Smith+Nephew

NOVOSTITCH® PRO Meniscal Repair System

EC REP

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NOVOSTITCH® PRO Meniscal Repair System

NOVOSTITCH® PRO
Meniskusreparatursystem

NOVOSTITCH® PRO
Sistema de reparación de menisco

Système de réparation méniscale NOVOSTITCH® PRO

NOVOSTITCH® PRO
Sistema di riparazione meniscale

NOVOSTITCH® PRO
meniskreparatorsystem

NOVOSTITCH® PRO
meniscusreparatiesysteem

Sistema de reparação meniscal NOVOSTITCH® PRO

NOVOSTITCH® PRO
-system til meniskreparation

NOVOSTITCH® PRO
-system för meniskreparation

NOVOSTITCH® PRO
Menisku Onarım Sistemi

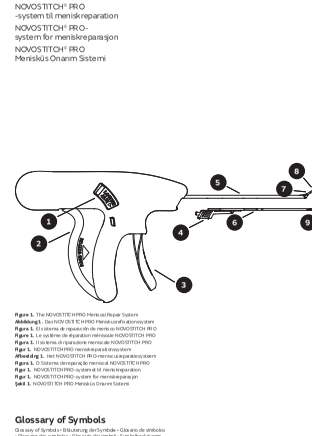

Figure 1. The NOVOSTITCH PRO Meniscal Repair System
Abbildung 1. Das NOVOSTITCH PRO Meniskusreparatursystem
Figura 1. El sistema de reparación de menisco NOVOSTITCH PRO
Figure 1. Le système de réparation méniscale NOVOSTITCH PRO
Figura 1. Il sistema di riparazione meniscale NOVOSTITCH PRO
Figuur 1. De NOVOSTITCH PRO meniskreparatiesysteem
Afbeelding 1. Het NOVOSTITCH PRO meniscusreparatiesysteem
Figura 1. O Sistema de reparação meniscal NOVOSTITCH PRO
Figur 1. NOVOSTITCH PRO-systemet för meniskreparation
Şekil 1. NOVOSTITCH PRO Menisküs Onarım Sistemi

Glossary of Symbols

Glossary of Symbols / Bildeutung der Symbole / Glossario de símbolos / Glossaire des symboles / Glossario dei simboli / Symbolverklaring / Verklaring bij uw symbolen / Glossário de símbolos / Symbolförklaring / Sembolleri anlamı

STERILE EO	Sterilized using ethylene oxide / Mit Ethylenoxid sterilisiert / Esterilizado con óxido de etileno / Stérilisé à l'oxyde d'éthylène / Sterilizzato usando ossido di etilene / Gesteriliseerd met ethylenoxide / Esterilizado por óxido de etileno / Steriliserad med etylenoxid / Etilen oksit ile sterilize edilmiştir
	Do not re-use / Nicht wiederverwenden / No reutilizar / Ne pas réutiliser / Non riutilizzare / Niet opnieuw gebruiken / Não reutilizar / Får ej återanvändas / Kullanılmaz
	Caution / Vorsicht / Precaución / Attention / Attenzione / Let op / Cuidado / Försiktighet / Dikkat
	Manufacturer / Hersteller / Fabricante / Fabricant / Produttore / Fabrikant / Tillverkare / Fabricante / Producent / Üretici
	Date of Manufacture / Herstellungsdatum / Fecha de fabricación / Date de fabrication / Data di fabbricazione / Fabricagedatum / Data de fabrico / Tillverkningsdatum / Üretim tarihi
LOT	Batch Code / Chargennummer / Código del lote / Code de lot / Codice lotto / Batchkod / Partipostnr / Código de lote / Partidan Kodu
REF	Catalog Number / Best.-Nr. / Número de catálogo / N° de référence de catalogue / Numero di catalogo / Catalogusnummer / Número do catálogo / Katalognummer / Katalognummer / Katalog Numarası
SN	Serial Number / Seriennummer / Número de serie / N° de série / Numero di serie / Serienummer / Serienummer / Número do série / Serienummer / Seri numarası
MR	MR safe / MR geeignet / Seguro para RM / Conforme aux normes de sécurité sur la résonance magnétique / Sicuro per la RM / Veilig voor MRI-scanner / Não apresenta risco em RM / MR-säker / MR-säker / MR güvenli
	Do not by date / Verfallsdatum / Fecha de caducidad / Date de péremption / Data di scadenza / Houdbaar tot / Utgångsdatum / Prazo de validade / Utgångsdatum / Son kullanma tarihi
	Consult Instructions for Use / Siehe Gebrauchsanweisung / Consulte el manual de instrucciones / Consulter le mode d'emploi / Consultare le istruzioni per l'uso / Raadpleeg de gebruiksaanwijzing / Consulte as instruções de utilização / Se bruksanvisningen / Se bruksanvisningen / Kullanım talimatlarına bakın

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Instructions for Use English

NOVOSTITCH® PRO Meniscal Repair System

STERILE EO

Device Description

The Smith+Nephew NOVOSTITCH® PRO Meniscal Repair System provides one 2-0 non-absorbable, non-sterile suture, single suture thread with tissue in arthroscopic surgery. It is comprised of a handheld surgical instrument (one for a left knee and one for a right knee) and a disposable cartridge (Figure 1). The device has a diameter less than 17 mm.

How Supplied

NOVOSTITCH® PRO is STERILE for SINGLE USE ONLY.
Non-attachable surgical suture is supplied sterile in 60 cm lengths preloaded in the device.
- The size 2-0 sutures composed of undyed (white) ultra-high-molecular-weight polyethylene braided with a coating of ultra-pure medical-grade polydimethylsiloxane (silicone) and polyethylene glycol (PEG) copper with a connector not. Is rated 0.75 lbs weight. Suture exceeds USP specifications for size 2-0. Diameter (the number average overall diameter is 0.363 mm)
- The size 0 sutures composed of undyed (white) ultra-high-molecular-weight polyethylene braided with two strands of green polyethylene terephthalate (PET) and a coating of ultra-pure medical-grade silicone. Is rated at a concentration not to exceed 0.75 lbs weight. Suture exceeds USP specifications for size 0 diameter (the number average overall diameter is 0.436 mm).

Intended Uses

The NOVOSTITCH PRO Meniscal Repair System is intended for use in health care professionals in arthroscopic surgery.

Indications for Use

The NOVOSTITCH® PRO Meniscal Repair System is indicated for approximation of soft tissue in meniscal repair procedures.

Contraindications

- The device is not to be used in orthopedic hardtissue.
- Surgical procedures other than those listed in the indications for Use section. Presence of infection.
- Patient conditions not allowing sufficient quantity or quality of tissue
- Insufficient bone quality to support the implant. Implants which may hinder the healing process.
- Foreign body sensitivity, if material sensitivity is suspected, testing should be completed prior to suture implantation.
- Patient conditions that prevent the patient's ability or willingness to follow postoperative instructions.

Warnings

Do not use if package is damaged. Do not use if the product has passed its use-by date or if sterile barrier is compromised.

- **The device is provided STERILE for SINGLE USE ONLY. It has not been validated for sterilization or reprocessing. Reprocessing or repeated sterilization can lead to an unsafe and failed device with the strength of the suture and component performance. Reprocessing of single-use devices can also cause cross contamination leading to patient infections. These risks may potentially affect patient outcomes.**
- **Detailed instructions regarding the safe and the intuitive of the device should be followed.**
- **Whether an arthroscopic assisted or in-open surgery, the device must be used under direct visualization.**
- **Arthroscopic surgery requires special skills and equipment and strict aseptic surgical technique. Knowledge of these and other appropriate techniques are important considerations for successful utilization of this device.**
- **Improper suture placement may elicit a minimal acute inflammatory reaction in tissue and in very rare cases it may lead to granuloma formation of the suture by fibrous connective tissue.**
- **Care should be taken with surgical procedures and techniques involving non-attachable sutures. Inflow employing polyethylene surgical sutures for wound closure, as the surgeon would normally do, may result in suture failure.**

Precautions

EU Federal Law (USA) restricts this device to sale by or on the order of a physician.

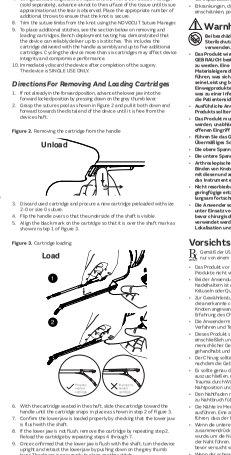
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- Avoid excessive handling, i.e. crushing or crimping resulting from use of surgical instruments such as forceps and needle holders.
- Use care when handling the device to prevent damage to the surface of flat, squarelike, with additional fibrous as well as textured by surgical instruments and the presence of the surgeon.
- Strong fixation with surgical procedures and techniques for non-absorbable sutures is required before use.
- The device should be handled and disposed of in accordance with all applicable regulations including, without limitation, those pertaining to human health and safety and the environment.
- A surgeon should not begin clinical use of the device without reviewing the instructions for use.
- Cuts/Lacerations can be the direct result of surgical hazards including, but not limited to infection, neurovascular damage, thermal/Frictional tissue damage, mechanical damage, improper suture position and inappropriate suture depth and length.
- Use caution when removing the device. Excessive tensioning may cause suture breakage.
- Use caution in meniscal tissue using steady, deliberate motion. Excessive speed or movement during use may result in unsuccessful suture passes.
- When the lower jaw is extended, do not squeeze the black handle until the devices in position to deploy suture. Doing so will deploy the suture prematurely. If this occurs, replace the cartridge before attempting to place the next suture.
- If the black handle of the upper jaw does not fully retract after it is released, the needle may still be engaged in the meniscal tissue. This can occur when the lower jaw is not fully constrained by the meniscal cuticle.
- The lower jaw will not open if the upper jaw is not fully retracted and both the black handles fully retracted.
- The lower jaw is fully constrained when the suture pool is housed within the handle. If the lower jaw does not retract, ensure that the black handle is fully released and that CAUTION and TROUBLESHOOTING above) If the lower jaw does not retract after ensuring that the black handle is fully released, remove the device from the patient. Allowing both jaws to open simultaneously or simultaneously until the lower jaw retracts.
- Apply varus or valgus force to open the compartment where the device is positioned.
- Advance the device incrementally to wherever femoral condyle stops so allowing the upper jaw to open.
- Pull back on the suture pool to assist the retraction spring until the lower jaw is fully retracted.
- Repeat pushing the grey thumb lever downward.

7. Using forceps and suture scissors and the NOVOSTITCH PRO Reamer (sold separately), advance strict to the office of the tissue until its suse approximately not the tear is clear and. Place the suture pool the number of additional throws to ensure that the knot is secure.
8. Tie the knot using the NOVOSTITCH® PRO Meniscal Suture Manager. To place additional stitches, see the section below on removing and loading cartridges. Bench deployment testing has demonstrated that the device can deploy suture up to a stitches. This includes the cartridge delivered with the handle as similiarly and up to five additional cartridges. Cut length device now than cis cartridges may affect device integrity and compromise performance.
9. Remove the device from the patient after completion of the surgery. Treatment is SINGLE USE ONLY.

Directions For Removing And Loading Cartridges

1. If not already in the Smith+Nephew Arthroscopic Instrument, advance the device into the sheath. Ensure the device is fully seated in the sheath.
2. Grasp the suture pool as shown in figure 2 and pull it both down and forwards towards the distal end of the device until it is free from the devices heft.

Figure 2. Removing the cartridge from the handle



3. Discard used cartridge and procure a new cartridge preloaded with suture. Or tie or cut to suture.
4. Flip the handle over so that the underside of the shaft is visible.
5. Align the hooks on the cartridge so that it is over the shaft markers shown on top 1 of figure 3.

Figure 3. Cartridge loading

6. With the cartridge seated in the shaft, slide the cartridge toward the handle until the cartridge snaps in place as shown in step 2 of Figure 3.
7. Confirm the lowerjaw is closed. Ensure the suture pool is in the lower jaw is flat with the shaft.
8. If the lower jaw is not flush, remove the cartridge by repeating step2. Reload the cartridge by repeating steps 4 through 7.
9. Once confirmed that the lower jaw is flush with the shaft, turn the device upright and retract the lowerjaw by pushing down on the grey thumb lever. Then place in new suture pool and repeat steps 2 through 8.

Storage

Store in a cool, dry place.

For Further Information

For further information on the medical devices, the information given at hand, or assistance in returning product contact Customer Service: +1 800 343 5717.

Directions For Passing Suture Through Meniscal Tissue

1. Squeeze the orange handle (see figure 1) to keep the upperjaw parallel with the shaft, and pass the device into the surgical site under arthroscopic visualization.
2. Advance the upperjaw into the superior surface of the meniscus following the radius of the meniscal tissue. The angle of the upper jaw can be modified by squeezing the orange handle.
3. Once the upperjaw is in place, release the orange handle. Fully extend the lowerjaw by pressing downward on the grey thumb lever (see figure 1). Ensure that the lowerjaw links underneath the meniscus and then release the grey thumb lever.
4. Squeeze the black handle, and then release upon, simultaneously squeeze the orange handle. Release the orange handle and the black handle. Then engaging the black handle will cause the needle to deploy and pass through the meniscal tissue. Pre-movement of the upperjaw, by depressing the upper jaw allowing it is signifiant the tissue is to be fully visible, relieve the suture if the pocket is compromised. Or if there is an appropriate target is concentrically repositioned the device in thirtee tissue is not the upper jaw. Release the orange handle and the grey thumb lever. Then release the black handle.
5. Repeat steps 1 through 4 as required to place the required number of sutures.
6. Release the orange handle and the black handle. Then engaging the black handle will cause the needle to deploy and pass through the meniscal tissue. The suture is where the lowerjaw is constrained by the meniscal cuticle.
7. The lower jaw will not open if the upper jaw is not fully retracted and both the black handles fully retracted.
8. The lower jaw is fully constrained when the suture pool is housed within the handle. If the lower jaw does not retract, ensure that the black handle is fully released and that CAUTION and TROUBLESHOOTING above) If the lower jaw does not retract after ensuring that the black handle is fully released, remove the device from the patient. Allowing both jaws to open simultaneously or simultaneously until the lower jaw retracts.
   - Apply varus or valgus force to open the compartment where the device is positioned.
   - Advance the device incrementally to wherever femoral condyle stops so allowing the upper jaw to open.
   - Pull back on the suture pool to assist the retraction spring until the lower jaw is fully retracted.
   - Repeat pushing the grey thumb lever downward.

Potential Adverse Effects

Adverse effects associated with the device use include: wound dehiscence, cutaneous formation in urinary and bile ducts when prolonged use, tissue reaction, pain, swelling, redness, and/or other inflammatory reactions, minimal acute inflammatory tissue reaction in very rare cases, granuloma. As with any foreign body, prolonged contact of this suture with soft solutions, such as those found in urinary or biliary tracts, may result in calculus formation.
Allergies and other reactions to elements/alloys.

Instructions for Use

Read the instructions for use in its entirety prior to use of the device. Inspect the device prior to use to ensure proper mechanical function. Ensure portal placement and preparation is appropriate to access the origin of the meniscus to be sutured.

The NOVOSTITCH PRO Meniscal Repair System

See Figure 1 – (Cartridge shown detached).

1. Grey thumb lever – Extend and retract lowerjaw
2. Black handle – Squeeze jaw parallel to the needle when the lower jaw is extended and the upper jaw is clamped. Otherwise, the handle remains locked
3. Orange handle – Controls upper jaw
4. Suture spool
5. Device shaft
6. Suture-size marking
7. Suture pool/upper jaw
8. Stitch targeting mark
9. Lower jaw

CAUTION: When the lowerjaw is extended do not squeeze the black handle until the device is in position to deploy suture. Doing so will deploy suture prematurely. If this occurs, replace the cartridge before attempting to place the next stitch.

Suture Size Selection

NOVOSTITCH PRO Meniscal Repair Systems are compatible with the NOVOSTITCH Meniscal Repair cartridge, size 2-0 (CT4700G) and the NOVOSTITCH Meniscal Repair cartridge, size 0 (CT4-0G02). Choose of suture size is at the discretion of the surgeon.

- When using NOVOSTITCH PRO with 2-0 sutures, ensure that the package labeling is marked 0. Alternopening the packaging and placing the cartridge into the sterile field. Remove the cartridge from the blue suture spool and flip "0" written inside the blue suture spool and reassemble.
- When using NOVOSTITCH PRO with 0 suture, ensure that the package labeling is marked 2-0. After opening the packaging and placing the cartridge into the sterile field, confirm the cartridge has a green suture spool and flip "0" written inside the blue suture spool and reassemble.

This product may be covered by one or more US patents.
See smith-nephew.com/patent for details.

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Certain marks are registered US Patent and Trademark Office.

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Gebrauchsanweisung Deutsch

NOVOSTITCH® PRO Meniskusrefixationssystem

STERILE EO

Produktbeschreibung

Das Smith+Nephew NOVOSTITCH® PRO Meniskusfixationssystem dient zum Führen von gefäßreinnahmen und resorbierbaren Fragmenten. Nichtfixieren Fixierung. Es besteht aus einem Handchirurgie und einer Einwegkartusche (Abbildung 1). Das System umfasst ein Nadelbaustein, die Zieldaten des Instrument, ordnen mit Nahtmaterial vorgeladen und Nahtmaterial bereits fertig (siehe Abbildung 1). Die Gesamtlänge des Instrumentes ist weniger als 17 mm.

Lieferumfang

Das Produkt wird STERIL geliefert und ist NUR FÜR EINMALIGEN GEBRAUCH bestimmt.
Nicht wiederbarer chirurgische Nadel werden steril mit einer Länge von 60 cm einer vorgeladen im Produkt bereitgestellt.

- Die Nähte der Größe 2-0 sind aus unpolierten (weißen) Polyethylenfasern mit einer Beschichtung aus ultrareinem medizinischem Polydimethylsiloxan (Silikon) und Polyethylenglykol (PEG) Kupfer mit einem Verbindungsstück. Es wird mit 0,75 lbs. Gewicht. USP Spezifikationen für die Größe 2-0 überschreitet. (Durchmesser ist der Durchmesser 0,363 mm)
- Die Nähte der Größe 0 sind aus unpolierten (weißen) Ultrahochmolekularem Polyethylen geflochten mit zwei Strängen grünem Polyethylenterephthalat (PET) und einer Beschichtung aus ultrareinem medizinischem Silikon. Es wird mit einer Konzentration von 0,75 lbs. Gewicht. Naht überschreitet USP-Spezifikationen für einen Durchmesser der Größe 0. (Mittelwert Durchmesser ist der Durchmesser 0,436 mm).

Bestimmungsgemäße Anwendungen

Das NOVOSTITCH PRO Meniskusfixationssystem ist nur zum vorsichtigen Fuchsia ® gemäß dieser Gebrauchsanweisung angewendet werden.

Pflicht zur Patienteninformation

Das Bundesgesetz (USA) beschränkt das Gerät auf den Verkauf durch oder auf Anordnung eines Arztes.

- Vor der Verwendung ist das Gerät zu prüfen, ob es nicht beschädigt ist. Das beschädigte Gerät darf nicht verwendet werden.
- Vermeiden Sie unnötige Handhabung, z. B. Quetschen oder Crimpen, das durch chirurgische Instrumente wie Pinzetten und Nadelhalter verursacht wird.
- Die Oberfläche des Gerätes ist flach, quadratisch, mit zusätzlichen faserigen und strukturierten Oberflächen, die durch chirurgische Instrumente und die Anwesenheit des Chirurgen entstehen. Bei der Handhabung des Gerätes ist Vorsicht geboten.
- Vor der Anwendung ist eine starke Fixierung mit chirurgischen Techniken und Techniken für nicht resorbierbare Nähte erforderlich.
- Die Verwendung von Nähten, die nicht resorbierbar sind, kann zu Entzündungen führen, die sich in Form von Granulomen bilden können.
- Es ist darauf zu achten, dass bei chirurgischen Eingriffen und Techniken, die nicht resorbierbare Nähte verwenden, Vorsicht geboten ist.
- Die Verwendung von Nähten, die nicht resorbierbar sind, kann zu Verletzungen führen, wenn der Chirurg die Nadelhalter und die Pinzetten verwendet

NOVOSTITCH® PRO meniskpeartasystem

STERILEO ②

Beskrivning av produkten

Smith & nephew NOVOSTITCH® PRO meniskpeartasystem för fibrös fixation av meniskskador med sutur i storlekar 2-0 eller 0 genom mjuka delar vid artroskopiska ingrepp. Den är vitt kroppsklinkmont som hålls i hendes nålar som är förberedda med sutur. Nålen är rostfri rostfritt stål (uttryck 1), förbetes diameter är mindre än 1,2 mm.

Leverans

Enkelsterilt NOVOSTITCH®, ENGÅNGSBRUK.

Ej absorberbar kirurgisk sutur av flerfilament med storlekar om 80 cm flätade med vitt material.

- Suturen i storlek 2-0 är flätad av vitfärgad (vit) polyester med skyddsmantel av polyeten. Den är vitfärgad med en röd polyestermarkering för gränsen till den flätade delen av (Polyester/mantel-2 Repeater).
- Suturen i storlek 0 är flätad av vitfärgad (vit) polyester med skyddsmantel av UHMWPE-polyeten med en röd markering för gränsen till den flätade delen av (Polyester/mantel-0 Repeater).
- Suturen i storlek 2-0 och storlek 0 är av typ 2 (Repeater) med en dubbelsvansad nålen som är förbunden med suturen.
- Suturen i storlek 2-0 och storlek 0 är av typ 2 (Repeater) med en dubbelsvansad nålen som är förbunden med suturen. Suturen i storlek 2-0 och storlek 0 (Polyester/mantel-0