

Anterior Cruciate Ligament Reconstruction All-Inside With ToggleLoc[®] Inline (Femur)/ToggleLoc[®]

Inline(Tibia) with Genie[™] Fixation



ToggleLoc[®] System

INDICATIONS FOR USE

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The ToggleLoc System devices, except the ToggleLoc XL device, are intended for soft tissue to bone fixation for the following indications:

Shoulder

- Bankart lesion repair
- SLAP lesion repairs
- Acromio-clavicular repair
- Capsular shift/capsulolabral reconstruction
- Deltoid repair
- Rotator cuff tear repair
- Biceps Tenodesis

Foot and Ankle

- Medial/lateral repair and reconstruction
- Mid- and forefoot repair
- Hallux valgus reconstruction
- Metatarsal ligament/tendon repair or reconstruction
- Achilles tendon repair
- Ankle Syndesmosis fixation (Syndesmosis disruptions) and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures (only for ToggleLoc with Tophat/ ZipTight Fixation Devices)

Elbow

- Ulnar or radial collateral ligament reconstruction
- Lateral epicondylitis repair
- Biceps tendon reattachment

Knee

- ACL/PCL repair / reconstruction
- ACL/PCL patellar bone-tendon-bone grafts
- Double-Tunnel ACL reconstruction
- Extracapsular repair: MCL, LCL, and posterior oblique ligament
- Illiotibial band tenodesis
- Patellar tendon repair
- VMO advancement
- Joint capsule closure

The ToggleLoc XL device is used for fixation of tendons and ligaments during orthopedic reconstruction procedures, such as Anterior Cruciate (ACL) or Posterior Cruciate (PCL) Reconstruction, as well as in cases of unanticipated intraoperative complications, such as cortical breaching.

CONTRAINDICATIONS

- 1. Infection.
- 2. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone or soft tissue.
- 3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

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- Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

Genie[™] Knotless Anchor

INDICATIONS FOR USE:

Genie Biocomposite Knotless/Suture Anchor is intended use for fixation of soft tissue to bone, using suture, in the following procedure; Orthopedic surgery for shoulders and knees.

CONTRAINDICATIONS

- If there is active infection or potential infection
- In the case of pathological bone conditions such as severe Osteopenia
- · Serious defects in bone and soft tissue
- Crushed-bone surface that may prevent secure anchoring
- If the blood supply is insufficient
- If a patient has hypersensitivity to the implant
- In the case of using for unspecified indications
- Patient who has mental or physical difficulty in post-operative treatment

BroadBand[™] Tape

INDICATIONS: BroadBand[™] / MaxBraid[™] sutures are indicated for use in general soft tissue approximation and/or ligation and the use of allograft tissues for orthopedic surgeries, but are not for use in cardiovascular procedures.

 $BroadBand^{\tt w} \ / \ MaxBraid^{\tt w} \ sutures \ are \ intended \ for \ one-time \ use \ only, \ and \ are \ not \ to \ be \ re-sterilized.$

ACTIONS: BroadBand[™] / MaxBraid[™] sutures elicit a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. BroadBand[™] / MaxBraid[™] sutures are not absorbed, nor is there any significant change in tensile strength retention known to occur in vivo.

CONTRAINDICATIONS: None known.

3 | Anterior Cruciate Ligament Reconstruction-All Inside With ToggleLoc[®] Inline (Femur) / ToggleLoc[®] Inline (Tibia) with Genie Fixation Surgical Technique



Grafting Preparation

1. Harvest semitendinosus graft using preferred tendon stripper.

Semitendinosus graft approximately length 23-27 cm will result in quadrupled graft length 6-7 cm.

Note: Gracilis graft can be added to increase diameter if required.

Tunnel Preparation

- With SwitchCut[™] Femoral Guide Arm (Figure 4) set at approximately 70°, position on the I.D.E.A.L.[™] femoral tunnel position (Figure 1).
- 3. Advance drill (bullet) sleeve down to lateral cortex and note bi-cortical tunnel distance.
- Drill on forward with appropriate SwitchCut[™] Reamer (Figure 5) across femur into joint space. Remove SwitchCut Guide, leaving guide bullet in place.

Option: Mallet guide bullet into lateral cortex to create a 7 mm safety stop.

Option: Exchange nitinol loop for BroadBand[™] Tape (Black) shuttling suture.

- 5. 'Zero' SwitchCut Reamer by aligning black laser line with lateral wall and slide rubber grommet to back of guide bullet.
- 6. Drill on reverse and slowly retro-ream socket to approximately 20-25 mm.

Note: Approximately 10 mm lateral femoral cortex is recommended to ensure strong cortical suspensory fixation.

- For tibial tunnel, set SwitchCut[™] Tibial Guide to approx. 50-60° and position within anatomical tibial footprint (Figure 2). Measure bicoritcal distance.
- Remove drill chuck, unscrew k-wire insert and pass nitinol loop passer (loop first) into joint space. Retrieve Nitinol Loop Passer for later graft passing. Remove SwithCut Reamer by hand with a forward twisting motion.
- 9. Repeat SwitchCut drilling steps above.

Note: For tibial tunnel, retro-ream socket to approximately 30-35 mm to allow additional 10 mm for tensioning. Option: For suture identification, exchange nitinol loop for BroadBand Tape (Black/Blue) shuttling suture.

4 | Anterior Cruciate Ligament Reconstruction-All Inside With ToggleLoc[®] Inline (Femur) / ToggleLoc[®] Inline (Tibia) with Genie Fixation Surgical Technique



Grafting Fixation

 With the femoral button in a "pre-flipped" position, mark femoral bicortical distance on ToggleLoc[®] Inline sutures (Figure 3).

Option: Mark femoral socket distance on graft construct.

- Retrieve femoral and tibial NItinol Loop Passers through medial portal and pass both femoral ToggleLoc[®] Inline shuttling sutures (white) and 'zip' strands (blue/white).
- 3. With the button in a pre-flipped position and tension applied distally, pull all suture limbs to advance button until it exits and flips on lateral femoral cortex.

Note: Pen marking on ToggleLoc Inline (Figure 3a) can be referenced at femoral socket aperture to indicate button exiting lateral femoral cortex.

- With firm distal tension on tibial end of graft, pull femoral ToggleLoc[®] Inline 'zip' strands until graft is docked in femoral socket.
- 5. Pass tibial ToggleLoc Inline shuttling sutures and 'zip' strands along with whipstitch sutures.
- 6. Position knee in full extension and clip ToggleLoc Inline button with needle holder. Pull 'zip' strands until button is seated firmly on tibial cortex.

Genie Fixation

- 8. Approximately 2 cm distal to tibial tunnel, drill with 2.4 mm Guide Pin to a depth of 25 mm. Over ream with 4.5 mm Cannulated Drill to a depth of 25 mm.
- Load whipstitch sutures through eyelet of Genie[™] Knotless Anchor.
- 10. Ensuring anchor body is contacting bone, hold inserter wings steady and rotate inserter head clockwise until anchor is flush with bone.
- 11. Maintaining knee extension, insert Genie[™] Anchor into bone socket until distal edge of black laser line is flush with bone and tension sutures.
- 12. Retension both femoral and tibial ToggleLoc implants and cut all suture tails flush.

7. Cycle knee as desired.

Ordering Information

Part Number	Description
110005087	ToggleLoc with ZipLoop Inline Technology
110045257	Genie Knotless Anchor, 5.5 mm
CM-0306SN	BroadBand Loop: Blue 25" Tape Loop (1.5mm), 1" #2 Suture Tail w/Straight Taper Needle
CM-0306CN	BroadBand Loop: Blue/Black 25" Tape Loop (1.5mm), 1" #2 Suture Tail w/Curved Taper Needle
CM-0322	BroadBand Tape Two-Pack: (1) Black/Blue Tape (1.5 mm), (1) Black Tape (1.5 mm)
909640	Drill Tip Guide Pin, 2.4 mm
904760	ToggleLoc Cannulated Drill, 4.5 mm
110027674	SwitchCut Reamer Kit, 4.5 x 6.0 mm
110027675	SwitchCut Reamer Kit, 4.5 x 6.5 mm
110027676	SwitchCut Reamer Kit, 4.5 x 7.0 mm
110027677	SwitchCut Reamer Kit, 4.5 x 7.5 mm
110027678	SwitchCut Reamer Kit, 4.5 x 8.0 mm
110027679	SwitchCut Reamer Kit, 4.5 x 8.5 mm
110027680	SwitchCut Reamer Kit, 4.5 x 9.0 mm
110027681	SwitchCut Reamer Kit, 4.5 x 9.5 mm
110027682	SwitchCut Reamer Kit, 4.5 x 10 mm
110027684	SwitchCut Reamer Kit, 6.0 x 11.0 mm
110027686	SwitchCut Reamer Kit, 6.0 x 12.0 mm
110026899	SwitchCut Universal Guide Body
110026900	SwitchCut Femoral Guide Arm Right
110026901	SwitchCut Femoral Guide Arm Left
110026903	SwitchCut Tibial Guide to Point, 22 mm
110026898	SwitchCut Guide Bullet, 4.5 mm ID
110026902	SwitchCut Guide Bullet, 6.0 mm ID

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Osteonic is the legal manufacturer of GENIE Knotless Anchor.

Riverpoint is the legal manufacturer of BroadBand Tape and MaxBraid.

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Legal Manufacturer Riverpoint Medical 825 NE 25th Ave. Portland, OR 97232 USA www.rpmed.com

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