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Ultra low displacement, ultra strong fixation and uniquely designed for graft protection.

ULTRABUTTON◇ Adjustable Fixation Device

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Product Overview

Unique Value Proposition

To the surgeon who prefers adjustable ACL fixation options, **ULTRABUTTON◇ Adjustable Fixation Device** is uniquely designed for graft protection while also featuring leading fixation strength and less displacement compared to other leading options with a simple one-handed reduction technique requiring minimal force.[1]

1. Data on file at Smith & Nephew, PN: 69889-01, 2016. The results of in vitro simulation testing have not been proven to predict clinical performance.

Product Description and Indications

DESCRIPTION

The ULTRABUTTON® Adjustable Fixation Device consists of a graft suspension loop and a titanium cortical button. The device facilitates repair / reconstruction through placement and retention of soft tissue within bone.

INDICATIONS FOR USE

The ULTRABUTTON® Adjustable Fixation Device is indicated for soft tissue to bone fixation for: 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, and Joint capsule closure.

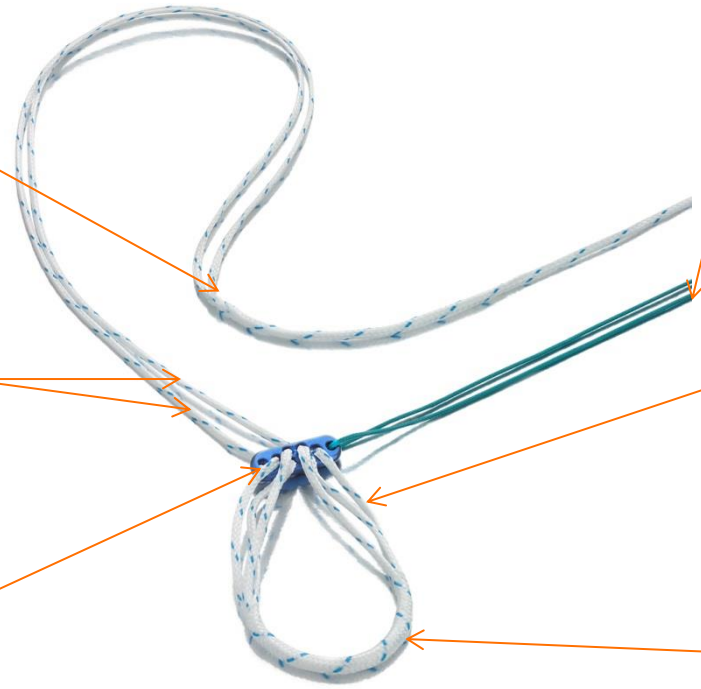
ULTRABUTTON◇ Adjustable Fixation Device

Ultra low displacement, ultra strong fixation and uniquely designed for graft protection.

Tail bridge
- Provides one-handed adjustment
- Helps ensure uniform graft ascension into tunnel

Adjustment tails
- Enable fine-tuning of fixation
- Employ a familiar loop reduction technique

Titanium button
- Strong with low profile
- Compatible with common extension devices



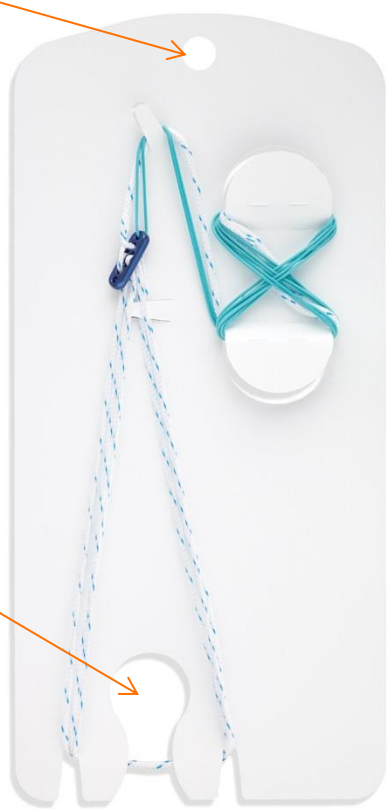
Flip suture
- Assists controlled button flip
- Easily removed when desired

Interlocking Adjustment
- Maximizes graft in tunnel
- Requires minimal force to reduce loop

Graft cradle
- Designed to protect graft with large contact area
- Designed to reduce relative motion and sawing effect between device and graft

Easy Graft Loading

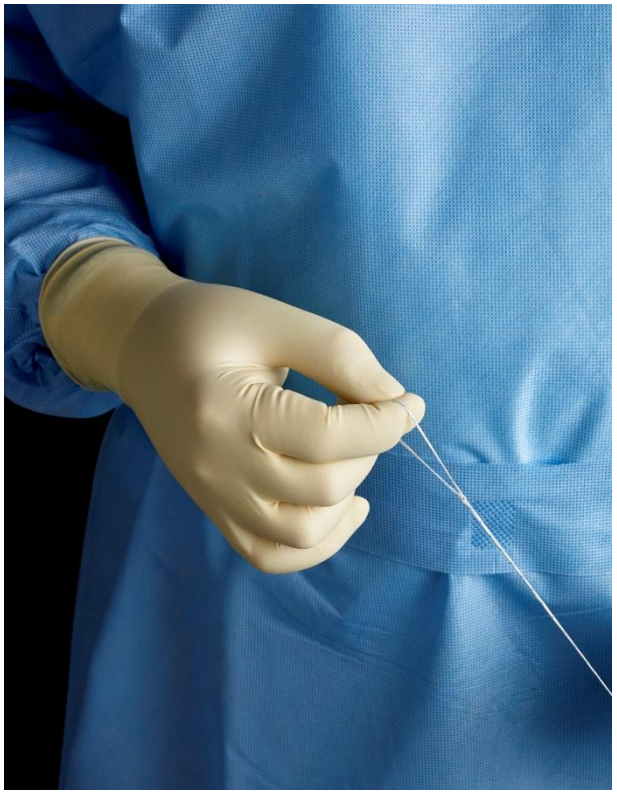
Hold the **SMALL** hole



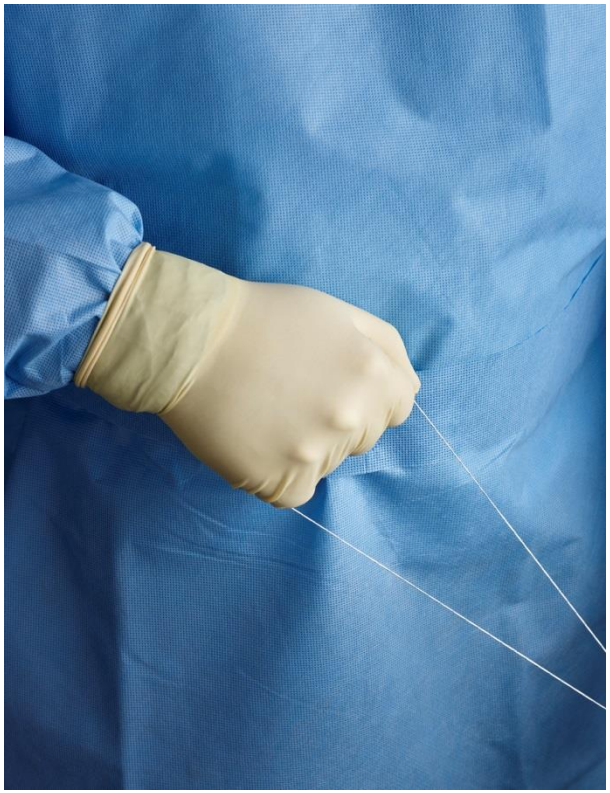
Load graft into **BIG** hole

One-handed Loop Reduction

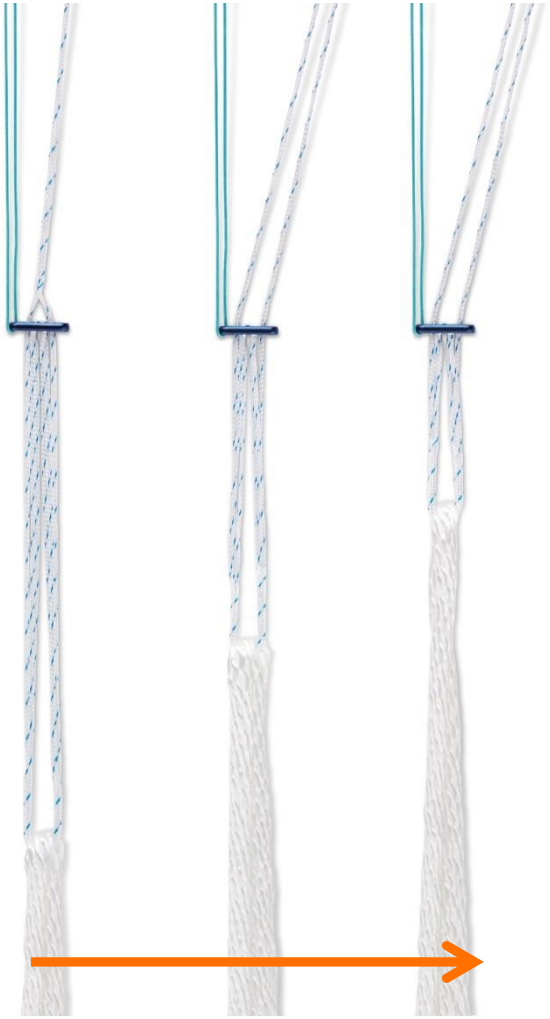
Finger Loop



Tail Bridge



Loop Can Only be Reduced, not Enlarged



Up to 60% Less Displacement

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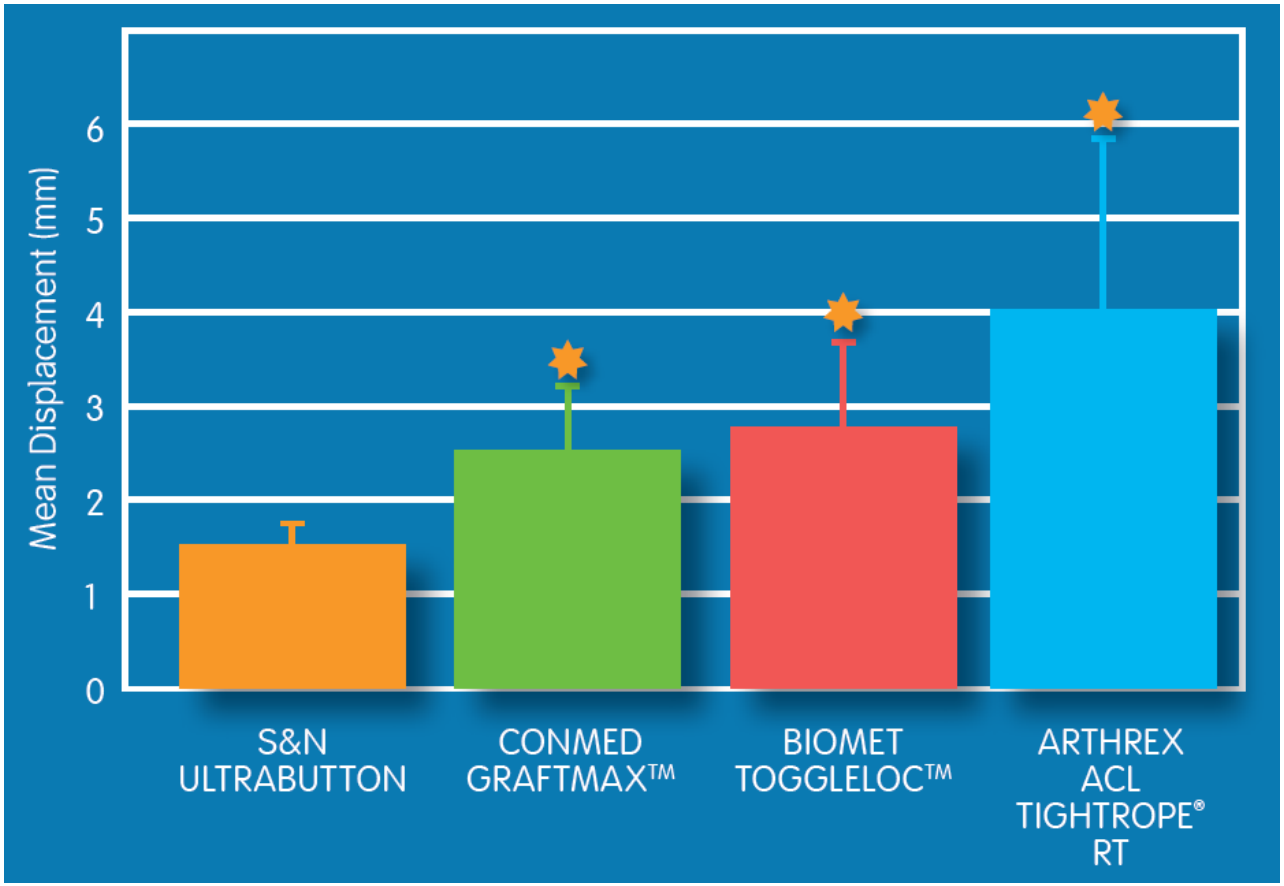
The ULTRABUTTON◇ Adjustable Fixation Device has less cyclic displacement after 4500 cycles in biomechanical testing when compared to leading competitors[1]

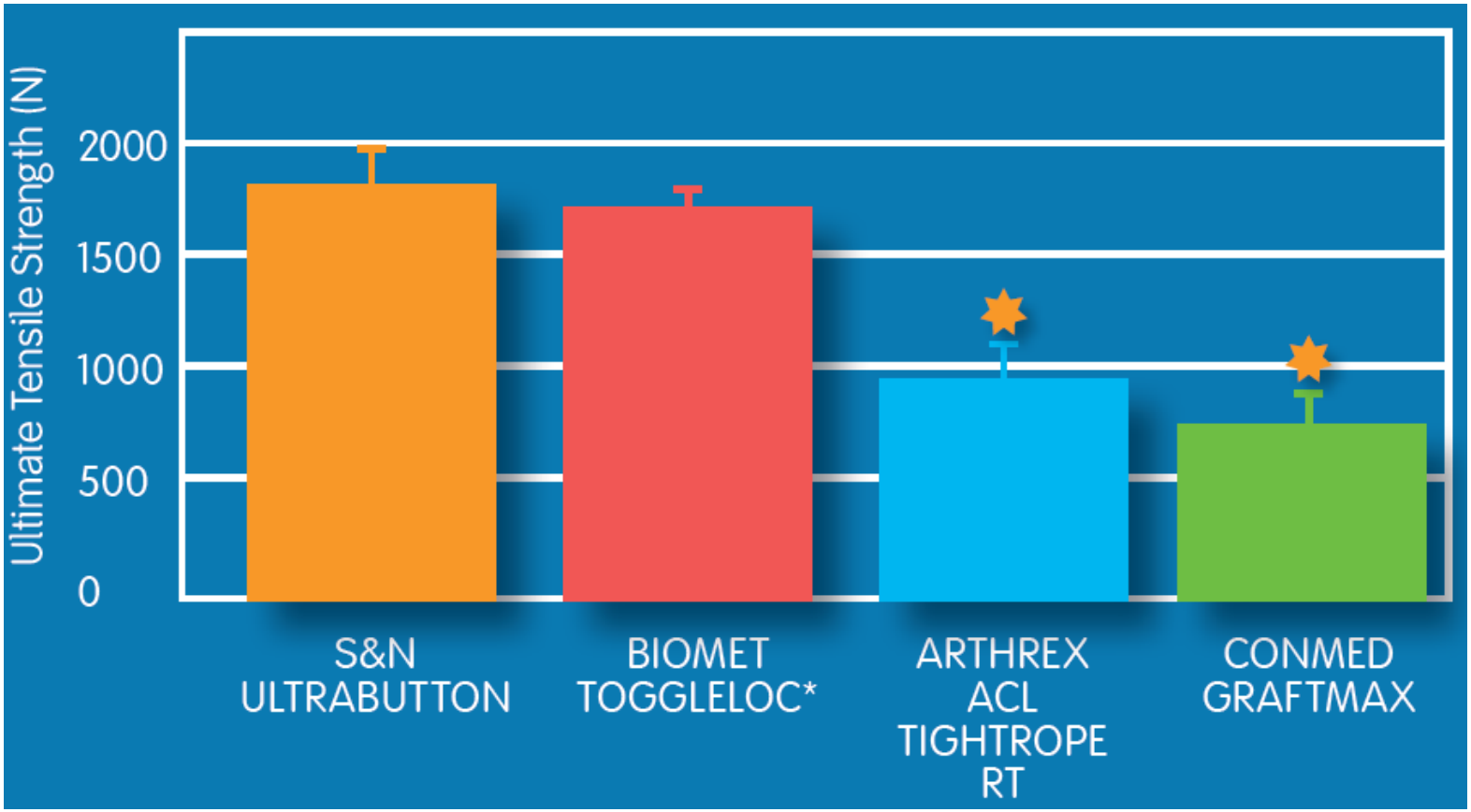


1. Data on file at Smith & Nephew, PN: 69889-01, 2016. The results of in vitro simulation testing have not been proven to predict clinical performance.

✸ Denotes comparison relative to the ULTRABUTTON Adjustable Fixation Device is statistically significant.

Leading Fixation Strength

The ULTRABUTTON◇ Adjustable Fixation Device provides stronger fixation when evaluated in biomechanical testing against leading competitors[1]



1. Data on file at Smith & Nephew, PN: 69889-01, 2016. The results of in vitro simulation testing have not been proven to predict clinical performance.

* Denotes comparison relative to the ULTRABUTTON Adjustable Fixation Device is statistically significant.

ULTRABUTTON® Device Ordering Information

- ULTRABUTTON® Adjustable Fixation Device 72290003
- Non-sterile version of the product **is NOT available**

Ancillary Device Ordering Info

Reference #	Description
7207315	4.5 mm Cannulated Drill
72202971	4.5 mm CLANCY™ Flexible Drill
7208678	2.4 mm x 15", Drill Tip passing pin, sterile, single use
7207220	2.4 mm x 17", TROCAR-Tip passing pin, sterile, single use
72201594	2.4 mm flexible passing pins, sterile (5 per package)
72203169	ACUFEX◊ Tunnel Gauge
72200134	XTENDOBUTTON◊ Fixation Device
72202589	Suture Cutter

ENDOBUTTON® CL ULTRA & ULTRABUTTON® Devices

	ENDOBUTTON CL ULTRA Device	ULTRABUTTON Device
Button	L: 12mm; W: 4mm; H: 2mm; 4 holes	Same; 8 holes
	Gold titanium	Blue titanium
Loop	Polyester	Ultrahigh Molecular Weight Polyethylene (UHMWPE)
	Fixed (11 SKUs); 10-60 mm, @ 5 mm	Adjustable (1 SKU); 10 - 90 mm
	Diameter = 5 mm	Diameter = 1.5 mm
Lead	White ULTRABRAID® # 5 suture	None – use flip suture
Flip	Green DURABRAID® #5 suture	Green #2 polyester suture
Adjust	None	White/blue adjustment tails

Technique Overview

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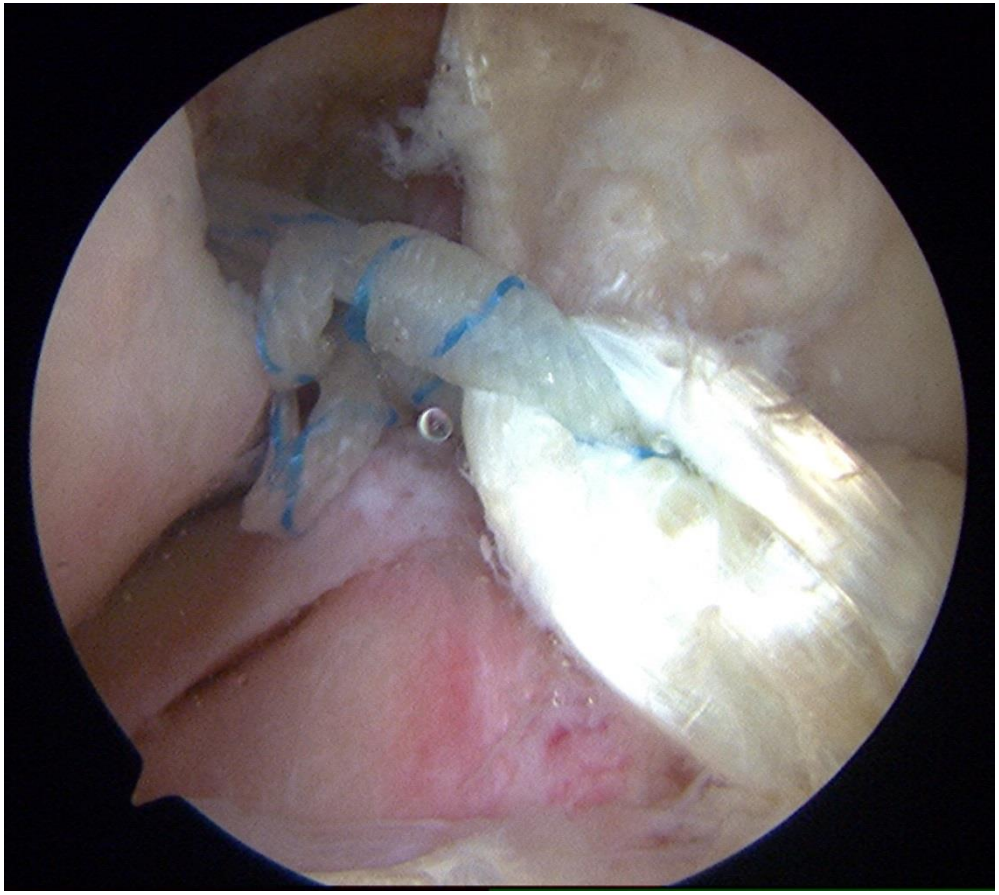
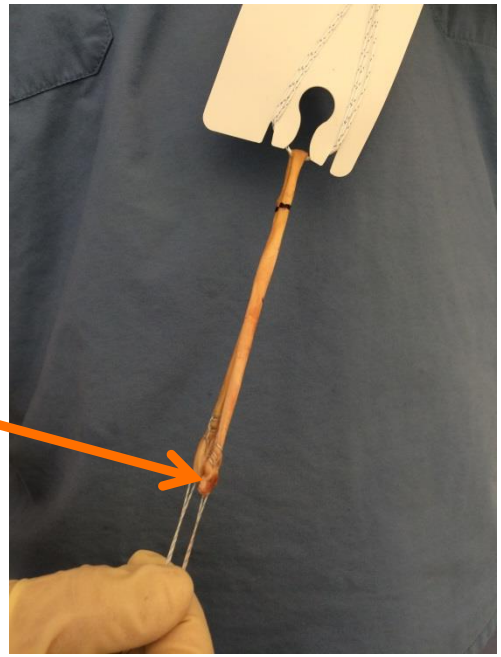
Technique at a Glance

1. Construct Preparation
2. Tunnel Creation
3. Suture Snaring
4. Button Flipping
5. Loop Reduction
6. Fine Tuning



Construct Prep: Loading Graft onto Backer Card

1. Use allograft or harvest soft tissue graft i.e. semitendinosus, gracillis or both, whip stitch graft tails and size the graft in a sizing block e.g. 7209214 Slotted Sizing Block
2. Feed one tail's whip stitches through the BIG hole at the bottom of the backer card
3. Line up the bottom of each of the tails so that the graft is centered on the graft cradle



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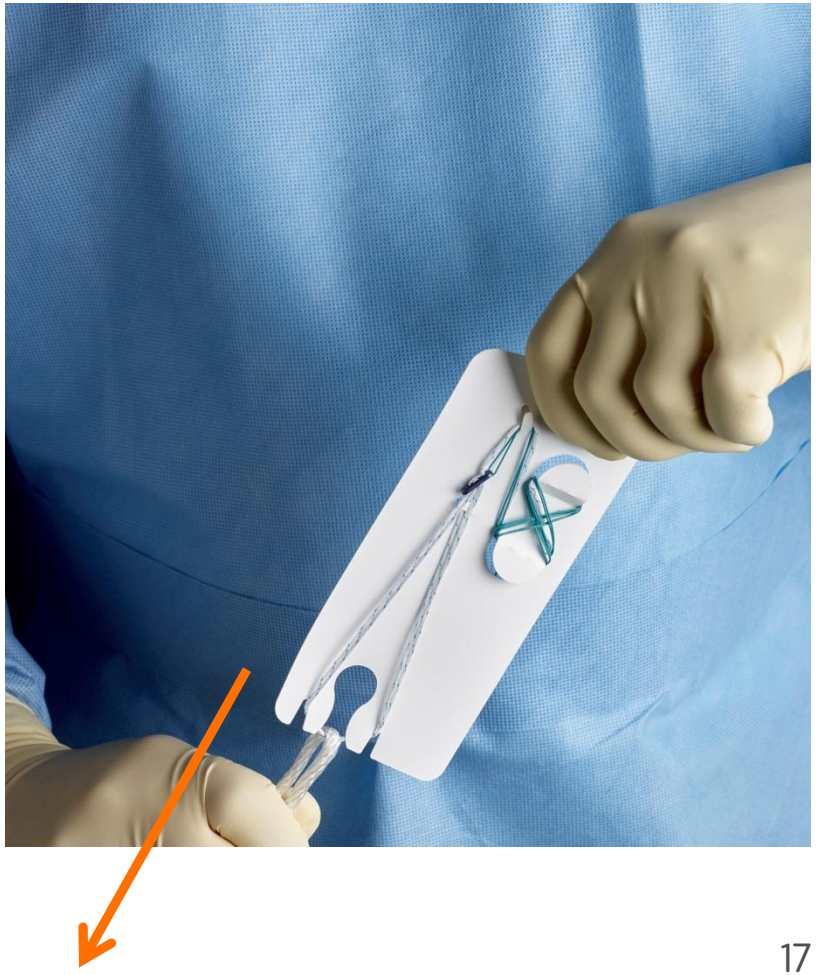
Removing Graft and Device from Backer Card

1. Hold the small circle with your non-dominant hand
2. Hold the loaded graft as shown with dominant hand and pull down
3. Graft is now ready for marking or passage

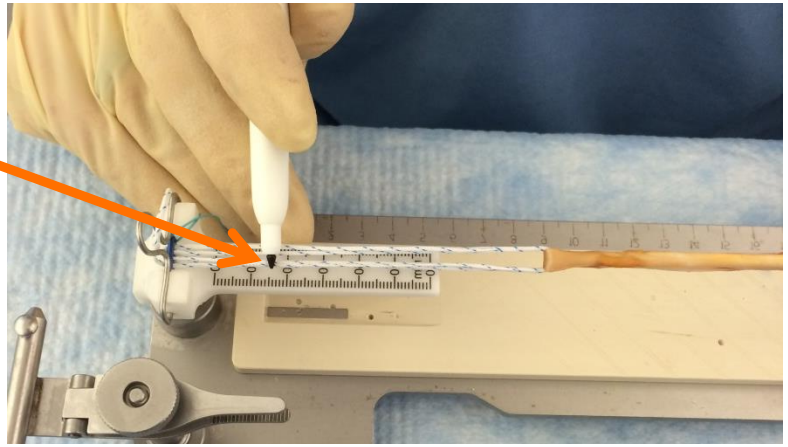


Optional Pearls: ULTRABUTTON® Device and Graft Marking

Pearl 1: Device Marking

What: Mark the length of the tunnel on the device

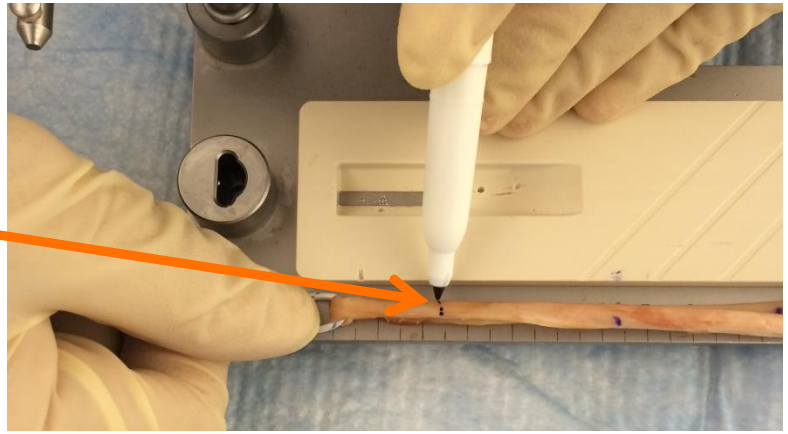
Why: Visual cue for surgeon to slow down green flip suture pulling because button will be close to flipping onto cortex



Pearl 2: Graft Marking

What: Mark the desired length of graft in the tunnel on the graft

Why: Visual cue for surgeon that desired graft length is in tunnel when flush with aperture



Note: This step is not required, but can be helpful to surgeons and can be done on the ACUFEX® GRAFTMASTER® III Graft Preparation System

Tunnel Creation

Use standard surgical drills/guidewires to create femoral tunnel/socket and tibial tunnel

Key items during tunnel creation:

1. **Use Passing Pin:**
   - 72201594 2.4 mm Flexible Passing Pin
   - 7207220 2.4 mm Trocar Tip Passing Pin
2. **Use a 4.5 mm drill**
   - 7207315 4.5 mm, sterile, disposable, single use or surgeon preferred 4.5 mm drill
3. **Measure femoral tunnel length**
   - 72203169 ACUFEX◇ Tunnel Gauge or surgeon preferred method
   - (Can eliminate this step by simply reading the drill too).

1

2

3

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Counter tension. Counter tension. Counter tension.

IMPORTANT: Always apply counter tension on the distal end of the graft during:

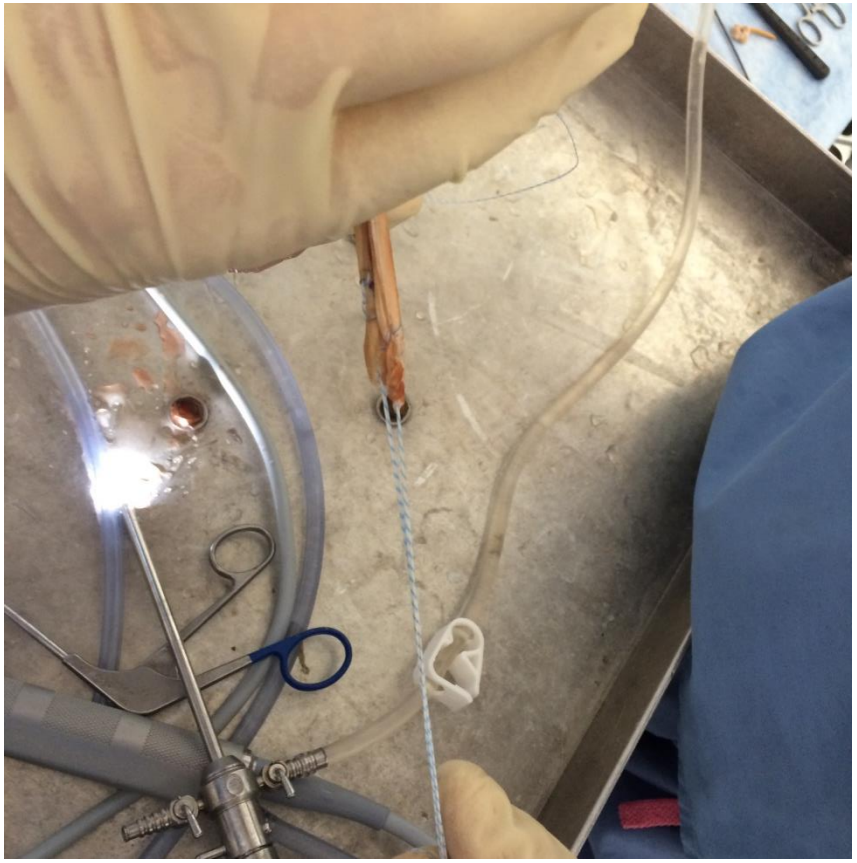
Button flipping: while pulling on the green flip suture

Initial reduction: while pulling on finger loop

Final reduction: while pulling on tail bridge

After knee cycling: while pulling on tail bridge

This is to minimize risk of the button passing through the Iliotibial (IT) Band and keep it flush to the femoral cortex.



Suture Snaring

1. Feed green AND adjustment tails into Snaring mechanism (passing pin eyelet, monofilament, suture etc.)

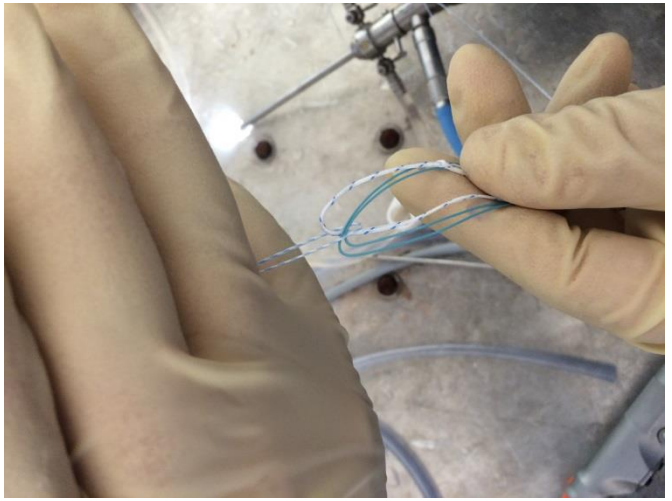
Tip: feed 5 cm superior to button

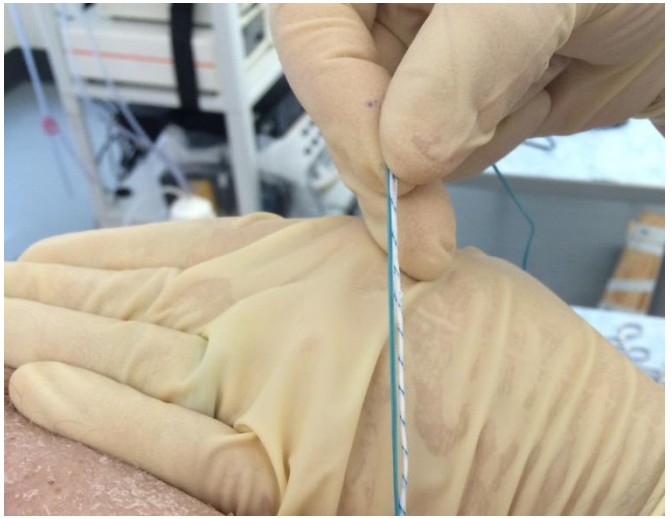
Tip: Ensure green tails line up

2. Hold the button/construct with dominant hand to ensure that button stays outside of knee

3. Pass the sutures with non-dominant hand so they come out of the lateral thigh

Tip: Make sure to **pull the green suture all the way out** as it is longer than the adjustment tails





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Flip Button Under Direct Visualization

Surgeon positions themselves at the knee as if "playing an accordion" and button flipping is like the "motion of flossing":

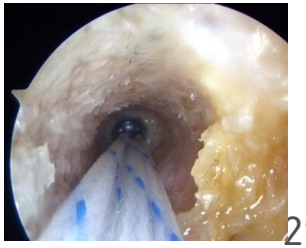
1. Place camera in preferred portal for viewing (AM)
2. Apply counter tension on distal graft tails and maintain counter tension throughout button flipping process

3. Pull on green flip suture till button reaches aperture

Tip: make sure there is no bunching of the adjustment tails, if there is, pull on finger loop to get the white suture taut

4. Continue to pull on the green suture and slow down when the button is close to the exiting the tunnel

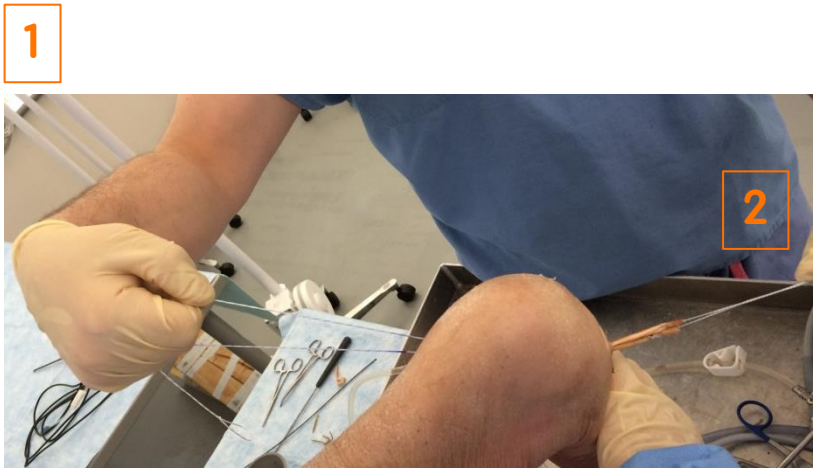
Tip: if ULTRABUTTON® device was marked, slow down when marking comes into view

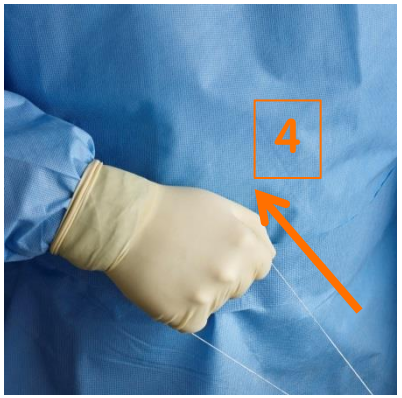


5. Watch the button flip and confirm it was flipped by not being able to pull button back down tunnel

Option 1: One-Handed Loop Reduction

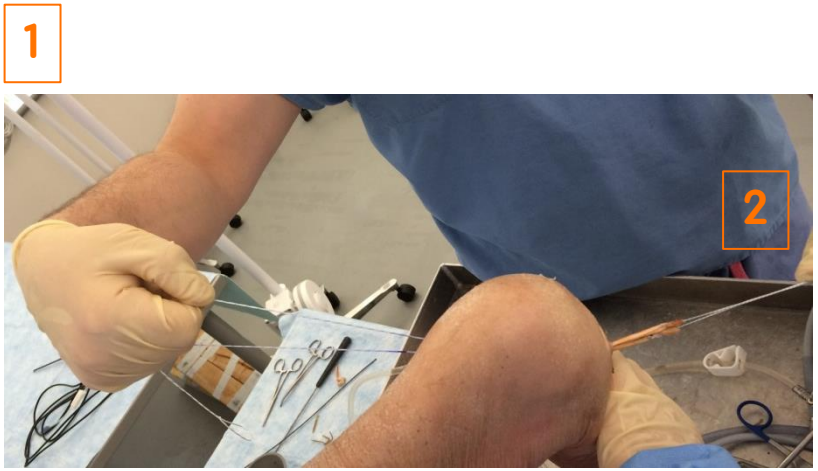
1. Surgeon can position themselves at the knee as if "playing an accordion":
2. Non-dominant hand holds counter-tension throughout reduction
3. Dominant hand pulls on finger loop for **initial reduction i.e.** till 8-10 cm of tail bridge are expressed
4. Dominant hand pulls on tail bridge directly up or in a rocking motion for **final reduction i.e.** till graft reaches the socket back wall

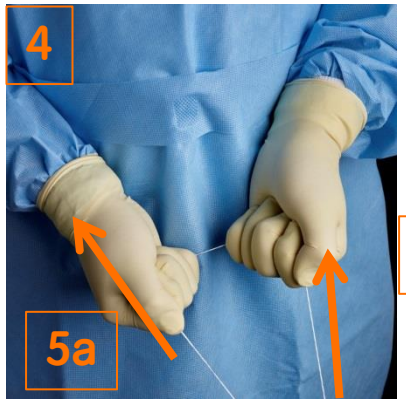




Option 2: Two-Handed Loop Reduction

1. Surgeon can position themselves at the knee as if “playing an accordion”
2. Non-dominant hand holds counter-tension throughout reduction
3. Dominant hand pulls on finger loop for **initial reduction i.e.** till 8-10 cm of tail bridge are expressed
4. Surgeon position on lateral side of knee, with **2nd person maintaining counter-tension**
5. Pulling on one tail at a time:
   a) Pull on one tail for 3-5 mm
   b) Followed by other tail for 3-5 mm
6. Repeat previous step till **final reduction complete i.e.** till graft reaches the socket back wall





Fine Tuning: Cycling, post-Tibial, Tail Knots/Cutting

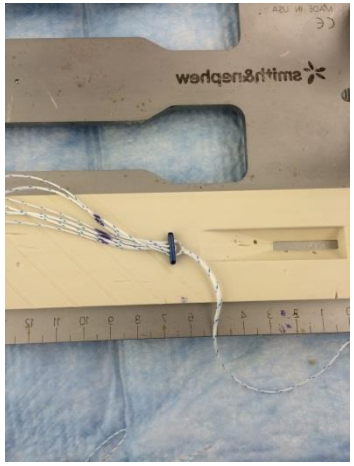
1. Depending on surgeon preference, cycle knee 10-20x
    1. Pull on tail bridge / adjustment tails per previous technique to ensure graft has reached the back of the socket wall
2. Depending on surgeon preference, complete tibial fixation
    1. Pull on tail bridge / adjustment tails per previous technique to ensure graft has reached the back of the socket wall
3. Cut adjustment tails using a suture cutter by cutting each tail below the tail bridge and then feed suture cutter down to 1-2 mm above the button and cut tail

Optional per surgeon preference: tie knot(s) using tails

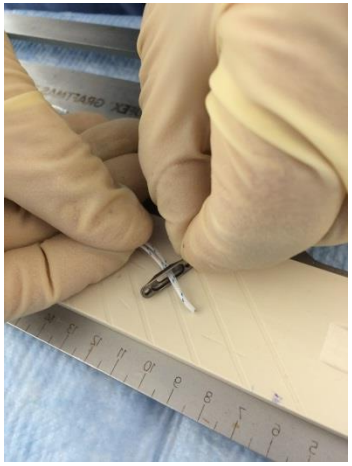
A solution to cortical blowouts...

...XTENDOBUTTON® Fixation Device

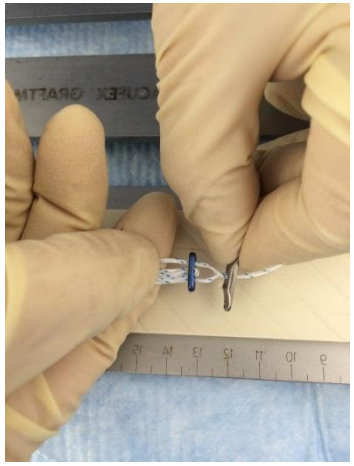
Loading ULTRABUTTON◇ Device into XTENDOBUTTON◇ Device, Need a Free Suture (not included in package)



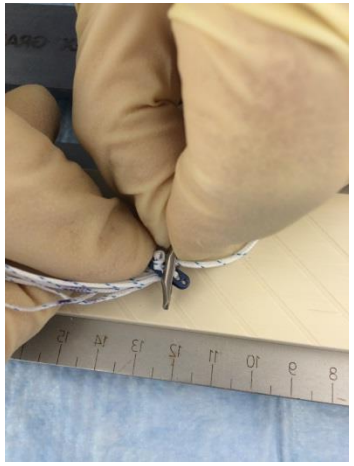
1. Remove green suture



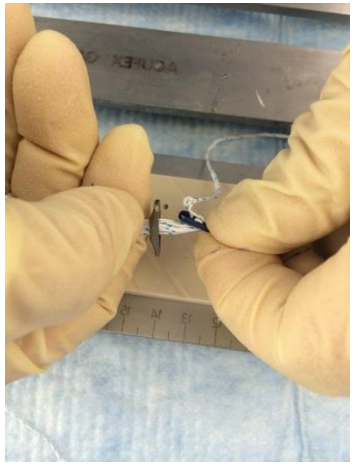
2. Feed finger loop through XB



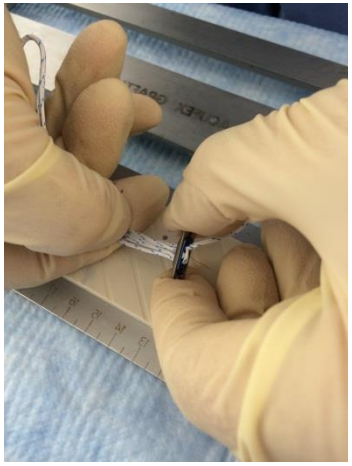
3. Pass XB down to UB



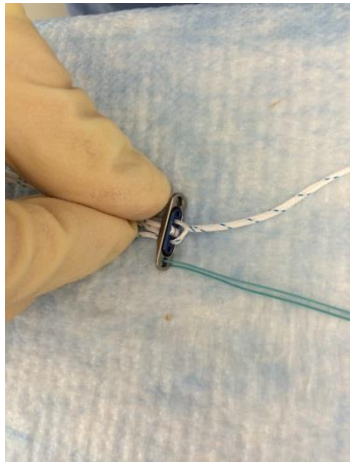
4. Feed UB through XB



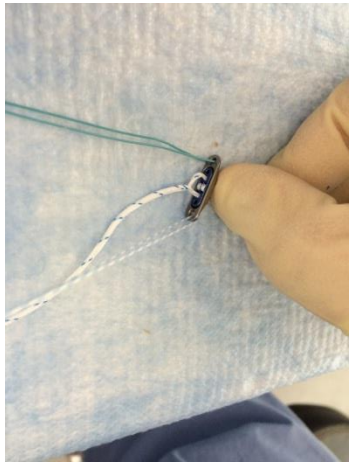
5. Ensure UB is through XB



6. Seat UB into XB cavity



7. Feed green suture into XB



8. Feed free suture into XB

References

1. Femoral Suspension Devices for Anterior Cruciate Ligament Reconstruction. Do Adjustable Loops Lengthen? Barrow et al. Am J Sports Med 2014 42: 343
2. 69889 Test Protocol: Comparative Testing of ULTRABUTTON◇ Adjustable Fixation Device to Competitive Devices
3. 69889-01 Test Report: Comparative Testing of ULTRABUTTON Adjustable Fixation Device to Competitive Devices
4. 66856 ULTRABUTTON Adjustable Fixation Device Instructions for Use

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PN: 71577 Rev. A 02/16