

VersaFIX

Meniscal Repair System

Versafix comes loaded with two implants which are sent vertically or horizontally to either side of the meniscus.

The system is designed to tighten and cut excess suture in sequential gestures using only one hand.

The quality of the molded parts, the laser cut parts, the molded implants and the meticulous assembly ensures that each instrument will perform flawlessly and consistently every time.

INCREASED

RELIABILITY

ENHANCED

ACCESSIBILITY

IN

MENISCAL

REPAIR



Lazer Cut Needle

Low profile laser cut needle reduces damage to the meniscus upon insertion.

Flexible needles available with 12 and 18 curves. User may bend needles further for easier access to anterior lesions.

Improvement of needle design avoids misfires of implant, common in competitive designs.

SOLID Peek Implant

Solid peek implants have no weak point and ensure strong fixation while keeping meniscal damage from insertion to a minimum.

UHMWPE Suture

Blue co-braid USP 2-0 UHMWPE suture helps user identify suture while providing strength needed for secure fixation.

Depth Setter

Adjustable depth setter permits optimal placement of implants. Fully retracted needle rests within blunt plastic sheath obviating need for cannula.

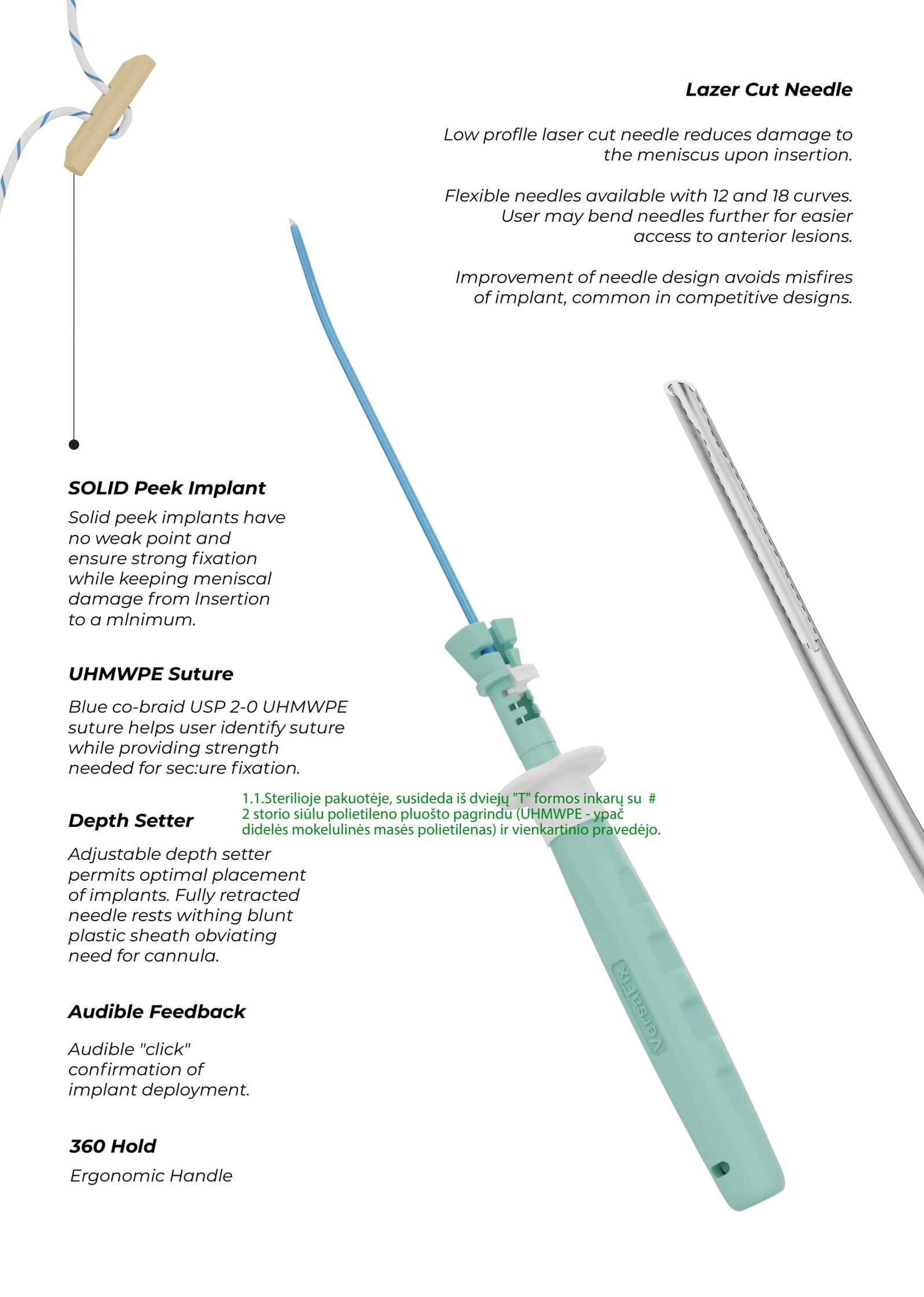
Audible Feedback

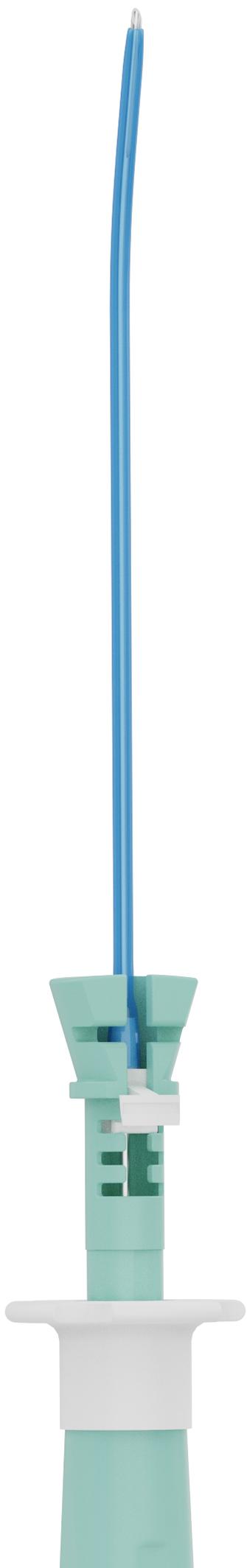
Audible "click" confirmation of implant deployment.

360 Hold

Ergonomic Handle

1.1. Sterilioje pakuotėje, susideda iš dviejų "T" formos inkarų su # 2 storio siūlu polietileno pluošto pagrindu (UHMWPE - ypač didelės molekulinės masės polietilenas) ir vienkartinio pravedėjo.





How is **VersaFIX** better?

The meniscus provides load transmission, shock absorption, joint stability, lubrication and plays a critical role in cartilage nutrition and neuromuscular proprioception. The meniscus contributes to optimal knee joint function. Clinical studies show that even partial meniscectomy can cause early joint chondrosis and has been shown to cause arthritis. As a result, repair of red/white meniscal tears is now standard care.

The all inside arthroscopic suture-based technique has addressed many of the limitations of the inside-out and outside-in techniques.

The technique based entirely on inside stitching has gained popularity due to the following advantages:

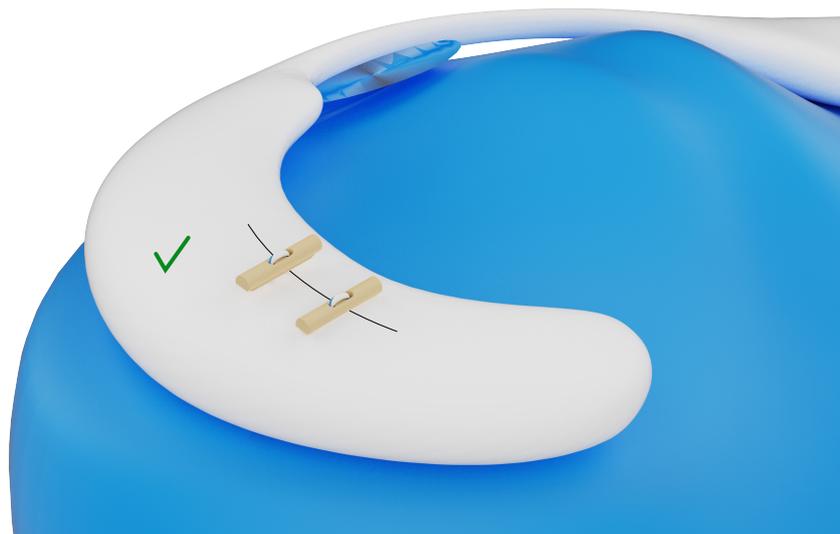
Repair can be done safely without a posterior incision.

The technique provides easy access to tears in the posterior and middle third of the meniscus.

Repair can be done without a trained assistant.

The technique allows placement of vertical or horizontal matrix sutures on the femoral or tibial surface of the meniscus.

These advantages allow for minimally invasive meniscal repair, resulting in less postoperative pain and morbidity for patients.



Comperative Study

The purpose of this study is to document and evaluate the biomechanical performance of VersaFix Meniscal Repair System.

Since there is no standardized test method for evaluating performance of meniscal repair systems, a literature search was performed. All comparable studies were performed on human or animal cadaveric menisci. Thus, 12 fresh bovine menisci were prepared since bovine menisci show biomechanical similarity to human menisci. To insure all the samples prepared similarly, 3D printed template is used to mark the artificial tear.

VersaFix Meniscal Repair System comes preloaded with UHMWPE USP 2-0 suture and PEEK implants (1.1 mm x 5 mm and 1.1 mm x 6 mm).

The Tear

Tears were repaired with a single stitch used in comparable studies. VersaFix uses a USP 2-0 nonabsorbable UHMWPE suture.

Sutured meniscus was secured to fixture jaws with stainless steel wire as shown in figure.

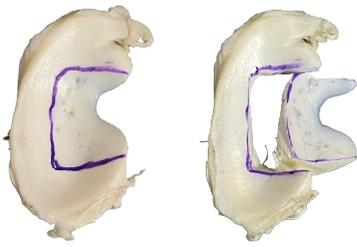


Figure A - Marked menisci and surgically torn meniscus



Figure B - Repaired meniscus

The Test

Test is started after a preload of 15 N is applied for 45 seconds to tension the steel wires enough to remove their effect on testing. Then a cyclic load ranging from 5 N to 20 N for 1000 cycles at a frequency of 0.5 Hz applied to fixated menisci. After the cyclic loading elongation is measured. This methodology is adopted to mimic in vivo postoperative loads after repair.

Peak load is measured on top of elongation after cyclic loading. Load-to-failure testing was performed at a rate of 0.5mm/s until failure. Yield load, displacement at yield load, stiffness, ultimate failure load and displacement at ultimate failure were analyzed.



The Results

Summary of the mechanical performance of various meniscal repair devices are presented below at Table 1.

System/Technique	Displacement after 1000 cycles, mm (± Std Dev)	Mean failure Load, N (± Std Dev)	Stiffness, N/mm (± Std Dev)
Smith & Nephew FAST-FIX 360 Meniscal Repair System	1.99 (0.70)	74.6 (11.3)	23.4 (2.20)
Smith & Nephew FAST-FIX Meniscal Repair System	2.32 (0.51)	66.6 (5.69)	20.1 (2.02)
Vertical mattress stitch (Ticron 2-0)	2.78 (0.47)	74.8 (5.54)	20.5 (1.16)
Arthrex MeniscalCinch Repair System	4.48 (0.95)	51.6 (11.8)	20.7 (4.81)
Biomet MaxFire Meniscal Repair System	N/A	15.9 (2.92)	N/A
Mitek RapidLoc Meniscal Repair System	3.59 (0.68)	36.9 (1.86)	17.1 (1.84)
Cayenne CrossFix Meniscal Repair System	3.64 (0.73)	35.0 (9.85)	20.2 (1.63)
Grandus VersaFix Meniscal Repair System	2.08 (0.61)	78.8 (7.9)	22.8 (1.75)

Table 1. Summary of the mechanical performance of various meniscal repair devices.

Table 1 is taken from "The Biomechanical Performance of the FAST-FIX 360 Meniscal Repair System". VersaFix Meniscal Repair System performance data is added to the bottom of the table for comparison.

VersaFIX

Versafix & Cutter

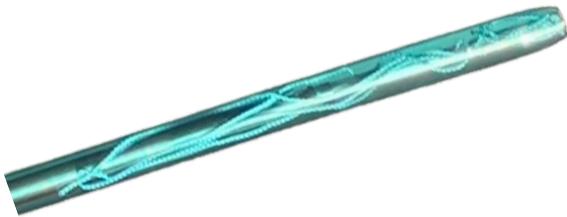


VERSAFIX ALL-INSIDE MENISCAL REPAIR SYSTEM SURGICAL GUIDE



1

Utilize the Meniscal Probe to evaluate the required penetration depth at the tear location. Adjust the depth limiter accordingly to match the appropriate distance. The depth probe is designed to gauge the meniscus thickness, allowing the surgeon to determine the correct needle exposure



2

Guide the VersaFix delivery needle into the joint via the designated arthroscopic portal. The insertion process can be aided by using a slotted cannula. Pass the delivery needle through the slotted cannula into the joint. Once positioned within the joint, the slotted cannula can be removed if preferred. Alternatively, the delivery needle may be inserted directly into the joint without a cannula by covering the needle during introduction. To cover the needle, adjust its exposure by pressing the depth tube lock while simultaneously sliding the lock toward the needle

3



Position the needle tip at the targeted entry point and carefully penetrate the meniscus. Advance the delivery needle until the depth penetration limiter contacts the meniscus surface. While maintaining the needle's position, push the deployment slider forward to release T1. Proper implant deployment is confirmed through tactile, auditory, and visual feedback. To optimize suture management and prevent dislodging the second implant (T2), release the deployment slider and slowly retract the needle from the meniscus, keeping it within the arthroscopic view.

TIP: Utilize the slotted cannula to stabilize the meniscus, improve visualization, and reduce the likelihood of needle skiving, ensuring more precise implant placement.

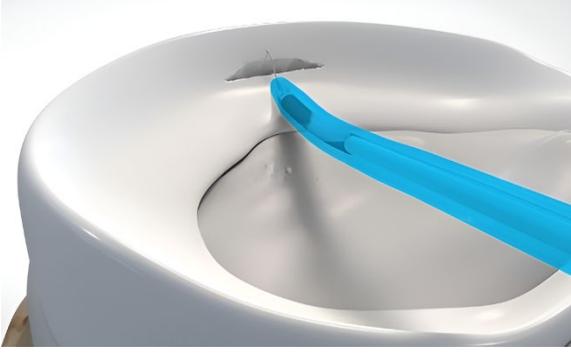
WARNING: Avoid pressing the deployment slider a second time, as this will cause premature deployment of the second implant.

Triple Confirmation of VersaFix Implant Deployment:

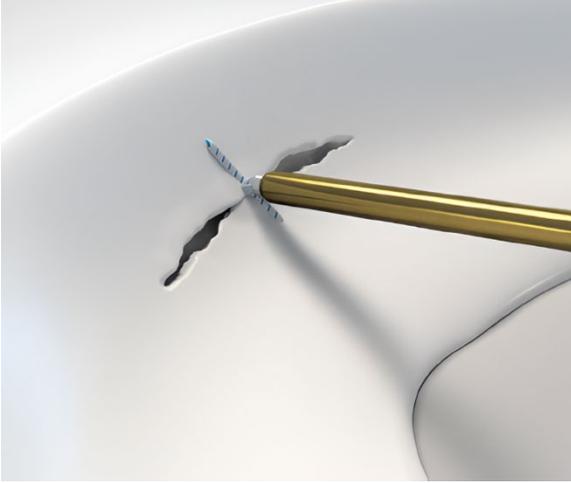


- The White Deployment Knob will move halfway and stop at an internal barrier (Tactile Feedback).
- A 'clicking' sound will indicate successful implant deployment after the internal stop is reached (Auditory Feedback).
- The surgeon will be unable to retract the deployment knob and will observe the T1 travel distance (Visual Feedback)

Withdraw the needle from the initial deployment site and reposition the needle tip to bridge the tear. The entry point for the second implant (T2) should be placed at least



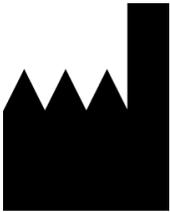
5mm away from the tear site. Advance the delivery needle until the depth penetration limiter contacts the meniscus surface. While keeping the needle steady, push the deployment slider fully forward to release T2. As with T1, successful implant deployment is confirmed through tactile, auditory, and visual feedback. After T2 is deployed, slowly retract the delivery needle from the meniscus and the joint



Pass the free end of the suture through the groove at the end of the knot pusher/suture cutter

Keep the suture coming out of the groove taut.

The surface of the knot pusher/suture cutter that contacts the knot is not sharp. While continuing to hold the suture taut, advance the knot with the knot pusher until the desired tension is achieved. After the knot is placed at the desired tightness, cut the suture coming out of the groove by sliding the trigger of the cutter forward while continuing to hold the suture taut.



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