The DePuy Mitek RIGIDFIX Cross Pin System offers an absorbable means of fixing grafts during anterior cruciate ligament (ACL) reconstruction, providing 360° of bone-to-graph contact.¹ The pins are available in two sizes: the 3.3mm diameter, used for soft-tissue (ST) grafts, and the 2.7mm diameter, used for bone-tendon-bone (BTB) grafts. The following studies prove that the RIGIDFIX System meets or exceeds all industry criteria for reliable performance.

¹ A study of bone-to-bone grafts showed 100% circumferential ingrowth at 12 weeks. Study conducted by Steven Arneson et al.: The healing of corticocancellous bone plugs fixed with DePuy Mitek BTB cross pins or an absorbable interference-fit screw (Linweve BioScrews) – an experimental study in dogs. Laboratory for Comparative Orthopedics, College of Veterinary Medicine, Michigan State University. Study on file at DePuy Mitek.
How does the pullout strength of RIGIDFIX® ACL Cross Pins compare to market standards for soft-tissue and bone-tendon-bone procedures?

**Soft Tissue (ST)**

An in vitro comparison of DePuy Mitek RIGIDFIX 3.3mm absorbable cross pins to the Smith & Nephew ACUFEX® EndoButton® was conducted in cadavers, using hamstring (semi-t and gracilis) to reconstruct the ACL. The comparison demonstrated no significant difference in the initial fixation strength and stiffness of the two fixation methods.

![Diagram of Soft-Tissue ACL Repairs](image)

**Bone-Tendon-Bone (BTB)**

An in vitro comparison of DePuy Mitek RIGIDFIX 2.7mm absorbable cross pins to the Linvatec 9mm BioScrew™ was conducted in cadavers using bone-patellar tendon-bone grafts to reconstruct the ACL. The comparison demonstrated no significant difference in the initial fixation strength and stiffness of the two fixation methods.

![Diagram of Bone-Tendon-Bone ACL Repairs](image)

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2From a cadaver study by John R. Went and Richard Greenswald: In vitro comparison of DePuy Mitek 3.3mm absorbable cross pins to ACUFEX EndoButton in hamstring-grafted anterior cruciate ligament reconstruction. Orthopedic Biomechanics Institute, Salt Lake City, October, 1997. Study on file at DePuy Mitek.

3Cadaver study conducted by John R. Went and Richard Greenswald of Orthopedic Biomechanics Institute: In vitro investigation of DePuy Mitek 2.7mm absorbable cross pins in patellar tendon-grafted anterior cruciate ligament surgery versus BioScrew absorbable interference screw. Study on file at DePuy Mitek.
A cadaver test was conducted to evaluate the effects of cyclic loading. The test compared RIGIDFIX® 3.3mm-diameter ACL Cross Pins to the EndoButton® for ACL reconstruction using hamstring tendons. No statistical difference emerged between the RIGIDFIX 3.3mm ACL Cross Pins and the EndoButton.⁴

*EndoButton with 25mm length of Dacron tape.

It is not necessary to loop the graft over the pins. The semi-t and gracilis tendons are whipstitched at the looped end, forming a tight bundle that is placed into the femoral tunnel. This allows RIGIDFIX absorbable pins to cross the graft in any plane and still provide rigid fixation.⁵

⁴ From a cadaver study conducted by Benjamin J. Ellis and Jeffrey A. Weiss. Cyclic stability of DePuy Mitek cross pins when used for hamstring and bone-tendon-bone grafted ACL reconstruction. Orthopedic Biomechanics Institute, Salt Lake City, May 1998. Study on file at DePuy Mitek.

⁵ From a study by John R. Wet and Richard Greensdale. In vitro evaluation of the effect of cross-pin orientation on the ultimate strength of hamstring grafts in anterior cruciate reconstruction. Orthopedic Biomechanics Institute, Salt Lake City, October 1997. Study on file at DePuy Mitek.
In vitro mechanical studies conducted to assess the strength of DePuy Mitek RIGIDEFIX ACL Cross Pins over time showed virtually no strength reduction through 8 weeks.\(^7\)

Figure 4. - Percentage of RIGIDEFIX ACL Cross Pin Strength Retained over Time

Is it necessary to make a lateral incision to insert the sleeves or pins?

No. Unlike other cross-pinning systems, DePuy Mitek trocar and sleeve assemblies pass percutaneously through the skin into the bone.

\(^6\)Study conducted by Steven Amsden et al.: The healing of cancellous bone plugs fixed with DePuy Mitek BTB cross pins or an absorbable interference-fit screw (Linvatec BioScrew) - an experimental study in dogs. Laboratory for Comparative Orthopaedics, College of Veterinary Medicine, Michigan State University. Study on file at DePuy Mitek.

\(^7\)Studies conducted by DePuy Mitek staff engineer. On file at DePuy Mitek.
What advantages do DePuy Mitek RIGIDFIX Cross Pins provide in a bone-tendon-bone procedure, compared to a bioabsorbable interference screw?

An animal study examined the osseous incorporation of a corticocancellous bone plug fixed with DePuy Mitek BTB cross pins and with an absorbable interference-fit screw (Linvatec BioScrew). Results were assessed at 3, 6, and 12 weeks’ time.

The study shows that the DePuy Mitek BTB cross pin permitted 360° of bone contact between the bone plug and the walls of the drill hole. In addition, placement of the 2.7-mm pin with the guide frame allowed central positioning of the pins.

**Bone Contact:** The bone-to-bone contact between the bone plug and the walls of the bone tunnel was 100% in the DePuy Mitek BTB cross-pinned group and an average of 74.7% of the bone plug surface in the Linvatec BioScrew interference-fit group. Results were statistically significant at all time periods.

**Bone Healing:** All bone plugs demonstrated a progressive incorporation into the host bed and there were no indications of implant migration, failure, or reaction in any of the specimens examined.

**3-Week Results:** Both the DePuy Mitek cross-pin and the BioScrew groups demonstrate a close apposition between the bone plug and the drill hole. Both groups showed early signs of healing, and there was no apparent adverse local reaction to the DePuy Mitek BTB cross pins or the BioScrew. In three of the 3-week Linvatec BioScrew specimens, the bone plug appeared to have “wrapped around” the screw. This suggests that the plug may have split or fragmented, allowing the screw to “settle” deeper into the plug.

**6-Week Results:** The bone plugs showed good integration into the surrounding bone in both groups. Evidence of endochondral bone repair was apparent throughout the interface of the bone plug and surrounding host bone in all specimens. Clinical union (mineralized callus spanning the plug and the host bone) was observed in all specimens. Two of the 6-week BioScrew specimens wrapped around the screw. This suggests that the plug may have split or fragmented, allowing the screw to settle deeper into the plug. There was no evidence of tissue reaction to either implant.

**12-Week Results:** Mature bone was seen bridging the interface between the bone plug and the surrounding host bone in all specimens. There was no evidence of tissue reaction to either implant.

This study demonstrates that DePuy Mitek cross pins do not affect the normal incorporation of a corticocancellous bone plug in comparison to an absorbable interference-fit screw (Linvatec BioScrew). The study also shows that DePuy Mitek cross pins permit a significantly (p < 0.001) larger healing surface area for the bone plug compared to an absorbable interference-fit screw (Linvatec BioScrew).
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, etc.
4. Conditions that would tend to preclude 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. 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 (ST) 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 (PLA) implants have been shown to cause some tissue reaction in a small percentage of patients.

Never re-use a DePuy Mitek RIGIDFIX Cross Pin kit.

Do not re-sterilize.

Discard opened and unused RIGIDFIX Cross Pins, sleeve assemblies, and interlocking trocar trocar.

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

For more information, call your DePuy Mitek representative at 1-800-382-4682 or visit www.mitek.com
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