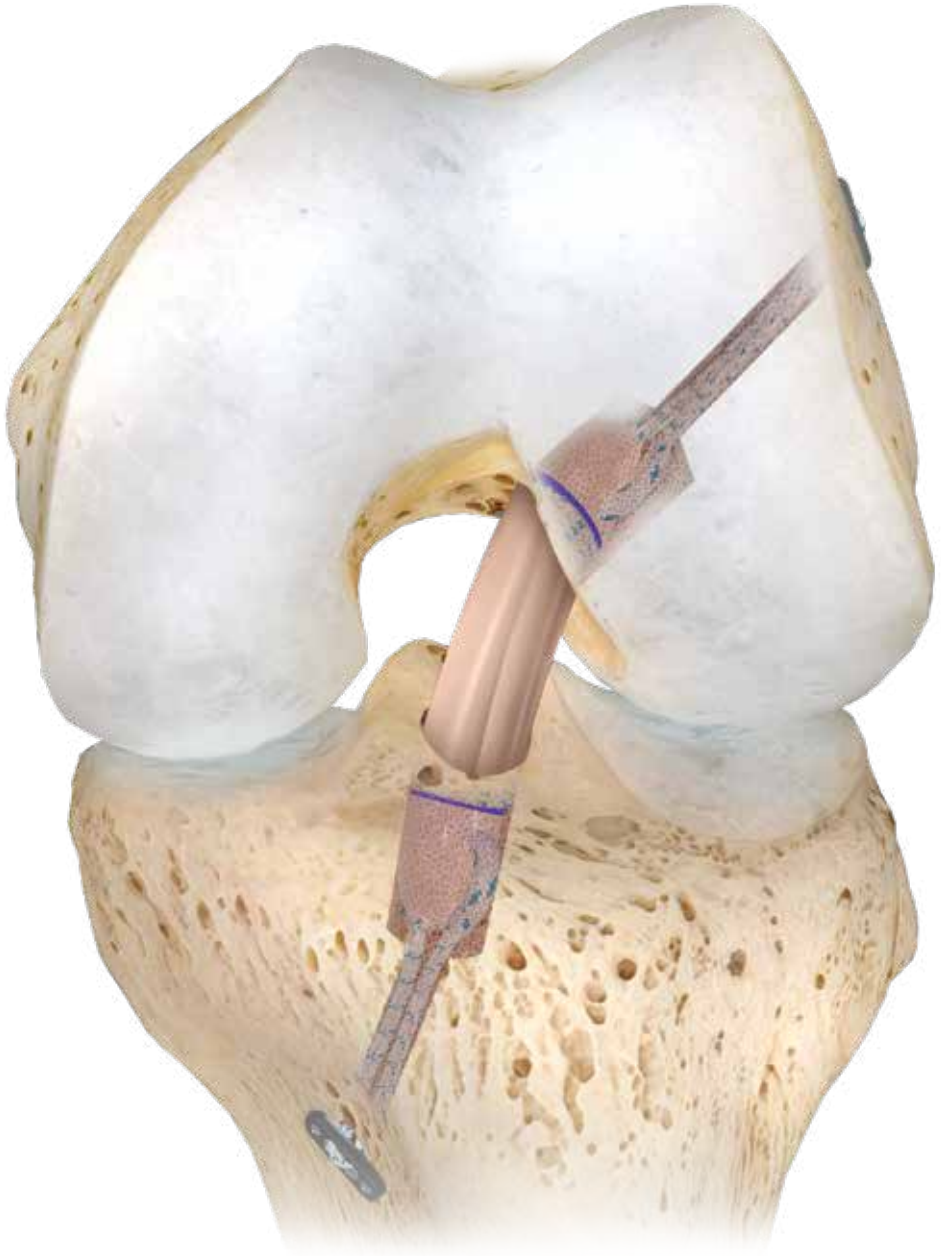
SwitchCut™ All-Inside ACL Reconstruction

Utilizing ToggleLoc Flip™ Inline with Ziploop®
with Autograft Hamstring

Surgical Technique



ZIMMER BIOMET
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ToggleLoc Flip™ Inline

ToggleLoc Flip™ Inline with Ziploop® Technology is a Riverpoint Medical ORTHOBUTTON® AL (OBAL) product.

Indications for Use: The Riverpoint Medical OrthoButton AL is intended for use in the fixation of bone and soft tissue in orthopedic procedures requiring ligament or tendon reconstruction

CONTRAINDICATIONS

- Do not use for surgeries other than those indicated
- Hypersensitivity to the implant material. In patients with suspected hypersensitivity, appropriate tests should be conducted to rule out sensitivity to the implant materials prior to implantation.
- Inadequate bone quality
- Inadequate bone quantity at implantation site
- Active infection, or previous infections which may retard healing
- Blood supply limitation
- Patients unable or unwilling to follow directions during the healing process

MaxBraid™ Sutures

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™ / MaxBraid™ sutures are intended for one-time use only, and are not to be re-sterilized.

CONTRAINDICATIONS

None known.

SwitchCut™ Reamer

INTENDED USE

The SwitchCut™ Reamer is intended for creating stepped tunnels and/or undercuts in bone for orthopedic reconstruction surgeries.

CONTRAINDICATIONS

The SwitchCut Reamer is NOT intended for use where one or more of the following conditions exist:

- Anatomic conditions requiring a bend radius.
- Use of device in patients with any known allergies or reactions to stainless steel and nitinol.
- Physical conditions that would retard healing, such as blood supply limitation and infection.
- Conditions which tend to limit the patient's ability or willingness to follow instructions during the healing period. ACL/PCL Guide System.

ExpressBraid™

INDICATIONS

The ExpressBraid Graft Manipulation is intended for use in soft tissue approximation and/or ligation. The suture may be provided individually or be incorporated as a component, into surgeries where constructs including those with allograft or autograft tissue are used for repair.

CONTRAINDICATIONS

- ExpressBraid Graft Manipulation is not for use in cardiac indications.
- ExpressBraid Graft Manipulation is not for use in direct contact with the central nervous system.

Figure 1a

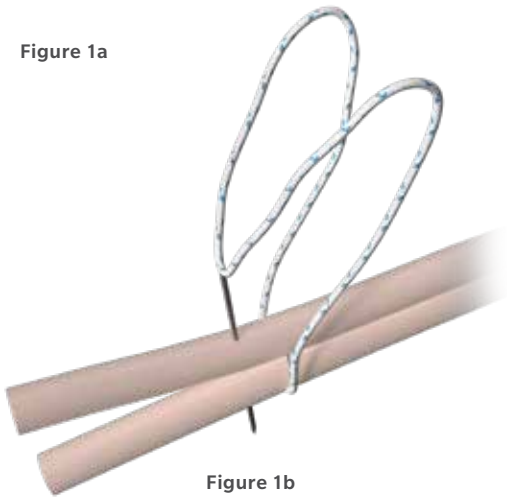

Figure 1b

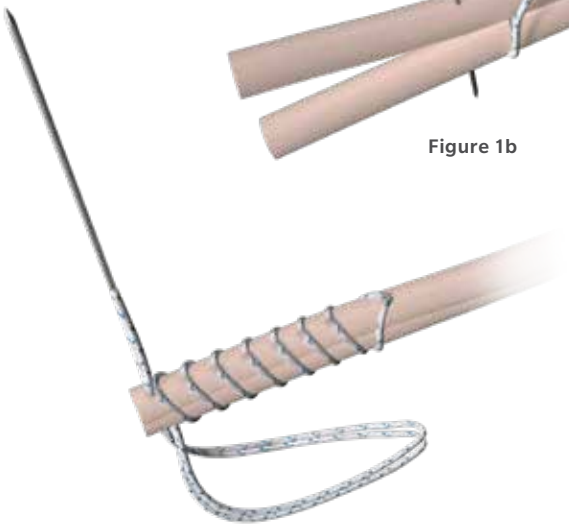

Figure 1c

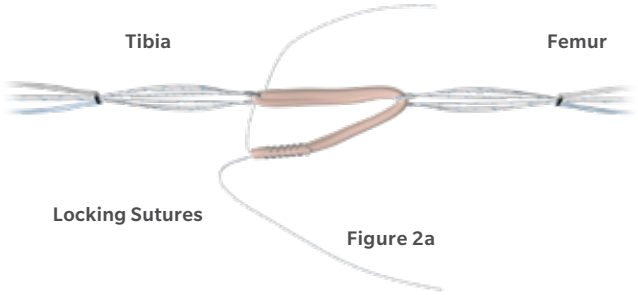

Figure 2a

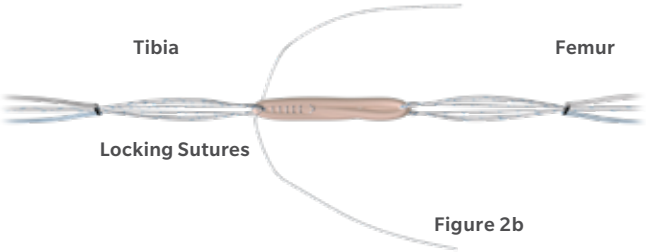

Figure 2b

Graft Harvest

Make an oblique incision anteriorly over the hamstring, this will allow for better visualization and hamstring mobilization. To help achieve a minimum of 270 mm of graft length, use the periosteal stripping technique.

Graft Preparation

The graft is loaded through the tibial ToggleLoc Flip™ Inline with Ziploop® Technology and folded in half. The two free ends of the hamstring graft are whip stitched together using the ExpressBraid™ suture (Figure 1). Cut the suture at the crimping of the ExpressBraid needle, leaving two free strands that will be used as the locking stitch.

Note: BroadBand™ Loop can also be used if large tape suture is desired

The hamstring graft is then loaded through the femoral ToggleLoc Flip Inline with Ziploop and folded over, creating a quadrupled hamstring graft (Figure 2).

Figure 3a

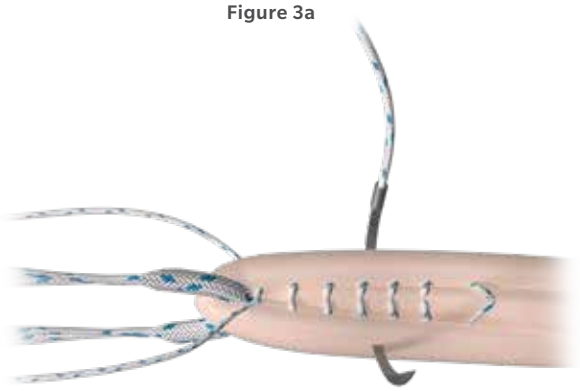

Figure 3b

Figure 3c

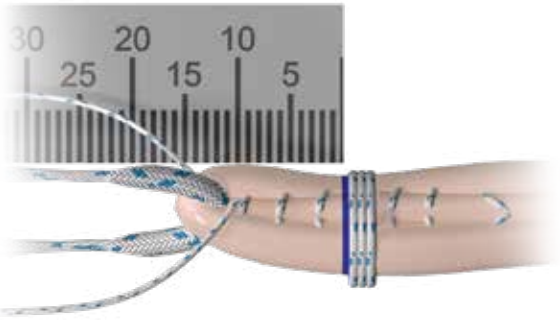

Figure 4

Graft Preparation (cont.)

The whip stitched free ends of the hamstring grafts are saved and docked into the core of the graft by passing one strand of the ExpressBraid suture to the center of the graft and then attaching to the graft tensioner post. Proceed by doing a single pass-triple circlage-single pass compression stitch utilizing two MaxBraid™ #2 sutures about 15 mm from each end of the quadrupled hamstring graft (Figure 3).

Note: BroadBand Loop can be used if larger tape suture is desired.

Size the quadrupled hamstring graft using the Zimmer Biomet graft sizing block. Use the Zimmer Biomet graft prep table to apply 10–15 lbs of tension to the graft construct. Leave under dampened gauze until ready to implant into patient.

Note: Mark the graft 15 mm from each end of the graft and at the mid portion of the graft (Figure 4).

Portal Preparation

The lateral portal is placed just off the patella at the level of the distal patella pole. The medial portal is established by inserting a spinal needle just above the anterior horn of the medial meniscus. After portals are placed, remove the fat pad and the ACL remnant. Widen the notch if warranted by patient anatomy to better visualize the I.D.E.A.L.™[1] femoral tunnel position and easier access for the SwitchCut Femoral guide.

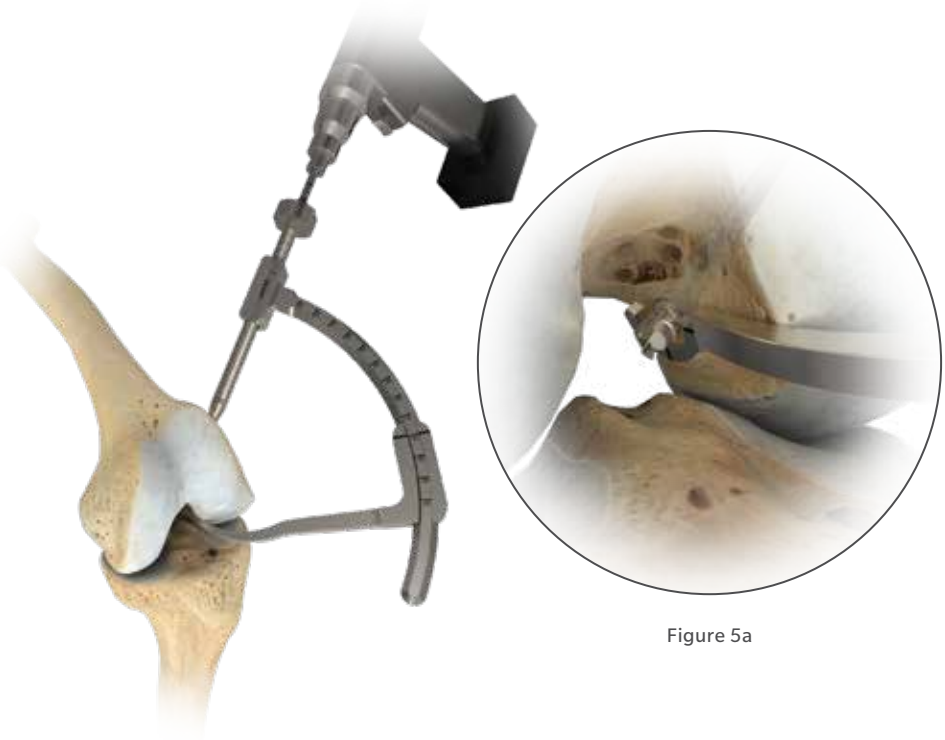

Figure 5

Figure 5a

Figure 6

Create a Femoral Tunnel with the SwitchCut™ Reamer

Ream in a clockwise forward direction through the lateral cortex into the joint space (Figures 5 & 5a).

Note: Overall transosseous tunnel length should measured off SwitchCut™ bullet.

Once the SwitchCut tip has penetrated the entrance of the joint, as shown in Figure 5a, then rotate the bullet 90˚. Remove the SwitchCut guide from the joint space, leaving the bullet in place (Figure 6).

Figure 7

Figure 8

Figure 8a

Create a Femoral Tunnel with the SwitchCut Reamer (cont.)

Take the SwitchCut 4.5 mm bullet until it hits the femoral lateral cortex bone bring down to cortex, measure, and ream back leaving 5–7 mm of cortical bone (Figure 7).

Advance the tip of the SwitchCut reamer to the bold black line. This will zero out the SwitchCut reamer (Figure 8). Once the black etched line is aligned with the intra-articular entrance, slide the O-ring to the back of the bullet (Figure 8a).

Figure 9

Figure 9a

Ream the Femoral Socket

Ream in a counterclockwise (reverse) direction to drill the femoral socket. The arm on the SwitchCut reamer will automatically deploy as soon as it contacts bone (Figure 9). Ensure the drill is running at a maximum counterclockwise speed and maintain a constant and slow retro reaming motion. While retro reaming, count the etch marks on the SwitchCut reamer to determine the femoral socket depth, knowing that each etch line represents 5 mm (Figure 9a).

If desired, retro-ream until the SwitchCut reamer bottoms out on the bullet tip, which will leave a 7 mm bone bridge. **Do NOT continue to ream once the reamer makes contact with the bullet, as this may cause the tip of the reamer to break.** Then disconnect the Jacobs® Chuck from the SwitchCut reamer.

Note: If using the ToggleLoc XL or ToggleLoc XL Inline, a 7 - 12 mm bi-cortical tunnel must be drilled.

Figure 10

Figure 10a

Shuttle the Nitinol Loop Passer

Remove the blue handled k-wire by twisting counterclockwise (reverse) (Figure 10) and pass the Nitinol loop passer, kite side first, down the SwitchCut reamer as shown (Figure 10a).

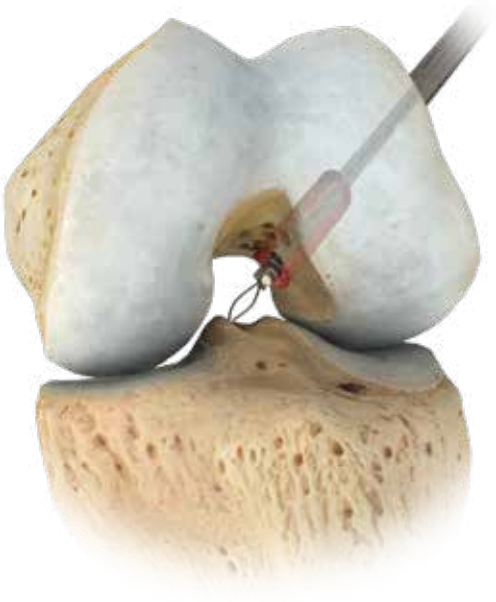

Figure 11

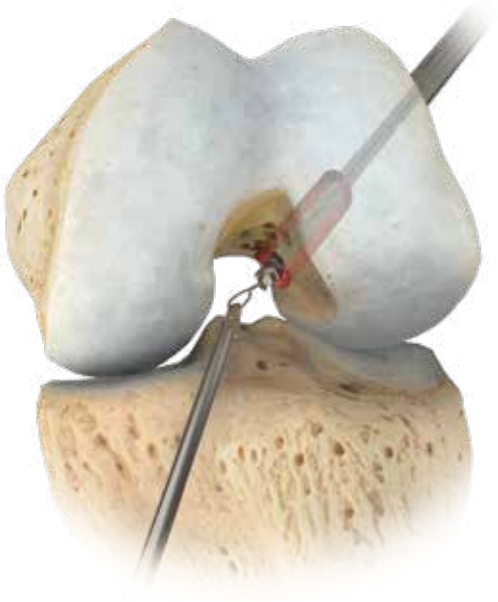

Figure 11a

Shuttle the Nitinol Loop Passer (cont.)

Pass the Nitinol loop passer until it is seen in the joint space. Use a suture retriever to pull the loop passer out of the joint space (Figures 11 and 11a).

Note: Once the loop passer is out of the joint space, gently remove the SwitchCut reamer by hand with a clockwise twisting motion. When the SwitchCut reamer has been withdrawn, bring both ends of the Nitinol wire together and clamp them using a hemostat.

Figure 12

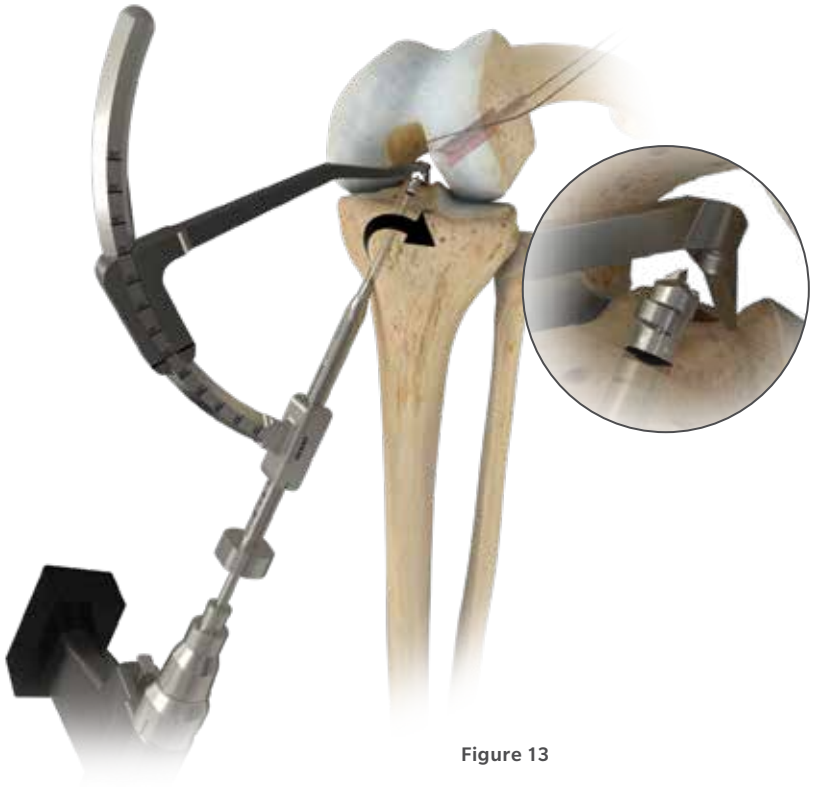

Figure 13

Tibial Tunnel Drilling

Before inserting the SwitchCut Tibial guide into the patient make sure the tibial guide is set between 50 and 60 degree based on patient's anatomy to accommodate a minimum tibial tunnel length of 30 mm. The SwitchCut Tibial guide is then placed in the heart of the tibial footprint in the medial half of the notch at the level of the anterior horn of the lateral meniscus. The SwitchCut Guide bullet is then locked into place on the tibial cortex through the hamstring harvest incision site. Read the laser etch marking on tibial bullet to determine the overall tibial tunnel length (Figure 12). Utilize the SwitchCut Drill that matches the diameter of the quadrupled hamstring graft. Drill in clockwise direction until the SwitchCut drill exits the tibial plateau and is capture by the elbow of the tibial guide (Figure 12 and 13). Rotate the bullet 90 degrees and remove the Tibial guide from joint space.

Set the blue grommet at the back of the bullet to monitor your tibial socket depth. The SwitchCut drill is run in reverse to the desired socket depth, aiming for a 5–10 mm boney bridge. Remove the blue handled k-wire from the SwitchCut drill and pass the nitinol kite through the reamer into the joint space. Use a retrieving instrument to pull the kite out the medial portal.

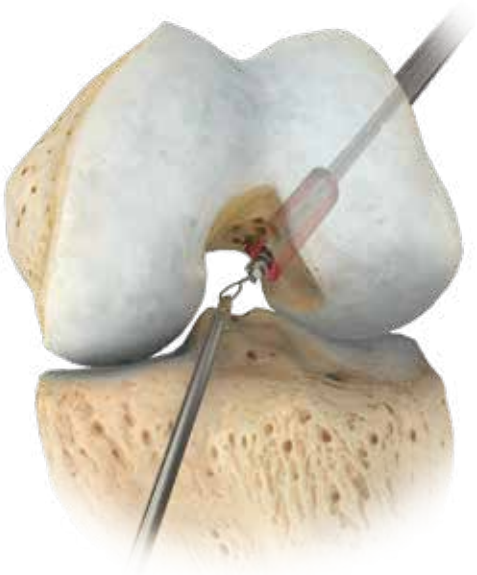

Figure 14

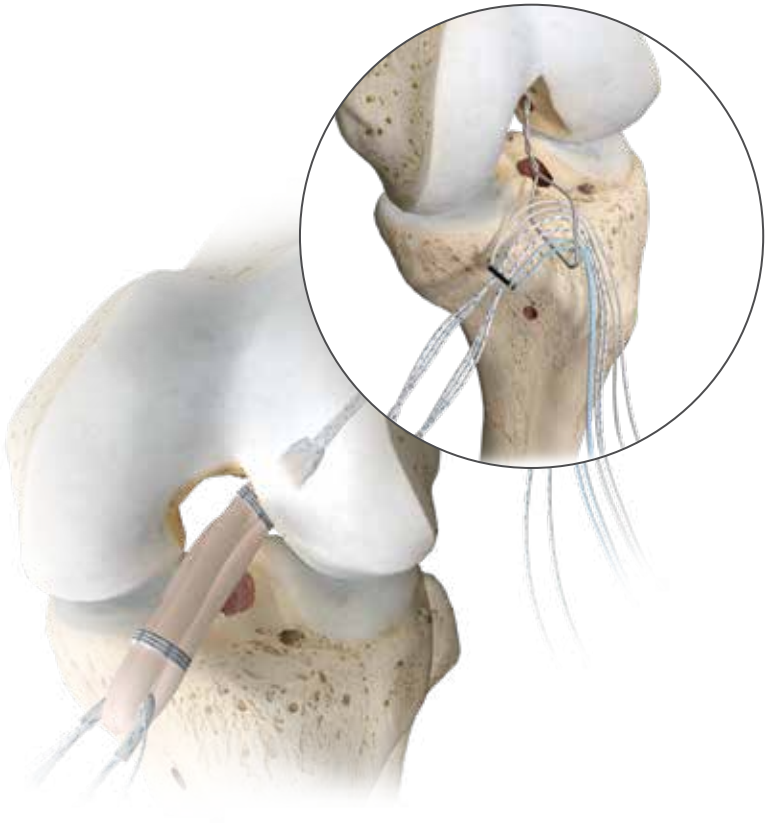

Figure 15

Graft Passage and Tensioning

Load all the ToggleLoc Flip passing, zipping, flipping strands (Figure 1a) into the SwitchCut nitinol kite that is passing through the femoral tunnel and outside the medial portal standard (Figure 14). Pull proximally on the kite to pass all six of the ToggleLoc Flip sutures described above through the portal and out the femoral tunnel to the lateral thigh. Use the white passing strands to advance the ToggleLoc Flip femoral button through the medial portal and onto the lateral cortex. Once the button exits the lateral femoral cortex the blue flipping sutures are pulled to secure fixation in place. Placing a mark on the ZipLoop strands equaling the interosseous tunnel length will help indicate that the button is beyond the lateral femoral cortex and ready to deploy (Figure 15).

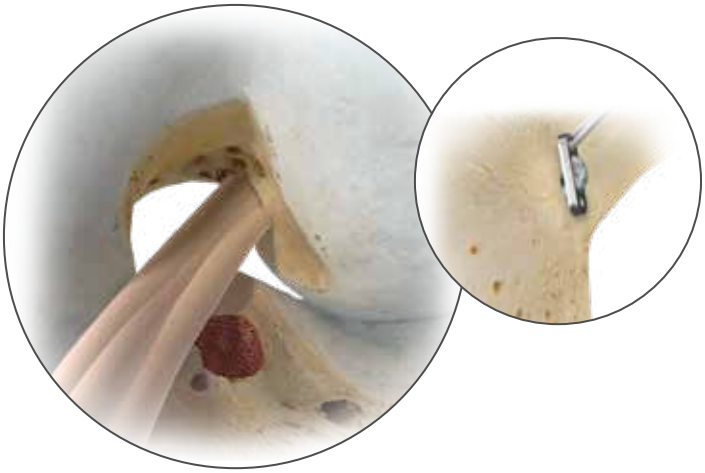

Figure 16

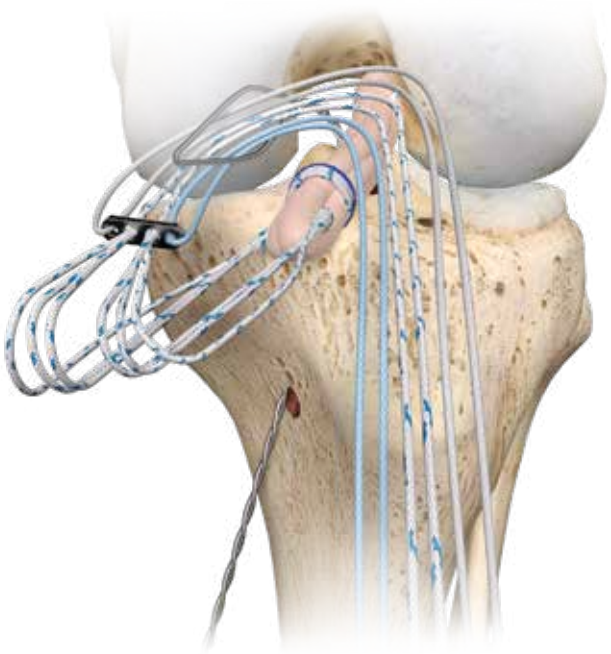

Figure 17

Graft Passage and Tensioning (cont.)

Advance the graft into the femoral socket using the zipping strands of the ToggleLoc Flip Inline with ZipLoop while maintaining slight back tension on the graft until 10 to 15 mm of graft fills the femoral socket (Figure 16). Ensure both zip strands are equal in length after zipping.

Using the tibial SwitchCut kite, shuttle all six passing, zipping, and flipping suture strands from the Tibial ToggleLoc Flip Inline device into the medial portal and down through the tibial tunnel. Then pull all six strands to shuttle the ToggleLoc Flip button through the medial portal and down through the tibial cortical hole.

Figure 18

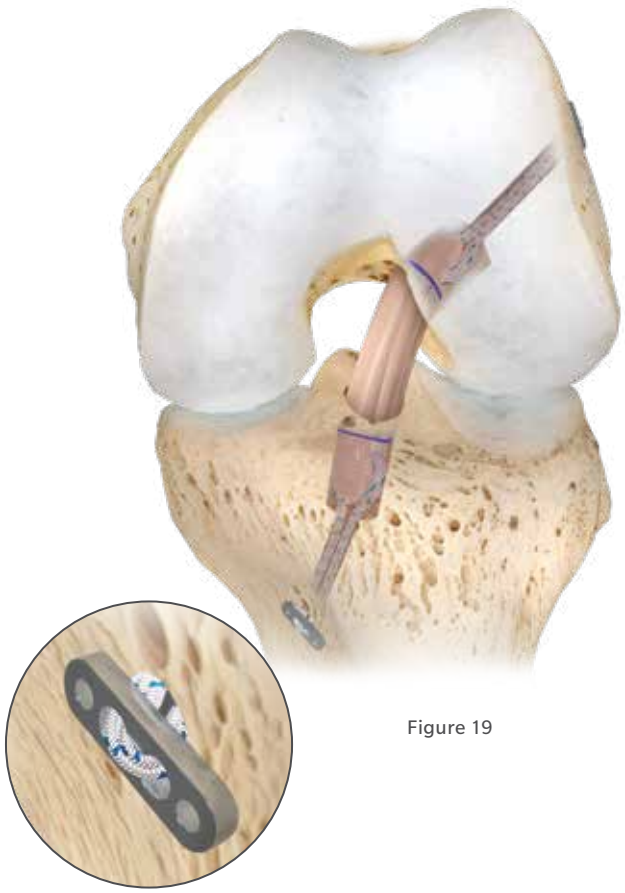

Figure 19

Graft Passage and Tensioning (cont.)

Hold the ToggleLoc button perpendicular to the tibial hole with needle drivers and slowly advance the button down to the tibial cortex by pulling on the ToggleLoc Inline with ZipLoop zipping strands (Figure 18). Continue this tensioning until the ToggleLoc button is flush to the tibial cortex (Figure 19). Adjust final tension on the femoral and tibial side using the zipping strands to ensure that the middle purple mark on the graft is approximately centered in the notch and the desired graft tension is achieved. Ensure zipping strands are equal in length. Tie core zip strands over the tibial button or washer for supplemental fixation if desired.

Alternative Technique: If the Tibial Tunnel socket is over-reamed completely through, then a desired washer or extender button in conjunction with the ToggleLoc Flip Inline should be used (Figure 20).

Figure 20

Ordering Information

Product Description	Size	Part Number
SwitchCut Reamer Kit	4.5 x 6.0 mm 4.5 x 6.5 mm 4.5 x 7.0 mm 4.5 x 7.5 mm 4.5 x 8.0 mm 4.5 x 8.5 mm 4.5 x 9.0 mm 4.5 x 9.5 mm 4.5 x 10 mm 6.0 x 11.0 mm 6.0 x 12.0 mm	110027674 110027675 110027676 110027677 110027678 110027679 110027680 110027681 110027682 110027684 110027686
SwitchCut Universal Guide Body	–	110026899
SwitchCut Femoral Guide Arm Right	–	110026900
SwitchCut Femoral Guide Arm Left	–	110026901
SwitchCut Tibial Guide Arm Point to Point	22 mm	110026903
SwitchCut Guide Bullet	4.5 mm ID 6.0 mm ID	110026898 110026902
ToggleLoc Flip Inline with ZipLoop Technology	–	OBAL80
BroadBand 25" Loop Blue/Black with Straight Tapered Needle	–	CM - 0306SN
BroadBand 25" Loop Blue with Straight Tapered Needle	–	CM - 0305SN
ExpressBraid Single White	–	110003540
ExpressBraid Single Blue/White	–	110003539
MaxBraid Suture 2 PK with Tapered Needle	–	CM-0222N

References

1. I.D.E.A.L. ACL Philosophy: Isometric, Direct fibers, Eccentric, Anatomic, Low tension Howell, S. M., McAllister, D., Pearle, A. D. 5 Points on Rationale for Strategic Graft Placement in Anterior Cruciate Ligament Reconstruction: I.D.E.A.L. Femoral Tunnel Position. The American Journal of Orthopedics. June; 2015 (1): 253–258.

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For indications, contraindications, warnings, precautions, potential adverse effects and patient counselling information, see the package insert or contact your local representative; visit legal manufacturer website for additional product information.

Please refer to the Instructions for Use and the package label for the products to be used with this surgical technique.

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Refer to the product labeling of each device for the legal manufacturer.

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Biomet Sports Medicine is the legal manufacturer of ExpressBraid sutures.

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Riverpoint Medical is the legal manufacturer of ToggleLoc Flip Inline with Ziploop Technology.

Jacobs Chuck is a trade mark of Apex Brands, Inc.

T.A.G. Medical Products Corporation Ltd. is the legal manufacturer of SwitchCut.

If using the ToggleLoc XL or ToggleLoc XL Inline, a 7-12 mm bi-cortical tunnel must be drilled.

Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity, and other variables. Not all patients are candidates for this product and/or procedure. Rx only.

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4132.1-GLBL-en-Issue Date 2023-02