LABORATORY DATA:
CYCLIC STABILITY OF THE
RIGIDfix™ TIBIAL 3.3 MM ST CROSS PIN SYSTEM
WHEN USED FOR HAMSTRING GRAFTED
ACL RECONSTRUCTIONS

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METHOD:

Three matched pairs of human cadaver tibias (average age 55.3 ± 13.3 years) were used to compare the effects of cyclic loading of knees reconstructed using RIGIDfix Tibial 3.3 mm ST Cross Pins to Linvatec BioScrews. Each specimen was reconstructed using the appropriate device, then cycled between 50 and 150N for 1000 cycles. Upon completion of the 1000 cycles, the reconstructions were tensile tested until failure occurred. The results were as follows:

RESULTS:	Migration after 1000 Cycles (mm)
RIGIDfix	2.09 ± 0.224
BioScrew	All failed prior to 1000 cycles (847 ± 92.4 cycles)

RESULTS:	Ultimate Strength (N)	Stiffness (N/mm)
RIGIDfix	744 ± 191	85.8 ± 12.0
BioScrew	All failed prior to 1000 cycles and could not be tensile tested.	

MODES OF FAILURE:

All of the RIGIDfix reconstructions failed by both pins failing during tensile testing. All of the BioScrew reconstructions failed by the graft slipping past the screw during cyclic loading testing. No tensile testing was performed on the BioScrew reconstructions.

CONCLUSION:

The DePuy Mitek RIGIDfix Tibial 3.3 mm Cross Pins have superior performance when exposed to cyclic loads when compared to the Linvatec BioScrew.

Indications:

The DePuy Mitek RIGIDFIX Tibial 3.3mm ST Cross Pin Kit is intended for 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 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.

Warnings:

1. Polylactic acid (PLA) implants have shown to cause some tissue reaction in a small percentage of patients.
2. The DePuy Mitek RIGIDFIX Tibial 3.3mm ST Cross Pin Kit must never be reused. Do not re-sterilize.
3. Discard opened and unused RIGIDFIX Cross Pins, Sleeve Assemblies and Interlocking Trocar.

Precautions:

1. Harvest the soft tissue (semitendinosus and gracilis) graft.
2. Discard used sleeve assemblies and interlocking trocars in a sharps container.

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