Box size: 260 mm x 300 mm Overall Size: 1208 mm x 645 mm Folds to: 151 mm x 215

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

COVIDIEN™

ProGrip™

Laparoscopic Self-Fixating Mesh

PT00176204

(99)7500328

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

ProGrip™ laparoscopic self-fixating mesh is designed for inguinal hernia repair when placed in an extraperitoneal space by laparoscopic surgical approach.

The mesh is made of a non-absorbable bi-dimensional monofilament polyester (polyethylene terephthalate) textile with monofilament polylactic acid resorbable grips on one side and an absorbable, continuous collagen film on the other side. This film is made of collagen from porcine origin and glycerol.

The mesh presents a green band (polyester dyed with D&C green no. 6) on the medial side of the mesh.

ProGrip™ laparoscopic self-fixating mesh is available in different shapes (rectangular and anatomical) and sizes.

The detailed composition listed below refers to the estimated maximum amount of each material and substance to which patient can be exposed when one unit of the largest size of ProGrip™ laparoscopic self-fixating mesh is implanted (i.e., 16 x 14 cm). These amounts could be less for smaller sizes or if the mesh is trimmed by the practitioner prior to implantation.

Mesh composition: monofilament polyester yarn (up to 0.9 g) | D&C green No. 6 dyed monofilament polyester yarn (up to 0.2 g, green yarn containing 0.084% by weight of D&C green No. 6 dye) | monofilament polylactic acid resorbable grips (up to 0.8 g) | hydrophilic collagen film (up to 1.6 g – ratio collagen/glycerol = 70/30% by weight).

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. The monofilament polylactic acid grips facilitate placement and positioning of the mesh, and they contribute to fixation of the mesh to the surrounding tissue for at least eight weeks. The polylactic acid grips are bioresorbable. Over the time, they resorb in vivo by hydrolysis and are metabolized by the body into CO_2 and H_2O. Preclinical studies showed that the polylactic acid material is essentially resorbed in 36 to 50 months post-implantation. However, the resorption period depends on numerous factors including patient-related factors. The green band (polyester dyed with D&C green no. 6) on the medial side of the mesh facilitates its orientation. The collagen film facilitates mesh handling and deployment.

INDICATIONS

ProGrip™ laparoscopic self-fixating mesh is indicated for the reinforcement of soft tissues during repair of inguinal hernia defects by laparoscopic approach.

CONTRAINDICATIONS

- As ProGrip™ laparoscopic self-fixating mesh will not stretch 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 ProGrip™ laparoscopic self-fixating 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.
- The collagen film is not intended to minimize tissue attachment, and thus this product cannot be used intraperitoneally.

POSSIBLE COMPLICATIONS

The possible complications associated with the use of ProGrip™ laparoscopic self-fixating mesh are those typically associated with surgically implantable mesh: seroma, hematoma, recurrence, infection, inflammation, acute and chronic pain, extrusion/erosion and/or allergic reactions to the components of the product. Other possible complication 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. Do not use product if the temperature dot on the package is black. ProGrip™ laparoscopic self-fixating mesh should not be exposed to elevated temperatures (i.e., above 44°C / 111°F).
3. The device is provided in a double 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.
4. Open the last packaging only for the placement of the mesh and handle the latter using clean sterile gloves and instruments.
5. 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. The mesh shall be placed with the grips towards the muscle fascia with the mesh completely covered with peritoneum.
6. ProGrip™ laparoscopic self-fixating mesh is not intended for repair of pelvic organ prolapse and treatment of stress urinary incontinence.
7. For women planning future pregnancies, the surgeon should be aware that this product will not stretch enough as the patient grows.
8. To limit the risk of recurrence, if the mesh is trimmed, the use of additional fixation should be considered depending on size and type of hernia and the patient's condition.
9. If an anatomical mesh is trimmed, special care should be taken to preserve the sewing of the flap to limit the risk of recurrence.
10. The placement of the mesh should assure necessary overlap beyond the margins of the defect, according to the surgeon's practice.
11. If fixation is used, ensure that the mesh is adequately fixated. To avoid injury, exercise caution if fixating the device in the presence of nerves or vessels.
12. 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.
13. Do not force the mesh through the trocar. Inappropriate insertion may lead to damage of textile and/or anatomical flap seam.
14. ☣ 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.

OPERATING STEPS

1. The choice of mesh size is determined by the surgeon. For the anatomical mesh, the right and left mesh are identified on the labels as such: "RIGHT" means the right side of patient and "LEFT" means left side of patient. This mesh can be used whole or cut to the required dimensions. The surgeon should assure necessary overlap of the mesh beyond the margins of the defect according to practice.

CAUTION: To limit the risk of recurrence, if the mesh is trimmed, the use of additional fixation should be considered depending on size and type of hernia and the patient's condition.

CAUTION: If an anatomical mesh is trimmed, special care should be taken to preserve the sewing of the flap to limit the risk of recurrence.

2. ProGrip™ laparoscopic self-fixating mesh should be hydrated in its original blister before being handled. This is carried out by immersing it completely in a sterile saline solution for several seconds.
3. Rolling/folding of the mesh:
   a. For the rectangular mesh, it is recommended to roll the mesh in the length-wise direction with the grips outside.
   b. For the anatomical mesh, it is recommended to fold the mesh on itself, grips outside, length-wise, starting at the anatomical flap seam.
4. Grasp the mesh at either end and insert it through the trocar. It is recommended to use a trocar of at least 8 mm internal diameter to introduce a mesh of size up to 15 x 10 cm and a trocar of at least 12 mm internal diameter to introduce a mesh of size 16 x 12 cm or above. Mesh insertion capability may vary depending on rolled mesh size and graspers/trocars used.

CAUTION: Do not force the mesh through the trocar. Inappropriate insertion may lead to damage of textile and/or anatomical flap seam.

5. Deploy the mesh in the inguinal area.
6. Place the green band towards the pubic zone and the grips up in the preperitoneal space to avoid their direct contact with peritoneum.

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. The mesh shall be placed with the grips towards the muscle fascia with the mesh completely covered with peritoneum.

CAUTION: Do not place the grips of the mesh in direct contact with peritoneum to avoid peritoneum injuries.

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

7. The technique used to anchor the mesh (no fixation, suture and/or tack) is left up to the surgeon. The textile's self-fixating feature allows positioning of the mesh without any additional fixation. If the mesh is re-cut, the use of additional fixation should be considered. 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: If fixation is used, ensure that the mesh is adequately fixated. To avoid injury, exercise caution if fixating the device in the presence of nerves or vessels.

CAUTION: 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.

STERILIZATION METHOD

ProGrip™ laparoscopic self-fixating mesh is a sterile single-use device. It is sterilized by ethylene oxide. Do not re-sterilize.

FOLLOW-UP

ProGrip™ laparoscopic self-fixating 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

ProGrip™ laparoscopic self-fixating mesh should not be exposed to elevated temperatures (i.e., above 44°C / 111°F). Do not use if the temperature dot on package is black.

MAGNETIC RESONANCE IMAGING (MRI) COMPATIBILITY

ProGrip™ laparoscopic self-fixating 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.

UPOZORENJA

1. Proizvod nemojte upotrebljavati nakon naznačenog roka upotrebe.
2. Proizvod nemojte upotrebljavati ako je temperatura točka na ambalaži crna. Laparoskopska samoučvršćujuća mrežica ProGrip™ ne smije se izlagati povišenoj temperaturi (tj. iznad 44 °C / 111 °F).

MJERE OPREZA

1. Korisnici prije upotrebe ovog proizvoda moraju biti upoznati s kirurškim postupcima i tehnikama koji uključuju upotrebu kirurške mrežice.
2. Ovaj proizvod smiju upotrebljavati samo iskusni zdravstveni radnici koji su za to dobili odgovarajuću obuku.

OPERATIVNI KORACI

METODA STERILIZACIJE

PRAĆENJE

ČUVANJE

KOMPATIBILNOST S POSTUPCIMA SNIMANJA UREĐAJIMA ZA MAGNETSKU REZONANCIJU (MR)

SLJEDIVOST

pt

Malha de autofixação laparoscópica

ANTES DE UTILIZAR O PRODUTO, LEIA ATENTAMENTE ESTAS INFORMAÇÕES.

IMPORTANTE!

Este folheto destina-se ao auxílio na utilização do produto. Não é uma fonte de consulta para técnicas cirúrgicas.

DESCRIÇÃO

INDICAÇÕES

CONTRAINDICAÇÕES

POSSÍVEIS COMPLICAÇÕES

AVISOS

PRECAUÇÕES

PASSOS OPERATÓRIOS

MÉTODO DE ESTERILIZAÇÃO

ACOMPANHAMENTO

ARMAZENAMENTO

COMPATIBILIDADE COM PROCEDIMENTO DE IMAGENS POR RESSONÂNCIA MAGNÉTICA (RM)

RASTREABILIDADE

pt-BR

Tela autofixante laparoscópica

ANTES DE USAR O PRODUTO, LEIA ATENTAMENTE ESTAS INFORMAÇÕES.

IMPORTANTE!

DESCRIÇÃO

INDICAÇÕES

CONTRAINDICAÇÕES

POSSÍVEIS COMPLICAÇÕES

AVISOS

PRECAUÇÕES

ETAPAS OPERACIONAIS

MÉTODO DE ESTERILIZAÇÃO

ACOMPANHAMENTO

ARMAZENAMENTO

COMPATIBILIDADE COM PROCEDIMENTOS DE RESSONÂNCIA MAGNÉTICA (RM)

RASTREABILIDADE

zh

腹腔镜自固定补片

使用本产品之前，请先仔细通读下列信息。

重要信息！

本手册旨在为使用本产品时提供帮助。但是，不作为外科手术的技术参考。

产品说明

适应证

禁忌证

可能的并发症

警告

注意事项

操作步骤

灭菌方法

随访

储存

磁共振成像（MRI）兼容性

可追溯性

zh-t

腹腔鏡用自行固定網片

使用本產品之前，請仔細閱讀下列資訊。

重要事項！

本手冊旨在協助使用本產品，不作為外科手術技術參考資料之用。

描述

適應症

禁忌症

可能的併發症

警告

注意事項

操作步驟

滅菌方法

後續追蹤

儲存

磁振造影 (MRI) 相容性

可追蹤性

ko

복강경 자체 고정 메쉬

제품을 사용하기 전에 다음 정보를 숙독하십시오.

중요!

이 소책자는 이 제품 사용에 도움을 제공하기 위해 작성되었습니다. 술식의 참조서가 아닙니다.

설명

적응증

금기사항

발생 가능한 합병증

경고

주의사항

조작 단계

멸균 방법

후속 조치

보관

자기공명영상(MRI) 호환성

추적성

kk

Лапароскопиялық өздігінен бекітілетін тор

ӨНІМДІ ПАЙДАЛАНУ АЛДЫНДА КЕЛЕСІ АҚПАРАТТЫ МҰҚИЯТ ОҚЫҢЫЗ.

МАҢЫЗДЫ!

СИПАТТАМАСЫ

КӨРСЕТІЛІМДЕРІ

ҚОЛДАНУҒА БОЛМАЙТЫН ЖАҒДАЙЛАР

ЫҚТИМАЛ АСҚЫНУЛАР

ЕСКЕРТУЛЕР

САҚТЫҚ ШАРАЛАРЫ

ПАЙДАЛАНУ ҚАДАМДАРЫ

СТЕРИЛЬДЕУ ӘДІСІ

КЕЙІНГІ БАҚЫЛАУ

САҚТАУ

МАГНИТТІК-РЕЗОНАНСТЫҚ ТОМОГРАФИЯМЕН (МРТ) ҮЙЛЕСІМДІЛІГІ

ҚАДАҒАЛАУ МҮМКІНДІГІ

uk

Лапароскопічна самофіксуюча сітка

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

ВАЖЛИВО!

ОПИС

ПОКАЗАННЯ

ПРОТИПОКАЗАННЯ

МОЖЛИВІ УСКЛАДНЕННЯ

ПОПЕРЕДЖЕННЯ

ЗАПОБІЖНІ ЗАХОДИ

ЕТАПИ РОБОТИ

МЕТОД СТЕРИЛІЗАЦІЇ

ПОДАЛЬШЕ СПОСТЕРЕЖЕННЯ

ЗБЕРІГАННЯ

СУМІСНІСТЬ ІЗ МАГНІТНО-РЕЗОНАНСНОЮ ТОМОГРАФІЄЮ (МРТ)

ВІДСТЕЖУВАНІСТЬ

et

Laparoskoopiline isekinnituv võrk

ENNE TOOTE KASUTAMIST LUGEGE JÄRGNEV TEAVE PÕHJALIKULT LÄBI.

TÄHTIS!

KIRJELDUS

NÄIDUSTUSED

VASTUNÄIDUSTUSED

VÕIMALIKUD TÜSISTUSED

HOIATUSED

ETTEVAATUSABINÕUD

OPERATSIOONI ETAPID

STERILISEERIMISMEETOD

JÄRELKONTROLL

HOIUSTAMINE

SOBIVUS MAGNETRESONANTSUURINGUKS (MRT)

JÄLGITAVUS

lt

Laparoskopinis savaime prisitvirtinantis tinklelis

PRIEŠ NAUDODAMI GAMINĮ, ATIDŽIAI PERSKAITYKITE TOLIAU PATEIKTĄ INFORMACIJĄ.

SVARBU!

APRAŠYMAS

INDIKACIJOS

KONTRAINDIKACIJOS

GALIMOS KOMPLIKACIJOS

UPOZORENJA

MERE OPREZA

KORACI ZA KORIŠĆENJE

sr

Laparoskopska samofiksirajuća mrežica

PRE KORIŠĆENJA PROIZVODA DETALJNO PROČITAJTE SLEDEĆE INFORMACIJE.

VAŽNO!

OPIS

INDIKACIJE

KONTRAINDIKACIJE

MOGUĆE KOMPLIKACIJE

METOD STERILIZACIJE

KONTROLA

SKLADIŠTENJE

KOMPATIBILNOST SA MAGNETNOM REZONANCOM (MR)

PRAĆENJE

lv

Laparoskopiskais pašfiksējošais tīkls

PIRMS IZSTRĀDĀJUMA LIETOŠANAS RŪPĪGI IZLASIET TĀLĀK SNIEGTO INFORMĀCIJU.

SVARĪGI!

APRAKSTS

INDIKĀCIJAS

KONTRINDIKĀCIJAS

IESPĒJAMĀS KOMPLIKĀCIJAS

BRĪDINĀJUMI

PIESARDZĪBAS PASĀKUMI

OPERĀCIJAS GAITA

STERILIZĀCIJAS METODE

APSEKOŠANA

UZGLABĀŠANA

SADERĪBA AR MAGNĒTISKĀS REZONANSES ATTĒLDIAGNOSTIKAS IEKĀRTĀM

IZSEKOJAMĪBA

mk

Лапароскопска самофиксирачка мрежа

ВНИМАТЕЛНО ПРОЧИТАЈТЕ ГИ СЛЕДНИТЕ ИНФОРМАЦИИ ПРЕД ДА ГО УПОТРЕБИТЕ ПРОИЗВОДОТ.

ВАЖНО!

ОПИС

ИНДИКАЦИИ

КОНТРАИНДИКАЦИИ

МОЖНИ КОМПЛИКАЦИИ

ПРЕДУПРЕДУВАЊА

МЕРКИ НА ПРЕТПАЗЛИВОСТ

ОПЕРАТИВНИ ЧЕКОРИ

МЕТОД НА СТЕРИЛИЗАЦИЈА

КОНТРОЛА

ЧУВАЊЕ

КОМПАТИБИЛНОСТ СО ТОМОГРАФИЈА СО МАГНЕТНА РЕЗОНАНЦИЈА (МРИ)

СЛЕДЛИВОСТ

id

Mesh Fiksasi Mandiri Laparoskopi

SEBELUM MENGGUNAKAN PRODUK, BACA INFORMASI BERIKUT SECARA MENYELURUH.

PENTING!

DESKRIPSI

INDIKASI

KONTRAINDIKASI

KEMUNGKINAN KOMPLIKASI

PERINGATAN

TINDAKAN PENCEGAHAN

LANGKAH PENGOPERASIAN

METODE STERILISASI

TINDAK LANJUT

PENYIMPANAN

KOMPATIBILITAS PENCITRAAN RESONANSI MAGNETIK (MRI)

KEMAMPUAN DILACAK

vi

Mảnh ghép thoát vị tự dính dùng trong nội soi

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

LƯU Ý QUAN TRỌNG!

MÔ TẢ

CHỈ ĐỊNH

CHỐNG CHỈ ĐỊNH

BIẾN CHỨNG TIỀM ẨN

CẢNH BÁO

BIỆN PHÁP PHÒNG NGỪA

CÁC BƯỚC SỬ DỤNG

PHƯƠNG PHÁP TIỆT TRÙNG

THEO DÕI

BẢO QUẢN

KHẢ NĂNG TƯƠNG THÍCH VỚI MÔI TRƯỜNG CHỤP CỘNG HƯỞNG TỪ (MRI)

TRUY XUẤT NGUỒN GỐC

Đối với cư dân Châu Âu: Sau khi trang web EUDAMED ra mắt, bạn có thể xem Báo cáo tóm tắt về độ an toàn và hiệu quả lâm sàng (SSCP) tại địa chỉ https://ec.europa.eu/tools/eudamed.

ar

شبكة ذاتية التثبيت لعمليات التنظير البطني

يجب عليك قراءة المعلومات التالية بعناية قبل الشروع في استخدام المنتج.

مهم!

الوصف

دواعي الاستعمال

موانع الاستعمال

المضاعفات المحتملة

تحذيرات

احتياطات

خطوات العملية

طريقة التعقيم

المتابعة

التخزين

التوافق مع التصوير بالرنين المغناطيسي (MRI)

إمكانية التعقب

STERILE EO — en: Sterilized using ethylene oxide

en: Double sterile barrier system

en: Single use

Rx ONLY — en: CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician

en: Biological risks

MD — en: Medical Device

MR — en: MR safe

111°F 44°C — en: Upper temperature limit

REF — en: Catalogue number

en: Manufacturer

en: Use-by date

LOT — en: Batch code

en: Date of manufacture

2 — en: Package contains 2 devices

BIO — en: Contains biological material of animal origin

en: Do not use if package is damaged

en: Do not resterilize

en: Consult instructions for use

en: Caution

en: Patient identification

31 — en: Date

en: Health care center or doctor

en: Patient information website

UDI — en: Unique device identifier

CE 2797 — en: CE Mark

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Sofradim Production, 116, avenue du Formans-01600 Trévoux-France.
www.covidien.com
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+1 763 514 4000
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CE 2797