

5. Pirktimo būlin

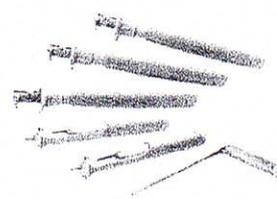
Meniscal Repair Systems  
FAST-FIX® (all-inside)

Menisko nuovimo interinė sistema

FAST-FIX 360

The FAST-FIX 360 meniscal repair system offers exceptional fixation strength, easier implant deployment, smaller insertion points that minimize disruption to the meniscus, a built in depth penetration limiter and a stiffer needle shaft for enhanced control. All this to help optimize the meniscus repair.

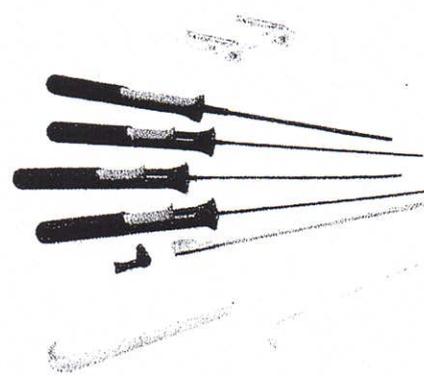
Reference #	Description
72202467	FAST-FIX 360 straight
72202468	FAST-FIX 360 curved
72202469	FAST-FIX 360 reverse curved
72202674	FAST-FIX 360 Straight Knot Pusher/Cutter and Slotted Cannula sets
72202675	FAST-FIX 360 Curved Knot Pusher/Cutter and Slotted Cannula sets



ULTRA FAST-FIX

Reference #	Description
72201490	ULTRA FAST-FIX, straight
72201493	ULTRA FAST-FIX, AB, straight
72201491	ULTRA FAST-FIX, curved
72201494	ULTRA FAST-FIX AB, curved
72201492	ULTRA FAST-FIX, reverse curved
72201495	ULTRA FAST-FIX AB, reverse curved
72201537	Knot Pusher/Suture Cutter, straight

5.2  
5.3  
5.6



Probe, Rasp and Accessories

015186	Meniscal Depth Probe
014549	45° Diamond Rasp
014550	90° Diamond Rasp
011703	Sterilization Tray, 9.25" W x 3" L x 1.5" H
7210977	Slotted Cannula
7209950	Suture Threaders, sterile (10 per box)
7210450	Suture Funnel, sterile (10 per box)



Kopija tikra  
Vadovo asistentė  
Beata Veličkienė

2016-03-09

**Menisko siuvimo sistemos****FAST-FIX**

FAST-FIX menisko siuvimo sistemos išskirtinumas:

- fiksacija yra ypatingai stipri ir paprasta
- implantu dislokacija
- mažesni įvedimo taškai, kurie sumažina menisko pažeidimus
- įsiskverbimo gilumo ribotumas
- tvirtesnė veleno adata

Visi šie bruožai padidina menisko siuvimo procedūros sėkmingumą.

Ref	Parametrai
72202467	FAST-FIX 360 tiesus
72202468	FAST-FIX 360 lenktas
72202469	FAST-FIX 360 atvirkščiai lenktas
72202470	FAST-FIX 360 AB, tiesus
72202471	FAST-FIX 360 AB, lenktas
72202472	FAST-FIX 360 AB, atvirkščiai lenktas
72202474	FAST-FIX 360 tiesus mazgo nustūmėjas/nukirpėjas ir pailgų kaniulių rinkinys
72202475	FAST-FIX 360 lenktas mazgo nustūmėjas/nukirpėjas ir pailgų kaniulių rinkinys

Ref	Parametrai
72201491	ULTRA FAST-FIX, lenktas
72201492	ULTRA FAST-FIX, atvirkščiai lenktas
72201494	ULTRA FAST-FIX AB, lenktas
72201495	ULTRA FAST-FIX AB, atvirkščiai lenktas
72201490	ULTRA FAST-FIX, tiesus
72201493	ULTRA FAST-FIX, AB, tiesus
72201537	mazgo nustūmėjas/nukirpėjas, tiesus

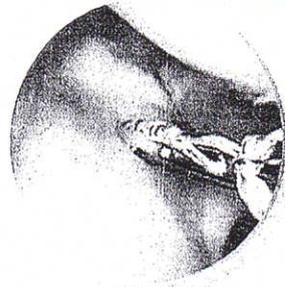
Priedai	
015186	Menisko gylis matuoklis
014549	45 <sup>0</sup> deimantinė dildė
014550	90 <sup>0</sup> deimantinė dildė
011703	Sterilizavimo dėklas, 9.25" x 3" x 1.5"
7210977	Kaniulė
7209950	Siūlo pravedėjai, sterilūs, dėžutė 10 vnt.
7210450	siūlo nukreipėjai, sterilūs, dėžutė 10 vnt.



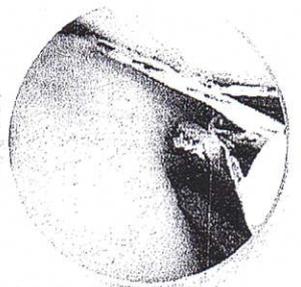
LIETUVOS RESPUBLIKA  
**OSTECA** ©  
 Kopija tikra  
 Vadovo asistentė  
 Neringa Veličkienė "Osteca"  
 2016-03-09

5.5

iš anksto paruošto  
 slydintinio mezgimo



1 Deploy preloaded implant 1.



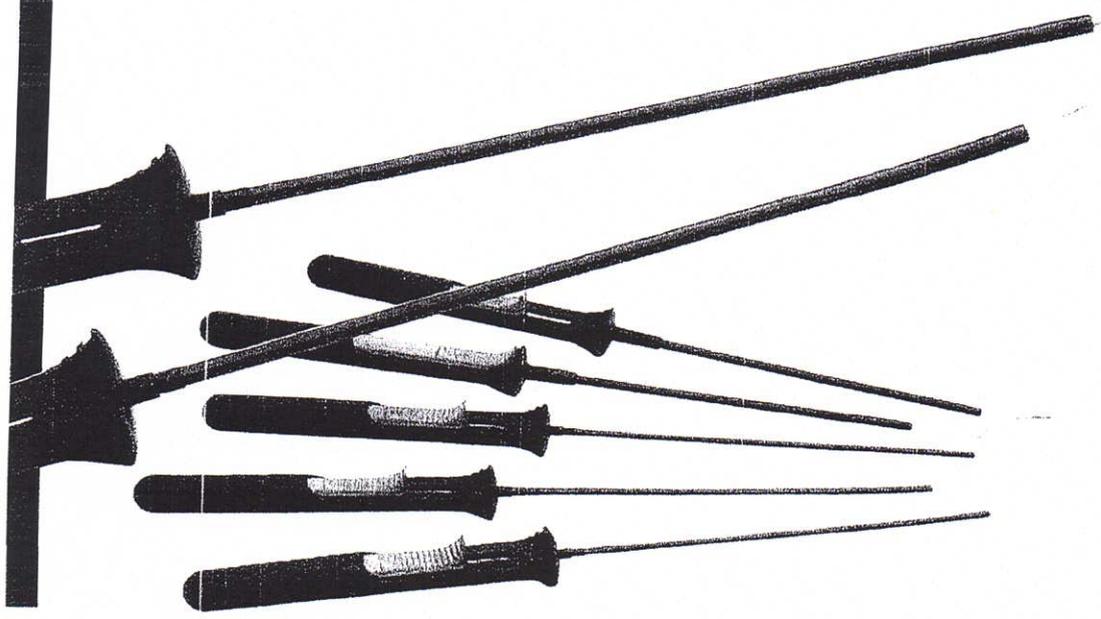
2 Deploy preloaded implant 2.

THE TECHNIQUE

The **ULTRA FAST-FIX<sup>®</sup> Meniscal Repair System** is a unique all-inside implant system, offering the fixation strength of an open-vertical mattress stitch without the invasive surgical procedure normally required for suture-based repairs.

When the original FAST-FIX<sup>®</sup> Meniscal Repair System was introduced in 2001, it set the benchmark for minimally-invasive, all-inside repairs. Thanks to its preloaded implants, pre-tied sliding knot, and innovative pusher/cutter device, this innovative system lets you deploy two implants vertically or horizontally on either side of the meniscus, lighten the suture and trim the excess.

Building on its proven clinical success, the all-new ULTRA FAST-FIX system adds easier knot sliding and stronger suture. The result is a faster, more secure meniscal repair system that will help maximize the chances of a successful meniscus tear recovery.

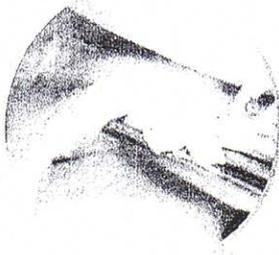




5.5

**3** Slide the pre-tied knot, tighten the suture, and trim the excess.

*Pis antisto perivosto, slystantis margo.*



**4** Use the reverse-curved needle to repair tears on the inferior surface (fibial side).



**5** Completed repair with vertical and horizontal mattress stitches.

*reversine' vertija 5.6*

*5.3 Chemine' sudetis PLLA*

Kopija tikra

Vadovo asistentė  
Neringa Veličkienė

2016-03-09



### Fast and easy

Unlike conventional suture-based repair systems, the ULTRA FAST-FIX system is an implant system with a pre-tied, self-sliding knot that eliminates the need for intra-articular knot tying.

### Strong and clinically proven

Provides a strong, reproducible and reliable meniscal repair with biomechanical properties equal to that of the open, vertical mattress suture technique.

### Contains no hard device heads

Minimizes trauma to articular cartilage.

### Easy knot sliding with ULTRABRAID® suture

Offers advantages over traditional polyester suture, including higher knot-breaking strength, increased lubricity and a stronger resistance to fraying.

### PEEK-OPTIMA® high strength non-absorbable, polymer implants

PEEK-OPTIMA polymer lends confidence that the implant will resist breakage when used with high-strength ULTRABRAID suture.

### PLLA absorbable implants

Bioabsorbable version of ULTRA FAST-FIX.

### Curved and reverse-curved needles

Curved needles promote safer and easier access to a multitude of tear sites. The reverse-curved needle is designed for repairing tears on the inferior surface. Because the needle's point is on the opposite side of the curve, it can safely enter the inferior area without skiving the meniscus or the tibial plateau.

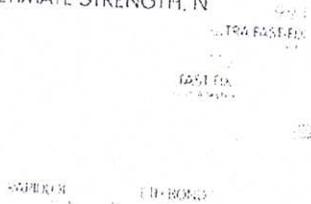
5.6

*lenktos ir reversine' adatos*

5.3

*Chemine' sudetis "PeeK-Optima"*

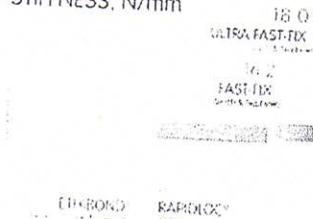
ULTIMATE STRENGTH, N



ELONGATION



STIFFNESS, N/mm



After 1000 cycles between 5N and 20N. All values are means  $\pm$  standard error. Bovine meniscus model.

An evaluation of the mechanical properties of the ULTRA FAST-FIX Meniscal Repair System showed a significant increase in ultimate strength and stiffness, and a decrease in elongation compared to ETHIBOND®, RAPIDLOC® and the conventional, clinically successful FAST-FIX device®. This in vitro mechanical evaluation of meniscal

1. Zontan J, Eppas A, Musahl V, Womann A, Petersen W. Cyclic loading of bovine all-inside meniscus suture anchors. *Am J Sports Med.* 2005; 33:1-7

2. Data on file at Smith & Nephew

H



## ULTRA FAST – FIX Menisko siuvimo sistema

Ultra Fast - Fix yra unikali menisko siuvimo sistema, garantuojanti stiprią fiksaciją be invazinių chirurginių procedūrų, kurios yra būtinos kitoms įprastoms menisko siuvimo sistemoms. Originali menisko siuvimo sistema Ultra Fast-Fix buvo pristatyta 2001 m. ir pakėlė minimalios invazijos menisko siuvimo technologijas į aukštesnį lygį. Iki galo paruoštų implantų, užrišimui paruošto slenkančio mazgo ir inovatyvaus stūmimo – kirpimo prietaiso dėka ši naujoviška sistema leidžia vertikaliai arba horizontaliai paskirstyti implantus iš abiejų menisko pusių, užveržti mazgą ir nukirpti likusį siūlą. Naujoji Ultra Fast-Fix sistema pasižymi stipresniu siūlu ir slenkančio mazgo mechanizmu. Tai užtikrina siuvimo sistemos greitumą bei saugumą.

Vienintelis tokio pobūdžio produktas

### Greita ir paprasta procedūra

Skirtingai nei tradicinės menisko siuvimo sistemos, Ultra Fast-Fix yra implantų sistema su iš anksto paruoštu, savaime slenkančiu mazgu. Dėl šios priežasties nebereikia intraartikuliarinio mazgo rišimo procedūros. 5.5

### Stipri ir kliniškai įrodyta sistema

Užtikrina stiprų ir patikimą menisko susiuvimą.

### Minimali invazija

Mažina sąnarių kremzlių traumos riziką.

### Slankiojantis mazgas su ULTRABRAID siūlais

Nuo tradicinių poliesterio siūlų šie skiriasi tuo, kad yra daug stipresni ir atsparesni susidėvimui; stipriai užsiveržia mazgas. 5.2; 5.5

### PEEK – OPTIMA® - itin stiprūs nesirezorbuojantys polimeriniai implantai

PEEK OPTIMA polimerai užtikrina, kad implantas nesulūš procedūros metu.

### PLLA absorbuojantys implantai

Tai absorbuojanti Ultra Fast-Fix implantų versija. 5.3

### Lenktos ir atvirkščiai lenktos adatos

Adatos yra lenktos dėl saugesnio ir lengvesnio priėjimo prie plyšio vietos. Atvirkščiai lenktos adatos yra skirtos susiūti apatinio paviršiaus plyšį. Kadangi adatos galas yra priešingoje linkio pusėje, ji gali saugiai pasiekti apatinį paviršių be menisko pjaustymo. 5.6

Kiekviena UTRA FAST-FIX sistema sudaryta iš dviejų integruotų 5 mm polimerinių inkarų su #2 neabsorbuojamu UHMW polietileno ULTRABRAID siūlu kuris turi anksto paruoštą slystantį mazgą. Visa ši sistema yra integruota į lengvai įvedamą adatą, sterili. 5.2

5.2

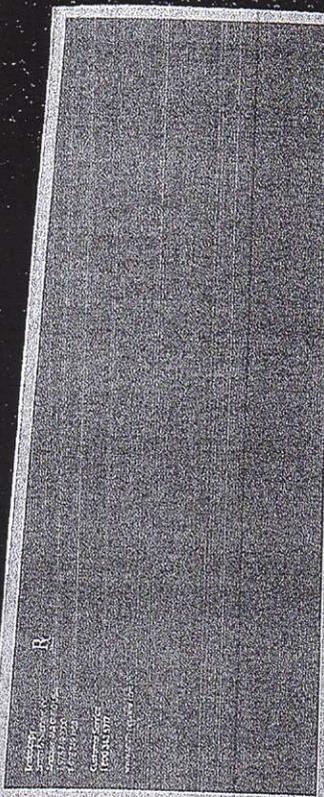
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Vedimas

Vadovo asistentė  
Kerina Veličkienė

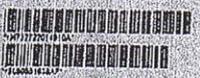
2016-03-09



5.1.

EDU 0241 72201491  
EDU 0241 50551638  
ULTRA FAST-FIX Curved Needle Delivery System - Spinal Cannula

ULTRA FAST-FIX Gebogenes Nadelnährlieferungssystem - Kanüle (geleitet) - Systeme d'implantation à aiguille incurvée  
ULTRA FAST-FIX: Cánula a la curva - Sistema di rilascio ago curvo  
ULTRA FAST-FIX: Cánula dividida - ULTRA FAST-FIX gebogen divisiva - ULTRA FAST-FIX gebogenes Nadelnährlieferungssystem - Verleitede Kanüle - Sistema de colocación con aguja curva  
ULTRA FAST-FIX: Cánula dividida - ULTRA FAST-FIX infiringsystem med böjligt nål - Uppdelad kanyl - ULTRA FAST-FIX infiringsystem med krummet nål - Divided kanylle - Sistema de colocación con aguja curva  
ULTRA FAST-FIX: Cánula dividida - ULTRA FAST-FIX infiringsystem med böjligt nål - Uppdelad kanylle



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Customer Support: 1-800-541-8717

Sterilus

U.S. Patent No. 7,817,817; 7,457,309

STERILE 05



Manufactured at Smith & Nephew

EDU 0241 72201491  
ULTRA FAST-FIX Curved Needle Delivery System - Spinal Cannula  
EDU 0241 50551638



STERILE 05  
ULTRA FAST-FIX Curved Needle Delivery System - Spinal Cannula  
ULTRA FAST-FIX Gebogenes Nadelnährlieferungssystem - Kanüle (geleitet) - Systeme d'implantation à aiguille incurvée  
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ULTRA FAST-FIX: Cánula dividida - ULTRA FAST-FIX infiringsystem med böjligt nål - Uppdelad kanylle



Setup

5.2

Each ULTRA FAST-FIX® device contains two 5 mm polymer integrated anchors (resorbable or bio-inert), with a pre-tied, self-sliding knot comprised of #2 non-absorbable, UHMW polyethylene ULTRABRAID® co-braid suture. The entire system is packaged in an easy-to-insert, integrated delivery needle. The anchors are placed into the meniscus sequentially, seated safely beyond the capsule, and are then tightened in a simple manner without the need for arthroscopic knot tying (Photos 2 and 3).

5.7

The dark blue sheath comes preset to a depth of 25 mm from the tip of the needle and 17 mm from the back of the implant, which has been shown to avoid neurovascular injury while allowing predictable meniscocapsular placement.

Peripheral, popliteal, hiatal, and mid-1/3 medial meniscus tears may require penetration less than the 17 mm allowed by the dark blue sheath. Use of the meniscal depth probe, in conjunction with the trimmable depth penetration limiter (white plastic sheath), allows controlled penetration (Figures 1a and 1b).

If the trimmable depth penetration limiter is used with the split cannula, then the split cannula should be completely split before inserting it over the white depth penetration limiter, to allow for easier removal.

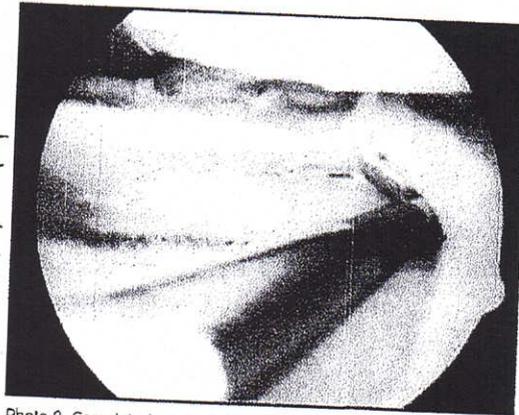


Photo 2. Completed repair - horizontal



Photo 3. Completed repair - vertical x 2

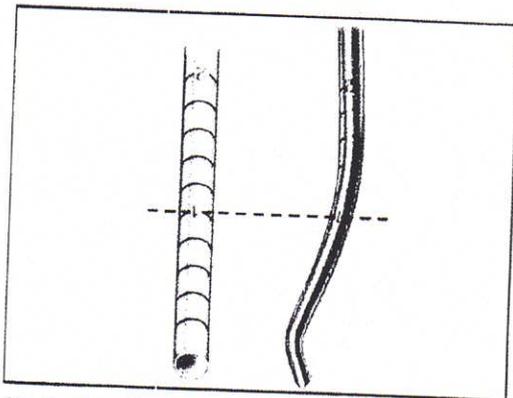


Figure 1a. Trimmable depth penetration limiter and meniscal depth probe

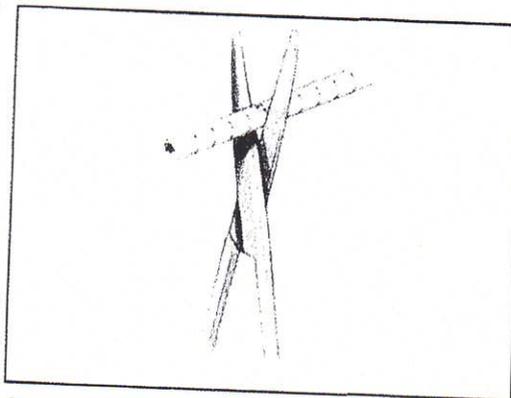


Figure 1b. Trimmable depth penetration limiter

Arthroscopic  
Ultra Fast Fix  
provides suture  
for in situ  
5 mm polymer  
integrated anchor  
resorbable or bio-  
inert, as is available  
percutaneous system  
via macro, micro-  
scope to #2 non-  
absorbable  
UHMW polyethylene  
ULTRABRAID  
anchors  
in built plastic  
sheath. This system  
allows you to substitute  
the split cannula  
and integrate  
to procedure  
easily

Intercan you post  
abnormality  
meniscus medial  
surface in sup-  
rotator, it fails  
intra-articular pop-  
liteal bursa, be  
poly anchor  
firmly anchors  
sutures

5  
4

**Caution:** The opening of the split cannula must be at 90° to the curved ULTRA FAST-FIX® needle to prevent the needle from slipping out as it is introduced into the knee (Figure 3). If using the slotted cannula, make sure the curve of the needle faces down (Figure 3a).

To minimize needle bending, grasp the cannula on the shaft and hold it like a dart or pencil when passing through the fat pad (Photo 4).

**Note:** The pretied, self-sliding knot, included in the ULTRA FAST-FIX device, slides from the first implant (T1) to the second implant (T2). Therefore, placing T1 further away than T2 will facilitate sliding of the knot.

**Note:** Maintaining the needle insertion tip within the arthroscopic view at all times avoids suture tangling.

- For a horizontal repair, place the first implant (T1) farthest away and advance the needle into the outer meniscal fragment until the implant pops through the meniscus.

For a vertical repair, place the superior implant first and advance the needle into the outer meniscal fragment (bisecting the fragment) until the implant pops through the meniscus (Photo 6).

Using the curved ULTRA FAST-FIX device may facilitate initial penetration.

Using the slotted cannula minimizes needle skiving when accessing more anterior tears. Leave the cannula in to help steer the needle tip.

- Oscillate the needle approximately 5° and pull the needle out of the meniscus, releasing T1 behind the meniscus (Figure 4).

To reduce the amount of suture in the field of view, slowly pull back on the needle after deploying implant 1. Use a forefinger for control upon withdrawal. Piercing the meniscus by 2-3 mm prior to advancing T2 can also help with suture management.

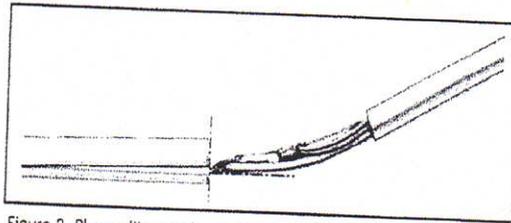


Figure 3. Blue split cannula positioned 90° to the curve of the delivery needle

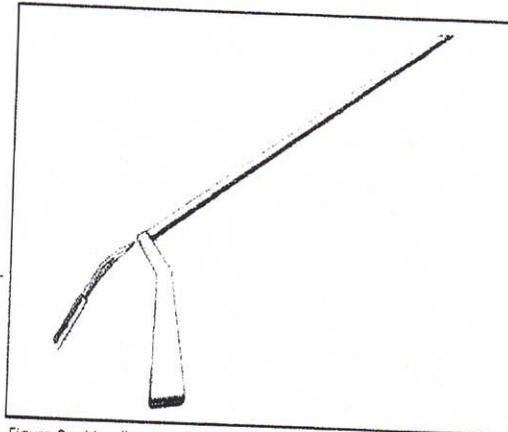


Figure 3a. Needle curve facing down

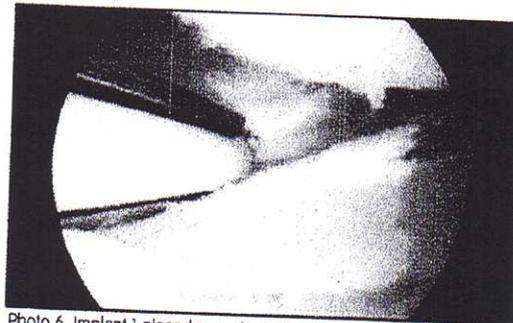


Photo 6. Implant 1 placed superior to tear

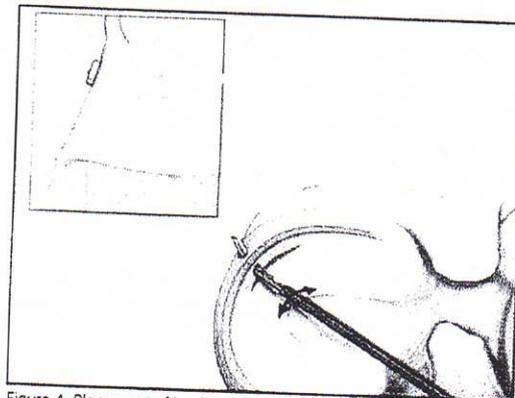


Figure 4. Placement of implant 1

5.2

is unisto per...  
 too shy...  
 needles...  
 Ultra Fast Fix  
 provide...  
 two pins T  
 implants...  
 into T implan  
 to T2...  
 position T1  
 anterior...  
 T2

5.3  
 5.5

5.2

5.4

position... T1 as...  
 60

8

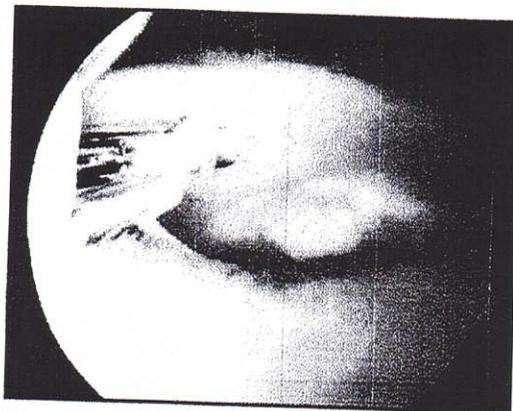


Photo 7. Implant 2 fully advanced to the ready position

- Using the tip (rather than the volar pad) of the thumb, slide the gold trigger forward to advance the second implant into the ready position (Photo 7 and Figure 5).

**Note:** It is normal to encounter resistance prior to achieving the ready position. A snap or click is heard when the trigger is fully advanced, ensuring that the implant is fully seated at the end of the needle (Figures 6 and 7).

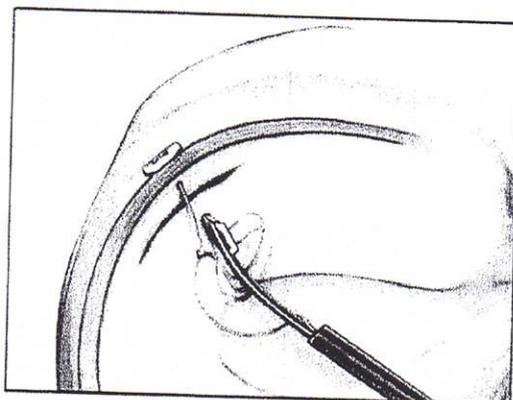


Figure 5. Implant 2 fully advanced to the ready position

*U. James J. S. S. S.*  
*S.H.*

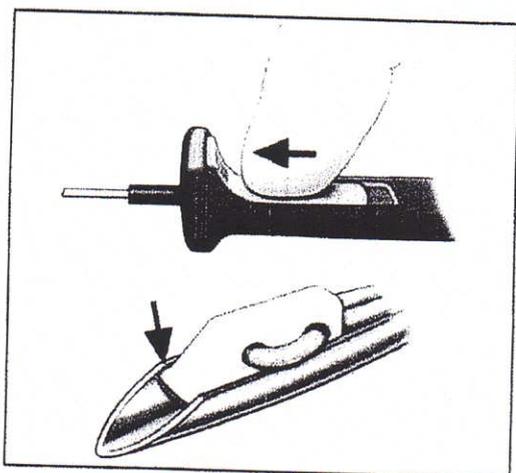


Figure 6. Proper positioning of implant 2

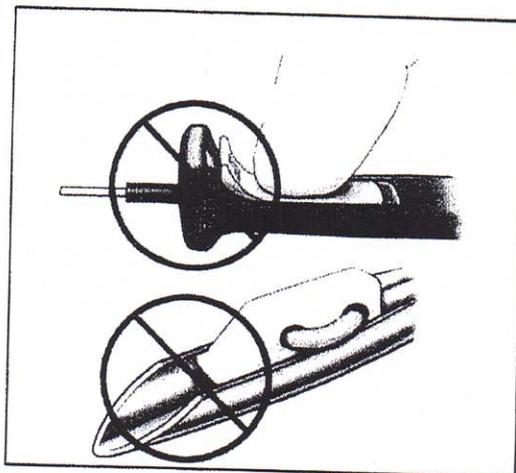


Figure 7. Improper positioning of Implant 2

Уч. Вазыбіўніке  
Адета Раблеўніен

*"U" former fibrous*

5. Insert the delivery needle to release implant 2.
  - For a horizontal repair, insert the needle between the entry point and the first implant, approximately 4-5 mm inferior from implant 1 (Figure 8, Photo 8).
  - For a vertical repair, insert the needle approximately 4-5 mm inferior from implant 1 (Figure 8, Photo 9).

5.4

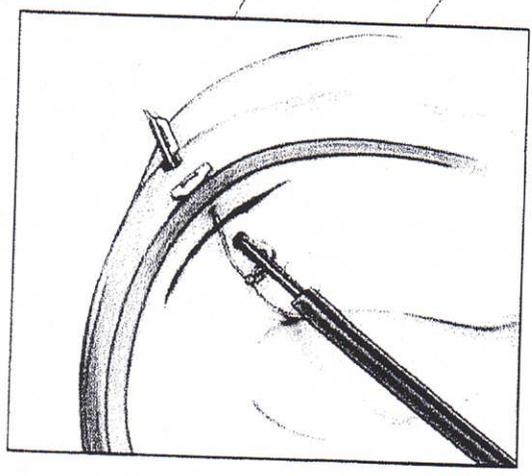


Figure 8. Implant 2 ready for release

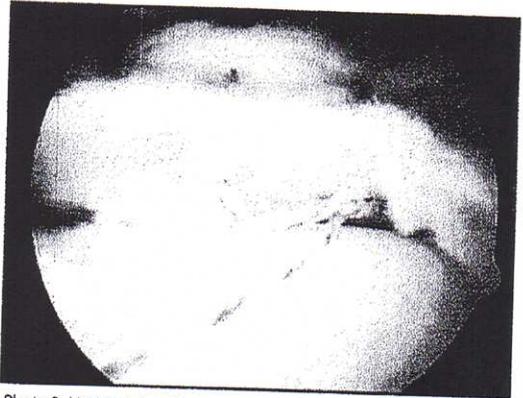


Photo 8. Horizontal mattress suture

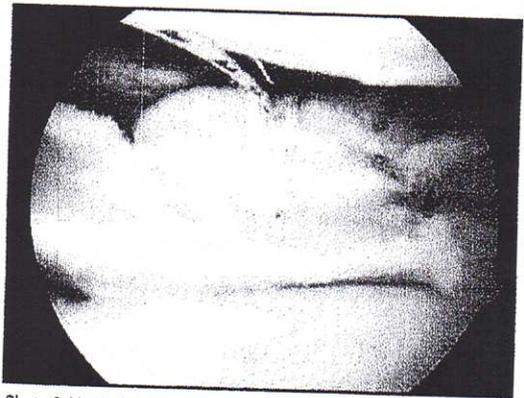


Photo 9. Vertical mattress suture


  
 Jyri Vaajonkka  
 Meta Rakkonen

*10*

5.4 Synovial tears

"L" forms

fibers

implant  
fibers

5.7

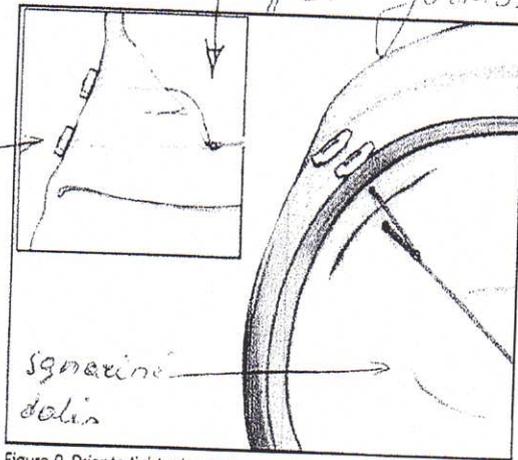


Figure 9. Prior to tightening suture construct

6. Remove the delivery needle from the knee, leaving the free end of the suture. Pull the free end of the suture to advance the sliding knot and reduce the meniscal tear (Figure 9, Photos 10 and 11). It is normal to encounter considerable resistance as the knot is snugged down. It is important to pull the free end of the suture in a line directly perpendicular to the tear site.

Avoid suture breakage by wrapping the suture around several fingers and using the tibia as a fulcrum to provide a tactile feel. Apply slow, increasing tension. In most cases, this steady pulling of the suture will cinch the knot down. As the knot is tightened, it may strangle the free leg of suture, creating a loop of suture. If controlled tightening does not eliminate the loop, place a probe under the tight leg of suture and use it as a pulley.

7. To further snug down the suture construct, thread the free end of the suture through the ULTRA FAST-FIX® Knot Pusher/Suture Cutter. Both curved and straight knot pushers/suture cutters are available. This threading can be facilitated with the use of the suture funnel.

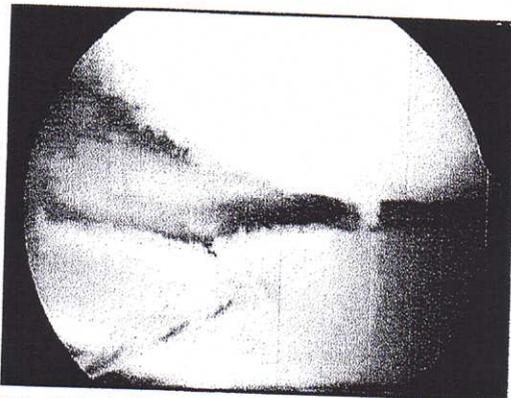


Photo 10. Hand-tightened suture construct - vertical mattress

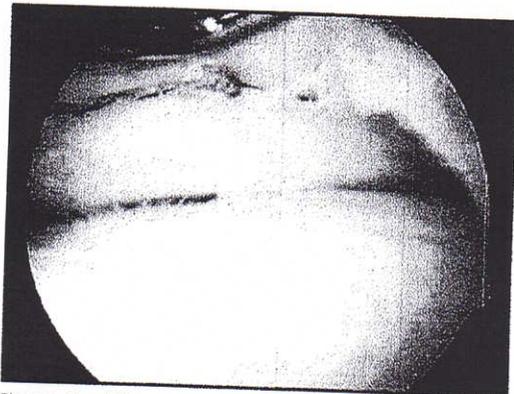


Photo 11. Hand-tightened suture construct - horizontal mattress

Handwritten signature and stamp area.

8. While holding the suture taut, gently slide the knot pusher/suture cutter to the meniscus to achieve the desired tension (Figure 10). The knot pusher should engage the suture in a direct line and perpendicular to the repair. A manual suture "pull"/"push" maneuver is suggested.
9. Rest the tip against the knot to allow for a 2-3 mm suture tail. Cut the suture by sliding the gold trigger forward (Photos 12 and 13, Figure 11). Alternatively, trim the suture with arthroscopic scissors.

To reduce puckering that may result from the femoral surface repair, the implants can subsequently be placed on the tibial side of the meniscus to help pull down the meniscal flap. The reverse curve ULTRA FAST-FIX\* device is recommended for tibial side tears.

### Postoperative Care

Reestablish full extension and quadriceps activation early, along with joint kinematics and proprioception involving the entire kinetic chain progression to full weight bearing; limit flexion to 90° for three weeks and to torsion for six weeks. Running is indicated at 8-12 weeks. Cutting activities are indicated at 10-12 weeks. Return to full activity is indicated at 3-6 months. Individualization is based on the stability of the tear, repair construct security, and associated pathology.

*U" femoral fixation 5.4*

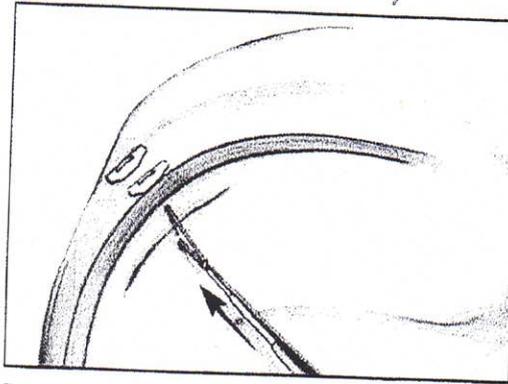


Figure 10. Suture construct tensioning

*5.4  
implant on  
tibial side*

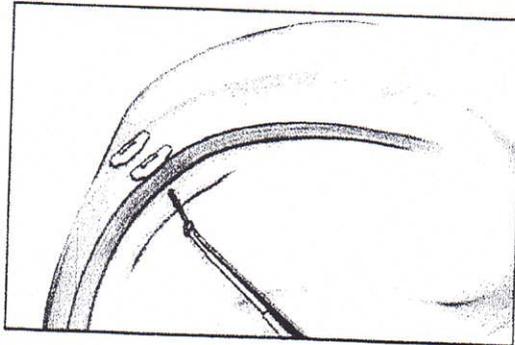


Figure 11. Suture cutting

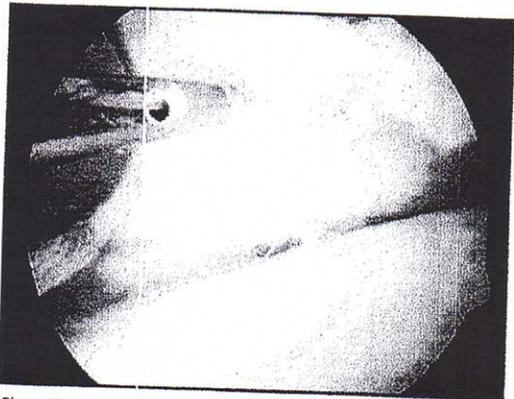


Photo 12. Suture cutting - horizontal mattress

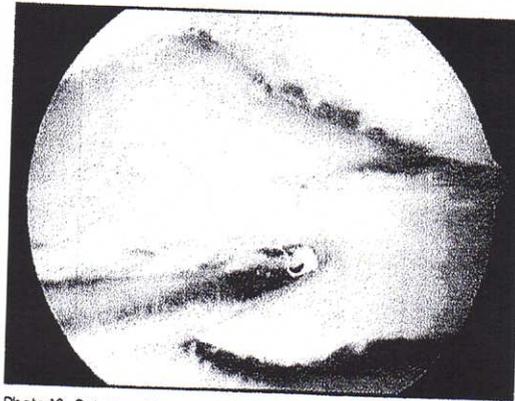


Photo 13. Suture cutting - vertical mattress

*Delta Kellomäki*

## Additional Instruction

Prior to performing this technique, consult the Instruction for Use documentation provided with individual components – including indications, contraindications, warnings, cautions, and instructions.

## References

1. Caborn, Borden, Nyland, Pienkowski: Biomechanical Comparison of the FAST-FIX Meniscal Repair Suture System with Vertical Mattress Sutures and Meniscus Arrows. *The American Journal of Sports Medicine*, Vol 31, No. 3, 2003.
2. Coen, Caborn, Urban, et al: *Arthroscopy* 1998.

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Endoscopy Division

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

## Pearls

- Prepare site and assess geometry of reduction.
- Reduce tear center-to-center to avoid "dog ears"/gapping/ruffles.
- Approach tear from contralateral portal/view from ipsilateral portal.
- Use curve of needle to increase safety zone of vector and improve insertion positioning.
- Hold delivery needle like a dart to stabilize.
- Insert curved delivery needle within split cannula with convexity up.
- Ease insertion using metal slotted cannula.
- Vertical mattress suture: T1 goes posterior and superior; T2 goes anterior and inferior.
- Insert T2 (implant 2) 4 mm to 5 mm from T1 (implant 1).
- Advance gold slide trigger and implant 2 completely to tip until a click is heard (requires force). Use the tip of the thumb on slide trigger rather than volar pad of thumb.
- If implant 1 does not deploy, it is most likely NOT inserted through the entire meniscal tissue: advance deeper.
- If implant 2 does not deploy, it is most likely NOT advanced to the deployment position at the tip of the delivery needle.
- Thread suture onto knot pusher/suture cutter with suture funnel.
- If the knot does not cinch smoothly, it usually requires a more forceful steady pull which is facilitated by wrapping the suture around several fingers like a pulley and applying traction.
- Cinch knot to obtain compression of the suture across the tear but avoid over-cinching or puckering the tissue.
- Alternate divergent femoral side and tibial (tensile) side suture placement.
- Consider reverse curved devices for tibial side fixation.

5.2 →

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