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

Permacol™

Surgical Implant

PT00172738

(99)7500316

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

Permacol™ surgical implant is designed to allow device placement by laparoscopic or open approach in soft tissue repair.

The implant is made of a sterile, off-white, moist, tough and flexible, fibrous flat sheet of crosslinked acellular porcine dermal collagen-based matrix.

Permacol™ surgical implant is available in different shapes (rectangular and square), thicknesses and sizes. The detailed composition listed below refers to the estimated maximum amount of each material and substance to which a patient can be exposed when 1 unit of the largest size of Permacol™ surgical implant is implanted (Surface: 1120 cm² and thickness: 1.5 cm thick)

- Mesh composition: Collagen (up to 60.5g) | Water (up to 141.2 g)

Once implanted, the Permacol™ surgical implant will act as a scaffold ensuring cellular infiltration, allowing native tissue to grow, and providing minimized tissue attachment to the implant in case of direct contact with the viscera, while being gradually degraded.

INDICATIONS

Permacol™ surgical implant is intended for use as a soft tissue implant to reinforce soft tissue where weakness exists in surgical procedures involving:

- Primary ventral and incisional hernia repair
- Abdominal wall reconstruction and closure
- Abdominal muscle flap reinforcement
- Plastic and reconstructive surgery of the face and head
- Pelvic floor reconstruction and reinforcement during colorectal surgery
- Chest wall reconstruction

CONTRAINDICATIONS

- Permacol™ surgical implant is derived from a porcine source and should not be used in patients who have known sensitivity to porcine materials.
- Do not use the 0.5 mm thickness Permacol™ surgical implant in load bearing applications. 0.5 mm thick Permacol™ surgical implant codes only should be used in plastic and reconstructive surgery of the face and head.

POSSIBLE COMPLICATIONS

The possible complications associated with the use of Permacol™ surgical implant are: infection, seroma, hematoma, dehiscence, diastasis, fistula formation, inflammation, discomfort, acute and chronic pain, induration, erosion/extrusion or implant migration, local necrosis, visceral adhesion, bowel obstruction, recurrence and revision of the surgery.

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 implant fixation, the surgical technique and patient-related factors (e.g., comorbidities, surgical site infection). 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. 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 if the temperature dot on package is black. Permacol™ surgical implant should not be exposed to elevated temperatures (i.e., above 100°F/38°C). Do not freeze.
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 open or damaged or if the integrity of the packaging appears compromised.
4. Open the last packaging only for the placement of the implant and handle the implant using clean sterile gloves and instruments.

NOTE: When handling Permacol™ surgical implant, use powder-free gloves or atraumatic surgical forceps.

5. Permacol™ surgical implant should be hydrated or moist when the package is opened. Dehydrated or dry Permacol™ surgical implant cannot be re-hydrated and should not be implanted.
6. Use of Permacol™ surgical implant in a contaminated or infected field may lead to a weakening or breakdown of the implant. Treat any existing or suspected infection according to accepted medical practice before implanting the device.
7. Permacol™ surgical implant is not intended for transvaginal implantation or for use in urogynecological surgery in the repair of pelvic organ prolapse and treatment of stress urinary incontinence. If Permacol™ surgical implant is used for laparoscopic ventral rectopexy, accepted practice and other guidelines should be strictly followed throughout the entire patient's care continuum.
8. Permacol™ surgical implant is not intended for breast reconstruction.
9. The effectiveness and safety of Permacol™ surgical implant in the repair and the prevention of parastomal hernia have not been established.
10. The effectiveness and safety of Permacol™ surgical implant in pediatric use have not been established.
11. When implanting the mesh in women planning future pregnancies and pregnant women, the surgeon should be aware that the effectiveness and safety of Permacol™ surgical implant have not been established in pregnant women.
12. The effectiveness and safety of Permacol™ surgical implant for hiatal paraoesophageal hernia repair have not been established.
13. Using "bridging" repair technique with the implant placed in an "inlay" position may compromise the mechanical performances of the implant. The "inlay" repair technique is defined as cutting the implant to the size of the defect, positioning the implant in the abdominal wall defect and then suturing the edges of the implant to the edges of the defect. In any case, every effort should be made to close the defect.
14. The mesh should not be overly stretched when it is being put in place in order to maintain its elasticity.
15. Care should be taken to ensure that the implant is adequately fixated. To avoid injury, exercise caution if fixating the device in the presence of nerves or vessels.
16. Not all Permacol meshes can be implanted using the laparoscopic approach. Permacol meshes that are 0.5 mm or 1.5 mm thick should not be implanted laparoscopically. Also, 1 mm thick rectangular implants with widths ranging from 18 cm to 20 cm should not be implanted laparoscopically. Do not force the implant through the trocar. Inappropriate insertion may lead to implant damage.
17. Unused product, explant and packaging may be a potential biohazard. Handle and dispose of 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. Based on surgeon or physician experience and training, a thorough assessment of each patient's medical history and condition should be made to determine their suitability for the implantation of Permacol™ surgical implant.
3. If infection is diagnosed frequent monitoring of the surgical site and appropriate use of antibiotics may be necessary.
4. Positioning on poorly vascularized tissues may compromise the patient outcome. If Permacol™ surgical implant is used in patients undergoing radiotherapy, neovascularization and tissue in-growth may be compromised.
5. Use of an appropriate surgical draining protocol is recommended in surgeries where risk of seroma is high.
6. If used in cases of abdominal incision dehiscence, restoration of the midline, where possible, with primary closure of fascia and/or component separation techniques may provide better outcomes.
7. In case of postoperative infections, it may not be required to remove Permacol™ surgical implant, if the infection can be controlled with the appropriate medical treatment that includes antimicrobial therapy

OPERATING STEPS

1. PREPARATION FOR USE OF Permacol™ SURGICAL IMPLANT

   Permacol™ surgical implant is ready to use straight from the packaging. It is recommended to open the package at the time of implantation. If not implanted immediately, place each Permacol™ surgical implant in a container of sterile saline or sterile lactated Ringer's solution in the sterile field in order to prevent dehydration of the implant.

2. IMPLANTATION AND FIXATION

   These recommendations are designed to serve only as a general guideline. They are not intended to supersede the institutional protocols or professional clinical judgment concerning patient care.

   a. Permacol™ surgical implant may be aseptically trimmed or layered to fill the tissue space and shaped to whatever contour is required. If layering is required, cut the material into separate sheets, rather than folding or rolling it.

   NOTE: If Permacol™ surgical implant is trimmed to a size that is too small for the defect, excessive tension may be placed on the fixation sutures and possibly result in recurrence of the original tissue defect or development of a defect in adjacent tissues.

   b. Adequate overlap is recommended to ensure sufficient margins for incorporation. It is important to ensure that Permacol™ surgical implant is sutured to vascularized tissue. A minimum of 3–5 cm overlap is recommended for hernia repair.

   c. Consider the biomechanical forces that the implanted site will be subject to when selecting the product thickness; thicker product tends to have greater initial strength.

   d. The technique used to anchor the implant (suture and/or tack) is left up to the practitioner. Compatibility of the permanent Covidien™ tacks only has been established for 1 mm thick implants. The permanent Covidien™ tacks should not be used for implants thicker or thinner than 1 mm. Compatibility with other fixation devices may have not been established. Using means of fixation other than those for which compatibility is established may lead to implant damage.

   e. Only 1 mm thick implants can be implanted using a laparoscopic approach. Implants thicker or thinner than 1 mm should not be implanted laparoscopically. It is recommended that:

   - All 1 mm thick square implants, should be used with trocars no smaller than 10 mm internal diameter, except that 10 cm x 10 cm sized implants should be used with trocars no smaller than 11 mm internal diameter.
   - Rectangular 1 mm thick implants should be used with trocars in the following manner:
     - implants with widths ranging from 2 cm to 6 cm can be used with trocars no smaller than 10 mm internal diameter.
     - implants with widths ranging from 8 cm to 10 cm can be used with trocars no smaller than 11 mm internal diameter.
     - implants with widths equal to 15 cm can be used with trocars no smaller than 15 mm internal diameter.
     - Trocars should not be used for implants with width ranging from 18 cm to 20 cm.

CAUTION: Do not force the implant through the trocar. Inappropriate insertion may lead to implant damage.

3. USE OF ANTIMICROBIAL AGENTS

   a. If Permacol™ surgical implant is used in surgical fields where sterility cannot be assured, the prophylactic use of antimicrobials according to accepted medical practice should be considered.

   b. The antimicrobial agents employed should provide aerobic and anaerobic cover.

STERILIZATION METHOD

Permacol™ surgical implant is a sterile single-use device. It is sterilized by gamma radiation. Do not re-sterilize.

FOLLOW-UP

Permacol™ surgical implant 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 within the surgery.

STORAGE

Permacol™ surgical implant should not be exposed to elevated temperatures (i.e., above 38°C/100°F). Do not freeze. Do not use if the temperature dot on package is black.

MAGNETIC RESONANCE IMAGING (MRI) COMPATIBILITY

Permacol™ surgical implant 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.

fr

Implant chirurgical

AVANT D'UTILISER LE PRODUIT, LISEZ ATTENTIVEMENT LES INFORMATIONS SUIVANTES.

zh

外科植入物

使用本产品之前，请先仔细阅读下列信息。

pt-BR

Implante cirúrgico

ANTES DE USAR O PRODUTO, LEIA ATENTAMENTE ESTAS INFORMAÇÕES.

pt

Implante cirúrgico

ANTES DE UTILIZAR O PRODUTO, LEIA ATENTAMENTE ESTAS INFORMAÇÕES.

hr

Kirurški implantat

PRIJE UPOTREBE PROIZVODA POZORNO PROČITAJTE SLJEDEĆE INFORMACIJE.

kk

Хирургиялық имплант

ӨНІМДІ ПАЙДАЛАНУ АЛДЫНДА КЕЛЕСІ АҚПАРАТТЫ МҰҚИЯТ ОҚЫҢЫЗ.

ko

수술용 임플란트

제품을 사용하기 전에 다음 정보를 숙독하십시오.

zh-t

外科手術植入物

使用本產品之前，請仔細閱讀下列資訊。

uk

Хірургічний імплантат

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

et

Kirurgiline implantaat

ENNE TOOTE KASUTAMIST LUGEGE JÄRGNEV TEAVE PÕHJALIKULT LÄBI.

lt

Chirurginis implantas

PRIEŠ NAUDODAMI GAMINĮ, ATIDŽIAI PERSKAITYKITE TOLIAU PATEIKTĄ INFORMACIJĄ.

sr

Hirurški implantat

PRE KORIŠĆENJA PROIZVODA DETALJNO PROČITAJTE SLEDEĆE INFORMACIJE.

lv

Ķirurģiskais implants

PIRMS IZSTRĀDĀJUMA LIETOŠANAS RŪPĪGI IZLASIET TĀLĀK SNIEGTO INFORMĀCIJU.

mk

Хируршки имплант

ВНИМАТЕЛНО ПРОЧИТАЈТЕ ГИ СЛЕДНИТЕ ИНФОРМАЦИИ ПРЕД ДА ГО УПОТРЕБИТЕ ПРОИЗВОДОТ.

id

Implan Bedah

SEBELUM MENGGUNAKAN PRODUK, BACA INFORMASI BERIKUT SECARA MENYELURUH.

vi

Mảnh ghép phẫu thuật

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

ar

غرسة جراحية

en: Do not resterilize

en: Consult instructions for use

en: Caution

en: Biological risks

MD **en:** Medical Device

MR **en:** MR safe

en: Temperature limit

REF **en:** Catalog number

en: Manufacturer

STERILE R **en:** Sterilized using irradiation

en: Double sterile barrier system

en: Use-by date

LOT **en:** Batch code

en: Date of manufacture

en: Single use

en: Patient identification

en: Date

en: Health care centre or doctor

en: Patient information website

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

BIO **en:** Contains biological material of animal origin

UDI **en:** Unique device identifier

CE2797 **en:** CE Mark

en: Do not use if package is damaged

CE2797

© 2022 Covidien.

Sofradim Production, 116, avenue du Formans-01600 Trévoux-France.
www.covidien.com
+1 800 633 8766
+1 763 514 4000

COVIDIEN, COVIDIEN with logo, and Covidien logo and Positive Results for Life are U.S. and internationally registered trademarks of Covidien AG. Other brands are trademarks of a Covidien company. ™* brands are trademarks of their respective owner.

Made in France. 2022 - 09 / 03