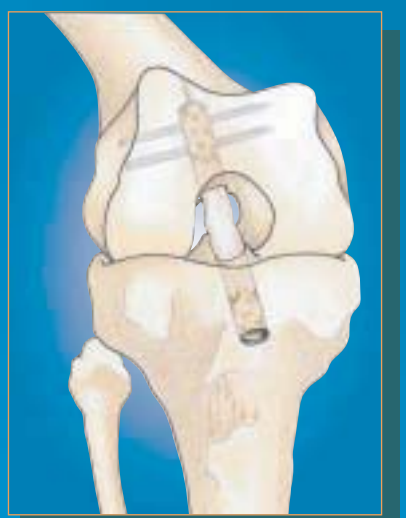
RIGIDFIX®

ACL CROSS PIN SYSTEM

Soft-Tissue (ST)



Bone-Tendon-Bone (BTB)



INDICATIONS

Femoral fixation of autograft or allograft ACL graft material, either soft tissue (semitendinosus, etc.), or bone-tendon-bone (patellar tendon, etc.).

CONTRAINDICATIONS

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

PRECAUTIONS

1. Surgeons should not attempt clinical use of the DePuy Mitek RIGIDFIX ACL Cross Pin System before reviewing the instructions for its use and mastering the installation procedure in a skills laboratory.
2. Used stepped trocar should be discarded in a sharps container.
3. DePuy Mitek RIGIDFIX ACL Cross Pin Instruments should be used only with the DePuy Mitek RIGIDFIX 2.7mm BTB Cross Pin Kit and the DePuy Mitek RIGIDFIX 3.3mm Soft Tissue Cross Pin Kit.
4. Discard used sleeve assemblies and interlocking trocars in a sharps container.

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. The DePuy Mitek RIGIDFIX 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.

DePuy Mitek
a Johnson & Johnson company

For more information, call your DePuy Mitek representative at 1–800–382–4 682, or visit us at www.mitek.com
DePuy Mitek, Inc., 325 Paramount Drive, Raynham, Massachusetts 02767