Box size: 260 mm x 300 mm Overall Size: 982 mm x 645 mm Folds to: 151 mm x 215

Myriad Pro: Regular 14pt, 10pt, 8pt, 6pt / Bold Condensed 6pt / Light Condensed 6pt

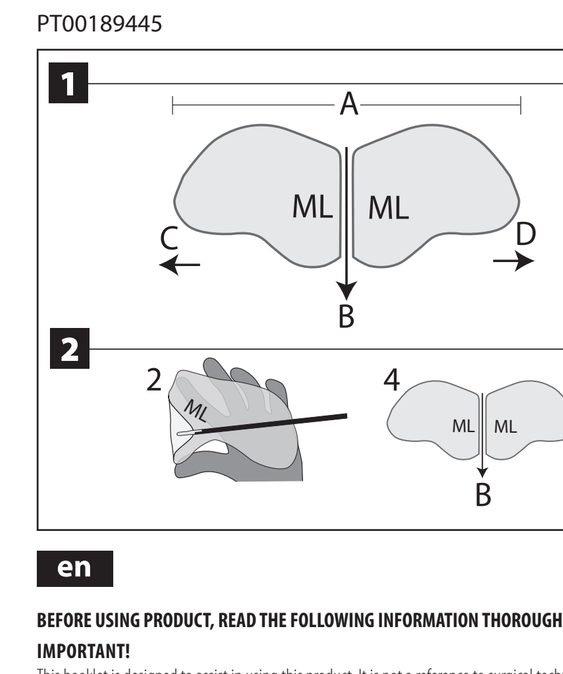
Medtronic

Dextile™

Anatomical Mesh

PT00189445

(99)7500343



en

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Reuse and/or reprocessing and/or re-sterilization of this device may lead to its failure, subsequent patient injury and may create the risk of contamination and patient infection. Do not reuse, reprocess or re-sterilize this device.

DESCRIPTION

Dextile™ anatomical mesh is designed to be placed in a pre-peritoneal site by laparoscopic approach to ensure long term reinforcement of soft tissues.

Dextile™ anatomical mesh has an anatomical shape with sealed edges allowing coverage of inguinal hernia defects and facilitating laparoscopic mesh deployment and handling.

The mesh is made of a non-absorbable macroporous monofilament polypropylene textile.

The non-absorbable textile is designed to ensure long term reinforcement of soft tissues. The macroporous textile provides strength required to withstand biomechanical stresses throughout the healing period, while allowing for tissue ingrowth. As the textile integrates, host tissue ingrowth is intended to provide strength to the repair.

A green marking is placed on the medial side of the mesh to help positioning and orienting the mesh: "ML" letters designate Medial Line. The green marking is made of monofilament polyester yarn.

The "D&C Green No. 6" dye is used for the marking.

Dextile™ anatomical mesh is offered in 3 sizes : 13 x 09 cm (Medium), 15 x 10 cm (Large) and 16 x 12 cm (Extra-Large).

The detailed composition listed below refers to the estimated maximum amount of each material and substance to which patient can be exposed when 1 unit of the largest size of Dextile™ anatomical mesh is implanted (i.e., 16 x 12 cm). These amounts could be less for smaller sizes.

Mesh composition: monofilament polypropylene yarn (up to 2.1g) D&C green No. 6 dyed monofilament polyester green yarn (up to 0.01g)

INDICATIONS

Dextile™ anatomical mesh is intended to be used for the reinforcement of soft tissues where weakness exists during repair of inguinal hernias by laparoscopic approach.

CONTRAINDICATIONS

As Dextile™ anatomical mesh will not stretch significantly to accommodate growth, its use is not appropriate in patients in a period of growth or pregnancy.

Any foreign material may potentiate or prolong infection in the presence of bacterial contamination, and as such, the use of Dextile™ anatomical mesh is not appropriate in an infected or contaminated site. Furthermore, this product should be used with the understanding that infection may require removal of the mesh.

POSSIBLE COMPLICATIONS

The possible complications associated with the use of the Dextile™ anatomical mesh are those typically associated with surgically implantable mesh: seroma, hematoma, recurrence, inflammation, infection, acute and chronic pain, extrusion/erosion and/or allergic reactions to the components of the product. Other possible complications inherent to the surgical procedure may occur, including but not limited to trocar site herniation and organ injury.

The incidence and severity of complications may depend on numerous factors, including but not limited to the type and size of the defect, the mesh fixation, the surgical technique and patient-related factors (e.g., comorbidities). A thorough assessment of each patient's medical history and condition should be made to determine the suitability for implantation of this device. The treatment of complications may require one or more revision surgeries, that may not necessarily resolve the complications and may pose risks of subsequent complications. Being a permanent implant designed to integrate into tissues, significant dissection may be required in case it needs to be removed, in part or in whole. It is important that patients are given complete information regarding possible complications.

Any adverse event or serious incident that occurs in relation to the device should be reported to the manufacturer and/or the competent authority of the country in which the patient is established, as applicable per the local, federal or national laws and regulations.

WARNINGS

1. Do not use the device past the labeled expiration date.
2. The device is provided in a single sterile packaging. Upon receipt of shipment, ensure that the packaging is not open or damaged and retains its sealed integrity. Do not use the device if the package is opened or damaged or if the integrity of the packaging appears compromised.
3. Open the packaging only for the placement of the mesh and handle the latter using clean sterile gloves and instruments.
4. Do not place the mesh in direct contact with the viscera. Direct contact with the viscera may lead to risks of adhesions, fistula formation and bowel obstruction. Do not implant the mesh in an intra-peritoneal position.
5. Dextile™ anatomical mesh is not intended for repair of pelvic organ prolapse and treatment of stress urinary incontinence.
6. For women planning future pregnancies, the surgeon should be aware that this product will not stretch enough as the patient grows.
7. The placement of the mesh should assure necessary overlap beyond the margins of the defect, according to the surgeon's practice.
8. It is recommended not to cut Dextile™ anatomical mesh as it may affect its effectiveness.
9. Do not force the mesh through the trocar. Inappropriate insertion may lead to textile damage and/or impact self-deployment.
10. The mesh should not be overly stretched when it is being put in place in order to maintain the elasticity and the porosity of the reinforcement. A moderate and equal tension should be applied in all directions in order to account for wound shrinkage during the healing process.
11. If fixation is used, care should be taken to ensure that the mesh is adequately fixated. To avoid injury, exercise caution if fixating the device in the presence of nerves or vessels.
12. ☣ Unused product, explant and packaging may be a potential biohazard. Handle and dispose them with the necessary precautionary measures in accordance with accepted medical practices and with applicable local, federal or national laws and regulations on disposal of packaging and medical waste.

PRECAUTIONS

1. Users should be familiar with surgical procedures and techniques involving the use of surgical mesh before employing this device.
2. This device should only be used by experienced practitioners who do so under their own responsibility.

1 SCHEMATIC VIEW

A) POSTERIOR VIEW
B) MEDIAL DIRECTION
C) LATERAL DIRECTION - PATIENT'S LEFT SIDE
D) LATERAL DIRECTION - PATIENT'S RIGHT SIDE

2 OPERATING STEPS

1. The choice of mesh size is determined by the surgeon. The right and left meshes are identified on the labels as such: "RIGHT" means the right side of patient and "LEFT" means the left side of patient.

CAUTION: The mesh should assure necessary overlap beyond the margins of the defect according to the surgeon's practice.

CAUTION: It is recommended not to cut Dextile™ anatomical mesh as it may affect its effectiveness.

2. To facilitate mesh insertion into the trocar, it is suggested to grasp the mesh medially and insert it directly into the trocar (see illustration section 2, step 2) :
3. It is recommended to use a trocar of at least 10 mm internal diameter to introduce meshes of size 13 x 09 cm and 15 x 10 cm, and a trocar of at least 11 mm internal diameter to introduce a mesh of size 16 x 12 cm. Mesh insertion capability may vary depending on mesh insertion method, mesh size and graspers/trocars used.

CAUTION: Do not force the mesh through the trocar. Inappropriate insertion may lead to textile damage and/or impact self-deployment.

CAUTION: Do not place the mesh in direct contact with the viscera. Direct contact with the viscera may lead to risks of adhesions, fistula formation and bowel obstruction. Do not implant the mesh in an intra-peritoneal position.

4. The marking has been designed to help orientate the mesh: the marking should be placed medially (B), (section 2, step 4) and marking letters should be readable when the mesh is correctly oriented with regards to the inguinal anatomy.
5. It may be possible not to fixate the mesh, depending on the size of the defect, the surgical technique used and the quality of the anatomical structures. The technique used to anchor the mesh (no fixation, suture and/or tack) is left up to the surgeon. If tacks are used to anchor the mesh, the use of Covidien™ fixation devices is recommended. Compatibility with other fixation devices may not have been established. Using means of fixation other than those for which compatibility is established may lead to mesh damage.

CAUTION: The mesh should not be overly stretched when it is put in place in order to maintain the elasticity and the porosity of the reinforcement.

CAUTION: If fixation is used, care should be taken to ensure that the mesh is adequately fixated. A moderate and equal tension should be applied in all directions in order to account for wound shrinkage during the healing process. To avoid injury, exercise caution if fixating the device in the presence of nerves or vessels.

STERILIZATION METHOD

Dextile™ anatomical mesh is a sterile single-use device. It is sterilized by ethylene oxide. Do not re-sterilize.

FOLLOW-UP

Dextile™ anatomical mesh is intended for permanent implantation. It is not intended to be removed, repaired or replaced in normal conditions of use. It does not require particular follow-up. Necessity and modalities of patient follow-up shall be determined by exerting medical judgment and per accepted medical practice inherent to hernia surgery.

STORAGE

Dextile™ anatomical mesh does not require any special storage conditions.

MAGNETIC RESONANCE IMAGING (MRI) COMPATIBILITY

Dextile™ anatomical mesh poses no known hazards resulting from exposure to any Magnetic Resonance (MR) environment. It is classified as MR Safe.

TRACEABILITY

A traceability label is attached to every device package which identifies the type and lot number of the device. This label should be affixed to the patient's permanent medical record to clearly identify the device that was implanted.

A patient implant card is also supplied with every device package. It shall be provided at discharge to the patient who has been implanted with the device if required by applicable local, federal or national laws and regulations. This patient implant card includes information allowing the identification of the device and a website address from which the patient can access additional information.

For European residents: After the EUDAMED website is launched, the Summary of Safety and Clinical Performance (SSCP) can be found at https://ec.europa.eu/tools/eudamed.

2 ETAPELE OPERATORII

1. Alegerea dimensiunii plasei este decisă de către chirurg. Plasele dreaptă și stângă sunt identificate pe etichete prin: „RIGHT", care înseamnă partea dreaptă a pacientului, și „LEFT", care înseamnă partea stângă a pacientului.

ATENȚIE: Poziționarea plasei trebuie să asigure suprapunerea necesară dincolo de marginile defectului, pe baza experienței chirurgului.

ATENȚIE: Nu se recomandă tăierea plasei anatomice Dextile™, întrucât acest lucru îi poate afecta eficacitatea.

ATENȚIE: Nu introduceți plasa cu forța prin trocar. Introducerea necorespunzătoare poate conduce la deteriorarea materialului textil și/sau poate afecta auto-amplasarea.

ATENȚIE: Nu puneți plasa în contact direct cu organele interne.

ATENȚIE: Plasa nu trebuie întinsă excesiv atunci când este pusă în poziție, pentru a se menține elasticitatea și porozitatea întăriturii.

METODA DE STERILIZARE
Plasa anatomică Dextile™ este un dispozitiv de unică folosință steril. Este sterilizată cu oxid de etilenă. A nu se resteriliza.

URMĂRIREA

DEPOZITAREA
Plasa anatomică Dextile™ nu necesită condiții speciale de păstrare.

COMPATIBILITATEA CU IMAGISTICA PRIN REZONANȚĂ MAGNETICĂ (IRM)

TRASABILITATEA

Pentru cetățenii rezidenți în Europa: după lansarea website-ului EUDAMED, Rezumatul caracteristicilor de siguranță și performanță clinică (SSCP) poate fi găsit la https://ec.europa.eu/tools/eudamed.

hr

Anatomska mrežica

PRIJE UPOTREBE OVOG PROIZVODA PAŽLJIVO PROČITAJTE SLJEDEĆE INFORMACIJE.

VAŽNO!

OPIS · **INDIKACIJE** · **KONTRAINDIKACIJE** · **MOGUĆE KOMPLIKACIJE** · **UPOZORENJA** · **MJERE OPREZA**

1 SHEMATSKI PRIKAZ
A) STRAŽNJI PRIKAZ
B) MEDIJALNI SMJER
C) LATERALNI SMJER – LIJEVA STRANA BOLESNIKA
D) LATERALNI SMJER – DESNA STRANA BOLESNIKA

2 OPERATIVNI KORACI

METODA STERILIZACIJE · **KONTROLA** · **SKLADIŠTENJE** · **KOMPATIBILNOST S POSTUPCIMA SNIMANJA UREĐAJIMA ZA MAGNETSKU REZONANCIJU (MR)** · **SLJEDIVOST**

pt

Malha anatómica

ANTES DE UTILIZAR O PRODUTO, LEIA ATENTAMENTE AS INFORMAÇÕES SEGUINTES.

IMPORTANTE!

DESCRIÇÃO

INDICAÇÕES · **CONTRAINDICAÇÕES** · **POSSÍVEIS COMPLICAÇÕES** · **AVISOS** · **PRECAUÇÕES**

1 VISTA ESQUEMÁTICA
A) VISTA POSTERIOR
B) DIREÇÃO MEDIAL
C) DIREÇÃO LATERAL – LADO ESQUERDO DO DOENTE
D) DIREÇÃO LATERAL – LADO DIREITO DO DOENTE

2 PASSOS OPERACIONAIS

MÉTODO DE ESTERILIZAÇÃO · **ACOMPANHAMENTO** · **ARMAZENAMENTO** · **COMPATIBILIDADE COM PROCEDIMENTOS DE RESSONÂNCIA MAGNÉTICA (RM)** · **RASTREABILIDADE**

pt-BR

Tela anatômica

ANTES DE USAR O PRODUTO, LEIA ATENTAMENTE ESTAS INFORMAÇÕES.

IMPORTANTE!

1 VISTA ESQUEMÁTICA
A) VISTA POSTERIOR
B) DIREÇÃO MEDIAL
C) DIREÇÃO LATERAL – LADO ESQUERDO DO PACIENTE
D) DIREÇÃO LATERAL – LADO DIREITO DO PACIENTE

2 ETAPAS OPERACIONAIS

zh

解剖补片

使用产品前，请仔细阅读以下信息。

重要信息！

1 示意图
A) 后视图
B) 正中方向
C) 横向 - 患者左侧
D) 横向 - 患者右侧

2 操作步骤

zh-t

解剖型網片

使用本產品之前，請先詳閱以下資訊。

重要事項！

1 示意圖
A) 後視圖
B) 中間方向
C) 側向 (病患左側)
D) 側向 (病患右側)

2 操作步驟

ko

인체공학적 메쉬

제품을 사용하기 전에 다음 정보를 숙독하십시오.

중요!

1 도식도
A) 후면상
B) 내측 방향
C) 횡측 방향 - 환자의 왼쪽
D) 횡측 방향 - 환자의 오른쪽

2 수술 단계

kk

Анатомиялық тор

ӨНІМДІ ПАЙДАЛАНАРДАН БҰРЫН, ТӨМЕНДЕГІ АҚПАРАТТЫ МҰҚИЯТ ОҚЫП ШЫҒЫҢЫЗ.

МАҢЫЗДЫ!

СИПАТТАМАСЫ · **КӨРСЕТІМДЕРІ** · **ҚАРСЫ КӨРСЕТІМДЕРІ** · **ЫҚТИМАЛ АСҚЫНУЛАР** · **ЕСКЕРТУЛЕР** · **САҚТЫҚ ШАРАЛАРЫ**

1 СХЕМАЛЫҚ КӨРІНІС
A) АРТҚЫ КӨРІНІСІ
B) ОРТАҢҒЫ БАҒЫТ
C) БҮЙІРЛІК БАҒЫТ – ЕМДЕЛУШІНІҢ СОЛ ЖАҒЫ
D) БҮЙІРЛІК БАҒЫТ – ЕМДЕЛУШІНІҢ ОҢ ЖАҒЫ

2 ОПЕРАЦИЯ КЕЗЕҢДЕРІ

СТЕРИЛЬДЕУ ӘДІСІ · **БАҚЫЛАУ** · **САҚТАУ** · **МАГНИТТІК РЕЗОНАНСТЫҚ ТОМОГРАФИЯМЕН (МРТ) ҮЙЛЕСІМДІЛІГІ** · **ҚАДАҒАЛАУ МҮМКІНДІГІ**

uk

Анатомічна сітка

ПЕРШ НІЖ ВИКОРИСТОВУВАТИ ВИРІБ, УВАЖНО ОЗНАЙОМТЕСЯ З НАВЕДЕНОЮ НИЖЧЕ ІНФОРМАЦІЄЮ.

ВАЖЛИВО!

1 СХЕМАТИЧНЕ ЗОБРАЖЕННЯ
A. ВИД ЗЗАДУ
B. МЕДІАЛЬНИЙ НАПРЯМОК
C. ЛАТЕРАЛЬНИЙ НАПРЯМОК — ЛІВА СТОРОНА ПАЦІЄНТА
D. ЛАТЕРАЛЬНИЙ НАПРЯМОК — ПРАВА СТОРОНА ПАЦІЄНТА

2 ЕТАПИ РОБОТИ

et

Anatoomiline võrk

ENNE TOOTE KASUTAMIST LUGEGE JÄRGMINE TEAVE PÕHJALIKULT LÄBI.

TÄHTIS!

1 SKEMAATILINE JOONIS
A) POSTERIOORNE VAADE
B) MEDIAALSUUND
C) LATERAALSUUND – PATSIENDI VASAK KÜLG
D) LATERAALSUUND – PATSIENDI PAREM KÜLG

2 OPERATSIOONI ETAPID

lt

Anatominis tinklelis

PRIEŠ NAUDODAMI GAMINĮ, ATIDŽIAI PERSKAITYKITE TOLIAU PATEIKTĄ INFORMACIJĄ.

SVARBU!

1 SCHEMA
A) VAIZDAS IŠ GALO
B) MEDIALINE KRYPTIS
C) ŠONINĖ KRYPTIS — PACIENTO KAIRIOJI PUSĖ
D) ŠONINĖ KRYPTIS — PACIENTO DEŠINIOJI PUSĖ

2 OPERACIJOS ETAPAI

sr

Anatomska mreža

PRE UPOTREBE PROIZVODA DETALJNO PROČITAJTE SLEDEĆE INFORMACIJE.

VAŽNO!

1 ŠEMATSKI PRIKAZ
A) POSTERIORNI PRIKAZ
B) MEDIJALNI PRAVAC
C) LATERALNI PRAVAC – PACIJENTOVA LEVA STRANA
D) LATERALNI PRAVAC – PACIJENTOVA DESNA STRANA

2 OPERATIVNI KORACI

lv

Anatomiskais tīkliņš

PIRMS IZSTRĀDĀJUMA LIETOŠANAS RŪPĪGI IZLASIET TĀLĀK SNIEGTO INFORMĀCIJU.

SVARĪGI!

1 SHEMATISKS SKATS
A) SKATS NO AIZMUGURES
B) MEDIĀLAIS VIRZIENS
C) LATERĀLAIS VIRZIENS — PACIENTA KREISĀ PUSE
D) LATERĀLAIS VIRZIENS — PACIENTA LABĀ PUSE

2 OPERĀCIJAS GAITA

mk

Анатомска мрежа

ВНИМАТЕЛНО ПРОЧИТАЈТЕ ГИ СЛЕДНИТЕ ИНФОРМАЦИИ ПРЕД ДА ГО УПОТРЕБУВАТЕ ПРОИЗВОДОТ.

ВАЖНО!

1 ШЕМАТСКИ ПРИКАЗ
A) ПРИКАЗ НА ЗАДНАТА СТРАНА
B) СРЕДИШНА НАСОКА
C) СТРАНИЧНА НАСОКА – ЛЕВА СТРАНА НА ПАЦИЕНТОТ
D) СТРАНИЧНА НАСОКА – ДЕСНА СТРАНА НА ПАЦИЕНТОТ

2 ЧЕКОРИ ЗА ОПЕРИРАЊЕ

id

Mesh Anatomis

SEBELUM MENGGUNAKAN PRODUK, BACA INFORMASI BERIKUT SECARA MENYELURUH.

PENTING!

1 TAMPILAN SKEMATIK
A) TAMPILAN POSTERIOR
B) ARAH MEDIAL
C) ARAH LATERAL – SISI KIRI PASIEN
D) ARAH LATERAL – SISI KANAN PASIEN

2 LANGKAH PENGOPERASIAN

vi

Mảnh ghép giải phẫu

TRƯỚC KHI SỬ DỤNG SẢN PHẨM, VUI LÒNG ĐỌC KỸ NHỮNG THÔNG TIN BÊN DƯỚI.

LƯU Ý QUAN TRỌNG!

1 SƠ ĐỒ
A) MẶT SAU
B) HƯỚNG TRUNG TÂM
C) HƯỚNG BÊN SƯỜN - PHÍA BÊN TRÁI CỦA BỆNH NHÂN
D) HƯỚNG BÊN SƯỜN - PHÍA BÊN PHẢI CỦA BỆNH NHÂN

2 CÁC BƯỚC SỬ DỤNG

ar

شبكة تشريحية

1 منظر تخطيطي
A) منظر خلفي
B) اتجاه الخط الناصف
C) الاتجاه الجانبي - الجانب الأيسر للمريض
D) الاتجاه الجانبي - الجانب الأيمن للمريض

2 خطوات الاستخدام

STERILE EO	**en:** Sterilized using ethylene oxide **fr:** Stérilisé à l'oxyde d'éthylène **de:** Sterilisiert mit Ethylenoxid **it:** Sterilizzato con ossido di etilene ... **ar:** مُعقم باستخدام أكسيد الإيثيلين
	en: Single sterile barrier with protective packaging inside ...
	en: Single Use **fr:** À usage unique **de:** Nur zur einmaligen Verwendung ...
Rx ONLY	**en:** Caution: U.S. Federal law restricts this device to sale by or on the order of a physician. ...
	en: Do not resterilize **fr:** Ne pas restériliser **de:** Nicht erneut sterilisieren ...
	en: Do not use if package is damaged **fr:** Ne pas utiliser si l'emballage est endommagé ...
	en: Consult instructions for use **fr:** Consulter le mode d'emploi ...
	en: Caution **fr:** Attention **de:** Vorsicht **it:** Attenzione **es:** Precaución ...
	en: Biological Risks **fr:** Risques biologiques **de:** Biologische Risiken ...
MD	**en:** Medical device **fr:** Dispositif médical **de:** Medizinprodukt ...
MR	**en:** MR safe **fr:** Compatible avec la RM **de:** MR-sicher ...
REF	**en:** Catalog number **fr:** Numéro de référence **de:** Katalognummer ...
	en: Manufacturer **fr:** Fabricant **de:** Hersteller **it:** Fabbricante ...
	en: Use-by Date **fr:** Date limite d'utilisation **de:** Verwendbar bis ...
LOT	**en:** Batch Code **fr:** Code de lot **de:** Chargennummer ...
	en: Date of manufacture **fr:** Date de fabrication **de:** Herstellungsdatum ...
	en: Patient Identification **fr:** Identification du patient **de:** Patientenidentifikation ...
	en: Date **fr:** Date **de:** Datum **it:** Data **es:** Fecha ...
	en: Health care center or doctor **fr:** Établissement de santé ou médecin ...
	en: Patient information website **fr:** Site Web d'informations destinées aux patients ...
UDI	**en:** Unique device identifier **fr:** Identifiant unique du dispositif ...
CE 2797	**en:** CE mark **fr:** Marquage CE **de:** CE-Kennzeichnung ...

CE 2797

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