ACUITIVE TECHNOLOGIES

CITRELOCK® ACL System

Anterior Cruciate Ligament Reconstruction

Operative technique

CITRELOCK ACL

ACL Reconstruction System

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This publication sets forth detailed recommended procedures for using Acuitive Technology devices and instruments.

It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

A workshop training is recommended prior to first surgery.

Please remember that the compatibility of different product systems have not been tested unless specified otherwise in the product labeling.

All non-sterile devices must be cleaned and sterilized before use.

Multi-component instruments must be disassembled for cleaning.

For additional information please refer to the Instructions for Use **(IFU) PI-010** delivered with each implant and (**IFU) PI-002** delivered with the instruments. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

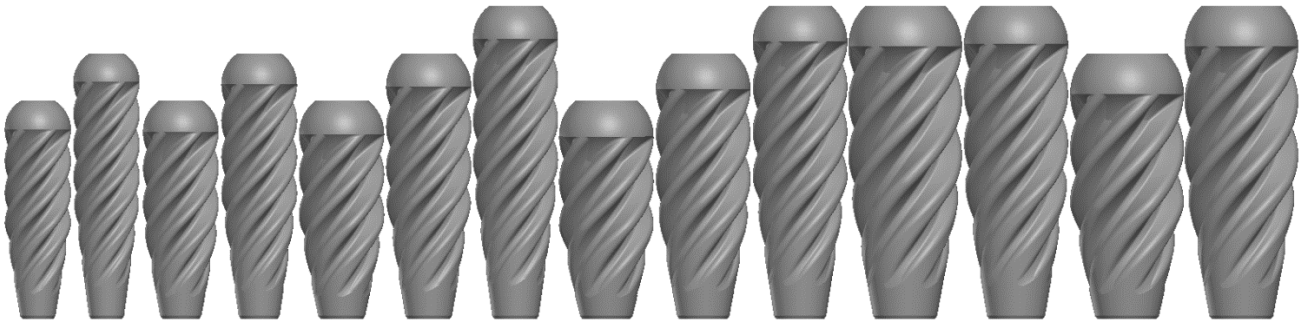
System general considerations

Anterior Cruciate Ligament (ACL) Reconstruction

using the **CITRELOCK ACL**

The ACL reconstruction procedure is indicated for patients with a torn or partially torn ACL. ACL injuries occur most commonly during participation in sports that involve frequent changes in direction and abrupt stops. Using either a bone-tendon-bone (BTB) graft or all-soft tissue graft, the torn ligament is replaced. An allograft or autograft may be used as the replacement ligament. Common grafts can come from the hamstring, quadriceps, or patellar tendon. On average, a nine-month recovery time is recommended. A successful ACL reconstruction should reestablish stability and knee function in the patient.

CITRELOCK ACL
ACL Reconstruction Devices



Sizes ∅7 to ∅12 mm
Lengths 23 to 33 mm

- The Only Implant made from **CITREGEN**™
- 60% Hydroxyapatite content mimics native bone and optimizes x-ray imaging
- Designed to prevent tendon laceration and maintain tendon tensile strength
- Optimized for ease of use and rapid insertion

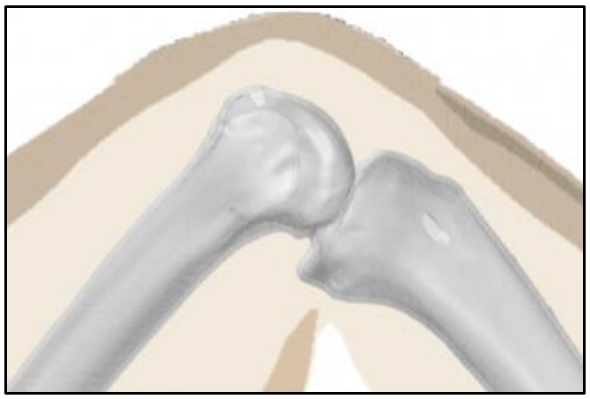
Surgical Technique as described by:
Robin Gehrmann M.D. & Robert Najarian M.D.

Acuitive would like to acknowledge and thank Robin Gehrmann M.D. & Robert Najarian M.D. for their contribution to the development of the surgical technique. This technique has been provided by our medical advisors only as guidance and it is not intended to limit the methods used by trained and experienced surgeons.

Operative Technique

Patient Positioning

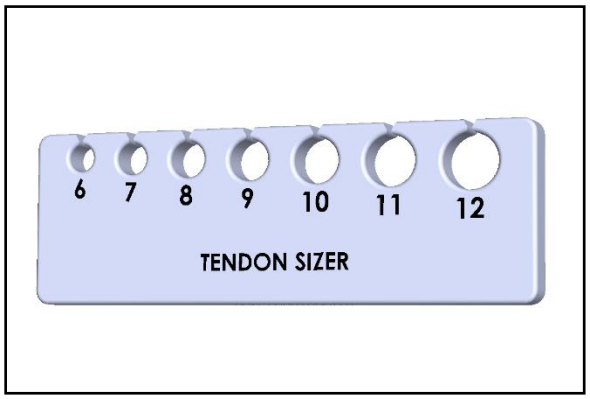
Position the patient supine on an operating table to allow knee flexion to 120 degrees and the option to extend the knee during surgery. A thigh holder is recommended. A tourniquet can be used on the thigh if bleeding is a concern. The desired autograft or allograft will be used and harvested according to surgeon's preference. Bone-tendon-bone grafts or all-soft tissue grafts can be used per this operative technique according to surgeon's preference.



Tendon Sizing (for soft tissue grafts)

Once a tendon graft is harvested, its size can be determined by placing it through the holes on the Sizing Guide. *Note: any nodules or bulbous protrusions from the tendon can be trimmed to provide a consistent diameter.* The tendon size will be defined by the marked diameter of the hole the tendon fits through. For example, if the tendon fits through and fills the size 10mm hole but does not fit through the size 9mm hole, the tendon is sized, and bone tunnel prepared for a 10mm graft.

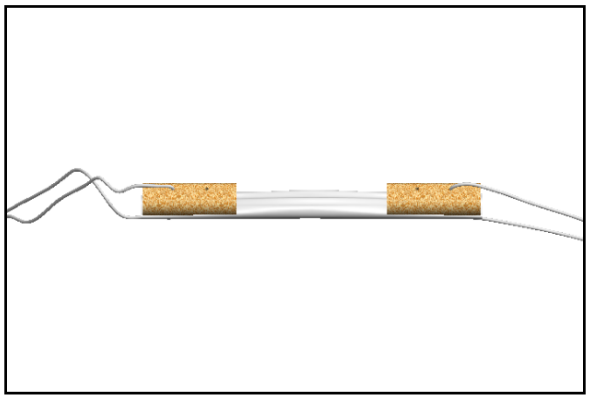
***Note**: Markings should be made on the tendon to indicate the expected length of graft within the femoral and tibial tunnels allowing for 30mm of intrarticular graft*.



Tendon Sizing (for BTB grafts)

Measure the graft length and diameter. The mm sized BTB pliers can be used to shape the graft to a consistent diameter while increasing bone plug density. Pass the harvested graft through the 8mm, 9mm, or 10mm Sizing Tube to confirm the diameter of the graft. The graft should pass through the selected tube without significant resistance.

***Note**: The femoral end of the graft should never be larger in diameter than the tibial end to ensure graft passage.*

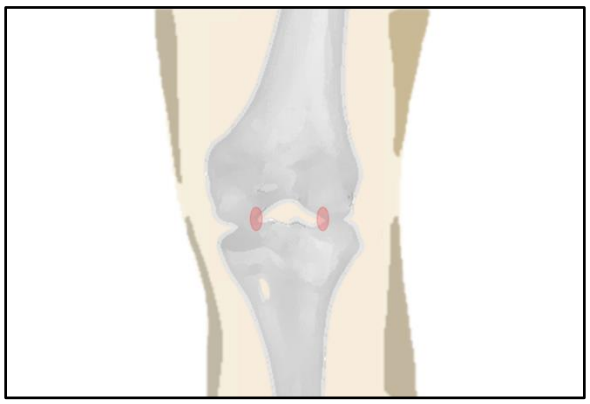


Preparing the Graft

Place sutures through the bone plugs of the BTB graft or whipstitch the ends of the all-soft tissue graft using preferred technique.

Exposure

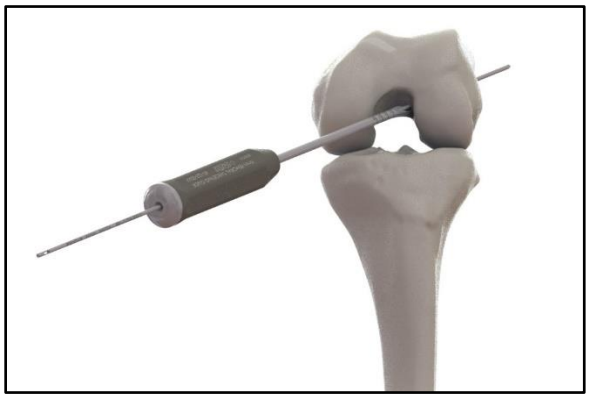
After carrying out a diagnostic arthroscopy, the approach portals can be created for ACL reconstruction. A spinal needle may be helpful for localization of the anteromedial portal. Once established, the ACL remnant can then be debrided and the reconstruction carried out.



Targeting Femoral Bone Socket

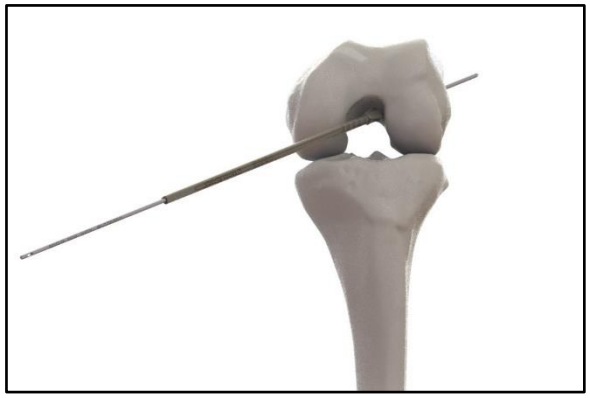
The Femoral Drill Guide is provided in 6mm and 7mm sizes to create a preferred backwall thickness. The chosen size is placed through the medial portal with the knee hyperflexed in the over-the-top position. The marking on the handle indicates the correct orientation of the drill guide. Place the 2.4mm Femoral K-Wire through the drill guide to deliver the k-wire to the femoral footprint of the ACL. Confirm tunnel trajectory arthroscopically. Advance the k-wire by drilling it through the femur until it exits the anterolateral region of the thigh.

***Note**: A Femoral Drill Guide with a straight tip is available in 6mm and 7mm sizes as an option. The Femoral Drill Guide, Straight Tip can be used to target the femoral footprint of the ACL through the tibial bone socket. All functions and markings are the same as the Femoral Drill Guide.*



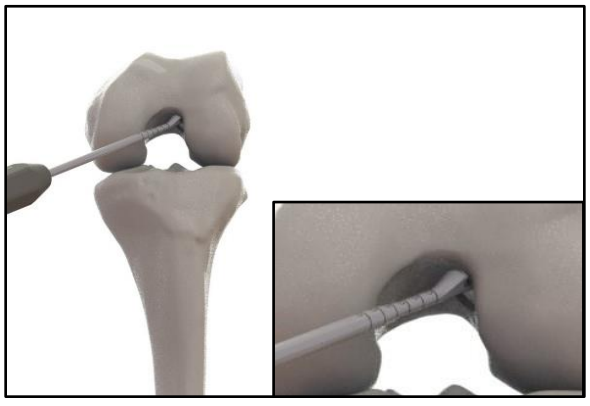
Reaming Femoral Bone Socket

Remove the drill guide and keep the 2.4mm Femoral K-Wire in place with a hemostat clamp on the end protruding laterally. Ream over the guidewire with the appropriate size Femoral Reamer *(same diameter, 0.5mm or 1mm larger than femoral bone plug for BTB graft; same diameter for all-soft tissue graft; depending on bone quality).* Ream to the appropriate depth for the graft *(usually between 20-25mm)* referencing the depth markers on the reamer. Remove the reamer. Place a passing suture through the guidewire eyelet and pull it through the medial portal and out through the femoral tunnel. Clamp the suture to itself to form a loop around the knee. This suture will be used later for graft passage.



Notching the Femoral Bone Socket

Impact the Tunnel Notch Curette to create a semi-circular notch on the anterior rim of the distal-medial end of the femoral socket. The marking on the handle indicates the top of the semi-circle on the notch curette. This will provide a starting point for insertion of the CITRELOCK ACL implant.



Targeting Tibial Bone Socket

Use the Tibial Drill Guide to establish the appropriate angle based on the length of the graft and to avoid a graft tunnel mis-match when using a BTB graft. Create a medial incision at the appropriate level, adjacent to the tibial tubercle. Insert the 2.4mm Tibial K-Wire through the guide tube. Confirm tunnel trajectory arthroscopically and advance the k-wire by drilling it from the distal-medial side of the tibiofemoral joint into the tibial footprint of the ACL. Place a heavy Kocher clamp over the wire to keep it in position when reaming.

***Note**: A Tibial Drill Guide with a flat hook is available as an option. The Tibial Drill Guide, Flat Hook lays parallel to the bone, rather than at an angle. All functions and markings are the same as the Tibial Drill Guide.*

Reaming Tibial Bone Socket

Remove the Tibial Drill Guide by disconnecting the assembled pieces. Place the appropriate size Tibial Reamer that corresponds to the diameter of the harvested graft over the k-wire and ream the tunnel into the ACL footprint. Remove the reamer.

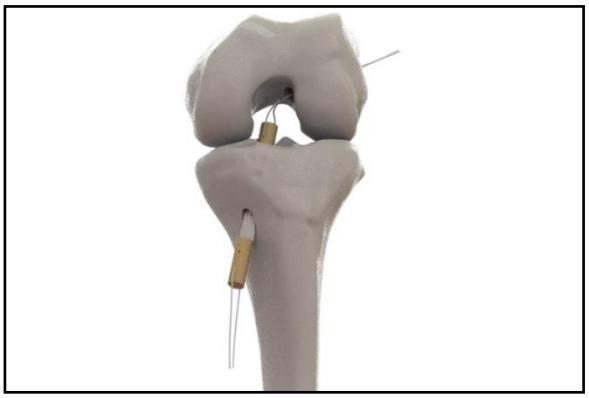
Notching the Tibial Bone Socket

Impact the Tunnel Notch Curette to create a semi-circular notch on the rim of the tibial socket at the anterior aspect of the orifice for placement of the 1.1mm K-Wire.

***Note**: A 1.5mm K-Wire is available as an option if a more rigid wire is desired. All functions and markings are the same as the 1.1mm K-Wire.*

Inserting the Graft

Retrieve the femoral passing suture out through the tibial tunnel so it can be used for graft passage. Mark the bone tendon junction on the femoral plug of a BTB graft or the depth of the tunnel on the all-soft tissue graft to provide a visual reference for final graft placement.



Use the passing suture to pull the graft into the knee until it is appropriately seated in the tunnels. It is recommended that the cancellous surface of the bone plug is facing anteriorly. Check to ensure the tibial bone plug is seated completely in the tibial tunnel and there is no impingement of the graft in the intercondylar notch.

Implanting CITRELOCK ACL in the Femoral Bone Socket

Place the 1.1mm K-Wire tip into the notched femoral tunnel while keeping the knee hyperflexed. Engage the cannulated tip of the Dilator that corresponds to the desired implant diameter over the 1.1mm K-Wire. The diameter of the Dilator can be line-to-line with the implant depending on bone quality and surgeon preference. Advance the Dilator until the desired depth for the implant is achieved. Remove the Dilator. Slide the CITRELOCK ACL implant over the 1.1mm K-Wire and fully insert using the Cannulated Inserter. Confirm arthroscopically that the CITRELOCK ACL implant is flush with the cortical bone and pen markings on the graft line up with the visible end of the CITRELOCK ACL implant.

***Note**: An inserter with a protruding pin is also provided if the cannulated inserter does not have adequate control of the implant or if the k-wire has been removed and further seating is necessary.*

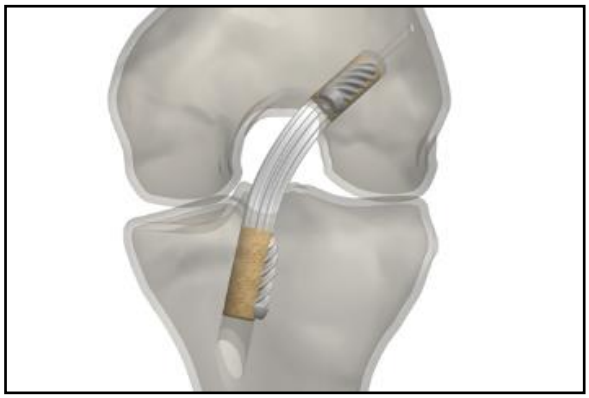
Implanting CITRELOCK ACL in the Tibial Bone Socket

Cycle the knee multiple times with tension on the sutures in the tibial end of the graft to remove any creep in the graft. Ensure there is no impingement of the graft anteriorly when in full extension. Bend the knee to 30 degrees of flexion for graft tensioning and tibial implant insertion. Pull the sutures in the tibial end of the graft until the desired tension is created. Place the 1.1mm K-Wire tip into the notched hole. Engage the cannulated tip of the Dilator that corresponds to the desired implant diameter over the 1.1mm K-wire. The diameter of the Dilator can be line-to-line with the implant depending on bone quality and surgeon preference. Advance the Dilator until the desired depth for the implant is achieved. Remove the Dilator. Slide the CITRELOCK ACL implant over the 1.1mm K-Wire and fully insert using the Cannulated Inserter while maintaining desired graft tension. Confirm knee stability after screw insertion.

***Note**: An inserter with a protruding pin is also provided if the cannulated inserter does not have adequate control of the implant or if the k-wire has been removed and further seating is necessary.*

Completing the Replacement and Closure

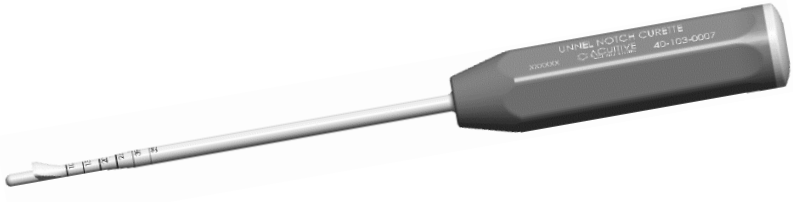
After implantation of the graft and the CITRELOCK ACL implants is complete, confirm there is no impingement and that stability is restored to the knee with Lachman testing. Wound closure is then performed according to the surgeon's standard protocol.

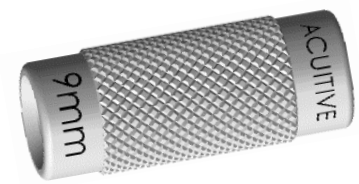


Removal

If for any reason the clinician decides that the CITRELOCK ACL device must be removed after it is implanted, it can be drilled out using a burr of a smaller diameter than the implant. Arthroscopy can be utilized to check the trajectory of the tool.

Ordering Information
Instrumentation

Description	ID Number	Size	
CITRELOCK ACL 2.4mm Tibial K-Wire	**40-103-0001**		
CITRELOCK ACL Sizing Guide	**40-103-0002**		
CITRELOCK ACL Inserter	**40-103-0003**		
CITRELOCK ACL Cannulated Inserter	**40-103-0004**		
CITRELOCK ACL 1.1mm K-Wire	**40-103-0005**	**1.1mm**	
CITRELOCK ACL 1.5mm K-Wire	***40-103-0015****	***1.5mm***	
CITRELOCK ACL 1/4 Inch Square Quick Connect Handle	**40-103-0006**		
CITRELOCK ACL Tunnel Notch Curette	**40-103-0007**		
CITRELOCK ACL 2.4mm Femoral K-Wire	**40-103-0008**		

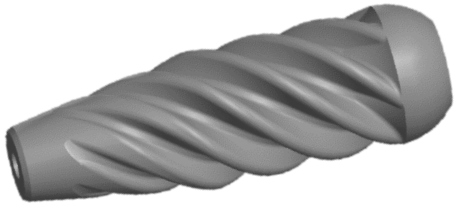
CITRELOCK ACL Tibial Drill Guide	**40-103-0009**		
CITRELOCK ACL Tibial Drill Guide, Flat Hook ***Note: Disassemble for cleaning***	***40-103-0016****		
CITRELOCK ACL Mallet	**40-103-0010**		
CITRELOCK ACL Sizing Tube	**40-103-0018**	**8mm**	
	40-103-0011	**9mm**	
	40-103-0012	**10mm**	
CITRELOCK ACL BTB Piler	**40-103-0013**	**9mm**	
	40-103-0014	**10mm**	
CITRELOCK ACL Femoral Drill Guide	**40-103-0060**	**6mm**	
	40-103-0070	**7mm**	
CITRELOCK ACL Femoral Drill Guide, Straight Tip	***40-103-0061****	***6mm***	
	40-103-0071*	***7mm***	

CITRELOCK ACL Tibial Reamer	**40-103-1070**	**7mm**	
	40-103-1075	**7.5mm**	
	40-103-1080	**8mm**	
	40-103-1085	**8.5mm**	
	40-103-1090	**9mm**	
	40-103-1095	**9.5mm**	
	40-103-1100	**10mm**	
	40-103-1105	**10.5mm**	
	40-103-1110*	**11mm**	
	40-103-1115*	**11.5mm**	
	40-103-1120*	**12mm**	
	40-103-1125*	**12.5mm**	
CITRELOCK ACL Dilator	**40-103-2070**	**7mm**	
	40-103-2080	**8mm**	
	40-103-2090	**9mm**	
	40-103-2100	**10mm**	
	40-103-2110*	**11mm**	
	40-103-2120*	**12mm**	
CITRELOCK ACL Femoral Reamer	**40-103-3070**	**7mm**	
	40-103-3075	**7.5mm**	
	40-103-3080	**8mm**	
	40-103-3085	**8.5mm**	
	40-103-3090	**9mm**	
	40-103-3095	**9.5mm**	
	40-103-3100	**10mm**	
	40-103-3105	**10.5mm**	
	40-103-3110*	**11mm**	
	40-103-3115*	**11.5mm**	
	40-103-3120*	**12mm**	
	40-103-3125*	**12.5mm**	
CITRELOCK ACL Reconstruction Case	**40-802-0006**		
CITRELOCK ACL Reconstruction Case, Base	**40-898-0006**		
CITRELOCK ACL Reconstruction Case, Lid	**40-999-0006**		

Product available upon special order

Implants

Description	ID Number	Size
CITRELOCK ACL Implant	30-103-0723	7mm x 23mm
	30-103-0728	7mm x 28mm
	30-103-0823	8mm x 23mm
	30-103-0828	8mm x 28mm
	30-103-0923	9mm x 23mm
	30-103-0928	9mm x 28mm
	30-103-0933	9mm x 33mm
	30-103-1023	10mm x 23mm
	30-103-1028	10mm x 28mm
	30-103-1033	10mm x 33mm
	*30-103-1128**	11mm x 28mm
	*30-103-1133**	11mm x 33mm
	*30-103-1228**	12mm x 28mm
	*30-103-1233**	12mm x 33mm



***Product available upon special order**

This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Acuitive products. This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Acuitive does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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ACUITIVE TECHNOLOGIES

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