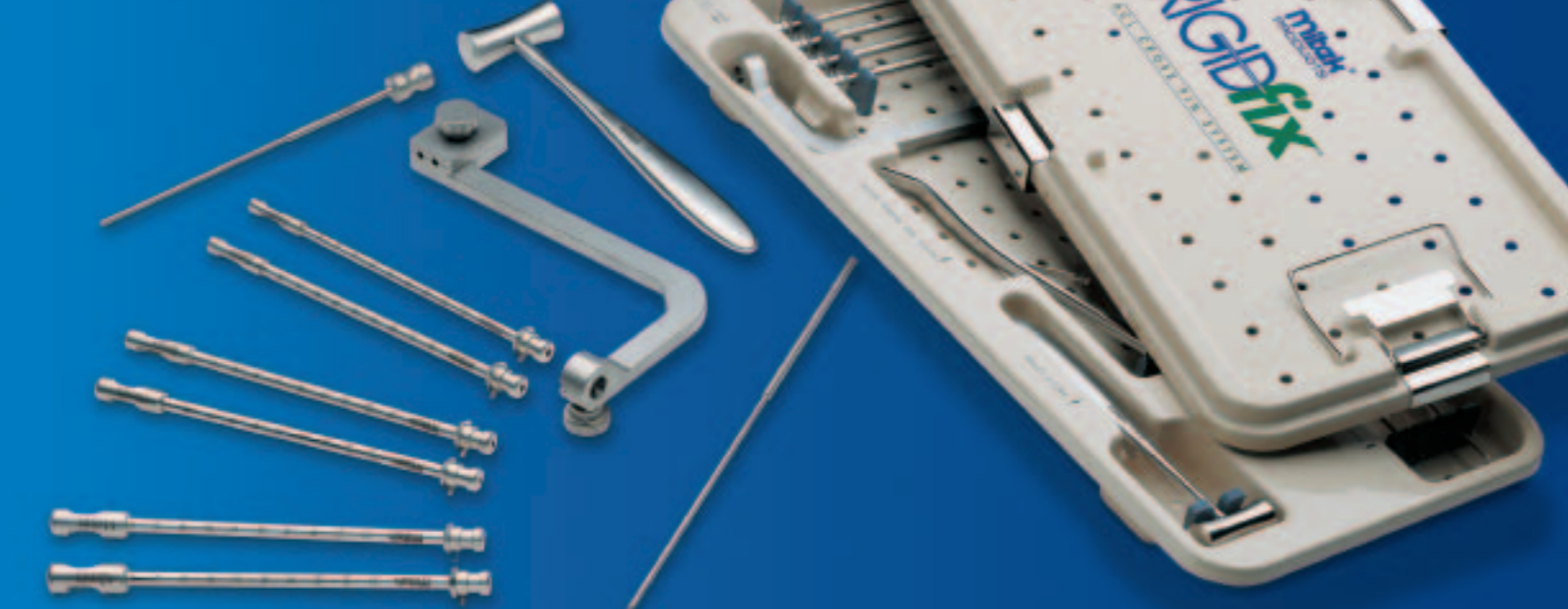


RIGIDfix®

ACL CROSS PIN SYSTEM



DePuy Mitek RIGIDFIX ACL Cross Pin

Instrumentation includes:

1 cross-pin guide frame, 6 interchangeable femoral rods,
1 stepped trocar (BTB only), 1 stepped pin insertion rod,
1 mallet, and 1 sleeve removal tool.

These instruments are reusable and nonsterile;

they must be cleaned and sterilized prior to each use.

INDICATIONS

Femoral fixation of autograft or allograft ACL graft material, either soft-tissue (semitendinosus and gracilis) 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 that would retard healing, such as blood supply limitations, infection, and so on.
4. Conditions that would tend to preempt the patient's ability to recover during the healing period, such as senility, mental illness, alcoholism, and so on.

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. Discard used stepped trocar in a sharps container.
3. Use DePuy Mitek RIGIDFIX ACL Cross Pin Instruments only with the DePuy Mitek RIGIDFIX 2.7mm BTB Cross Pin Kit and the DePuy Mitek RIGIDFIX 3.3mm 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.

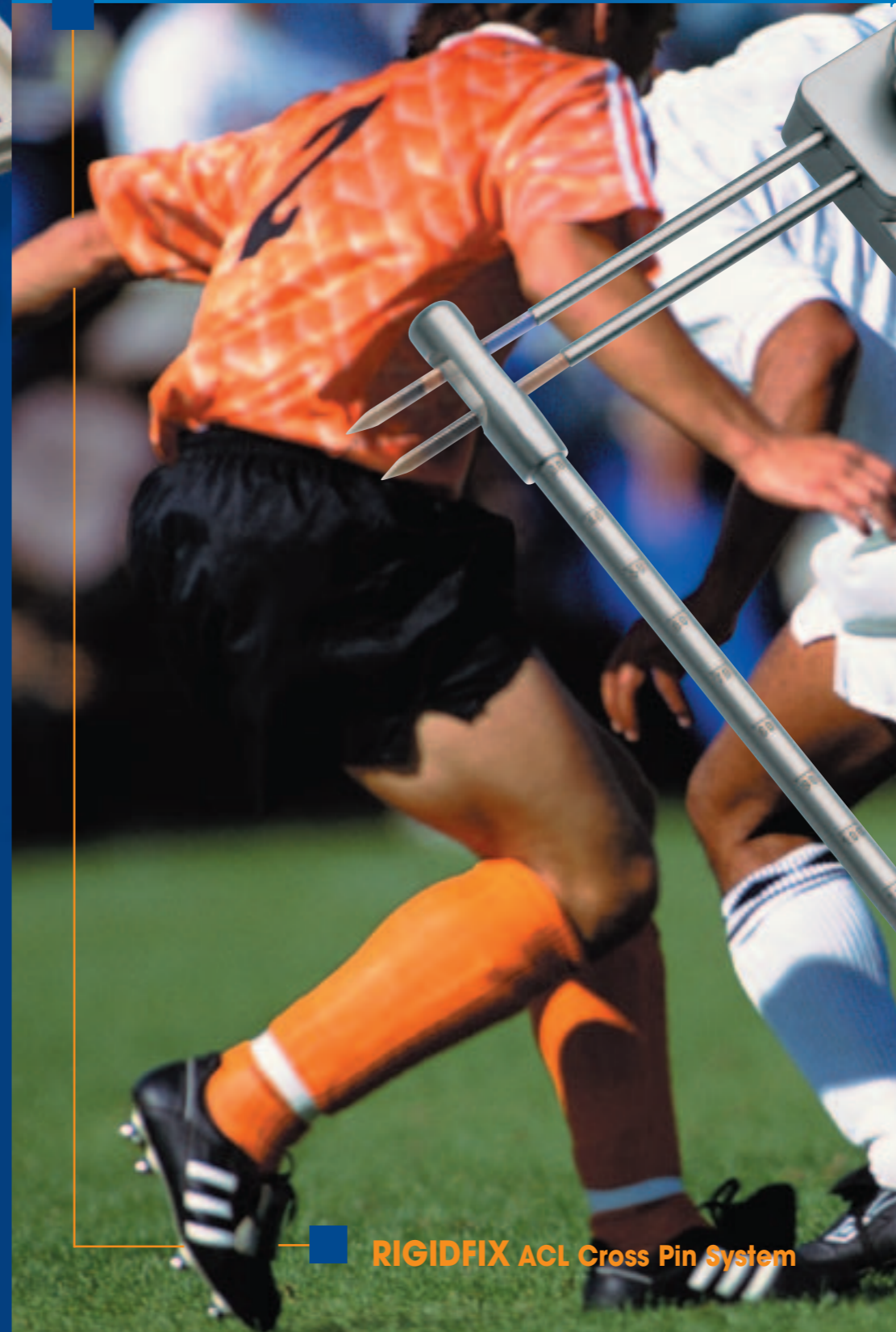
DePuy Mitek
a Johnson & Johnson company

For more information, call your DePuy Mitek representative at 1-800-382-4682 or visit us at www.depuymittek.com.
DePuy Mitek, Inc., 325 Paramount Drive, Raynham, MA 02767

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█ Bone-Tendon-Bone (BTB)
█ Soft-Tissue (ST)
█ BTB and ST

Ordering Information

		Order Qty.
210127	RIGIDFIX 2.7mm Bone-Tendon-Bone (BTB) Cross Pin Kit*	_____
210133	RIGIDFIX 3.3mm Soft-Tissue (ST) Cross Pin Kit*	_____
213701	RIGIDFIX ST Guide Frame	_____
213702	RIGIDFIX BTB Guide Frame	_____
213703	RIGIDFIX BTB Stepped Trocar	_____
213704	RIGIDFIX Stepped Pin Insertion Rod	_____
213705	RIGIDFIX Mallet	_____
213706	RIGIDFIX Sleeve Removal Tool	_____
213707	RIGIDFIX Femoral Rod, 7mm (ST Only)	_____
213708	RIGIDFIX Femoral Rod, 8mm (ST Only)	_____
213709	RIGIDFIX Femoral Rod, 9mm	_____
213710	RIGIDFIX Femoral Rod, 10mm	_____
213711	RIGIDFIX Femoral Rod, 11mm (BTB Only)	_____
213712	RIGIDFIX Femoral Rod, 12mm (BTB Only)	_____
215701	RIGIDFIX ST Sterilization Tray	_____
215702	RIGIDFIX BTB Sterilization Tray	_____

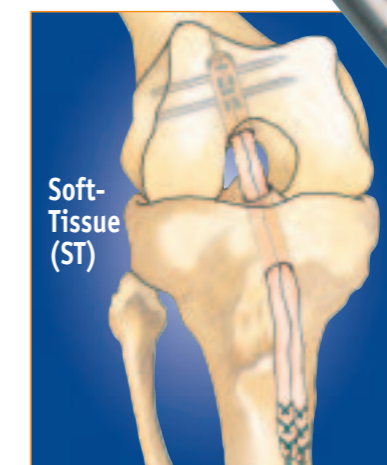
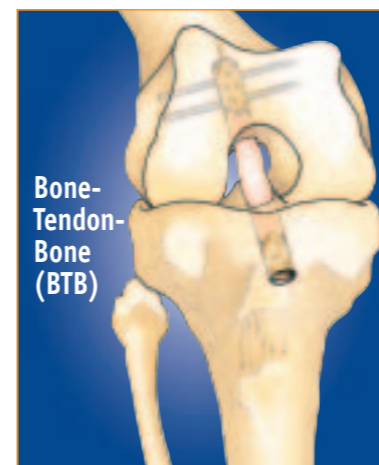
Surgeon's Signature _____

Date _____

*Cross Pin Kits include 2 absorbable cross pins, 2 sleeves, and 1 interlocking trocar.

Easy to use, the RIGIDFIX ACL Cross Pin System is an innovative method of femoral fixation during ACL reconstruction. It can be used for bone-tendon-bone or soft-tissue grafts.

The RIGIDFIX Cross Pins are designed to occupy a small portion of the femoral tunnel, promoting complete circumferential ingrowth during healing.



RIGIDFIX ACL Cross Pin System

*A study of bone-to-bone grafts showed 100% circumferential ingrowth at 12 weeks. Study on file at DePuy Mitek, Inc., conducted by Steven Arnoczky et al.: The healing of cortiocancellous bone plugs fixed with DePuy 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.

Bioabsorbable ACL Cross Pin

- BIOABSORBABLE (PLA) FIXATION AT THE GRAFT-TUNNEL INTERFACE
- DELIVERS 360° OF BONE-TO-GRAFT CONTACT*
- INSTRUMENTS ELIMINATE INTRAOPERATIVE MEASURING

DePuy Mitek
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