This brochure is presented to demonstrate the surgical technique utilized by Robert Frederick, M.D. Arthrotek, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for each individual patient. Arthrotek is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

The AXL™ Cannulated Cross Pin was developed in conjunction with Robert Frederick, M.D., Philadelphia, Pennsylvania.

Prepare hamstring autograft or soft tissue allograft in appropriate manner. Size graft, mark as necessary and pre-tension as per surgeon preference. Perform initial diagnostic arthroscopy, treat other associated intra-articular pathology, debride torn ACL and perform notchplasty.

Make proximal medial tibial longitudinal incision. Create periosteal flaps in location of ACL tibial tunnel. At the completion of the procedure, re-approximate the periosteal flaps with sutures to enclose graft and hardware.

Position ACL tibial guide and drill guide pin into desired location. Over-ream tibial guide pin with appropriate sized tibial reamer corresponding to diameter of prepared graft (if using WasherLoc™ Tibial Fixation, ream distal aspect of tibial tunnel to accept fixation device).

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Make proximal medial tibial longitudinal incision. Create periosteal flaps in location of ACL tibial tunnel. At the completion of the procedure, re-approximate the periosteal flaps with sutures to enclose graft and hardware.

Place Femoral Aimer trans-tibially into the appropriate “over-the-top” position at posterior aspect of lateral femoral condyle and drill guide pin into position. Remove guide. Drill ACL femoral tunnel to appropriate depth (approximately 40mm) utilizing reamer that corresponds to the graft diameter (remember to place knee into the appropriate degree of flexion prior to drilling the femoral tunnel).

Place the appropriate diameter “insertion rod” into the AXL™ Cannulated Cross Pin U-Guide and tighten securely (do not place any “swing arms” between the base of the rod and the U-Guide). Pass a #2 suture through holes in distal tip of insertion rod (Figure 1). The two ends of the suture are then pulled taut as they pass proximally along the rod shaft to the base of the U-Guide where they are tightened securely around the adjacent grommets (Figure 2).

Soft-tissue grafts have gained popularity over recent years as many surgeons’ graft preference for anterior cruciate ligament reconstruction. Interference screws were thought to be the gold standard for fixating any graft (soft-tissue or BTB) in an ACL reconstruction. Interference screws offered a simple technique for surgeons. Recent literature suggests that transverse, or cross pin, fixation may provide a stronger and stiffer construct and be better suited for fixating soft-tissue grafts in the femur. The strength of cross pin fixation is attributed to the ability of these devices to purchase the cortical bone in the femur rather than solely relying on the cancellous bone quality of a given patient. The higher strength of a cross pin fixation device may allow for the promotion of aggressive rehabilitation and enabling patients a quicker return to full sport. Having a technique that is reliable and reproducible, as well as having a strong device, is essential for a successful ACL reconstruction.

The AXL™ Cannulated Cross Pin is:

Reproducible and Reliable
• New U-Guide aids in accurate transverse tunnel placement
• New graft pusher simplifies graft passage and aids in proper placement of the AXL™ Cannulated Cross Pin

Strong
• AXL™ Cannulated Cross Pin can capture the cortical bone of the femur giving it superior strength

Biologically Friendly
• Made of either titanium or LactoSorb™ L-15 material for different material options without sacrificing biocompatibility


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The distal tip of the insertion rod (on the properly prepared "U-Guide") is inserted trans-tibially into the femoral tunnel to the appropriate depth.

Insert the measuring bullet into the lateral arm of the U-Guide and rotate the guide so that the bullet touches the skin anterior to the lateral epicondyle, as per surgeon preference. Mark the skin and make an incision using a #11 blade through the skin, iliotibial band, and periosteum directly to bone.

Adjust orientation of U-Guide so that the measuring bullet is parallel with floor or slightly angled posterolateral to anteromedial.

Lock the targeting bullet into place (with its tip touching the bone of the lateral cortical wall) with the adjacent thumbscrew. Read the calibrated markings on the bullet to determine the AXL™ Cross Pin implant length (Figure 3).

Pass guide-wire through targeting bullet and drill across both femoral condyles, exiting through a small puncture wound in the skin medially (Figure 4).

Remove targeting bullet. Drill the AXL™ cannulated drill over the guide-wire until drill stop contacts lateral surface of U-Guide (indicating tip of drill bit reaching appropriate depth through lateral wall of ACL femoral tunnel) (Figures 5 & 6). Remove AXL™ Drill.

Thread a #2 transverse pin alignment suture through eyelet of the AXL™ implant passing pin. Hold two ends of suture and slide pin to opposite end. Take free ends of transverse pin alignment suture and now pass them through the eyelet in the proximal tip of the transverse guide-wire (the one that passes lateral to medial through the femoral condyles).

Pull the transverse guide wire by its medial tip so it passes across both femoral condyles and out the skin medially (pulling the #2 transverse pin alignment suture with it across both condyles) (Figure 7).
Remove the guide-wire from the sutures (on medial aspect of knee) and clamp both ends of the transverse pin alignment suture together with a Kelly or similar clamping instrument.

Remove the U-Guide from the knee pulling the transverse pin alignment suture (via the suture passed through the eyelets in the end of the insertion rod) out of the tibial tunnel (Figure 8). Release the transverse pin alignment suture from the U-Guide and clamp it to the drape above the knee. Note: Make sure the transverse pin alignment suture does not rotate or twist and maintains its orientation...i.e., the suture exiting medial condyle stays medial, that which exits the lateral tunnel remains lateral (Figure 9).

Place the previously prepared soft tissue graft over the forked end of the graft inserter such that the graft is folded in half with the two free ends passing proximally along shaft of the inserter. The sutures from the ends of tendons are wrapped around the spring loaded channels in their respective handle and the handle is then ratcheted to pull both tendon strands taut to facilitate graft passage.

Pass the graft inserter assembly transtibially and up into the femoral tunnel maintaining the proper orientation of the graft (graft strands sitting anterior and posterior within femoral tunnel, handle perpendicular to path of transverse guide-wire). The inserter is passed to top of femoral tunnel until it is fully seated with the loops of the graft positioned above the transverse tunnel (you can confirm appropriate passage with depth markings on graft or shaft pre-measured and marked prior to securing graft to inserter) (Figure 10).

Release transverse pin alignment suture from the drape while maintaining proper orientation of its strands. Pass the anterior limb(s) of the graft through the free loop of this suture (Figure 11). (DO NOT let the suture twist!!!
Pull on both ends of the transverse pin alignment suture as they exit both femoral condyles so the suture passes to the top of the femoral tunnel between the anterior and posterior strands of the soft tissue graft. Pull the graft inserter out both tunnels while maintaining tension on both ends of the transverse pin alignment suture (Figure 12).

Pull the transverse pin alignment suture medially to advance the AXL™ implant passing pin into the lateral femoral condyle, below the loop in the soft tissue graft and then across the medial femoral condyle (Figure 13).

Advance AXL™ obturator and sheath over the AXL™ implant passing pin through skin incision, through iliotibial band and down to the lateral cortex of the femur (Figure 14). Remove obturator making certain the sheath stays on the lateral cortex of the femur.

Load the pre-determined length AXL™ Cannulated Cross Pin onto the implant passing pin (Figure 15). Mate the AXL™ Implant driver with the AXL™ Cannulated Cross Pin. Advance the AXL™ Cannulated Cross Pin through the sheath until the implant is countersunk 5mm (Figure 16).

Place sufficient traction on tendon strands exiting tibial tunnel to tension graft against AXL™ Cannulated Cross Pin and cycle knee to surgeons preference. Secure the soft tissue graft distally with the desired tibial fixation device (Figure 17).
Alternative AXL™ Cannulated Cross Pin Insertion Technique

Load the pre-determined length of AXL™ Cannulated Cross Pin onto the implant passing pin (Figure A). Mate the AXL™ implant driver with the AXL™ Cannulated Cross Pin and advance into place to the appropriate depth (countersunk 5mm) (Figures B & C). The depth is determined by reading markings on the drive as it passes through the insertion sheath. BE SURE that the insertion sleeve is on cortical bone to ensure accurate depth measurements. Tension and secure the soft tissue graft distally with the desired tubial fixation device (Figure D).

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Arthrotek at the contact information provided here.

**Figure A, B, C, D**

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**Contraindications**

1. Infection.
2. Metal sensitivity, or allergic reaction to a foreign body.
3. Loosening or migration of the implant.
4. Nerve damage due to surgical trauma.
5. Metal sensitivity, or allergic reaction to a foreign body.
6. Rupture of the soft tissue around the fixation device.
7. Adequately instruct the patient. Postoperative care is important. The patient's ability to follow instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examinations.
8. Devices are available to aid in the accurate implantation of internal fixation devices. Intraoperative instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examinations. The patient is to be advised that the device does not replace normal healthy bone, and that the device can break, bend or be fractured. Ceiling supports, walking aids, and braces that are intended to immobilize the fracture site and support bone fracture management. Patients affected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore postoperative care instructions and/or activities of daily living. It is important to follow the postoperative care instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examinations. The patient is to be advised that the device does not replace normal healthy bone, and that the device can break, bend or be fractured.
9. Intraoperative or postoperative bone fracture and/or postoperative pain.

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**Possibility of Adverse Effects**

1. Infection.
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3. Loosening or migration of the implant.
4. Nerve damage due to surgical trauma.
5. Metal sensitivity, or allergic reaction to a foreign body.
6. Rupture of the soft tissue around the fixation device.
7. Adequately instruct the patient. Postoperative care is important. The patient's ability to follow instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examinations. The patient is to be advised that the device does not replace normal healthy bone, and that the device can break, bend or be fractured. Ceiling supports, walking aids, and braces that are intended to immobilize the fracture site and support bone fracture management. Patients affected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore postoperative care instructions and/or activities of daily living. It is important to follow the postoperative care instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examinations. The patient is to be advised that the device does not replace normal healthy bone, and that the device can break, bend or be fractured.

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**Precautions**

1. Infection.
2. Metal sensitivity, or allergic reaction to a foreign body.
3. Loosening or migration of the implant.
4. Nerve damage due to surgical trauma.
5. Metal sensitivity, or allergic reaction to a foreign body.
6. Rupture of the soft tissue around the fixation device.

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**Summary**

Arthrotek’s metal internal fixation implants are typically implanted and are sterilized by exposure to a minimum of 25kGy of gamma radiation or by Ethylene Oxide Gas (ETO) if device contains MaxBraid® PE suture. If supplied sterile, do not resterilize the implant.
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