

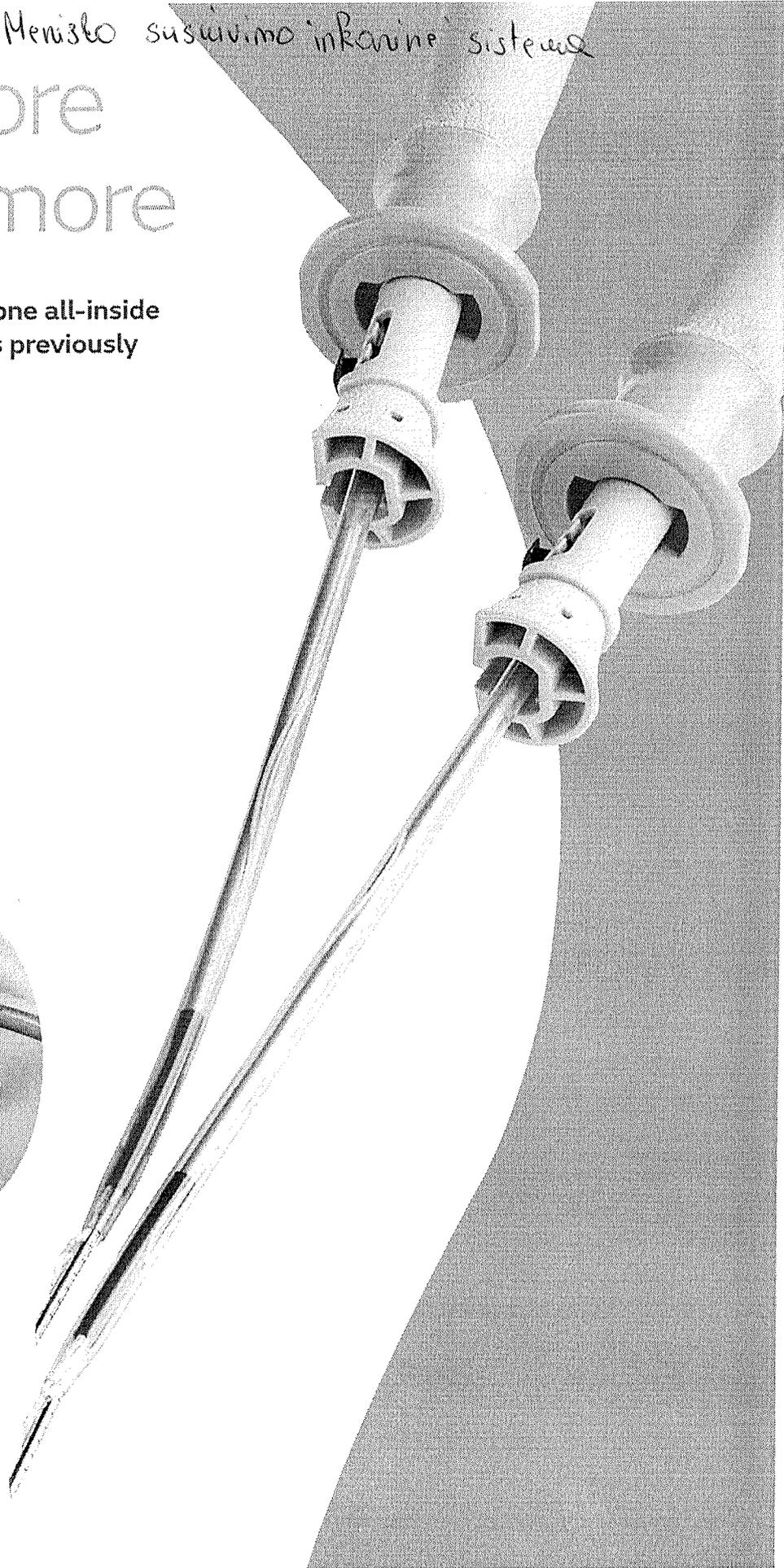
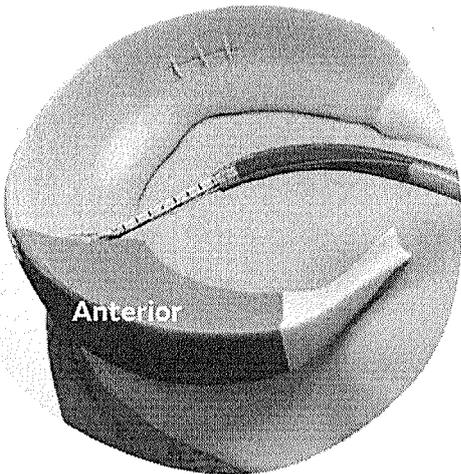
8. Menislo susivimo inkavine sisteme

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

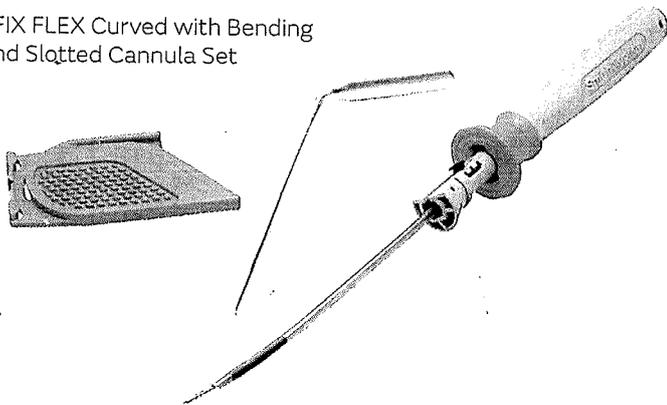


*compared to predicate device

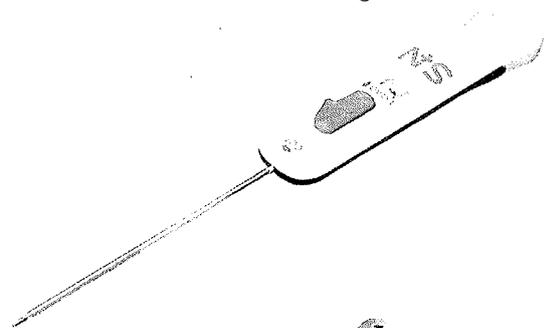
Meniscus Repair: All-Inside Repair

Product code	Description	Per carton
FAST-FIX® FLEX Meniscal Repair System		
✓ 72205324	FAST-FIX FLEX Curved with Bending Tool and Slotted Cannula Set	1 <i>Lenkte</i>
✓ 72205325	FAST-FIX FLEX Reverse Curved with Bending Tool and Slotted Cannula Set	1 <i>Reversine</i>
✓ 72205676	FAST-FIX FLEX Curved Needle Inserter (requires also 72205324 or 72205325)	1 <i>Lenkte</i>
✓ 72205677	FAST-FIX FLEX Reverse Curved Needle Inserter (requires also 72205324 or 72205325)	1 <i>Reversine</i>
NOVOCUT® Suture Manager		
CTX-C001	NOVOCUT Suture Manager	1
FAST-FIX Instruments		
015186	Meniscal Depth Probe	1
7210977	Slotted Cannula	1
014549	Diamond Rasp 45°	1
014550	Diamond Rasp 90°	1

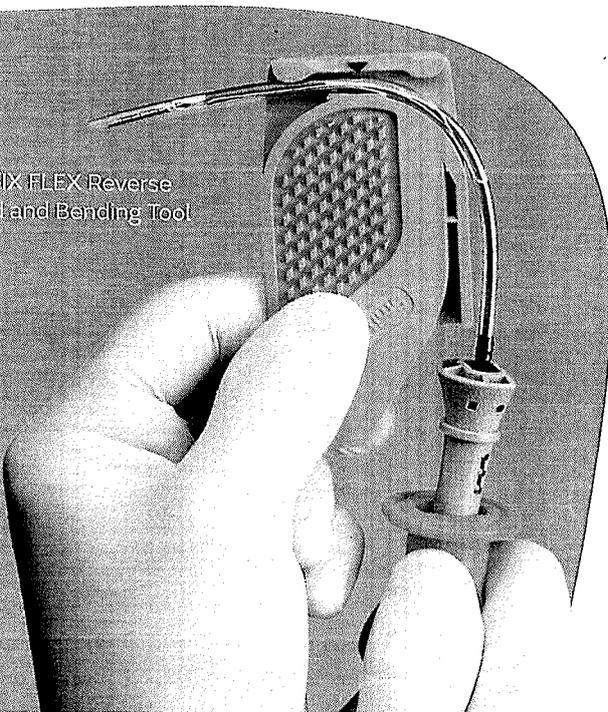
FAST-FIX FLEX Curved with Bending Tool and Slotted Cannula Set



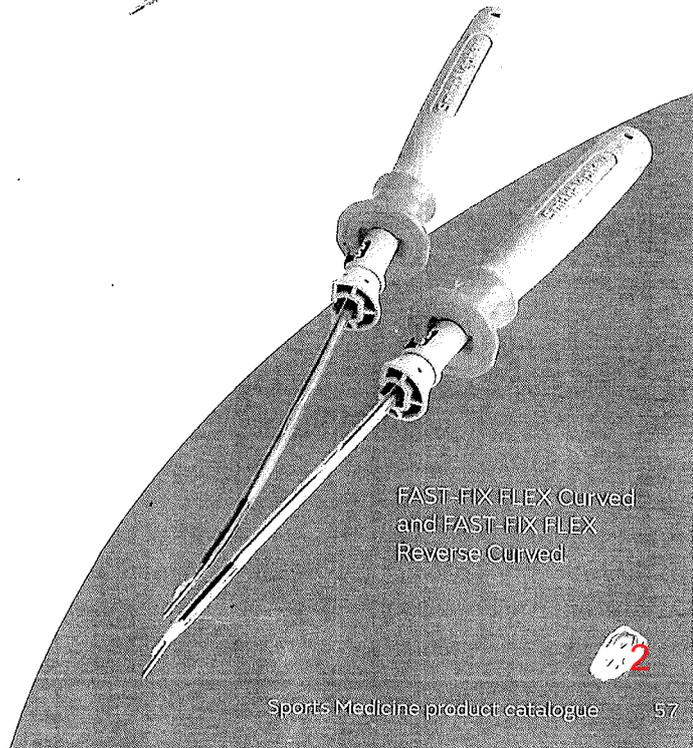
NOVOCUT Suture Manager

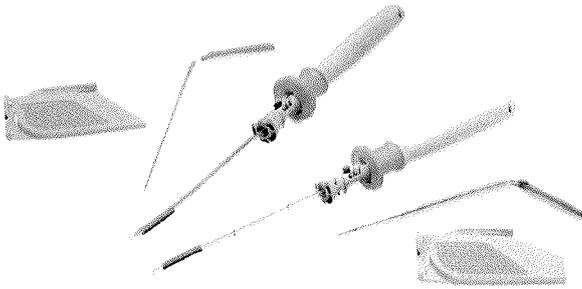


FAST-FIX FLEX Reverse Curved and Bending Tool



FAST-FIX FLEX Curved and FAST-FIX FLEX Reverse Curved





FAST-FIX[◇] FLEX

Meniscal Repair System

Instructions for Use

Smith+Nephew

<input type="checkbox"/> EN English	<input type="checkbox"/> FI Suomi	<input type="checkbox"/> PL Polski
<input type="checkbox"/> BG Български	<input type="checkbox"/> DE Deutsch	<input type="checkbox"/> PT Português
<input type="checkbox"/> HR hrvatski	<input type="checkbox"/> EL Ελληνικά	<input type="checkbox"/> RO Română
<input type="checkbox"/> CS Česky	<input type="checkbox"/> HU magyar	<input type="checkbox"/> SK Slovensky
<input type="checkbox"/> DA Dansk	<input type="checkbox"/> IT Italiano	<input type="checkbox"/> SL slovenščina
<input type="checkbox"/> NL Nederlands	<input type="checkbox"/> LV Latviešu	<input type="checkbox"/> ES Español
<input type="checkbox"/> ET Eesti	<input type="checkbox"/> LT Lietuvių	<input type="checkbox"/> SV Svenska
<input type="checkbox"/> FR Français	<input type="checkbox"/> NO Norsk	<input type="checkbox"/> TR Türkçe

FAST-FIX[◇] FLEX Meniscal Repair System

INSTRUCTIONS FOR USE

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.

Performance Characteristics

The implant-suture construct can be deployed vertically or horizontally on either side of the meniscus and reduced by the pre-tied self-sliding knot.

How Supplied

The system is supplied sterile and is for SINGLE USE ONLY.

Contents

The contents are supplied in one of two configurations:

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

OR

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

Materials

Implants: 100% Polyetheretherketone

Delivery Needle Assembly: Stainless steel needle, Nitinol actuator, Polyether block amide depth tube, ABS (acrylonitrile-butadiene-styrene) and polycarbonate handle.

Suture: Uncoated ultrahigh-molecular weight polyethylene fiber braided with polypropylene monofilament fiber

Cannula: Stainless steel

Bend Tool: ABS (acrylonitrile-butadiene-styrene)

susideda iš dviejų „T“ inkanų
su #2-0 storio UHMW
(ultra high molecular weight)
pinto polietileno pluošto.
Smith+Nephew

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 a professional healthcare facility.

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 transplantation 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.

Target Patient Groups

The patient population is comprised of adult patients for whom meniscal repairs, allograft transplant procedures, and anchoring the allograft to the meniscal rim during allograft transplantation procedures is determined to be necessary by the healthcare professional.

Expected Clinical Benefits

Meniscal tears repaired with FAST-FIX FLEX lead to an improvement in clinical outcomes from pre-operative baseline scores.

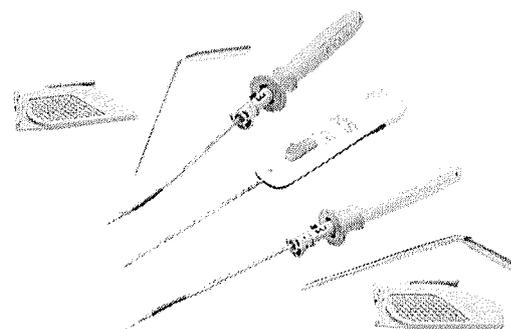
Meniscal allograft transplantations (MAT) conducted with FAST-FIX FLEX lead to an improvement in clinical outcomes from pre-operative baseline scores.

Kartu su termoplastinio polimero
lenkimo instrumentu ir nerūdijančio
plieno įvedimo kanule.

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 +878 749 1000
US Customer Service:
+1 800 343 5717

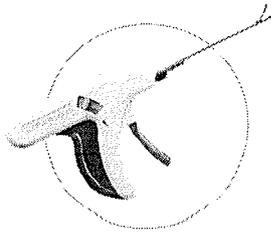
Trademark of Smith+Nephew.
All trademarks acknowledged.
©2021 Smith+Nephew. All rights reserved. 27713 V2 05/21

References

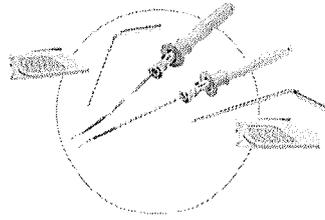
- Smith+Nephew 2021 Validation, FAST-FIX FLEX, Internal Report, 15010267 Rev A.
- Smith+Nephew 2021 Validation, FAST-FIX FLEX, Attachment B, Internal Report, 15010267 Rev A.
- Smith+Nephew 2021 FAST-FIX FLEX- Surgeon Surveys, Internal Memo.
- Smith+Nephew 2021 Competitive, FAST-FIX FLEX Dimensional Analysis, Internal Report, 15010419 Rev A.
- Li WP, 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.
- Metcalf MH, Barrett GR. Prospective evaluation of 1455 meniscal tear patterns in patients with stable knees. *AJSM.* 2004;32(3):675-680.
- Smith+Nephew 2020 Biomechanical testing, FAST-FIX FLEX, Internal Report, 15010180 Rev A.
- Smith+Nephew 2019 Evidence Outcomes Reports EO/SPH/FASTFIX/002A-1 and EO/SPH/FASTFIX/003/v2.
- Briggs KH, Steadman JR, Hay CJ, Hines SL. Lysholm Score and Tegner Activity Level in Individuals With Normal Knees. *AJSM.* 2005;33:889-901.
- Anderson AF, Irrgang JJ, Kocher MS, et al. The International Knee Documentation Committee Subjective Knee Evaluation Form. *AJSM.* 2006;34(1):128-135.

+ All tears, all repairs

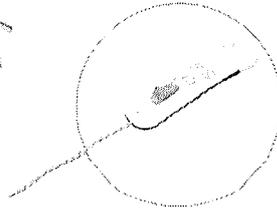
Meniscal Repair Solutions



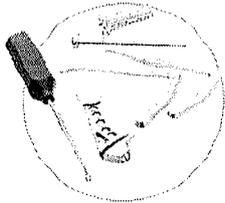
NOVOSTITCH[®] PRO
Meniscal Repair System



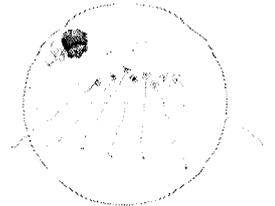
FAST-FIX[®] FLEX
Meniscal Repair System



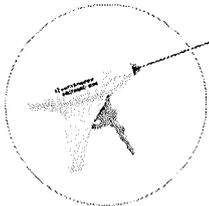
NOVOCUT[®]
Suture Manager



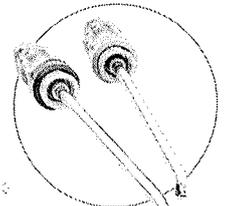
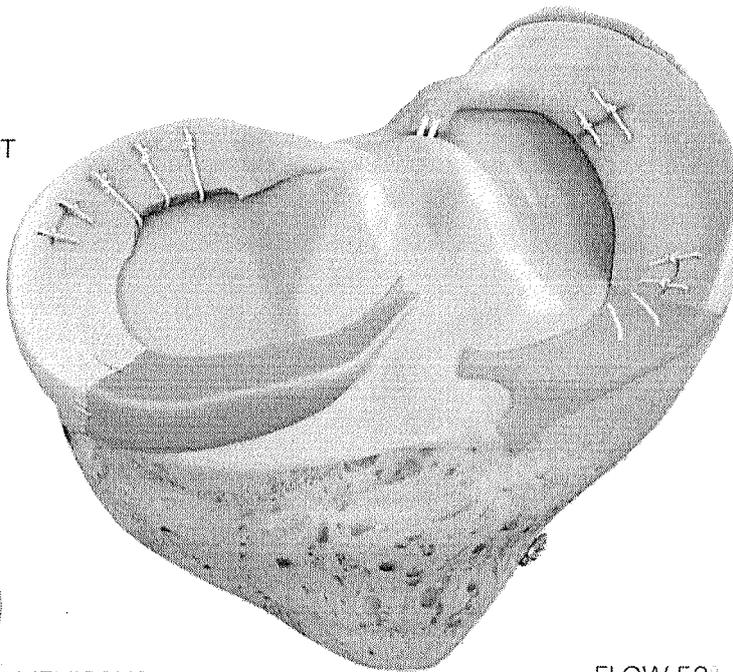
MENISCAL ROOT
Repair System



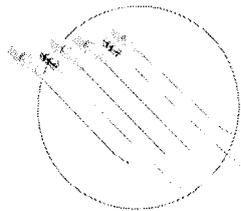
MENISCAL STITCHER
Repair System



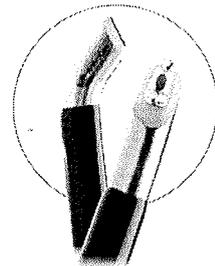
FIRSTPASS[®] MINI
Family of Suture Passers



DYONICS[®] PLATINUM
Curved Blades



MENISCUS MENDER II
Repair System



FLOW 50[®]
COBLATION[®] Wand



Watch the All tears, all repairs animation

Accelerating the standard of care toward meniscal repair

All-inside FAST-FIX[®] repair is clinically proven to restore healthy knee function⁸

+ More than 20 years of innovation in meniscal repair

click on product names for pop up images

Lysholm score

92.3 mean FAST-FIX postoperative score⁸

94 mean healthy control score⁸

0

92

Tegner activity score (TA)

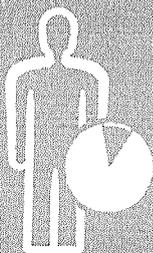
5.7 mean score in healthy adults⁹

6.3 mean postoperative score⁹



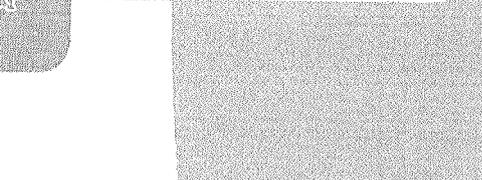
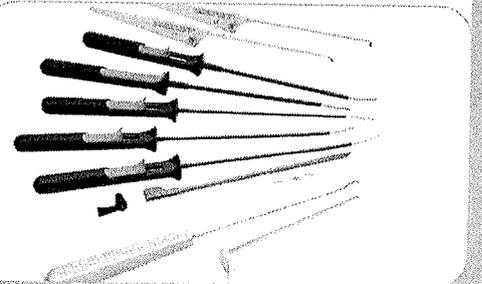
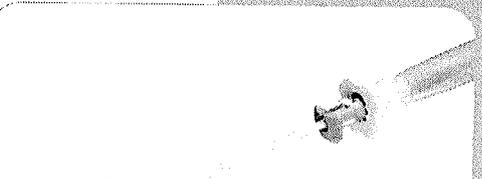
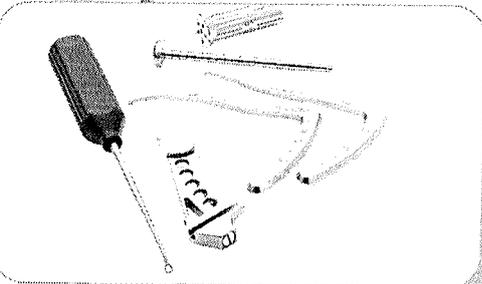
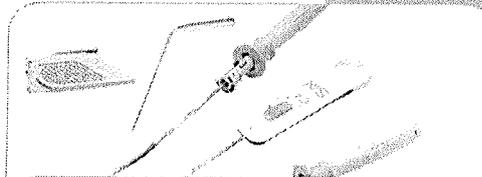
0

5.7 6.3



86%

mean success rate of all-inside FAST-FIX repair¹⁰



2021 FAST-FIX FLEX Meniscal Repair System

2019 NOVOSTITCH PRO Meniscal Repair System

2018 FIRSTPASS MINI Suture Passer

2017 MENISCAL ROOT Repair System

2013 MAT Procedure Indication

2011 FAST-FIX 360 Meniscal Repair System

2007 ULTRA-FAST FIX Meniscal Repair System

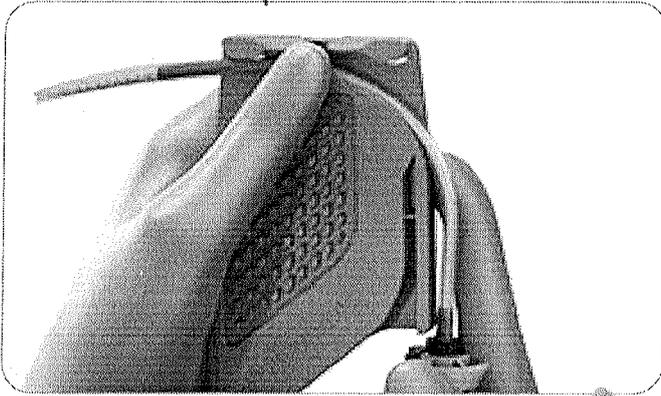
2001 FAST-FIX Meniscal Repair System

1999 T-Fix Suture

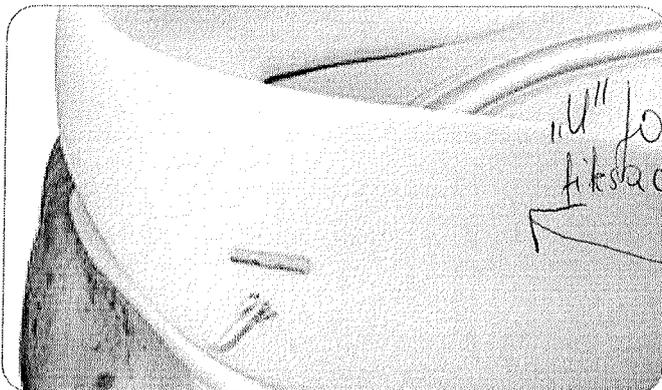
All-Zone All-Inside Meniscal Repair

+ FLEX

lepšanas instrumenta palīdzība



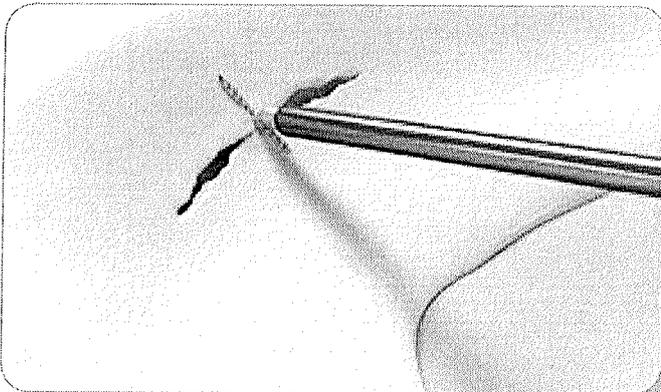
+ Fix



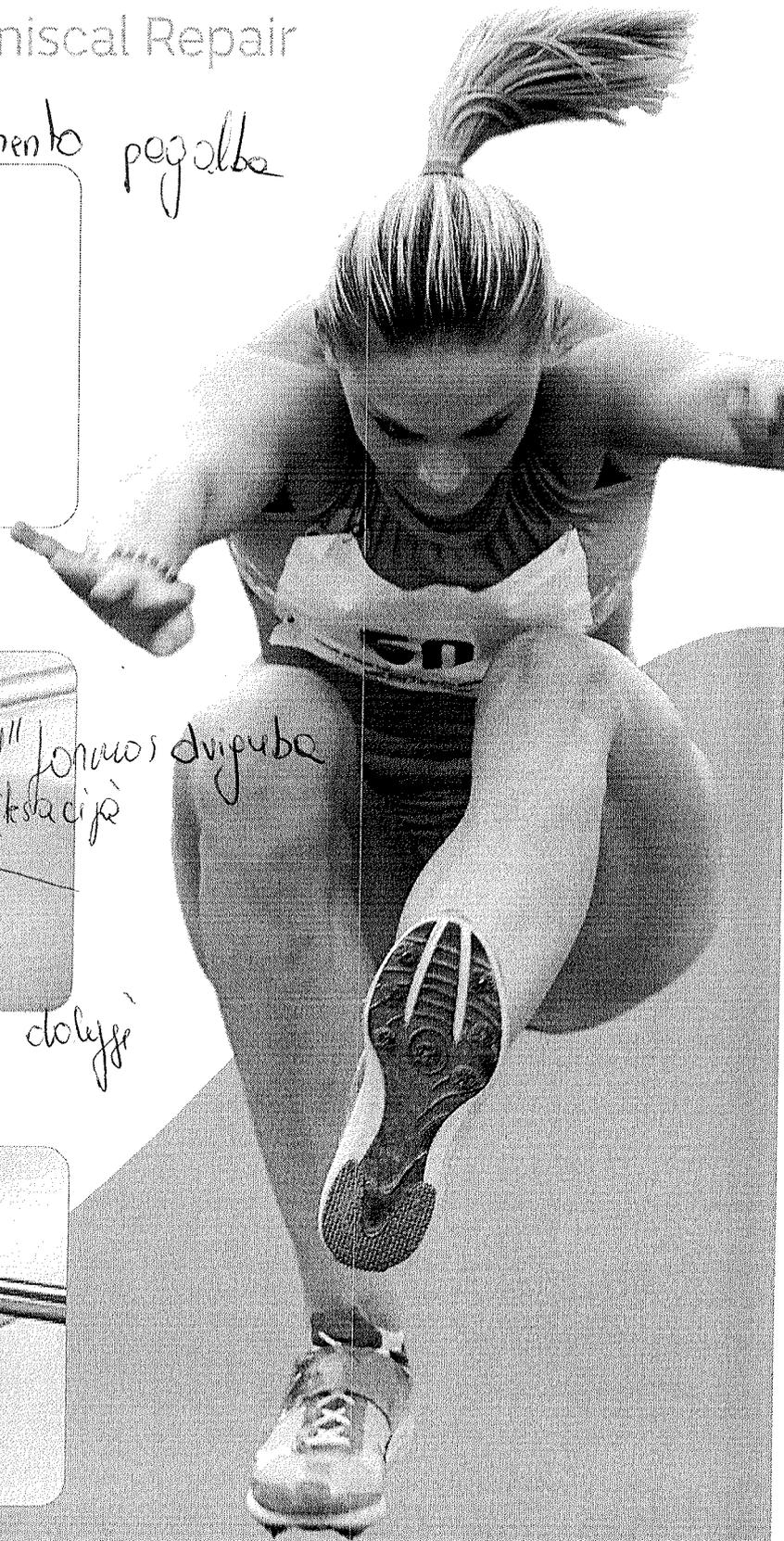
11" foras divpabe
fiksācija

Nepalietā implanta sānrajēnā daļēji

+ Finish

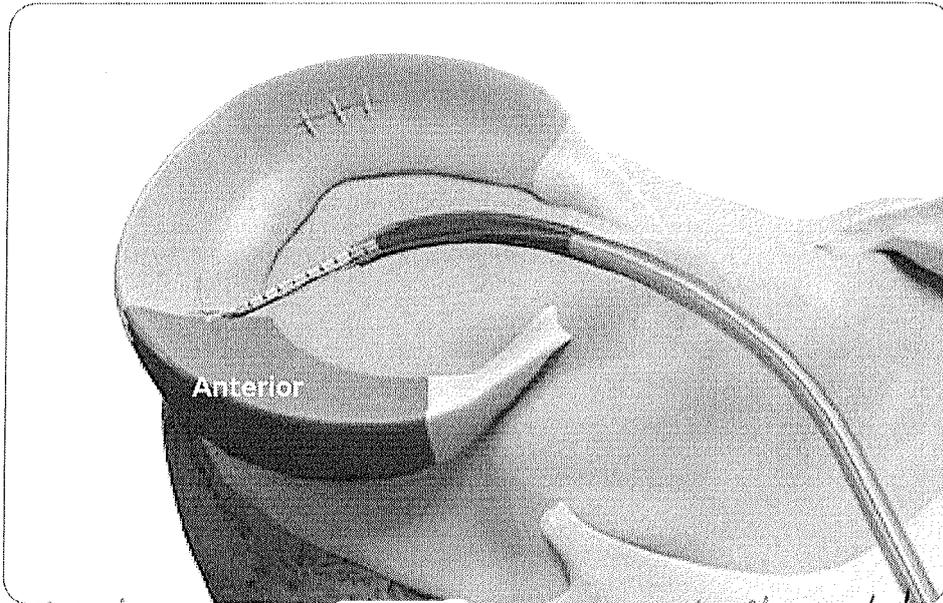


Read the technique guide



+ 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}

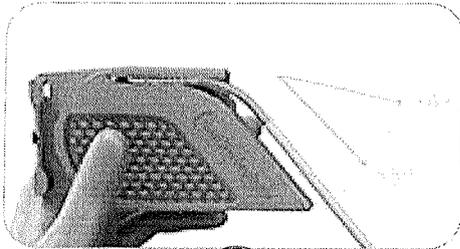


lenkta

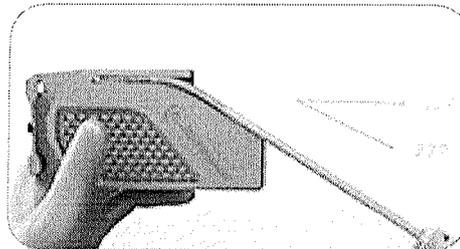
FAST-FIX FLEX Curved

Reversine lenkta adato

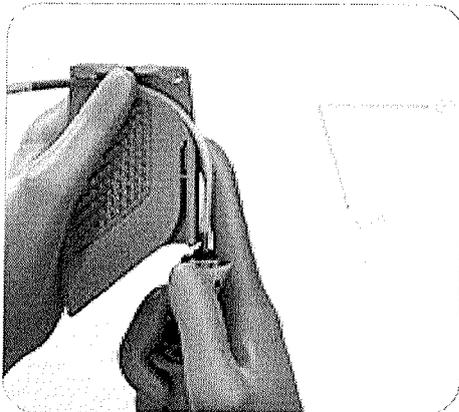
FAST-FIX FLEX Reverse Curved



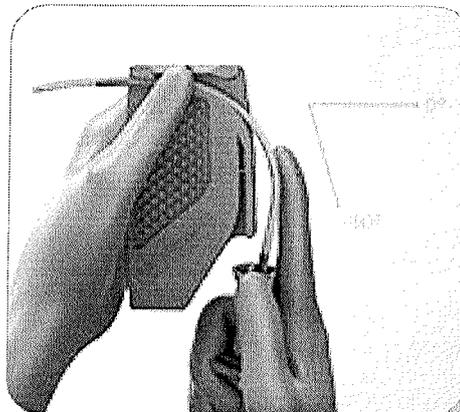
Needle bend up to 35°



Needle bend up to -22°



Shaft bend up to 80° *sticbas*



Shaft bend up to -80°

*Adato paline
palenkti iki 35°*

*lenkimo instru-
mento papdaba
paline palenkti
iki 80°*

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

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}

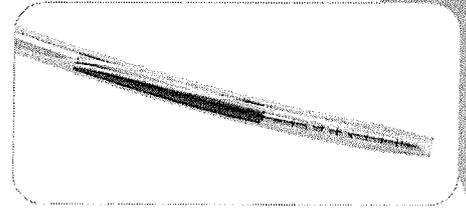
through one-handed 360° active deployment confirmed through touch, sound and sight¹

Vienkoviinis 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
(12mm, 16mm as shipped, 20mm)



Braided suture

may provide visibility against the white meniscus

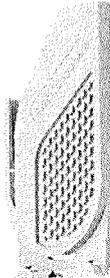
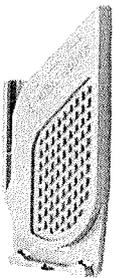
Adato lenkte

Adato reversinė

FAST-FIX FLEX
Curved + Bend Tool

FAST-FIX FLEX Reverse
Curved + Bend Tool

Laser-marked needle tip serves as a quick reference for needle depth penetration



FAST-FIX FLEX can facilitate:

- Vertical tear repairs
- Bucket handle tear repairs
- Ramp lesion tear repairs
- Meniscal allograft transplant
- And many more

*compared to predicate device

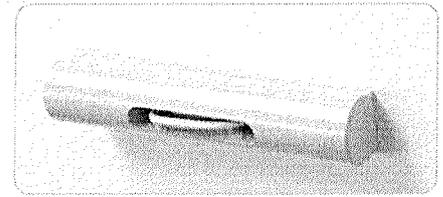
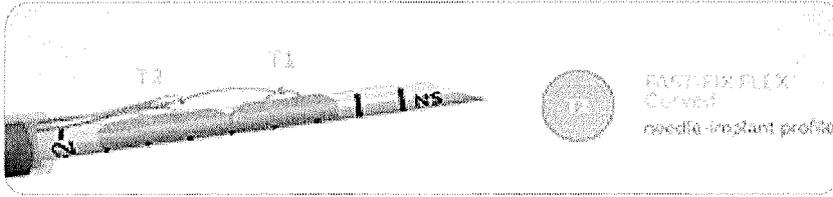
Lenkimo instrumentas



Watch the animation

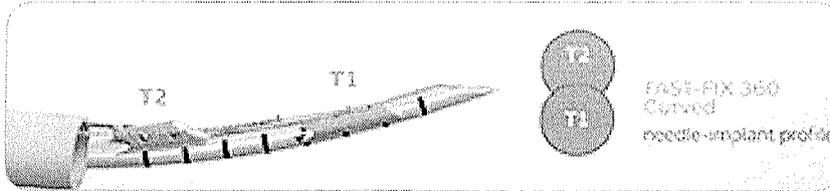
+ Preserve Anatomy

FAST-FIX® FLEX



Susidede is a "T" inkarey

FAST-FIX 360

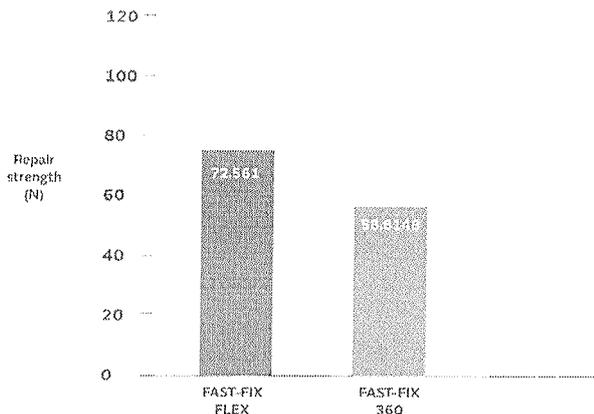


In-line implants and a 17 gauge needle create a 25% smaller needle insertion area⁴

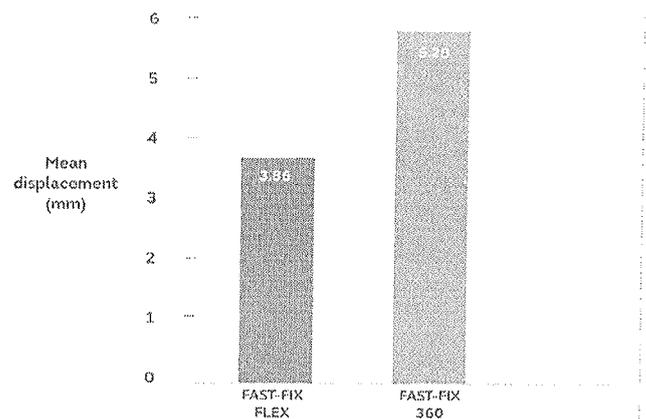
~20% less contact⁴ with the capsule but ~20% stronger⁷

Improved Performance*

MEAN OF THE REPAIR STRENGTH AFTER 1000 CYCLES⁷



MEAN CYCLIC DISPLACEMENT AFTER 1000 CYCLES⁷



~20% stronger⁷

27% less displacement⁷

*compared to our predicate device as demonstrated in biomechanical testing

Sterilizirane pakotėje
Fast Fix Flex, leukieta adose,
su leukiemo instrumentu ir
↓ kanule. Dėkingų

SmithNephew

REF CATALOG NUMBER 72205324
LOT BATCH CODE 2088622

(1) FAST-FIX® FLEX Curved Inserter, Bender, Cannula Set

Gekrümmtes Setzinstrument, Bieger, Kanülenset • Ensemble
comprenant dispositif d'insertion courbé, cintreuse et canule •
Inseritore curvo, piegatrice, set con cannula • Gebogen
plaatsingsinstrument, buiger, canuleset • Juego de cánula,
curvadora y posicionador curvado • Böjt sättinstrument,
böjare, kanylset • Buet innsetningsinstrument, bøyer,
kanylesett • Kavisti Yerleştirici, Bükücü, Kanül Seti • Κυρτός
εισαγωγέας, εργαλείο κάμψης, σει κάνουλας • Inserter curvo,
arqueador, conjunto de cánulas • Buet indfører, bukker,
kanylesæt

Pažymėta
CE bendri

USE BY 2025-04-20



MADE IN Costa Rica

Endoscopy
Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810 USA
T + 1 978 749 1000 • F + 1 978 749 1108
Customer Service +1 800 343 3717

Smith & Nephew Orthopaedics
GmbH, Altmannstrasse 14,
78532 Tuttlingen, Germany

This product may be covered by one or more U.S. patents. See
smith-nephew.com/patents for details.
*Trademark(s) of Smith & Nephew.



Internal Use Only
E03V55AD; 1