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 implantation procedure in a skills laboratory.
2. Used stepped trocar should be discarded in a sharps container.
3. DePuy Mitek’s RIGIDfix ACL Cross Pin Instruments should be used only with the DePuy Mitek RIGIDfix 2.7 mm BTB Cross Pin Kit and the DePuy Mitek RIGIDfix 3.3 mm 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 ACL Cross Pin Kits must never be reused. Do not re-sterilize. Discard opened and unused RIGIDfix Cross Pins, Sleeve Assemblies, and Interlocking Trocars.

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

Introduction
The DePuy Mitek RIGIDfix ACL Cross Pin System is an innovative method for fixing bone-tendon-bone grafts during ACL reconstruction. It was developed with the following three goals in mind:

1. PROVIDES BIOABSORABLE (PLA) FIXATION AT THE GRAFT-TUNNEL INTERFACE
2. DELIVERS 360º OF BONE-TO-GRAFT CONTACT
3. INSTRUMENTS ELIMINATE INTRAOPERATIVE MEASURING
**Graft Harvesting**

Make a sagittal incision about 4 to 6 cm in the midline or slightly medially. Take dissection directly through skin and subcutaneous tissue and down to fascia. The skin and subcutaneous tissue are undermined down to the underlying fascia. This allows the wound to be mobilized for access to the patellar tendon and for the tibial drilling on the medial side.

Using sharp dissection, incise the paratenon in the midline. This is reflected for lateral closure down to bone to create the patellar bed. Use a rongeur to make the central hole (9 to 10 mm diameter) for the patellar tendon graft. Again, using sharp dissection, incise the central ridge of bone in the tibial bed and the inferior aspect of the patellar tendon (Fig. 4). This is reflected for future closure.

Next, use an oscillating saw to create the tibial bone plug. With appropriate retraction, the superior aspect of the patellar tendon can be visualized. Once again, use the sawing setup to make cuts on the inferior patellar bone plug. Gently remove the bone plug and set aside. The knee is held in slight flexion for preparation. Next, to prevent injury to the underlying underlying structures, do not use any retractors with any force or impact on the patellar side.

**Graft Preparation**

In preparing the free graft on the back table, carefully dissect any soft remaining soft tissue or adipose tissue from the bone. The bone plugs are used in 10mm sizing. If a slightly smaller graft has been obtained, then bone plugs can be appropriately sized. Your bone plugs have been appropriately sized, as the 10mm size only provides for proper fit. An attempt is made to ensure that the bone plug is cut as close as possible to the bone plug for the femoral tunnel and that the bone plug is cut as close as possible to the bone plug for the tibial tunnel. This step should be done carefully to avoid injury to the bone plug. The bone plug should be carefully cleaned and shaped to ensure a proper fit.

**Notochraptomy**

The notochraptomy procedure is the appropriate time for dealing with all concomitant intra-articular pathology. The notochraptomy procedure performed to ensure that the patella is completely and snugly filled.

**Tibial Tunnel**

Using a drill guide, place a pin where the anterior cruciate ligament (ACL) meets the bone plug. Then, the guide pin is inserted through the central hole (9 to 10 mm in diameter) for the patellar tendon graft. An appropriately sized cannulated drill is then used to drill the tibial tunnel. The drill size corresponds with the prepared free graft. Clear the tunnel of any debris to permit easy passage of the graft. Now, a cannulated drill is used to drill the tibial tunnel. Next, the guide pin is inserted to drill the tibial tunnel. Make sure that the hole is completely plugged with bone plugs. The drill guide should be changed with a step to ensure complete clearance of the graft along the bone edge surface.

**Femoral Tunnel**

Using an offset guide pin, place the drill guide pin at the appropriate superior position, which corresponds to appropriately sized for the right knee and 2 cm inferior for the left knee. Advance the guide pin far enough so that you can feel the tip forward through the subcutaneous tissue at the anterior aspect of the hip. This will ensure that the guide pin pierces easily when the graft is placed in the bone. Place an appropriately sized cannulated reamer over the guide wire up through the tunnel. This step should be done carefully to avoid injury to the bone plug. The bone plug is checked for complete clearance of the graft within the intercondylar region. Use a shaver to excise any remnant of the ligamentum mucosum to improve visualization of the graft. Release and excise the ligamentum mucosum to improve visualization of the graft. Perform an appropriately sized notchplasty to ensure clearance of the bone-tendon-bone graft. This will eliminate any impingement of the graft onto the anterior or posterior tibial crest. Perform an appropriately sized notchplasty to ensure clearance of the bone-tendon-bone graft. This will eliminate any impingement of the graft onto the anterior or posterior tibial crest.

**Femoral Fixation**

Using the offset guide pin, place the drill guide pin at the appropriate superior position, which corresponds to appropriately sized for the right knee and 2 cm inferior for the left knee. Advance the guide pin far enough so that you can feel the tip forward through the subcutaneous tissue at the anterior aspect of the hip. This will ensure that the guide pin pierces easily when the graft is placed in the bone. Place an appropriately sized cannulated reamer over the guide wire up through the tunnel. This step should be done carefully to avoid injury to the bone plug. The bone plug is checked for complete clearance of the graft within the intercondylar region. Use a shaver to excise any remnant of the ligamentum mucosum to improve visualization of the graft. Release and excise the ligamentum mucosum to improve visualization of the graft. Perform an appropriately sized notchplasty to ensure clearance of the bone-tendon-bone graft. This will eliminate any impingement of the graft onto the anterior or posterior tibial crest.

**Tibial Fixation**

The graft in the tibial side can be fixed with appropriate interference fixation devices. If the bone plug is completely outside the tibial tunnel, then a temporary staple or screw fixation technique can be employed. If so, use the same interference fixation device. The bone plugs can be fixed superficially for a temporary or hand-retrievable interference fixation device.

**Rehabilitative Protocol**

Follow standard postoperative protocol. Full weight bearing is permitted, and an anterior tibial rehabilitation protocol can be employed. A knee immobilizer is used for their protection until they obtain quadriceps control.