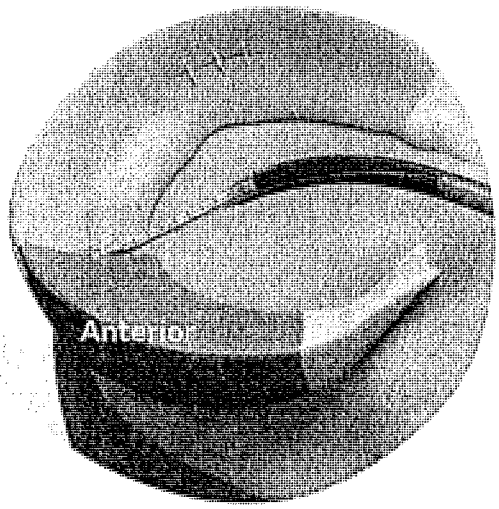
9. Menisko siuvimo inkarine sistema su lenkiama adata

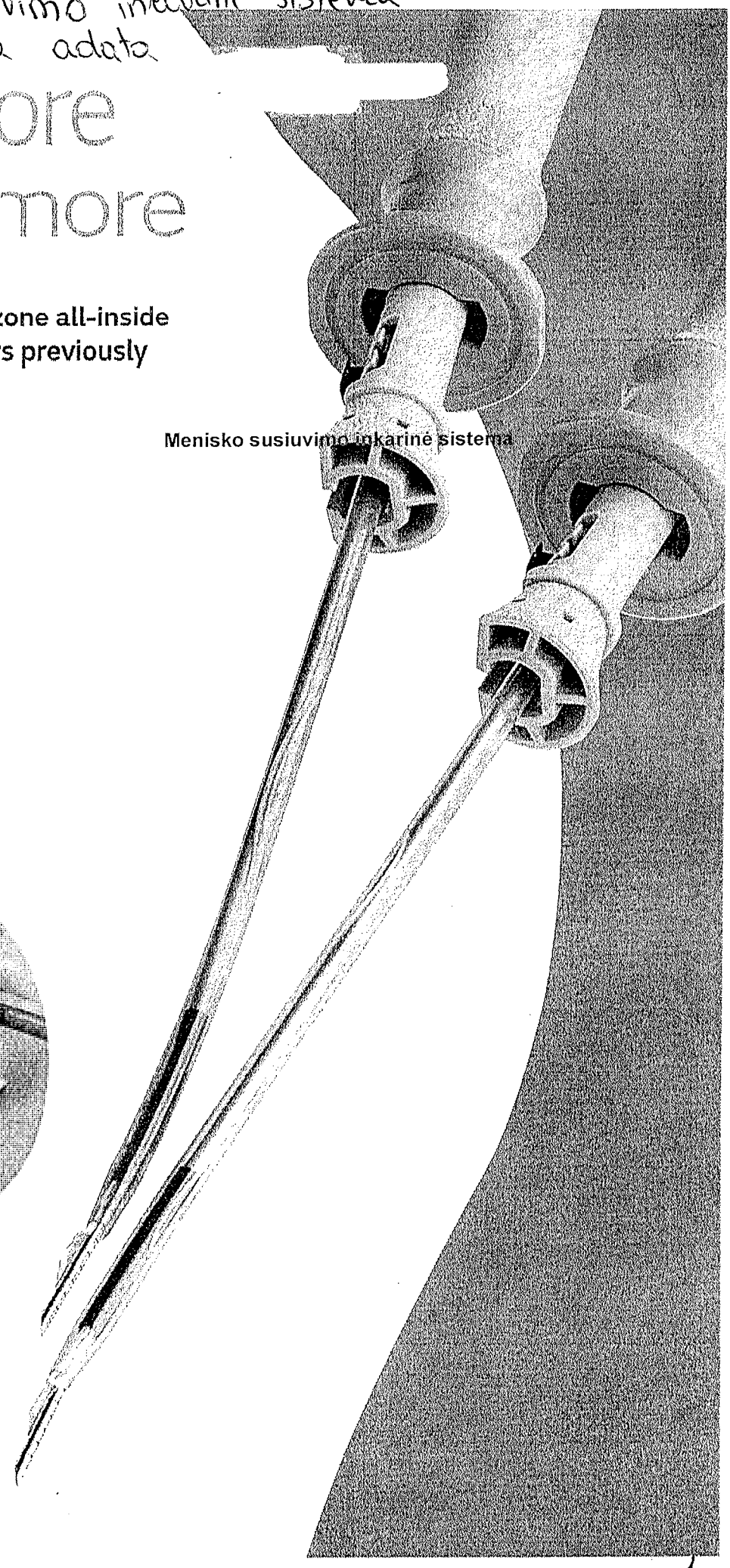
Reach more
+ repair more

FAST-FIX FLEX enables all-zone all-inside meniscal repair to treat tears previously not accessible*[1-3]

Smith+Nephew

FAST-FIX◊ FLEX
Meniscal Repair System





*compared to predicate device

1

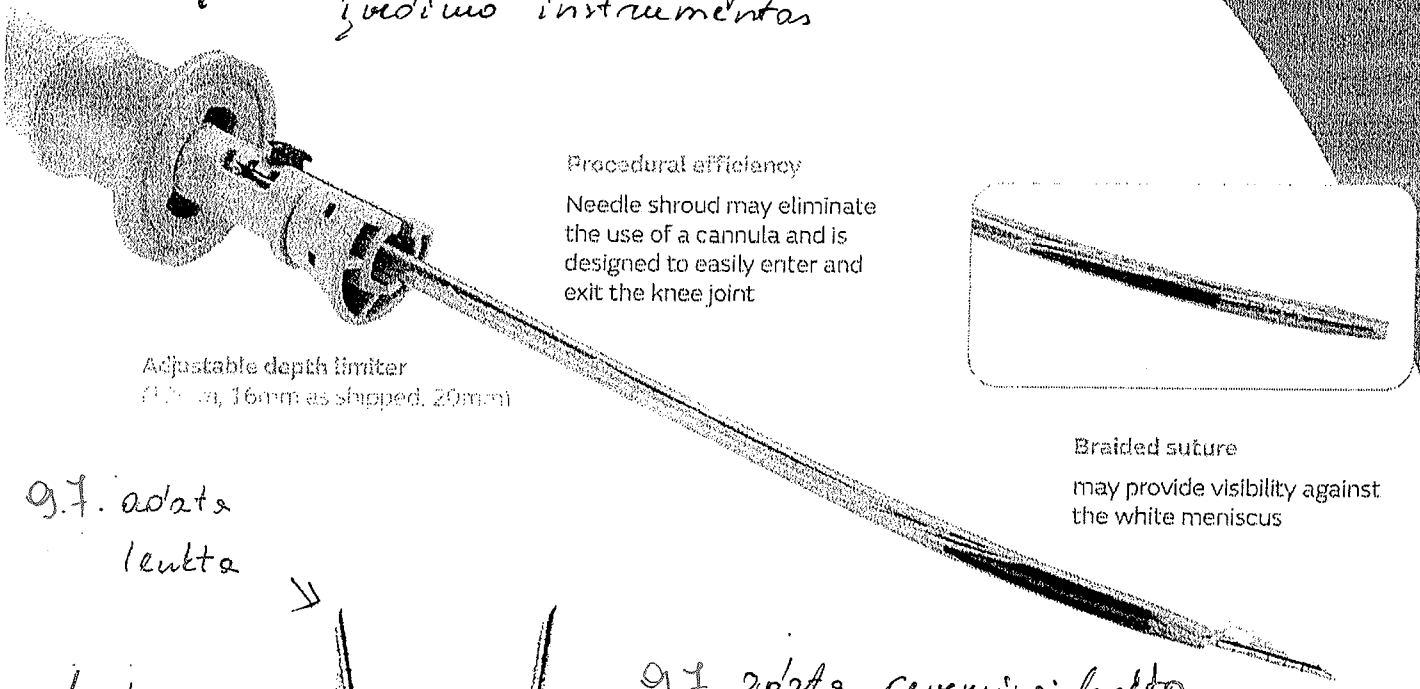
Reach more, repair more

Smith+Nephew has extended the reach of all-inside meniscal repairs with FAST-FIX® FLEX. The unique guided needle and shaft flexibility allow access to all zones across the meniscus using a standard anterior portal.[1]

Increase reliability*[1-3]

through one-handed 360° active deployment confirmed through touch, sound and sight[1]

9.1. vientartinis cilindro formos įvedimo instrumentas



Procedural efficiency

Needle shroud may eliminate the use of a cannula and is designed to easily enter and exit the knee joint

Adjustable depth limiter

(5mm, 16mm as shipped, 20mm)

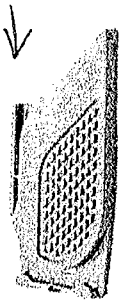
Braided suture

may provide visibility against the white meniscus

9.7. adata lenkta

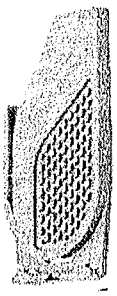
9.1. lenkimo instrumentas

FAST-FIX FLEX Curved + Bend Tool



9.7. adata reversinė lenkta

FAST-FIX FLEX Reverse Curved + Bend Tool



Laser-marked needle tip

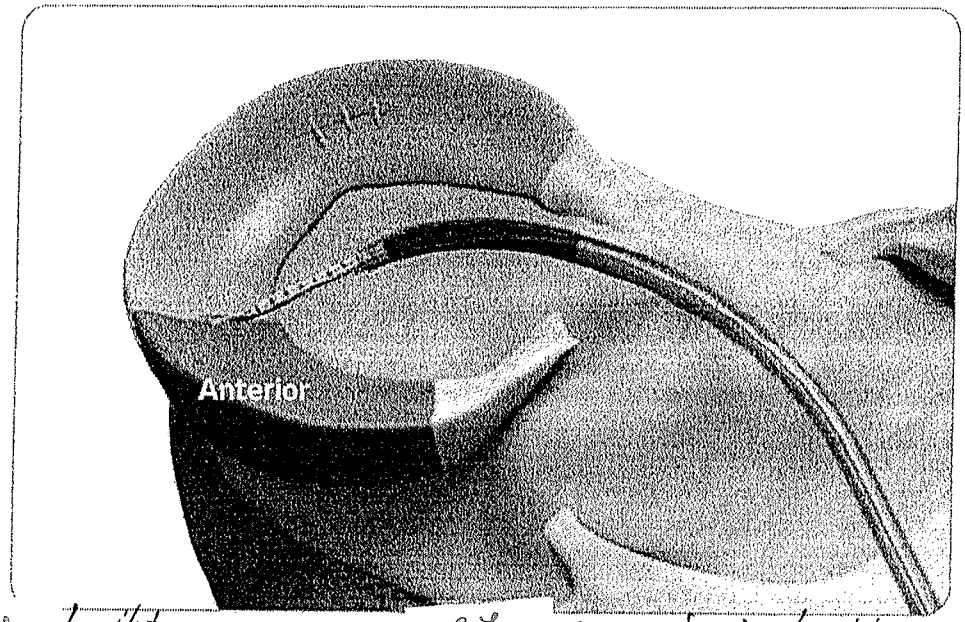
serves as a quick reference for needle depth penetration

*compared to predicate device

Watch the animation

Enhance accessibility

FAST-FIX® FLEX provides access to the posterior zone as well as the mid-body and anterior third of the meniscus, which has been shown to account for more than 40% of meniscal tears in stable adult knees[1,2,6]



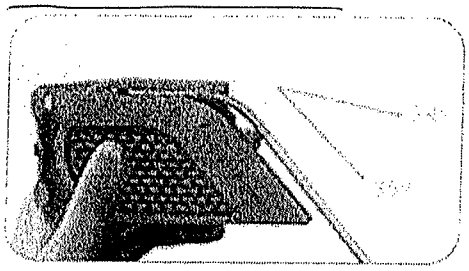
8.7. lenkton

8.7. reversine lenkte adate

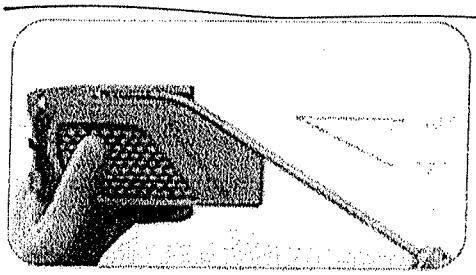
FAST-FIX FLEX Curved

FAST-FIX FLEX Reverse Curved

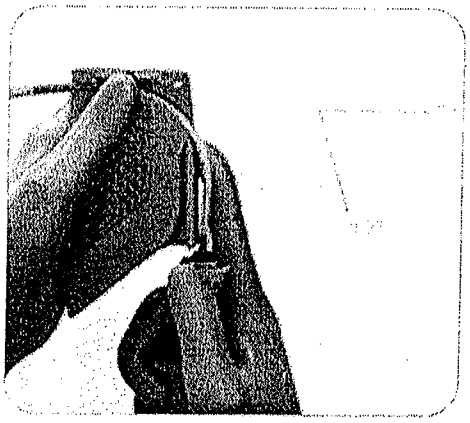
9.6 adats pelima polenkti ibi 35°



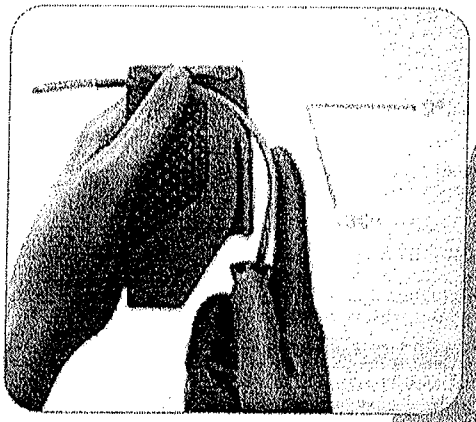
Needle bend up to 35° adate



Needle bend up to -22°



Shaft bend up to 80° stiebas



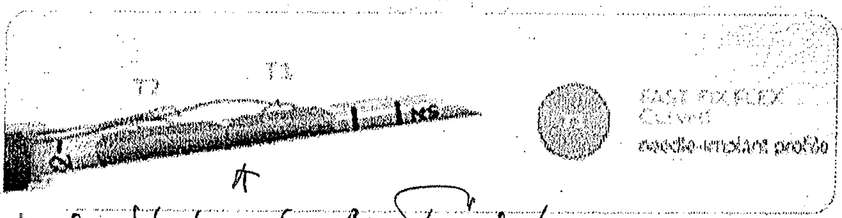
Shaft bend up to -80°

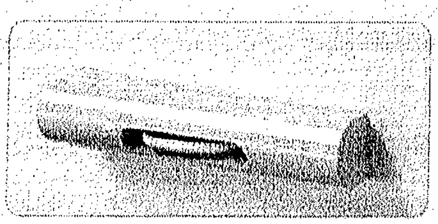
9.6. lenkimo instrumento popelbe pelima polenkti ibi 80°

does not provide measurement. Maximum bend degree was established by benchtop testing.

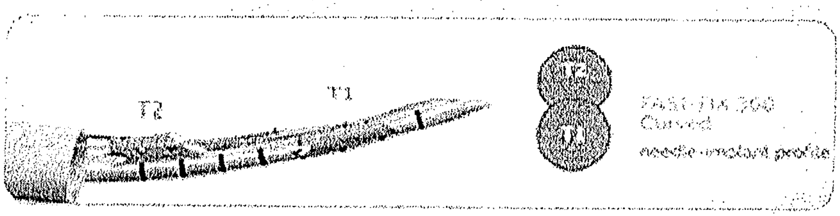
Preserve Anatomy

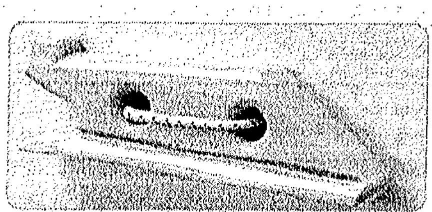
FAST-FIX° FLEX





FAST-FIX 360

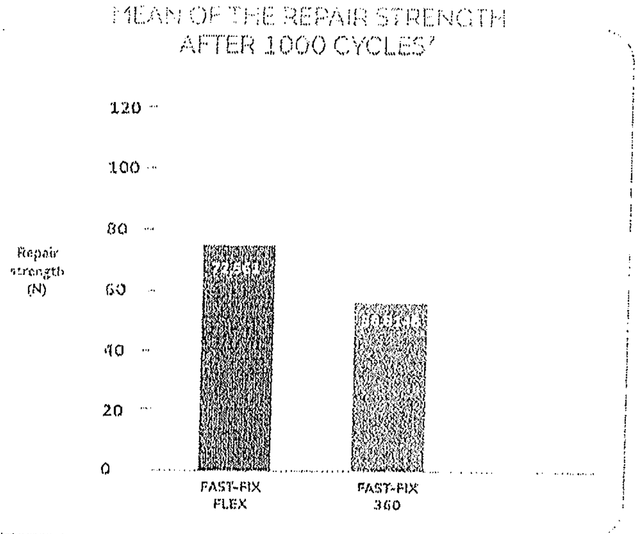


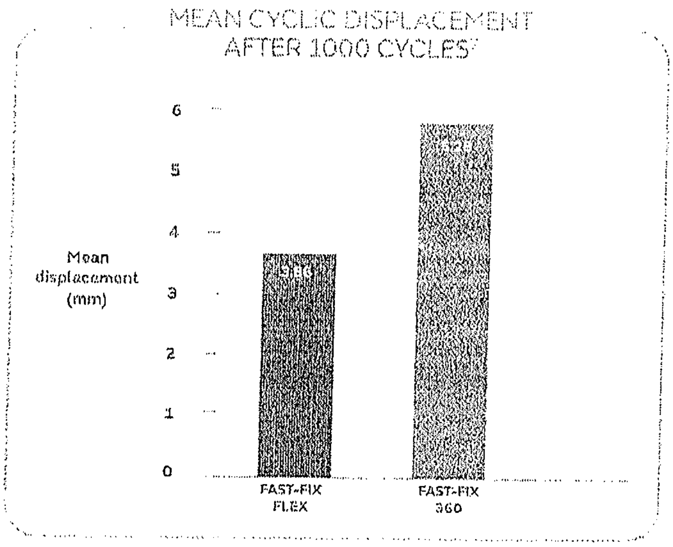


In-line implants and a 17 gauge needle create a 25% smaller needle insertion area*[3]

~20% less contact*[4] with the capsule but ~20% stronger*,**[7]

Improved Performance*





~20% stronger*,**[7]

27% less displacement*,**[7]

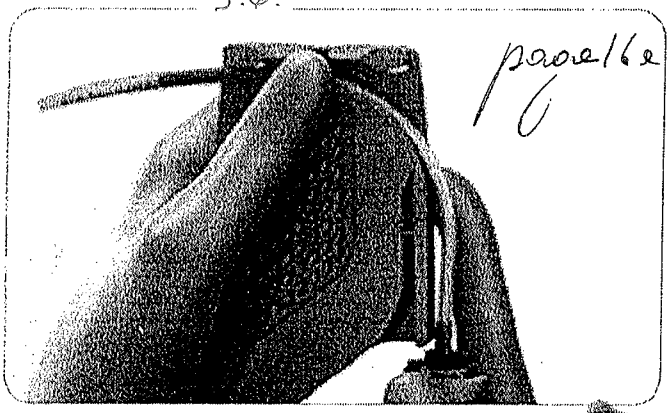
* Compared to our predicate device

** As demonstrated in biomechanical testing

All-Zone All-Inside Meniscal Repair

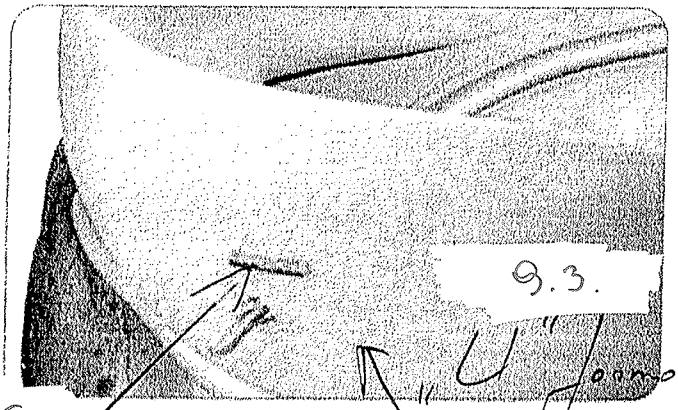
FLEX

9.6. Lenkiamas instrumentu



paveikslo

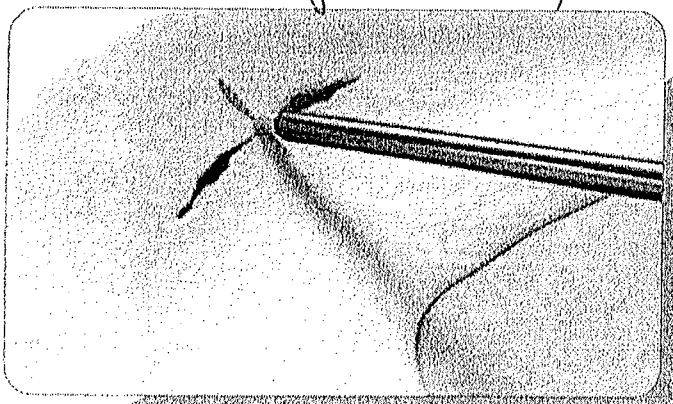
FIX



9.3.

Įkišamos dvi jungtys

9.5. Nepalieka implanto sąnarinėje dalyje. Įsisavinama



Read the technique guide

All-inside FAST-FIX® repair is clinically proven to restore healthy knee function[8]

Lysholm score

92.3
mean FAST-FIX postoperative score[7]

94
mean
healt

0 92.

Tegner activity score (TA

5.7
mean score in healthy adults[9]

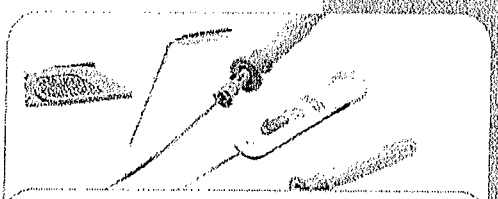
6.3
mean
poste
score

0 5.7 6.3

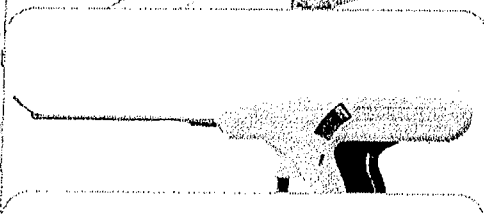
86%
mean success
rate of all-ins
FAST-FIX repair

More than 20 years of innovation in meniscal repair

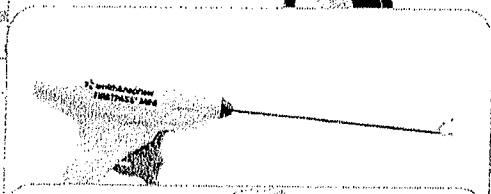
click on product names for pop up images



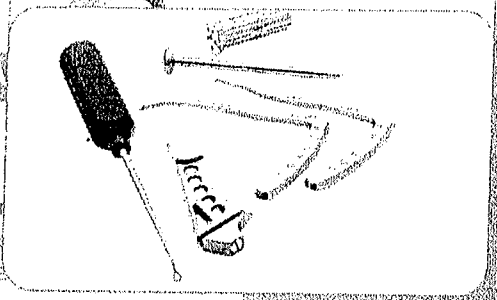
2021[10]
FAST-FIX FLEX
Meniscal Repair System



2019
NOVOSTITCH FAST-FIX
Meniscal Repair System™

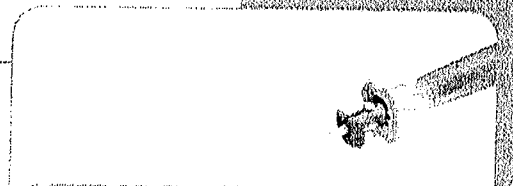


2016
FIRSTPASS™ Mini
Suture Passer

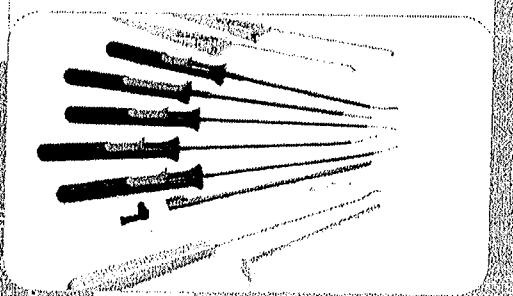


2014
MENISCAL ROOT Repair
System

2013
MAT procedure indication



2010
FAST-FIX 360
Meniscal Repair System



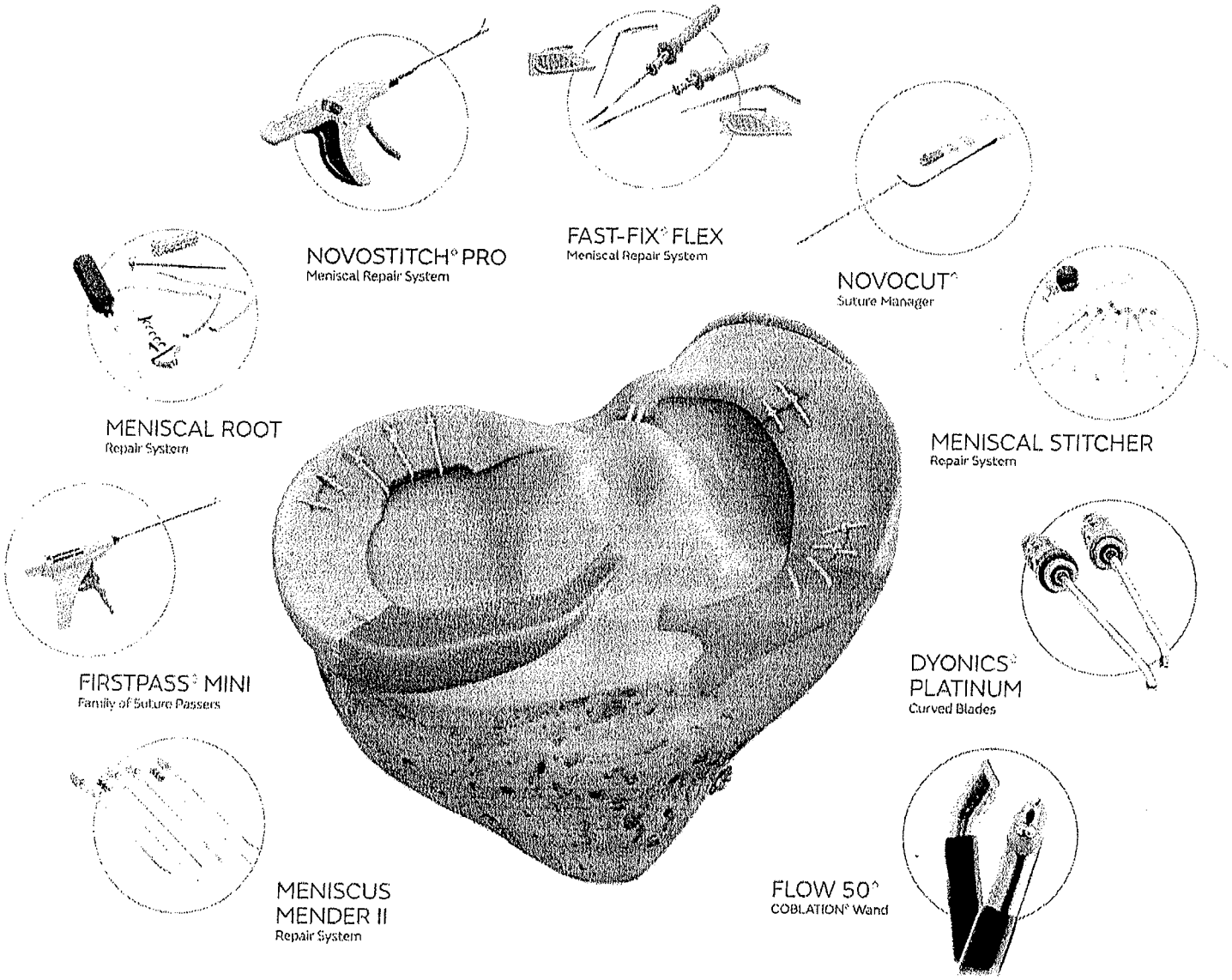
2007
ULTRA FAST-FIX
Meniscal Repair System

2001
FAST-FIX
Meniscal Repair System

1999
T-Fix Suture

All tears, all repairs

Meniscal Repair Solutions

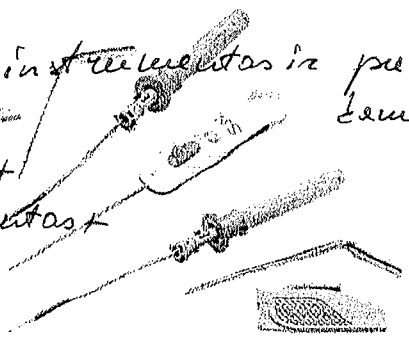


Watch the All tears, all repairs animation

Accelerating the standard of care toward meniscal repair

Ordering information

FAST-FIX® FLEX	
Reference #	Description
72205324	FAST-FIX FLEX Curved with Bend Tool and Slotted Cannula
72205325	FAST-FIX FLEX Reverse Curved with Bend Tool and Slotted Cannula
CTX-C001	NOVOCUT® Suture Manager
Accessories	
015186	Meniscal Depth Probe, reusable
014549	45° Diamond Rasp, reusable
014550	90° Diamond Rasp, reusable
7210977	Slotted Cannula, reusable
7209950	Suture Threaders, sterile, box of 10
COBLATION®	
72290105	WEREWOLF® COBLATION System
72290007	WEREWOLF Wired Foot Pedal
72290008	WEREWOLF Wireless Foot Pedal
72290037	FLOW 50° COBLATION Wand
DYONICS® PLATINUM Blades	
72205292	DYONICS PLATINUM FLYER® Shaver Blade



Some products may not be available in all markets due to the regulatory and/or medical practices in individual markets.
Please contact your Smith+Nephew representative if you have questions about the availability of Smith+Nephew products in your area.

Learn more at AllTearsAllRepairs.com

Sports Medicine
Smith & Nephew, Inc
150 Minuteman Road
Andover, MA 01810

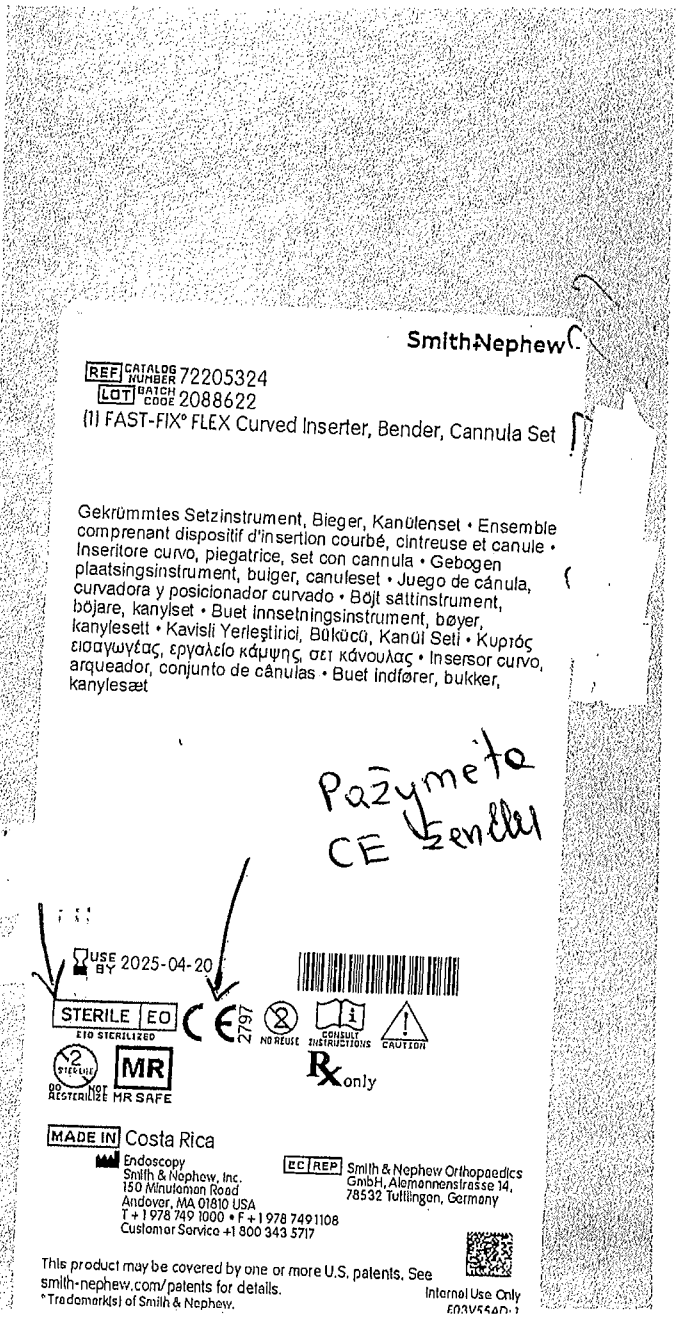
www.smith-nephew.com
T +978 749 1000
US Customer Service
+1 800 343 5717

References

1. Smith+Nephew 2021 Validation. FAST-FIX FLEX™ Internal Report. 15010267 Rev A. 2. Smith+Nephew 2021 Validation, FAST-FIX FLEX, Attachment B. Internal Report. 15010267 Rev A. 3. Smith+Nephew 2021.FAST-FIX FLEX™ Surgeon Surveys. Internal Memo. 4. Smith+Nephew 2021.Competitive, FAST-FIX FLEX Dimensional Analysis. Internal Report 15010919 Rev A. 5. Li WR Chen Z, Song B, Yang R, Tan W. The FAST-FIX Repair Technique for Ramp Lesion of the Medial Meniscus. Knee Surg Relat Res. 2015;27(1):56-60. 6. Metcalf MH, Barrett GR. Prospective evaluation of 1485 meniscal tear patterns in patients with stable knees. AJSM. 2004;32(3):675-680. 7. Smith+Nephew 2020 Biomechanical Testing, FAST-FIX FLEX™ Internal Report. 15010180 Rev A. 8. Smith+Nephew 2019. Evidence Outcomes Reports EO/SPM/FASTFIX/002/v2 and EO/SPM/FASTFIX/003/v2 9. Briggs KK, Steadman JR, Hay CJ, Hines SL. Lysholm Score and Tegner Activity Level in Individuals With Normal Knees. AJSM.2009;37:898-901. 10. Andersen AF, Irrgang JJ, Kocher MS, et al. The International Knee Documentation Committee Subjective Knee Evaluation Form. AJSM.2006;34(1):128-135.

9.1.

Sterilios pakuotės
Fast Fix Flex, lenkta adata,
su lenkimo instrumentu ir
kanule. Linkimo



FAST-FIX® FLEX Meniscal Repair System

Device Description

The FAST-FIX FLEX Meniscal Repair System consists of an all-inside meniscal repair device, a slotted delivery cannula and a bend tool. Each device includes two non-absorbable polymer implants, pre-tied with #2-0 non-absorbable suture and preloaded into a needle delivery system. The adjustable depth penetration limiter is preset to approximately 16mm from the tip of the needle. It can be adjusted in 4mm increments between 12mm and 20mm.

How Supplied

The system is supplied sterile and is for SINGLE USE ONLY. The contents are supplied in one of two configurations:

(1) Single use delivery needle assembly preloaded with (2) PEEK-OPTIMA™ (polyetheretherketone) implants pre-tied with #2-0 non-absorbable suture made of uncoated ultrahigh-molecular-weight polyethylene fiber braided with polypropylene monofilament fiber

(2) The same single use delivery needle assembly with provided accessories: (1) Single use FAST-FIX FLEX Slotted Delivery Cannula, and (1) Single use Bend Tool

Intended Users

The FAST-FIX FLEX Meniscal Repair System is intended to be used by healthcare professionals in accordance with these instructions for use. The use environment is an operating room.

Intended Use

The FAST-FIX FLEX Meniscal Repair System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures.

Indications for Use

The FAST-FIX FLEX Meniscal Repair System is indicated for use in meniscal repairs, allograft transplant procedures, and anchoring the allograft to the meniscal rim during allograft transplant procedures.

Contraindications

- Pathological conditions in the soft tissue that would prevent secure fixation of the device.
- Known hypersensitivity to the implant material. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.

Warnings

Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging is compromised.

- **Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only. Discard any open, unused product. Do not use after the expiration date.**
- **The device is supplied sterile, and is for SINGLE USE ONLY. Do not clean, resterilize, or reuse the device, as this may damage or compromise the performance resulting in product malfunction, failure, or patient injury. Cleaning, resterilization, or reuse of the device may also expose the patient to the risk of transmitting infectious diseases.**
- **It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.**
- **Read these instructions completely prior to use.**
- **Only bend the needle with the bend tool provided in the package with accessories.**
- **Do not bend the needle along area indicated by black retaining tube.**
- **Excessive bending of the delivery needle may make it difficult or impossible to deliver the T1 and T2 implants.**
- **If resistance is encountered during deployment, a new delivery device may be needed.**
- **Do not push the deployment slider twice or the implants will deploy prematurely.**
- **Do not push the deployment slider until the needle is fully penetrated through the meniscus to the preset depth or T1 and T2 will deploy prematurely.**
- **The patient should be warned of**

2. **Bending the needle (optional).**
   a. Remove device from joint space.

   Note: Prior to bending, ensure the bend tool from the package with accessories is being used with the appropriate needle delivery device per the table below:

Bend Tool	REF
Curved (Orange)	72205324 72205676
Reverse Curved (Purple)	72205325 72205677

   b. Press and slide depth limiter button to expose needle a minimum of 16mm.
   c. (To adjust distal curvature) Insert needle fully into the channel of the bend tool and bend the needle to the desired curvature.

   WARNING: Only bend the needle with the bend tool provided in the package with accessories.

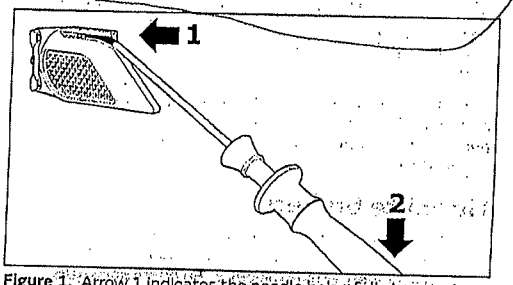


Figure 1. Arrow 1 indicates the needle being fully inserted in the bend tool. Arrow 2 indicates where the surgeon should apply force when bending the needle.

   d. (To adjust proximal curvature) Insert needle into proximal bend feature and bend the needle to the desired curvature.

   WARNING: Do not bend the needle along area indicated by black retaining tube.

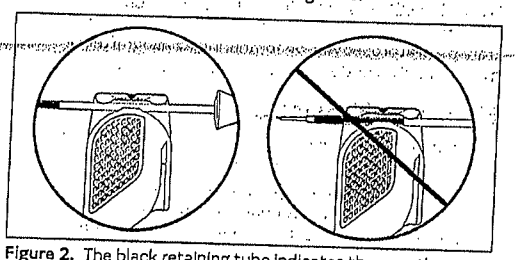


Figure 2. The black retaining tube indicates the area that should not be adjusted for proximal curvature.

   e. Introduce device into joint space again, using step 1.

3. **Deploy the first implant (T1).**
   a. For a horizontal or vertical repair, place the needle tip in the desired location for T1 and puncture the meniscus across the repair site to the preset depth.

   For allograft transplantation using a horizontal or vertical technique place T1 in the desired location and puncture the needle into the outer meniscal fragment to the preset depth.
   b. Leave the needle in position and push the deployment slider forward until a click is heard to deploy T1.

   WARNING: Do not push the deployment slider twice or the second implant will deploy prematurely.

4. **Deploy the second implant (T2).**
   a. Slowly retract the needle out of the meniscus, keeping the needle within arthroscopic view. For allograft transplantation insert the needle approximately 4–5mm from T1 and puncture the needle into the outer meniscal fragment to the preset depth.

   WARNING: Do not push the deployment slider until the needle is fully penetrated through the meniscus to the preset depth or T2 will deploy prematurely.
   b. Push the slider all the way forward until a click is heard to deploy T2.

5. **Remove the device from the knee.**
   a. Pull the free end of the suture to advance the pretied sliding knot reapproximating tissue

9 Priedas tęsinys

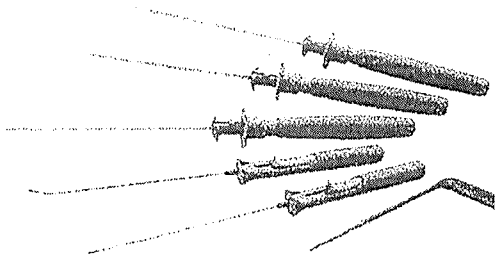
Meniscal Repair Systems

FAST-FIX® (all-inside)

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.

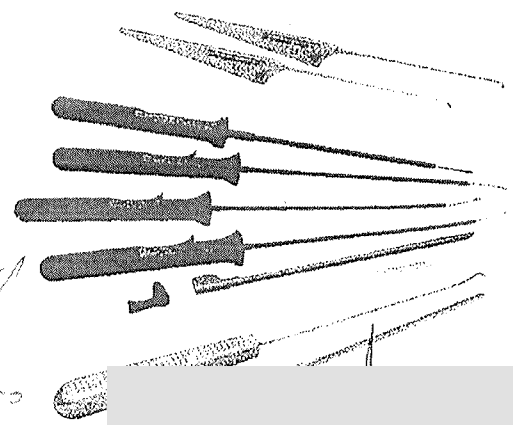
Reference #	Description
72202467	FAST-FIX 360 straight
72202468	FAST-FIX 360 curved
72202469	FAST-FIX 360 reverse curved
72202674	FAST-FIX 360 Straight Knot Pusher/Cutter and Slotted Cannula sets
72202675	FAST-FIX 360 Curved Knot Pusher/Cutter and Slotted Cannula sets



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

9.7.



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)

9.1. cilindro formos įvedimo instrumentas, rišantis mazgą

Menisko siuvimo sistemos

FAST-FIX

FAST-FIX menisko siuvimo sistemos išskirtinumas:

- fiksacija yra ypatingai stipri ir paprasta
- mažesni įvedimo taškai, kurie sumažina menisko pažeidimus
- įsiskverbimo gilumo ribotuvas
- 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
72202474	FAST-FIX 360 tiesus mazgo nustūmėjas/nukirpėjas ir pailgų kaniulių rinkinys
72202475	FAST-FIX 360 lenktas mazgo nustūmėjas/nukirpėjas ir pailgų kaniulių rinkinys

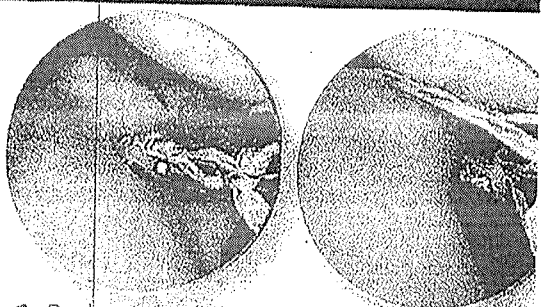
Ref	Parametrai
72201490	ULTRA FAST-FIX, tiesus
72201493	ULTRA FAST-FIX, AB, tiesus
72201491	ULTRA FAST-FIX, lenktas
72201492	ULTRA FAST-FIX, atvirkščiai lenktas
72201494	ULTRA FAST-FIX AB, lenktas
72201495	ULTRA FAST-FIX AB, atvirkščiai lenktas
72201537	mazgo nustūmėjas/nukirpėjas, tiesus

Priedai	
015186	Menisko gylio matuoklis
014549	45^0 deimantinė dildė
014550	90^0 deimantinė dildė
011703	Sterilizavimo dėklas, 9.25" x 3" x 1.5"
Nevienkartiniai:	
7210977	Kaniulė
7209950	Siūlo pravedėjai, sterilūs, dėžutė 10 vnt.
7210450	siūlo nukreipėjai, sterilūs, dėžutė 10 vnt.
7210104	daugkartinis lenktas mazgo nustūmėjas
7210076	daugkartinis tiesus mazgo nustūmėjas

12

9.4.

iš anksto paruoštas slystantis mazgas



1 Deploy preloaded implant 1.

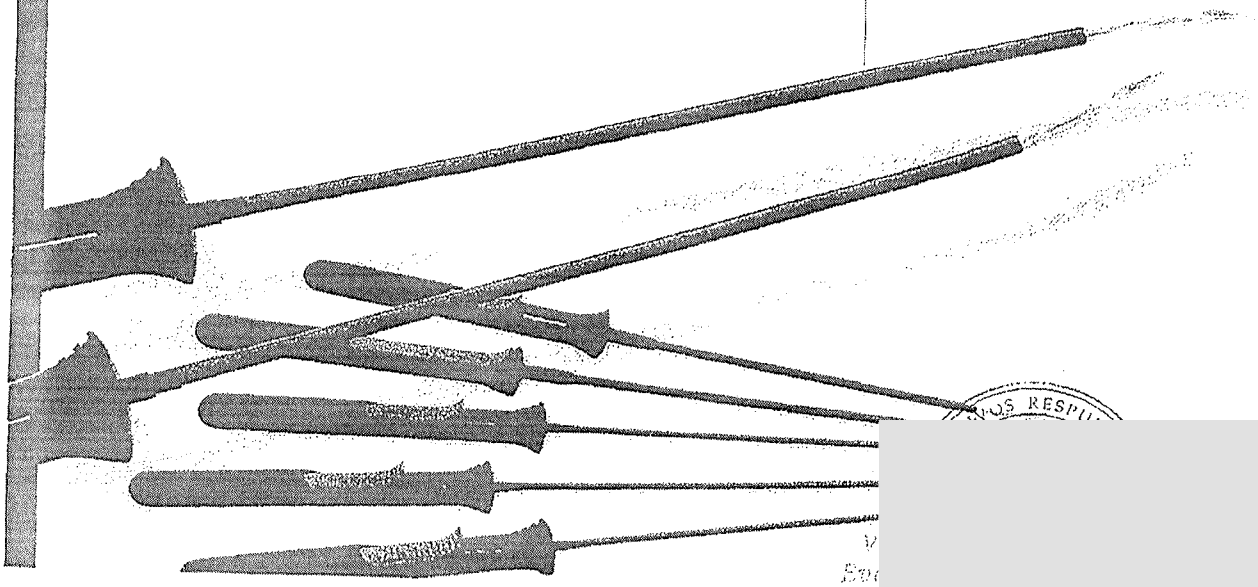
2 Deploy preloaded implant 2.

THE TECHNIQUE

The **ULTRA FAST-FIX® 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.

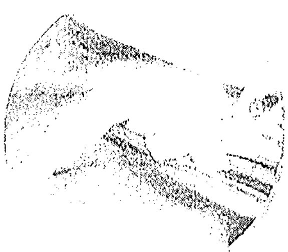
When the original FAST-FIX® Meniscal Repair System was introduced in 2001, it set the benchmark for minimally-invasive, all-inside repairs. Thanks to its preloaded implants, pre-tied sliding knot, and innovative pusher/cutter device, this innovative system lets you deploy two implants vertically or horizontally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

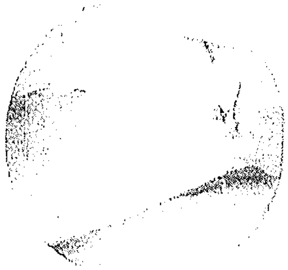


Kopija tikra

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



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



5 Completed repair with vertical and horizontal mattress stitches.

9.7. reversinė versija

9.4. Iš anksto paruoštas slystantis mazgas

Cheminė sudėtis 9.2 PLLA

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 arthroscopic 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 stitch 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 strength, an eight- to tenfold [illegible] 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.

9.2. Cheminė sudėtis „Peek-Optima"

PLLA absorbable implants

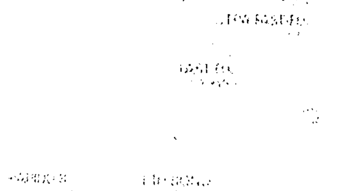
Bioabsorbable version of ULTRA FAST-FIX.

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.

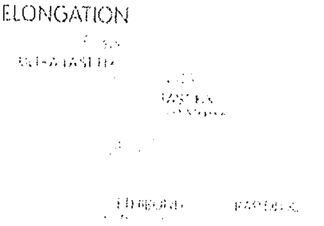
lenktos ir reversinė adata. 9.7.

ULTIMATE STRENGTH, N



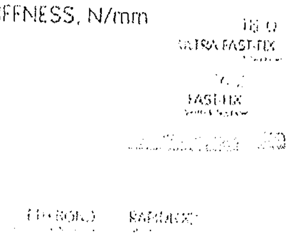
After 5000 cycles between [illegible] and [illegible]. All values are [illegible] ± standard error. Bovine menisci as model.

ELONGATION

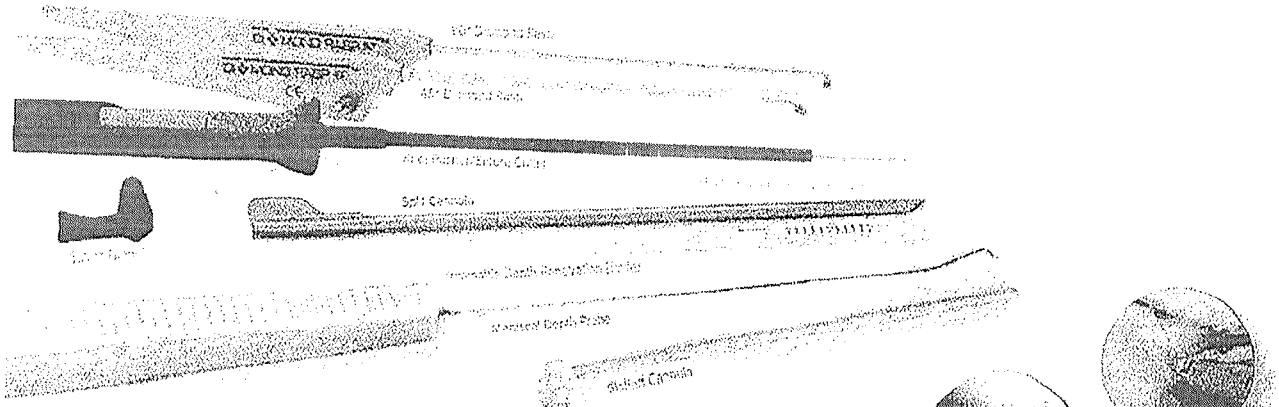


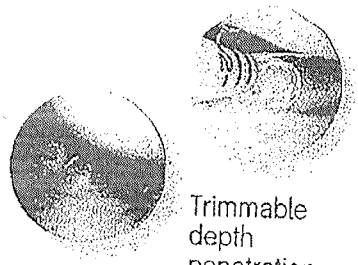
An evaluation of the mechanical properties of the ULTRA FAST-FIX Meniscal Repair System showed a significant increase in ultimate strength and stiffness, and a decrease in elongation compared to [illegible], RAPIDLOC and the conventional, clinically successful FAST-FIX device. [illegible]

STIFFNESS, N/mm



1. [illegible] Cyclic testing of flexible all-inside meniscus suture anchors. AM J Sports Med. 2005; 33:1-7
2. Data on file at Smith & Nephew





Meniscal depth probe

Measures the depth of penetration required for the ULTRA FAST-FIX® needle.

Trimmable depth penetration limiter

Controls the depth of needle penetration, enhancing safety in patients and allowing predictable meniscocapsular placement, while avoiding neurovascular structure injury.[1]

45° and 90° diamond rasps

These angled, diamond rasps are designed specifically to freshen the edge of the meniscal tear surfaces prior to repair, to induce a bleeding response.

Slotted cannula

Introduces the delivery needle into the joint safely, aids in steering to the desired position; can be used to reduce the tear; and minimizes needle skiving. For inferior surface repairs, the cannula can be used to lift the meniscus, providing greater accessibility to the tear.

Split cannula

Safely introduces the delivery needle into the joint, keeps debris off the needle and protects the articular cartilage.

Knot pusher/ cutter

This innovative device combines two instruments in one, allowing you to advance the knot to achieve the desired tension and trim the excess suture. The cutter is designed especially to cut ULTRABRAID®.

Ordering Information

72201491	ULTRA FAST-FIX, Curved
72201492	ULTRA FAST-FIX, Reverse Curved
72201494	ULTRA FAST-FIX AB, Curved
72201495	ULTRA FAST-FIX AB, Reverse Curved
72201537	Knot Pusher/Suture Cutter
7210977	Slotted Cannula, reusable
015186	Meniscal Depth Probe, reusable
014549	45 degree Diamond Rasp, reusable
014550	90 degree Diamond Rasp, reusable
7210450	Suture Funnel, sterile, box of 10
7209950	Suture Threaders, sterile, box of 10
011703	Sterilization Tray

Contact your sales representative about information regarding the ULTRA FAST-FIX Technique Guide

Endoscopy
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Andover, MA 01810
USA

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US Customer Service: +1 800 343 5717
International Customer Service: +1 978 749 1140

. Arthroscopy 1998

0353 Rev. A

smith&nephew

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.

Stipri ir kliniškai įrodyta sistema
Užtikrina stiprų ir patikimą menisko susiuvimą.

Minimali invazija
Mažina sąnarinių kremzlių traumos riziką.

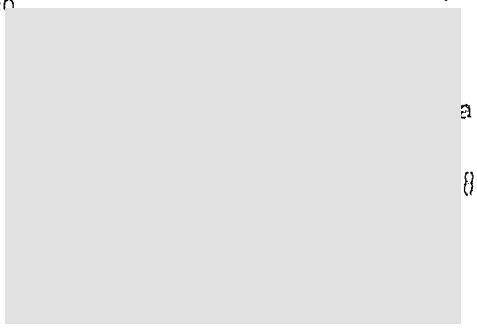
Slankiojantis mazgas su ULTRABRAID siūlais
Nuo tradicinių poliesterio siūlų šie skiriasi tuo, kad yra daug stipresni ir atsparesni susidėvėjimui; stipriai užsiveržia mazgas.

9.2.

PEEK – OPTIMA® - itin stiprūs nesirezorbuojantys polimeriniai implantai
PEEK OPTIMA polimerai užtikrina, kad inplantas nesulūš procedūros metu.

PLLA absorbuojantys implantai
Tai absorbuojanti Ultra Fast-Fix implantų versija.

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



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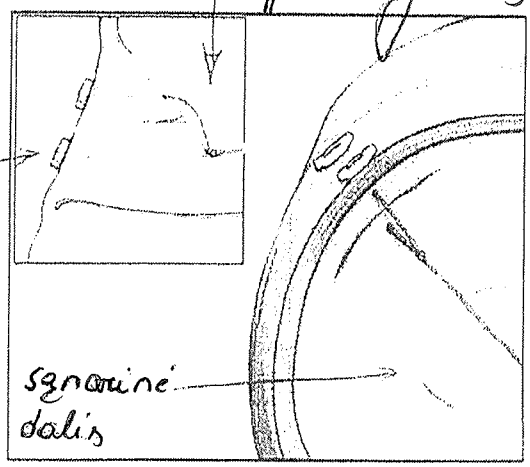

Figure 9. Prior to tightening suture construct

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.

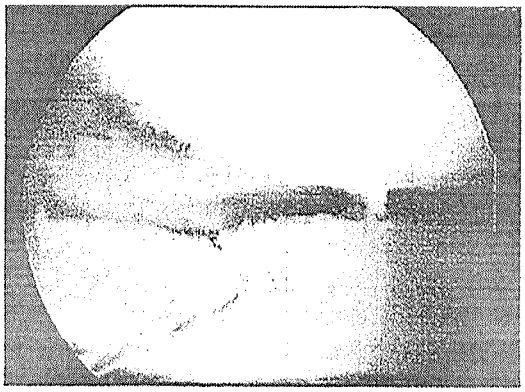

Photo 10. Hand-tightened suture construct - vertical mattress

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.

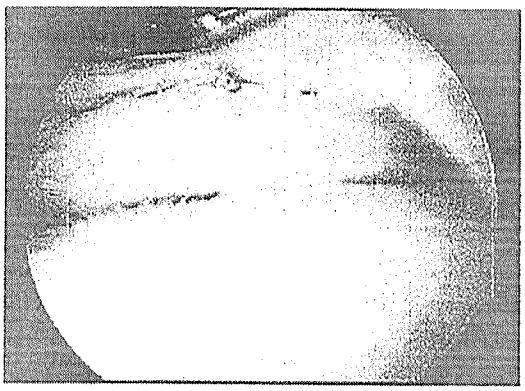

Photo 11. Hand-tightened suture construct - horizontal mattress

Setup

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 non-absorbable, UHMW polyethelene 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, sealed safely beyond the capsule, and are then tightened in a simple manner without the need for arthroscopic knot tying (Photos 2 and 3).

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[2].

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.

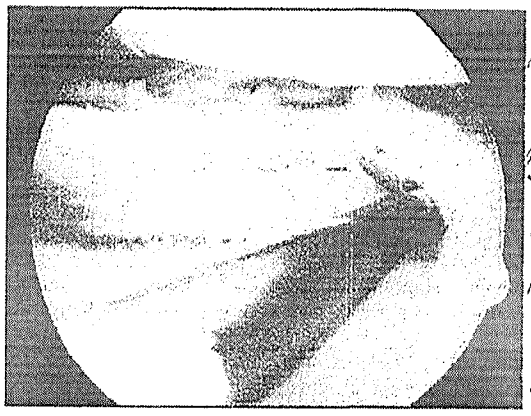

Photo 2. Completed repair - horizontal

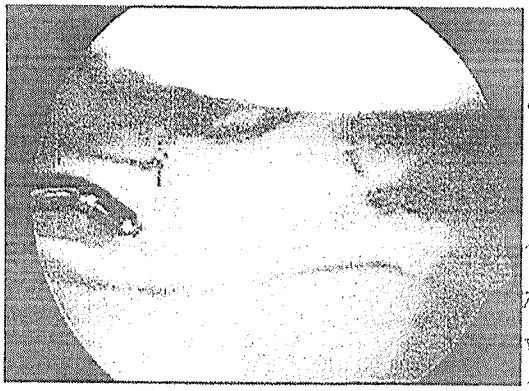

Photo 3. Completed repair - vertical x 2

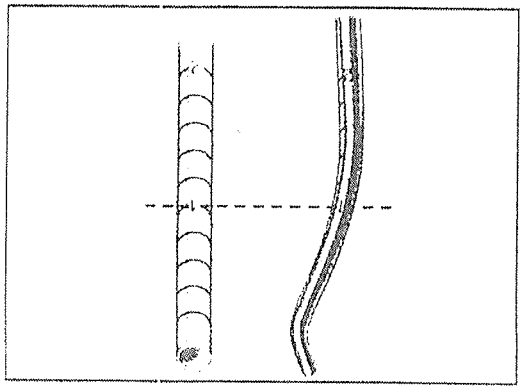

Figure 1a. Trimmable depth penetration limiter and meniscal depth probe

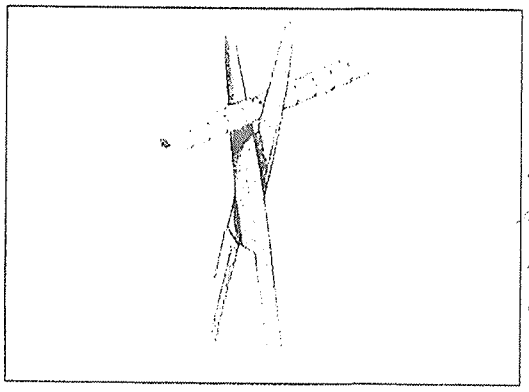

Figure 1b. Trimmable depth penetration limiter

Setup

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 polyethelene 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).

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[2].

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.

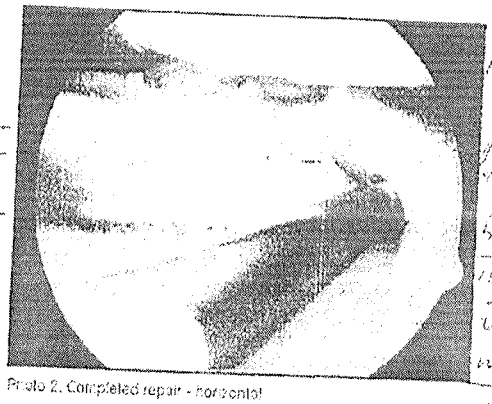

Photo 2. Completed repair - horizontal

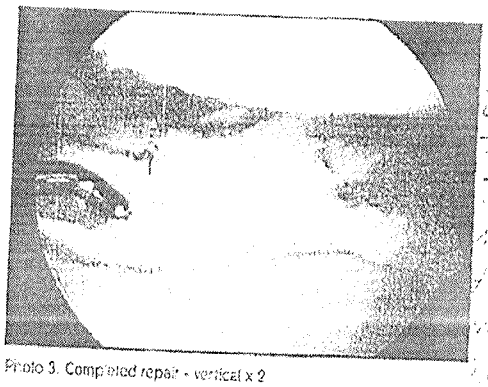

Photo 3. Completed repair - vertical x 2

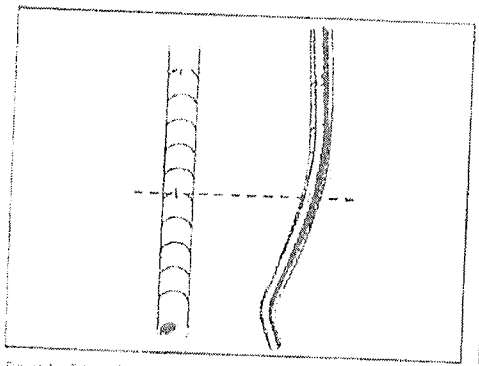

Figure 1a. Trimmable depth penetration limiter and meniscal depth probe

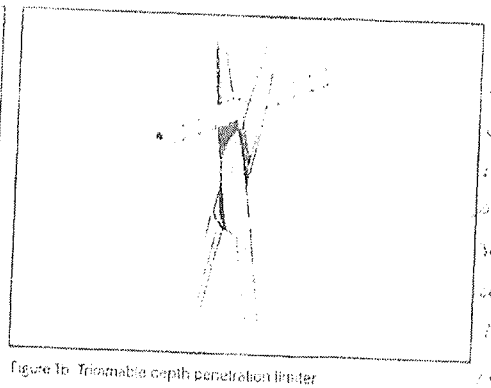

Figure 1b. Trimmable depth penetration limiter

19

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

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.

2. 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.

3. 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.

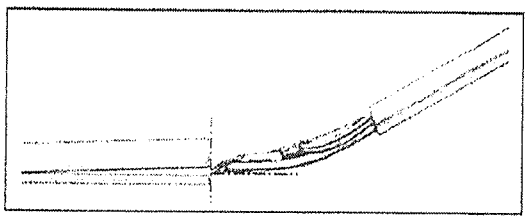

Figure 3. Blue split cannula positioned 90° to the curve of the delivery needle

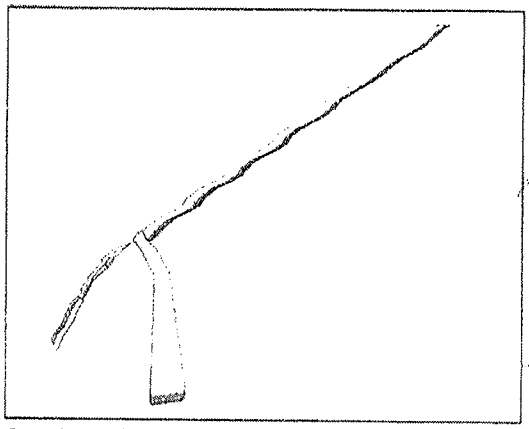

Figure 3a. Needle curve facing down

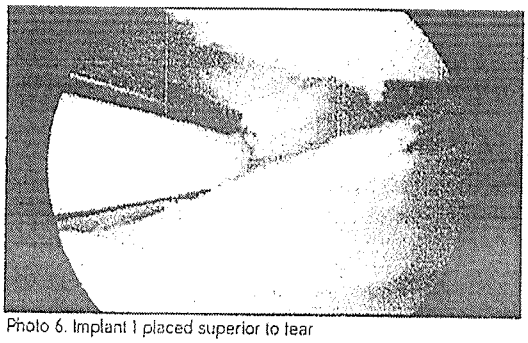

Photo 6. Implant 1 placed superior to tear

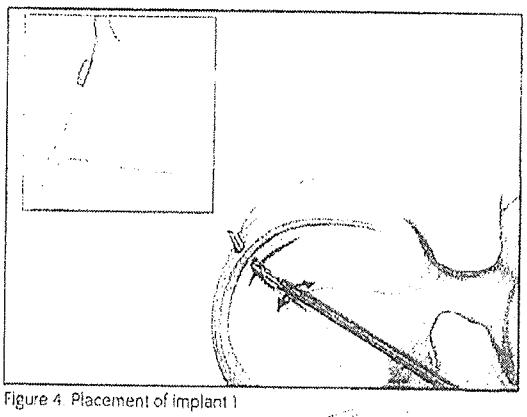

Figure 4. Placement of implant 1

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.

Viršutinis kokio paviršiaus 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.

Stipri ir kliniškai įrodyta sistema

Užtikrina stiprų ir patikimą menisko susiuvimą.

Minimali invazija

Mažina sąnarinių kremzlių traumos riziką.

Slankiojantis mazgas su ULTRABRAID siūlais

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

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.

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.

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.

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.

Courtesy of Smith & Nephew, Inc., 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.

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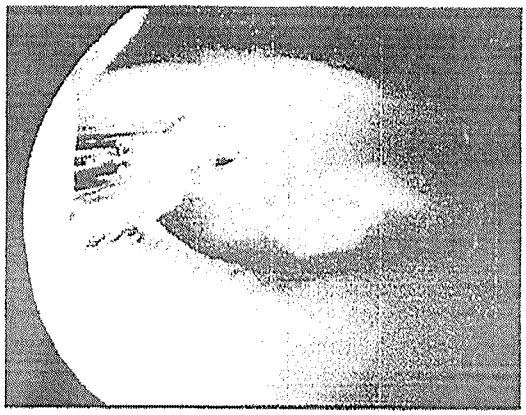

Photo 7. Implant 2 fully advanced to the ready position

4. 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).

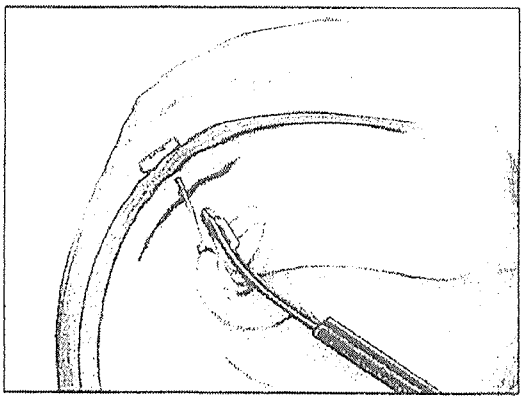

Figure 5. Implant 2 fully advanced to the ready position

8.3.

„U" formos fiksacija

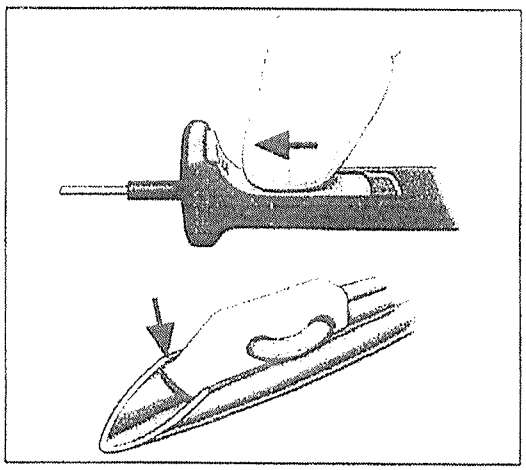

Figure 6. Proper positioning of implant 2

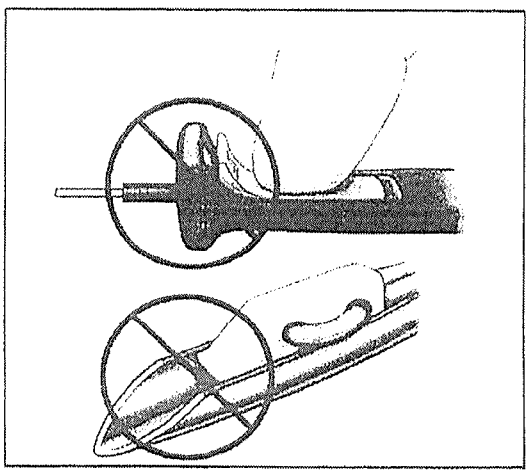

Figure 7. Improper positioning of implant 2

24

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.

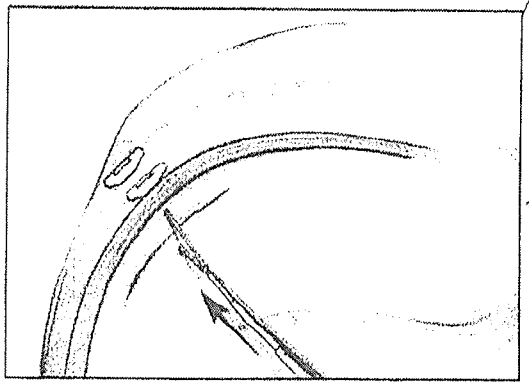

Figure 10. Suture construct tensioning

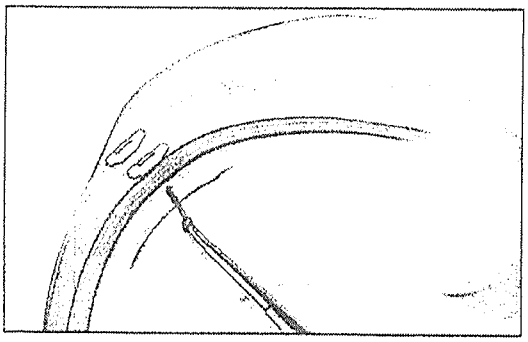

Figure 11. Suture cutting

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.

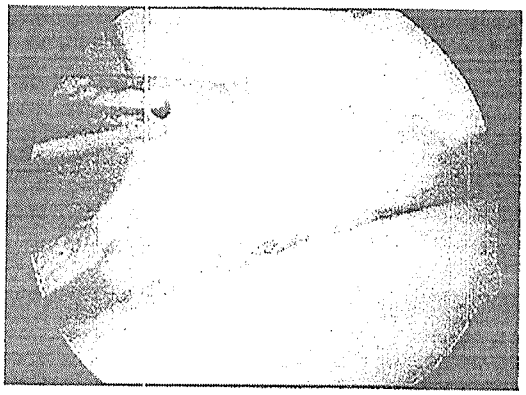

Photo 12. Suture cutting - horizontal mattress

Photo 13. Suture cutting - vertical mattress

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).

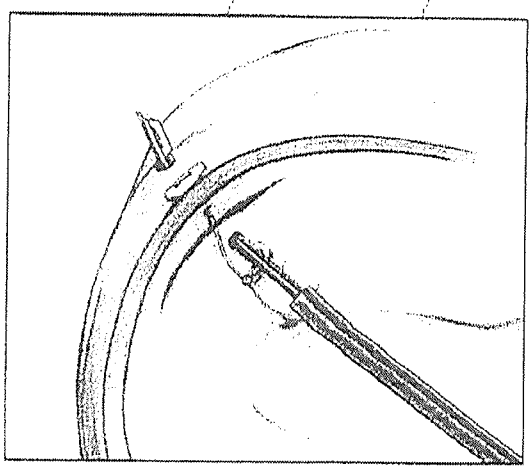

Figure 8. implant 2 ready for release

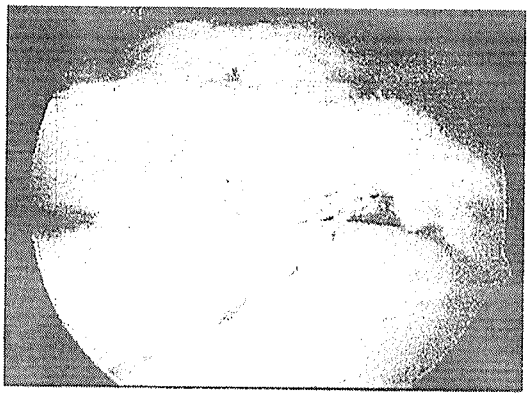

Photo 8. Horizontal mattress suture

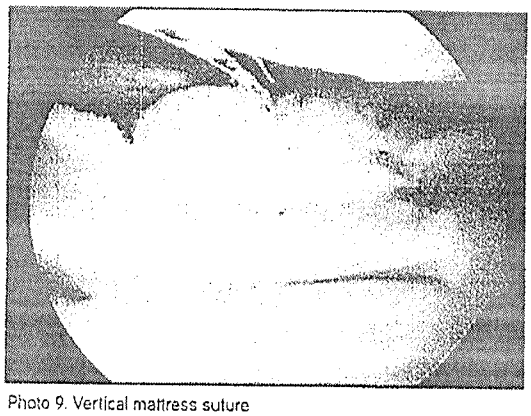

Photo 9. Vertical mattress suture

9.1. Sterilioji poluotėjė