Observational Registry Study for Symbotex™ Composite Mesh in Ventral Hernia Repair

The SymCHro Study

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Sponsor

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Background

An abdominal wall hernia is an abnormal protrusion of the contents of the abdominal cavity or of pre-peritoneal fat through a defect or weakness in the abdominal wall. Repair of abdominal wall hernia is one of the most common procedures performed by surgeons.

Until the 1990s, the fascia-duplication and the fascia-adaptation were the "gold standard" in ventral hernia repair. Because of this unacceptably high recurrence rates after simple reconstruction and the development of new tissue-compatible, prosthetic materials, many surgeons share the opinion that an additional strengthening of the frontal abdominal wall by implantation of allo- and autoplastic material should be obligatory. According to DEN HARTOG et al Cochrane review [1] there is good evidence that mesh repair is superior to suture repair in terms of recurrences.

As pointed out by ROBINSON et al [2] ideal mesh has been sought since prosthetic materials for hernia repair were first introduced in the 1950s. Authors have generally agreed on several properties of this theoretically ideal mesh:

- be strong enough to withstand physiologic stresses over a long period of time
- conform to the abdominal wall
- promote strong host tissue ingrowth, which mimics normal tissue healing
- resist the formation of bowel adhesions and erosions into visceral structures
- not induce allergic or adverse foreign body reactions
- resist infection
- be non-carcinogenic

There is little agreement or consensus in the literature as to the ideal approach for this difficult problem. In recent years population based studies have provided better data on the true failure rates associated with the various herniorrhaphies [3].
The use of meshes became popular during the 20th century following several studies which showed recurrence rates significantly lower than suture repairs (approximately 10% of recurrence for mesh repairs against 25 to 55% for suture repairs) [4].

According to a review of the literature pooling recurrence data from 2,559 patients, the global recurrence rate varies between 0 and 6% for Parietex™ Composite Mesh at a mean follow-up of 26.1 months.
As described in the literature, the worst recurrence rate following incisional hernia repairs using synthetic meshes by laparoscopic and open approach, is 5.9 % [5] and 5.6 %[6] respectively.

Within 10 years, the tension repairs were outnumbered by tension-free, mesh-based techniques, and these latter hernioplasties now dominate hernia repair in the marketplace [7]. Literature demonstrates prosthetic repair as the best solution even though no consensus is currently established regarding the ideal technique (choice of mesh, surgical technique, and implantation site). Currently, the gold standard for ventral hernia repair according to many surgeons [8],[9],[10],[11] is the Rives Stoppa retro-rectus repair. However, open intraperitoneal technique (the mesh is placed behind all layers of the abdominal wall including the parietal peritoneum [12]) could be an alternative to a retromuscular repair [13]. In this technique, where one side of the mesh faces the abdominal wall, and the other side is in contact with the viscera, hernia repair requires minimizing tissue attachment properties or two-sided (i.e. composite) mesh.
Parietex composite mesh (first generation) available since 1998 has become one of the most effective mesh when an intraperitoneal placement is required [14, 15].

Symbotex™ composite mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving primary abdominal wall and incisional hernia surgeries.

Symbotex™ composite mesh is made out of a three-dimensional monofilament polyester textile, which is covered with an absorbable, continuous and hydrophilic film on one of its sides. This film is made up of a mix of collagen from porcine origin and glycerol.
The non-absorbable three-dimensional polyester mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.
Symbotex™ Composite Mesh was developed based on the Parietex™ Composite (PCO) and Parietex Optimized Composite (PCOX) design and collagen technology for minimizing tissue attachment to the mesh in case of direct contact with the viscera.

In addition, Symbotex ™ Composite has been specifically designed for ease of use for example:

- ✓ Green flap for helping to visualization of the fixation area
- ✓ Presence of green marking for orienting and placing the mesh; the green drop-shaped marker in the center of the mesh helps the orientation and placement of the mesh to the medial line of the body.
- ✓ Mesh transparency for improved anatomy visualization during placement
- ✓ Conformability of textile for position against the abdominal wall.

In order to assess the clinical outcomes following the use of Symbotex™ Composite Mesh in primary abdominal wall and incisional hernia repair, this observational registry study has been initiated.

1. Study Objectives

The aim of this Observational Registry Study is to assess the short- and long-term clinical outcomes following the use of Symbotex™ Composite Mesh in primary and incisional

abdominal wall hernia surgeries by open or laparoscopic approach, according to the Instruction for use (IFU) (Appendix B).

One hundred consecutive, adult patients scheduled for primary and incisional abdominal wall hernia surgeries using Symbotex™ Composite Mesh will be reported in the Club Hernie online database, with standard data captured of all preoperative, perioperative and post-operative data, for patient's outcomes measurements.

1.1 Primary Objective

Evaluate the incidence of peri-operative and post-operative complications, with post-operative evaluations occurring, at discharge , 1 week (D1 and D8 follow up), 1 month (D30 follow up), 1Year and 2 Year follow up after primary and incisional abdominal wall hernia surgeries using Symbotex™ Composite Mesh by open or laparoscopic approach (such as anticipated device related complications such as pain, recurrence, complications related to adhesions, wound complications, other postoperative complications, SAE…).

1.2 Secondary Objectives

Description and assessment of the use of Symbotex™ Composite Mesh for primary and incisional abdominal wall hernia surgeries (surgical techniques, description of dissection, mesh handling, ease of use, surgeon's satisfaction, Quality of life and patient satisfaction...).

2. Study Design and Methodology

This is an observational multicenter registry Study.

2.1 Definition

According to MEDDEV 2.12.2 rev 2 for post-market follow up studies,
Device Registry: An organized system that uses observational study methods to collect defined clinical data under normal conditions of use relating to one or more devices to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure and that serves predetermined scientific, clinical or policy purpose(s).

2.2 Scope

One hundred consecutive adult patients scheduled for primary and incisional abdominal wall hernia surgeries using Symbotex™ Composite Mesh will be reported in the Club Hernie database in real time.

A working group of hernia surgeons, under the auspices of the Club Hernie Society board, have created a French Registry of Abdominal Wall Hernias called Club Hernie. The Club Hernie is a non-profit organization created in 2009, currently including 30 French surgeons' members, with the aim to improve the healthcare treatments in parietal surgery by an assessment of surgical practices, promoting research in abdominal wall surgery using an internet database open to surgeon members to monitor their own hernia practice and outcomes.

This online database consists of a systematic and consecutive data entry of all patients treated for Inguinal Hernia and Ventral Hernia by the 30 French surgeon members, with standard data captured of all preoperative, perioperative and post-operative data.

Covidien is contracting with Club Hernie to act as a authorized representative to perform sponsor's clinical study-related duties and functions, such as implementation and conduct of this observational registry study.

The Club Hernie database will be used for the 100 patient registry from the Club Hernie surgeon members using Symbotex™ Composite Mesh. The Club Hernie database is free for use by surgeons. Only Hernia Club surgeon members are allowed to get an account for the database, protected by identifier and password. The surgeon members having signed the Quality Charter are committed to respecting its principles Club Hernie surgeon members participating in the study will be surgeon members using Symbotex™ Composite Mesh for primary abdominal wall and incisional hernia surgeries according to their current therapeutic practice.

The database is required to be completed anonymously. Therefore, it does not contain any patient data such as name, date of birth, social security number or address of the patient.

One hundred patients will be followed using the online database for registration and patient outcome measurements, including pre-operative, operative, discharge, post-operative course (D1 and D8 follow up), 1 month (D30 follow up), 1Year and 2 Year follow up. The pain nurses will carry out the pain evaluation on the day of surgery (D0) and on postoperative day 1 (D1) (by phone call in case of day surgery). Pain on day 8 is assessed either during clinical exam or by phone if the patient is already discharged. Patients will be given an appointment for a clinical visit on day 30 (D30 follow up).
The post-operative visit at 1 month (D30 follow up) is the standard of care for patient follow up following primary abdominal wall and incisional hernia surgeries.

For long-term follow up, two sets of self-administered QOL questionnaires will be administered by phone call at 1 Year and 2 Year follow-up.
Follow up by phone questionnaires will be performed by a Clinical Research Associate mandated by Club Hernie, independent from the operative surgeons

The Clinical Research Associate will enter into the database answers from the patient-based self-assessment questionnaires.

The answers will be registered without any medical adjustment into the database. The patients who complain of any trouble will be invited to have a clinical visit at the surgeon's office. The correlation between the patient's answer and clinical assessment and physical examination will then be determined.

A patient will be considered lost to follow-up after 5 failed attempts of meticulous postal reminders and phone calls at various times, therefore minimizing the non-response bias.

2.3 Monitoring procedures

No source data verification will be done.
Quality data control of all data captured into the online database will be performed by coherence analysis by Club Hernie authorized representative.

3. Product Description

The product description and Instructions for Use are described in Appendix A & B.

Symbotex™ Composite Mesh is proposed in three configurations (flat mesh without preplaced suture yarns, flat mesh with preplaced suture yarns, and mesh with open skirt (flap).
Symbotex™ Composite Mesh is available in several shapes and sizes.

Symbotex™ composite mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving primary abdominal wall and incisional hernia surgeries. The non-absorbable three-dimensional Polyethylene terephthalate (polyester) mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

In addition, Symbotex ™ Composite has been specifically designed for ease of use, for example:

- ✓ Presence of green marking for orienting and placing the mesh, the green drop-shaped marker in the center of the mesh helps the orientation and placement of the mesh to the medial line of the body.
- ✓ Mesh transparency for improved anatomy visualization during placement
- ✓ Conformability of textile for position against the abdominal wall

The Symbotex ™ Composite Mesh will be CE marked and manufactured by the sponsor of the study, SOFRADIM PRODUCTION (subsidiary of Covidien).

4. Patient Selection

The first one hundred consecutive adult patients scheduled for primary and incisional abdominal wall hernia surgery by Club Hernie members surgeons using Symbotex™

Composite Mesh (Flat sheet (SYM), Flat Sheet with sutures (SYM-F), with flap (SYM-OS) by open or laparoscopic approach. Patients' data will be reported in the Club Hernie database in real time.

4.1 Inclusion Criteria

- All patients regardless of gender ≥ 18 years of age presenting with ventral hernias.
- Patients will be informed by surgeon with a written information notice of the nature of the observational registry study.

4.2 Exclusion Criteria

No exclusion criteria outside the product IFU (Appendix B)

5. Clinical Assessments

Patients will be followed using the online database for registration and patient outcome measurements, including pre-operative, operative and discharge data, post-operative course (D1 and D8 follow up), 1 month (D30 follow up), 1Year and 2 Year follow up.

The study patients will be evaluated and the data will be recorded at time of consultation at the following time points.

5.1 Preoperative data

- Demographic data (age , gender, ASA score, BMI, patient's occupation)
- Relevant prior medical/surgical history (previous surgical procedure including
- Hernia antecedents and abdominal surgical history) and comorbidities
- Hernia symptoms, disorders, region, discomfort and frequency

5.2 Operative data (D0)

- Date of surgery
- Surgical technique approach
- Defect size, Hernia type and location
- Mesh size and type (SYM, SYMF; SYMOS)
- Amount of Overlap
- Type of fixation
- Operative time (from incision to closure, skin to skin), ,
- Mesh positioning and time

- Peri-operative events (including SAEs)
- Surgeon satisfaction (Mesh handling, mesh manipulability, ease of use)
- Pain assessment measured with VAS* score (The pain nurse will carry out the pain evaluation)

* VAS: The postoperative pain is assessed using a 0–10 Visual Analogue Scale.

Worst pain experienced over the last 24 hours.

5.3 Discharge data

- Date of discharge
- Length of Hospital stay (number of nights in the institution after the surgery)
- Post-operative complications (including SAEs)

5.4 Post-operative course (D1) Follow up

- Pain assessment measured with VAS score (The pain nurse will carry out the pain evaluation, either during systematic clinical visit or by phone call in case of day surgery

5.5 Post-operative course (D8) Follow up

Pain assessment measured with VAS score, either during systematic clinical visit or by phone call when a patient is already discharged.

5.6 1 month (D30) Follow up

- Pain assessment measured with VAS* score
- * Mid pain for VAS score between 0 and 3; Moderate pain for VAS score > 3 and > 6 ; Severe pain for VAS scores > 6.
- Post-operative complications (including SAEs)
- Quality of Life « QoL » Questionnaire (Appendix C)

5.7 1 year follow-up

- QoL and patient satisfaction Questionnaire (Appendix C)

- Post-operative complications (including SAEs)
- Pain assessment measured with VAS score*

Follow-up at 1 year: All patients will be contacted by phone in order to complete a self-assessment questionnaire.

*The patients who complained of any trouble will be invited to have a clinical visit at the surgeon's office. Post-operative complications and VAS score will be recorded.

5.8 2 year follow-up

- QoL and patient satisfaction Questionnaire (Appendix C)
- Post-operative complications (including SAEs)
- Pain assessment measured with VAS score*

Follow-up at 2 year: All patients will be contacted by phone in order to complete a self-assessment questionnaire.

*Patients who complain of any trouble will be invited to have a clinical visit at the surgeon's office. Post-operative complications and VAS score will be recorded.

6. Statistical Methods

6.1 Sample Size Calculation

As described in the literature, the worst recurrence rate following incisional hernia repairs using synthetic mesh by laparoscopic and open approach, is 5.9 % [5] and 5.6 %[6] respectively.
Assuming a 95% confidence interval, a recurrence rate of 5.9 % with a +/- 5% precision, N=86 patients are needed for the Evaluable Population. Anticipating a 15% lost to follow up at 24 months, we plan to recruit a *minimum* of 100 patients for this observational registry as the Evaluable Population. Patients that are lost to follow-up or that withdraw consent will not be replaced.

6.2 Statistical Analysis Plan Summary

General Considerations

Statistical analysis will consist of descriptive analysis. A statistical analysis plan will be developed by Club Hernie.

- Qualitative variables will be described by their absolute and relative (%) frequencies of each class or value, and by two-tailed 95% confidence intervals.
- Quantitative variables will be described by their mean, standard deviation (SD), extreme values (minimum and maximum values), and number of missing data and by two-tailed 95% confidence intervals.

Statistical Analysis Plan Summary

The analysis will be performed for primary and secondary endpoints, all data will be analyzed, according to the methods previously described in the general considerations section.

1) Descriptive Analysis of patients registration and outcomes measurement

2) Baseline and Demographic Data Analysis

3) Operative Data Analysis

4) Primary endpoints measured within 1month, 1 Year and 2 Year follow-up

    a. Peri-operative complications
    b. Post-operative complications such as anticipated device related complications as pain, recurrence, complications related to adhesions, wound complications, other postoperative complications, SAEs…
    c. All complications

5) Secondary endpoints analysis during the whole follow-up

    a. Surgical technique and mesh fixation
    b. Operative time descriptive analysis
    c. Ease of use / mesh manipulability assessment by surgeons
    d. Length of hospital stay analysis
    e. Quality of life and patient satisfaction analysis
    f. Surgeon satisfaction

Statistical Analysis Schedule

Interim analyses and one final analysis will be performed on the follow-up data in its entirity.
One final clinical study report will be issued.

7 Ethical Considerations, Data storage and Confidentiality

This study is an observational study; therefore the ISO 14155 Standard is not applicable.
This Observational Registry Study will be conducted according to applicable French regulation. No specific examinations or lab tests are to be performed above and beyond those usually undertaken by the surgeon, and no additional visits are required for study purposes.
The study will be registered on the www.clinicaltrials.gov and the study results will be posted on this website.

7.1 Patient Information Notice

A written information notice will be given by the surgeon to inform the patient about the nature of the study.

The physician will provide the patient with the information sheet during the pre-operative visit. This form will contain information concerning the nature and purpose of the Study.

7.2 Data Storage and Confidentiality

Only Hernia Club surgeon members are allowed to get an account for the database, protected by identifier and password.
The database is completed anonymous. Therefore, it does not contain any patient data such as name, date of birth, social security number or address of the patient.

8 Safety Assessment

Adverse Event/ Complications

.
Symbotex™ Composite mesh is currently marketed within US and this observational registry study will be initiated as soon as marketed in EU. Therefore any device related complications noted in this study will be reported to Covidien.
Study reported device-related events will be reviewed periodically to assess for any potential trends

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10 Appendix

10.1 Appendix A: Product description
10.2 Appendix B: Instruction for use
10.3 Appendix C: Quality of Life and patient satisfaction Questionnaire

Appendix A

Product description

The proposed Symbotex™ Composite Mesh configurations are summarized in the table below:

	Proposed Symbotex™ Composite Mesh		
	Flat sheet (SYM)	Flat Sheet with sutures (SYM-F)	With flap (SYM-OS)
Photos			
Description	Symbotex™ composite mesh is made out of a three-dimensional monofilament polyester textile, which is covered with an absorbable, continuous and hydrophilic film on one of its sides. This film is made up of collagen from porcine origin and glycerol. The collagen film is essentially degraded in less than 1 month. A dyed monofilament polyester (D&C Green No. 6) marking is positioned on the center of the textile, on the opposite side of the film, and helps center and orient the mesh.	Symbotex™ composite mesh is made out of a three-dimensional monofilament polyester textile, which is covered with an absorbable, continuous and hydrophilic film on one of its sides. This film is made up of a mix of collagen from porcine origin and glycerol. The collagen film is essentially degraded in less than 1 month. Non-absorbable pre-placed sutures are tied to the three-dimensional mesh. A dyed monofilament polyester (D&C Green No. 6) marking is positioned on the center of the textile, on the opposite side of the film, and helps center and orient the mesh.	Symbotex™ composite mesh is made out of a three-dimensional monofilament polyester textile, which is covered with an absorbable, continuous and hydrophilic film on one of its sides. This film is made up of collagen from porcine origin and glycerol. The collagen film is essentially degraded in less than 1 month. A dyed (D&C Green No. 6) bi-dimensional monofilament polyester textile flap is attached to the three-dimensional reinforcement and helps place and fix the mesh.
Shape, Reorder and Sizes	Rectangular: SYM1510 (15x10cm) SYM2015 (20x15cm) SYM2520 (25x20cm) SYM3020 (30x20cm) SYM3728 (37x28cm) SYM4232 (42x32cm) Elliptical : SYM1710E (17x10cm) SYM2012E (20x12cm) SYM2515E (25x15cm) SYM3420E (34x20cm) SYM4024E (40x24cm) Circular : SYM9 (9cm diameter) SYM12 (12cm diameter) SYM15 (15cm diameter)	Rectangular: SYM1510F (15x10cm) SYM2015F (20x15cm) SYM2520F (25x20cm) SYM3020F (30x20cm) SYM3728F (37x28cm) SYM4232F (42x32cm) Elliptical : SYM1710EF (17x10cm) SYM2012EF (20x12cm) SYM2515EF (25x15cm) SYM3420EF (34x20cm) SYM4024EF (40x24cm) Circular : SYM9F (9cm diameter) SYM12F (12cm diameter) SYM15F (15cm diameter)	Circular : SYM8OS (8cm) Rectangular: SYM1510OS (15x10cm) SYM2015OS (20x15cm) SYM2520OS (25x20cm) SYM3020OS (30x20cm)

APPENDIX B
Instruction for Use

COVIDIEN™

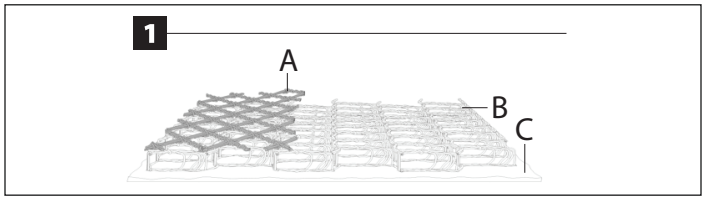
Symbotex™

Composite Mesh

FPO

(99)7500074

1074068



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 or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or resterilize this device.

DESCRIPTION

Symbotex™ composite mesh is made out of a three-dimensional monofilament polyester textile, which is covered with an absorbable, continuous and hydrophilic film on one of its sides. This film is made up of a mix of collagen from porcine origin and glycerol. The collagen film is essentially degraded in less than 1 month.

A dyed (D&C Green No. 6) bi-dimensional monofilament polyester textile flap is attached to the three-dimensional reinforcement and helps place and fix the mesh.

INDICATIONS

Symbotex™ composite mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving primary abdominal wall and incisional hernia surgeries.

The non-absorbable three-dimensional polyester mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

CONTRAINDICATIONS

• As Symbotex™ composite mesh will not stretch to accommodate growth, its use is not appropriate in patients in a period of growth.

• Any foreign material may potentiate or prolong infection in the presence of bacterial contamination, and as such, the use of Symbotex™ composite 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 device.

POSSIBLE COMPLICATIONS

The possible complications associated with the use of Symbotex™ composite mesh are those typically associated with surgically implantable mesh: seroma, hematoma, recurrence, adhesions, fistula formation, infection, inflammation, chronic pain, and/or allergic reactions to the components of the product.

Potential events associated with state of the art mesh with similar indication may include: organ injury (including bowel and visceral injury), trocar-site herniation, bowel obstruction and urinary retention (related with the use of anesthetics).

WARNINGS

1. To avoid injury, exercise caution if fixating the device in the presence of nerves or vessels.

2. In order to maintain the elasticity and the porosity of the reinforcement, it is recommended that the mesh should not be overly stretched when it is being put in place. A moderate and equal tension should be applied in all directions for fixation in order to account for wound shrinkage during the healing process.

3. The mesh should be used in the form in which it is provided without being cut.

4. The effectiveness and safety related to the use of this device in pregnant women have not been established. For women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

5. The device is provided in a sterile packaging. The packaging is to be checked for any damage before use. Do not use the mesh if the packaging is opened or damaged.

6. The device is provided in a double sterile packaging. It is recommended to open the last packaging only for the placement of the mesh and to handle the latter using clean gloves and instruments.

7. Symbotex™ composite mesh is designed to be used in open approach only.

PRECAUTIONS

Users should be familiar with surgical procedures and techniques involving the use of surgical mesh before employing this device.

This device should only be used by experienced practitioners who do so under their own responsibility.

1 SCHEMATIC VIEW

A) BI-DIMENSIONAL MONOFILAMENT POLYESTER GREEN FLAP

B) THREE-DIMENSIONAL MONOFILAMENT POLYESTER TEXTILE

C) FILM MADE OF COLLAGEN AND GLYCEROL

OPERATING STEPS – POSITIONING

1. Symbotex™ composite 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 to ensure its conformability and flexibility.

2. When putting it in place, it is essential to identify the film side from the porous textile side in order to situate the device correctly: the porous textile side is placed against the wall for tissue integration while the film side is facing the structures on which the tissue attachment is to be limited.

3. The green flap attached to the textile side helps place and fix the mesh.

4. After placement of the mesh, ensure that no tissue is trapped between the mesh and the abdominal wall.

5. The edge of the reinforcement should extend 2 to 5 cm over the edge of the defect(s) on all sides. The technique used to anchor the mesh (suture or staples) is left up to the practitioner. Place fixation means in the green flap as close as possible to the mesh periphery.

NOTE: Careful attention should be paid not to fixate on the film.

STERILIZATION TECHNIQUE

Sterile single-use device. Sterilized by gamma radiation. Do not re-sterilize.

STORAGE

Recommended storage conditions: room temperature.

Do not use the device past the last day of the labeled month of expiration.

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 integrity of the packaging appears compromised.

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 which was implanted.

FR

Renfort Composite

AVANT D'UTILISER CE PRODUIT, LIRE ATTENTIVEMENT LES INFORMATIONS CI-DESSOUS.

IMPORTANT !

Cette notice est destinée à faciliter l'utilisation de ce produit. Elle ne constitue pas une référence en matière de techniques chirurgicales. Ce dispositif a été conçu, testé et fabriqué pour un usage chez un seul patient. Sa réutilisation ou son retraitement peut provoquer un dysfonctionnement et des blessures chez le patient. Son retraitement et/ou sa restérilisation peuvent entrainer un risque de contamination et d'infection du patient. Ne pas réutiliser, retraiter ou restériliser ce dispositif.

DESCRIPTION

Le renfort Symbotex™ composite est constitué d'un textile tridimensionnel en polyester monofilament recouvert sur une face, par un film hydrophile, continu et résorbable à base de collagène d'origine porcine et de glycérol. Le film de collagène est essentiellement résorbé en moins d'un mois.

Un rabat textile bidimensionnel en polyester monofilament de couleur verte (D&C Green No. 6) est fixé sur le renfort tridimensionnel et aide à placer et fixer le renfort.

INDICATIONS

Le renfort Symbotex™ composite est utilisé pour le renforcement des tissus mous de la paroi abdominale en présence d'une faiblesse, dans les procédures chirurgicales impliquant les hernies primaires de la paroi abdominale et les hernies incisionnelles.

Le renfort en polyester tridimensionnel non résorbable permet le renforcement à long terme des tissus mous. Sur la face opposée, le film hydrophile résorbable réduit les phénomènes d'adhérence pouvant survenir entre la prothèse et les tissus en cas de contact direct avec les viscères.

CONTRE- INDICATIONS

• Comme le renfort Symbotex™ composite ne s'allongera pas avec la croissance, son utilisation n'est pas appropriée chez les patients en période de croissance.

• Tout matériau étranger est susceptible de provoquer ou de prolonger une infection en présence d'une contamination bactérienne et, de ce fait, l'utilisation du renfort Symbotex™ composite peut ne pas convenir en cas d'intervention en site infecté ou contaminé. De plus, ce produit doit être utilisé en sachant que l'infection peut nécessiter le retrait du dispositif.

COMPLICATIONS EVENTUELLES

Les éventuelles complications associées à l'utilisation du renfort Symbotex™ composite sont celles classiquement associées à l'implantation d'un renfort chirurgical: sérome, hématome, récidive, adhérence, formation de fistules, infection, inflammation, douleur chronique, et/ou réactions allergiques aux constituants du produit.

L'état de l'art des renforts utilisés conformément à l'indication, établie que les évènements suivants peuvent se produire : dommages aux organes (tels que dommages aux intestins et aux viscères), hernies de trocart, occlusion intestinale et rétention urinaire (qui peut se produire lors de l'utilisation d'anesthésiques).

AVERTISSEMENTS

1. Pour prévenir toute blessure, une attention particulière est requise lors de la fixation du dispositif en présence de nerfs ou de vaisseaux.

2. Afin de préserver l'élasticité et la porosité du renfort, il est recommandé de ne pas le tendre exagérément au moment de la pose. La tension doit être modérée et équivalente dans toutes les directions pour fixer le renfort afin de tenir compte de la rétraction de plaie lors de la cicatrisation.

3. Le renfort doit être utilisé tel que livré sans découpe ultérieure.

4. L'efficacité et la sécurité relatives à l'utilisation de ce dispositif chez la femme enceinte n'ont pas été établies. Pour les femmes en âge de mener une grossesse, le chirurgien doit être attentif au fait que le dispositif ne s'allongera pas de manière significative lors de la croissance survenant lors de la grossesse.

5. Le dispositif est livré sous emballage stérile. Vérifier l'intégrité de l'emballage avant toute utilisation. Ne pas utiliser le dispositif si l'emballage est ouvert ou endommagé.

6. Le dispositif se présente sous double emballage stérile. Il est recommandé de n'ouvrir le dernier emballage qu'au moment de la mise en place du renfort et de manipuler celui-ci à l'aide de gants et d'instruments non souillés.

7. Le renfort Symbotex™ composite a été conçu pour être utilisé uniquement par voie ouverte.

PRECAUTIONS D'EMPLOI

Les utilisateurs doivent être familiers des procédures et techniques chirurgicales impliquant l'utilisation de renforts chirurgicaux avant d'utiliser le dispositif. Ce dispositif est réservé aux praticiens spécialistes qui l'utilisent sous leur seule responsabilité.

1 VUE SCHéMATIQUE

A) RABAT TEXTILE BIDIMENSIONNEL POLYESTER VERT

B) TEXTILE TRIDIMENSIONNEL POLYESTER MONOFILAMENT

C) FILM À BASE DE COLLAGÈNE ET DE GLYCÉROL

INTERVENTIONS - MISE EN PLACE

1. Avant toute manipulation, le renfort Symbotex™ composite doit être hydraté dans son emballage d'origine par immersion complète, quelques secondes dans une solution physiologique stérile afin de restituer au renfort sa conformabilité et sa souplesse.

2. Au moment de la mise en place, il est indispensable de repérer parfaitement la face du film de la face poreuse du textile, de façon à correctement l'orienter : la face poreuse du textile contre la paroi pour une intégration tissulaire / la face du film en regard des structures pour lesquelles on souhaite limiter les adhérences tissulaires.

3. Le rabat textile vert présent sur la face textile facilite le positionnement et la fixation du renfort.

4. Après avoir positionné le renfort, il faut s'assurer qu'aucun tissu n'est inséré entre le renfort et la paroi abdominale.

5. Le renfort doit déborder de 2 à 5 cm les berges du ou des orifice(s). La technique de fixation du renfort (sutures ou agrafes) est laissée au choix du praticien. Les moyens de fixation doivent être placés sur le rabat vert aussi près que possible du pourtour du renfort.

NOTE : une attention particulière doit être apportée afin de ne pas fixer sur le film.

MODE DE STERILISATION

Dispositif stérile à usage unique. Stérilisé par irradiation gamma .Ne pas restériliser.

CONSERVATION

Conditions de stockage recommandées : température ambiante.

Ne pas utiliser le dispositif au-delà du dernier jour du mois d'expiration figurant sur l'étiquette.

A réception du dispositif, s'assurer que le conditionnement n'a été ni ouvert ni endommagé et conserve intègre son scellage. Ne pas utiliser le dispositif si l'emballage présente un défaut d'intégrité pouvant compromettre la stérilité.

TRACABILITE

Une étiquette de traçabilité identifiant le type et le numéro de lot du dispositif est jointe à chaque emballage de dispositif. Cette étiquette est destinée à être collée sur le dossier médical permanent du patient afin de clairement identifier le dispositif implanté.

Marquage CE initial: 2014

Do not use if package is opened or damaged. / Ne pas utiliser en cas d'endommagement ou d'ouverture de l'emballage.

STERILE R

Single use

Rx ONLY

Do not resterilize

Caution, consult accompanying documents

CE 0459

Sofradim Production, 116, avenue du Formans-01600 Trévoux-France.

www.covidien.com

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COVIDIEN™

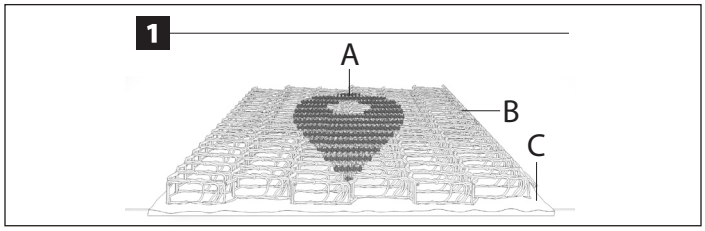
Symbotex™

Composite Mesh

FPO

(99)7500072

1074070



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 or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or resterilize this device.

DESCRIPTION

Symbotex™ composite mesh is made out of a three-dimensional monofilament polyester textile, which is covered with an absorbable, continuous and hydrophilic film on one of its sides. This film is made up of a mix of collagen from porcine origin and glycerol. The collagen film is essentially degraded in less than 1 month.

A dyed monofilament polyester (D&C Green No. 6) marking is positioned on the center of the textile, on the opposite side of the film, and helps center and orient the mesh.

INDICATIONS

Symbotex™ composite mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving primary abdominal wall and incisional hernia surgeries.

The non-absorbable three-dimensional polyester mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

CONTRAINDICATIONS

• As Symbotex™ composite mesh will not stretch to accommodate growth, its use is not appropriate in patients in a period of growth.

• Any foreign material may potentiate or prolong infection in the presence of bacterial contamination, and as such, the use of Symbotex™ composite 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 device.

POSSIBLE COMPLICATIONS

The possible complications associated with the use of Symbotex™ composite mesh are those typically associated with surgically implantable mesh: seroma, hematoma, recurrence, adhesions, fistula formation, infection, inflammation, chronic pain, and/or allergic reactions to the components of the product.

Potential events associated with state of the art mesh with similar indication may include: organ injury (including bowel and visceral injury), trocar-site herniation, bowel obstruction and urinary retention (related with the use of anesthetics).

WARNINGS

1. To avoid injury, exercise caution if fixating the device in the presence of nerves or vessels.

2. In order to maintain the elasticity and the porosity of the reinforcement, it is recommended that the mesh should not be overly stretched when it is being put in place. A moderate and equal tension should be applied in all directions for fixation in order to account for wound shrinkage during the healing process.

3. Particular attention should be paid not to cut the green marking. It may no longer be centered and lose its functions if the mesh is trimmed.

4. The effectiveness and safety related to the use of this device in pregnant women have not been established. For women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

5. The device is provided in a sterile packaging. The packaging is to be checked for any damage before use. Do not use the mesh if the packaging is opened or damaged.

6. The device is provided in a double sterile packaging. It is recommended to open the last packaging only for the placement of the mesh and to handle the latter using clean gloves and instruments.

PRECAUTIONS

Users should be familiar with surgical procedures and techniques involving the use of surgical mesh before employing this device.

This device should only be used by experienced practitioners who do so under their own responsibility.

1 SCHEMATIC VIEW

A) GREEN COLORED POLYESTER MARKING

B) THREE-DIMENSIONAL MONOFILAMENT POLYESTER TEXTILE

C) FILM MADE OF COLLAGEN AND GLYCEROL

OPERATING STEPS - POSITIONING

1. Symbotex™ composite 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 to ensure its conformability and flexibility.

2. When putting it in place, it is essential to perfectly differentiate the film side from the porous textile side in order to situate the device correctly: the porous textile side is placed against the wall for tissue integration while the film side is facing the structures on which the tissular attachment is to be limited.

3. The green marking is then placed against the abdominal wall. It should be visible through the composite mesh. The circular portion of the marking should be centered on the defect, while the triangular portion shall indicate the orientation of the mesh in order to correctly align it to the medial line of the body.

4. Should it be used in a laparoscopic approach, Symbotex™ composite mesh is to be rolled after hydration, with the film facing inside. The film is then protected when inserted in the trocar.

5. The edge of the reinforcement should be at least 5 cm over the edges of the defect(s). The technique used to anchor the mesh (suture or staples) is left up to the practitioner. It is suggested to fixate the mesh at a distance approximately 1cm from the edge of the mesh.

6. Symbotex™ composite mesh can be trimmed to the desired size without impairment to the minimizing tissue attachment properties of the film.

NOTE: The green textile marking should not be cut. It may no longer be centered and could lose its functions if the mesh is trimmed.

STERILIZATION TECHNIQUE

Sterile single-use device. Sterilized by gamma radiation. Do not re-sterilize.

STORAGE

Recommended storage conditions: room temperature.

Do not use the device past the last day of the labeled month of expiration.

Upon receipt of shipment, ensure that the packaging is not open or damaged and retains its sealed integrity. Do not use the device if theintegrity of the packaging appears compromised.

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 which was implanted.

FR

Renfort Composite

AVANT D'UTILISER CE PRODUIT, LIRE ATTENTIVEMENT LES INFORMATIONS CI-DESSOUS.

IMPORTANT !

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DESCRIPTION

Le renfort Symbotex™ composite est constitué d'un textile tridimensionnel en polyester monofilament recouvert sur une face, par un film hydrophile, continu et résorbable à base de collagène d'origine porcine et de glycérol. Le film de collagène est essentiellement résorbé en moins d'un mois.

Un marquage en polyester monofilament de couleur verte (D&C Green No. 6) est placé au centre du textile, sur la face opposée du film, et aide à centrer et à orienter le renfort.

INDICATIONS

Le renfort Symbotex™ composite est utilisé pour le renforcement des tissus mous de la paroi abdominale en présence d'une faiblesse, dans les procédures chirurgicales impliquant les hernies primaires de la paroi abdominale et les hernies incisionnelles.

Le renfort en polyester tridimensionnel non résorbable permet le renforcement à long terme des tissus mous. Sur la face opposée, le film hydrophile résorbable réduit les phénomènes d'adhérence pouvant survenir entre la prothèse et les tissus en cas de contact direct avec les viscères.

CONTRE- INDICATIONS

• Comme le renfort Symbotex™ composite ne s'allongera pas avec la croissance, son utilisation n'est pas appropriée chez les patients en période de croissance.

• Tout matériau étranger est susceptible de provoquer ou de prolonger une infection en présence d'une contamination bactérienne et, de ce fait, l'utilisation du renfort Symbotex™ composite peut ne pas convenir en cas d'intervention en site infecté ou contaminé. De plus, ce produit doit être utilisé en sachant que l'infection peut nécessiter le retrait du dispositif.

COMPLICATIONS EVENTUELLES

Les éventuelles complications associées à l'utilisation du renfort Symbotex™ composite sont celles classiquement associées à l'implantation d'un renfort chirurgical: sérome, hématome, récidive, adhérence, formation de fistules, infection, inflammation, douleur chronique et réactions allergiques aux constituants du produit.

L'état de l'art des renforts utilisés conformément à l'indication, établie que les évènements suivants peuvent se produire : dommages aux organes (tels que dommages aux intestins et aux viscères), hernies de trocart, occlusion intestinale et rétention urinaire (qui peut se produire lors de l'utilisation d'anesthésiques).

AVERTISSEMENTS

1. Pour prévenir toute blessure, une attention particulière est requise lors de la fixation du dispositif en présence de nerfs ou de vaisseaux.

2. Afin de préserver l'élasticité et la porosité du renfort, il est recommandé de ne pas le tendre exagérément au moment de la pose. La tension doit être modérée et équivalente dans toutes les directions pour fixer le renfort afin de tenir compte de la rétraction de plaie lors de la cicatrisation.

3. Une attention particulière doit être apportée pour ne pas découper le marquage vert. En cas de découpe du renfort, il se peut que le marquage ne soit plus centré et ne conserve pas ses fonctionnalités.

4. L'efficacité et la sécurité relatives à l'utilisation de ce dispositif chez la femme enceinte n'ont pas été établies. Pour les femmes en âge de mener une grossesse, le chirurgien doit être attentif au fait que le dispositif ne s'allongera pas de manière significative lors de la croissance survenant lors de la grossesse.

5. Le dispositif est livré sous emballage stérile. Vérifier l'intégrité de l'emballage avant toute utilisation. Ne pas utiliser le dispositif si l'emballage est ouvert ou endommagé.

6. Le dispositif se présente sous double emballage stérile. Il est recommandé de n'ouvrir le dernier emballage qu'au moment de la mise en place du renfort et de manipuler celui-ci à l'aide de gants et d'instruments non souillés.

PRECAUTIONS D'EMPLOI

Les utilisateurs doivent être familiers des procédures et techniques chirurgicales impliquant l'utilisation de renforts chirurgicaux avant d'utiliser le dispositif. Ce dispositif est réservé aux praticiens spécialistes qui l'utilisent sous leur seule responsabilité.

1 VUE SCHÉMATIQUE

A) MARQUAGE VERT EN TEXTILE POLYESTER

B) TEXTILE TRIDIMENSIONNEL POLYESTER MONOFILAMENT

C) FILM À BASE DE COLLAGÈNE ET DE GLYCÉROL

INTERVENTIONS - MISE EN PLACE

1. Avant toute manipulation, le renfort Symbotex™ composite doit être hydraté dans son emballage d'origine par immersion complète, quelques secondes dans une solution physiologique stérile afin de restituer au renfort sa conformabilité et sa souplesse.

2. Au moment de la mise en place, il est indispensable de repérer parfaitement la face du film de la face poreuse du textile, de façon à correctement l'orienter : la face poreuse du textile contre la paroi pour une intégration tissulaire / la face du film en regard des structures pour lesquelles on souhaite limiter les adhérences tissulaires.

3. Le marquage vert est placé contre la paroi abdominale. Il devrait être visible à travers le renfort composite. La partie circulaire du marquage sera centré sur l'orifice, la partie triangulaire devra être alignée par rapport à la ligne médiale du corps.

4. Dans le cas d'une utilisation par voie laparoscopique, le renfort Symbotex™ composite doit être roulé après hydratation, face film orientée vers l'intérieur, de façon à protéger le film lors du passage dans le trocart.

5. Le renfort doit déborder d'au moins 5 cm les berges du ou des orifice(s). La technique de fixation du renfort (sutures ou agrafes) est laissée au choix du praticien. Il est recommandé de fixer le renfort à une distance d'environ 1 cm du bord du renfort.

6. Le renfort Symbotex™ composite peut être découpé à la taille désirée, sans perte de la propriété de minimisation des adhérences du film.

NOTE : Le marquage vert ne devra pas être découpé. En cas de découpe du renfort, il se peut que le marquage ne soit plus centré et ne conserve pas ses fonctionnalités.

MODE DE STERILISATION

Dispositif stérile à usage unique. Stérilisé par irradiation gamma. Ne pas restériliser.

CONSERVATION

Conditions de stockage recommandées : température ambiante.

Ne pas utiliser le dispositif au-delà du dernier jour du mois d'expiration figurant sur l'étiquette.

A réception du dispositif, s'assurer que le conditionnement n'a été ni ouvert ni endommagé et conserve intègre son scellage. Ne pas utiliser le dispositif si l'emballage présente un défaut d'intégrité pouvant compromettre la stérilité.

TRACABILITE

Une étiquette de traçabilité identifiant le type et le numéro de lot du dispositif est jointe à chaque emballage de dispositif. Cette étiquette est destinée à être collée sur le dossier médical permanent du patient afin de clairement identifier le dispositif implanté.

Marquage CE initial: 2014

Do not use if package is opened or damaged. / Ne pas utiliser en cas d'endommagement ou d'ouverture de l'emballage.

STERILE R

Single use

Rx ONLY

Do not resterilize

Caution, consult accompanying documents

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COVIDIEN™

Symbotex™

Composite Mesh

FPO

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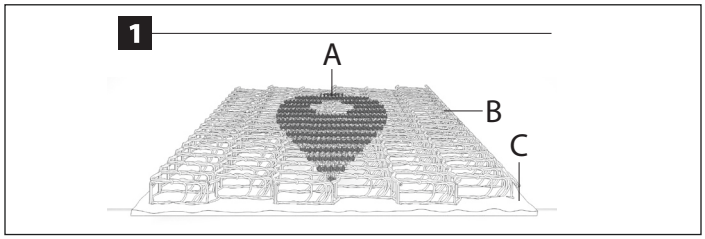

EN

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IMPORTANT!

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DESCRIPTION

Symbotex™ composite mesh is made out of a three-dimensional monofilament polyester textile, which is covered with an absorbable, continuous and hydrophilic film on one of its sides. This film is made up of a mix of collagen from porcine origin and glycerol. The collagen film is essentially degraded in less than 1 month.

Non-absorbable pre-placed sutures are tied to the three-dimensional mesh.

A dyed monofilament polyester (D&C Green No. 6) marking is positioned on the center of the textile, on the opposite side of the film, and helps center and orient the mesh.

INDICATIONS

Symbotex™ composite mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving primary abdominal wall and incisional hernia surgeries.

The non-absorbable three-dimensional polyester mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

CONTRAINDICATIONS

• As Symbotex™ composite mesh will not stretch to accommodate growth, its use is not appropriate in patients in a period of growth.

• Any foreign material may potentiate or prolong infection in the presence of bacterial contamination, and as such, the use of Symbotex™ composite 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 device.

POSSIBLE COMPLICATIONS

The possible complications associated with the use of Symbotex™ composite mesh are those typically associated with surgically implantable mesh: seroma, hematoma, recurrence, adhesions, fistula formation, infection, inflammation, chronic pain, and/or allergic reactions to the components of the product.

Potential events associated with state of the art mesh with similar indication may include: organ injury (including bowel and visceral injury), trocar-site herniation, bowel obstruction and urinary retention (related with the use of anesthetics).

WARNINGS

1. To avoid injury, exercise caution if fixating the device in the presence of nerves or vessels.

2. In order to maintain the elasticity and the porosity of the reinforcement, it is recommended that the mesh should not be overly stretched when it is being put in place. A moderate and equal tension should be applied in all directions for fixation in order to account for wound shrinkage during the healing process.

3. Particular attention should be paid not to cut the green marking. It may no longer be centered and lose its functions if the mesh is trimmed.

4. The effectiveness and safety related to the use of this device in pregnant women have not been established. For women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

5. The device is provided in a sterile packaging. The packaging is to be checked for any damage before use. Do not use the mesh if the packaging is opened or damaged.

6. The device is provided in a double sterile packaging. It is recommended to open the last packaging only for the placement of the mesh and to handle the latter using clean gloves and instruments.

PRECAUTIONS

Users should be familiar with surgical procedures and techniques involving the use of surgical mesh before employing this device.

This device should only be used by experienced practitioners who do so under their own responsibility.

1 SCHEMATIC VIEW

A) GREEN COLORED POLYESTER MARKING

B) THREE-DIMENSIONAL MONOFILAMENT POLYESTER TEXTILE

C) FILM MADE OF COLLAGEN AND GLYCEROL

OPERATING STEPS - POSITIONING

1. Symbotex™ composite 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 to ensure its conformability and flexibility.

2. When putting it in place, it is essential to perfectly differentiate the film side from the porous textile side in order to situate the device correctly: the porous textile side is placed against the wall for tissue integration while the film side is facing the structures on which the tissular attachment is to be limited.

3. The green marking is then placed against the abdominal wall. It should be visible through the composite mesh. The circular portion of the marking should be centered on the defect, while the triangular portion shall indicate the orientation of the mesh in order to correctly align it to the medial line of the body.

4. Should it be used in a laparoscopic approach, Symbotex™ composite mesh is to be rolled after hydration, with the film facing the inside. The film is then protected when inserted in the trocar.

5. The pre-placed sutures are positioned on the textile side to help with the mesh handling once it is unrolled in the abdominal cavity. These yarns allow to easily pinpoint the mesh textile side. They can be used for the transparietal fixation of the mesh.

6. The edge of the reinforcement should be at least 5 cm over the edges of the defect(s). The technique used to anchor the mesh (suture or staples) is left up to the practitioner. It is suggested to fixate the mesh at a distance of approximately 1cm from the edge of the mesh.

7. Symbotex™ composite mesh can be trimmed to the desired size without impairment to the minimizing tissue attachment properties of the film.

NOTE: The green textile marking should not be cut. It may no longer be centered and could lose its functions if the mesh is trimmed.

STERILIZATION TECHNIQUE

Sterile single-use device. Sterilized by gamma radiation. Do not re-sterilize.

STORAGE

Recommended storage conditions: room temperature.

Do not use the device past the last day of the labeled month of expiration.

Upon receipt of shipment, ensure that the packaging is not open or damaged and retains its sealed integrity. Do not use the device if theintegrity of the packaging appears compromised.

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 which was implanted.

FR

Renfort Composite

AVANT D'UTILISER CE PRODUIT, LIRE ATTENTIVEMENT LES INFORMATIONS CI-DESSOUS.

IMPORTANT !

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DESCRIPTION

Le renfort Symbotex™ composite est constitué d'un textile tridimensionnel en polyester monofilament recouvert sur une face, par un film hydrophile, continu et résorbable à base de collagène d'origine porcine et de glycérol. Le film de collagène est essentiellement résorbé en moins d'un mois.

Des fils de suture pré-placés, non résorbables, sont accrochés au renfort tridimensionnel.

Un marquage en polyester monofilament de couleur verte (D&C Green No. 6) est placé au centre du textile, sur la face opposée du film, et aide à centrer et à orienter le renfort.

INDICATIONS

Le renfort Symbotex™ composite est utilisé pour le renforcement des tissus mous de la paroi abdominale en présence d'une faiblesse, dans les procédures chirurgicales impliquant les hernies primaires de la paroi abdominale et les hernies incisionnelles.

Le renfort en polyester tridimensionnel non résorbable permet le renforcement à long terme des tissus mous. Sur la face opposée, le film hydrophile résorbable réduit les phénomènes d'adhérence pouvant survenir entre la prothèse et les tissus en cas de contact direct avec les viscères.

CONTRE- INDICATIONS

• Comme le renfort Symbotex™ composite ne s'allongera pas avec la croissance, son utilisation n'est pas appropriée chez les patients en période de croissance.

• Tout matériau étranger est susceptible de provoquer ou de prolonger une infection en présence d'une contamination bactérienne et, de ce fait, l'utilisation du renfort Symbotex™ composite peut ne pas convenir en cas d'intervention en site infecté ou contaminé. De plus, ce produit doit être utilisé en sachant que l'infection peut nécessiter le retrait du dispositif.

COMPLICATIONS EVENTUELLES

Les éventuelles complications associées à l'utilisation du renfort Symbotex™ composite sont celles classiquement associées à l'implantation d'un renfort chirurgical: sérome, hématome, récidive, adhérence, formation de fistules, infection, inflammation, douleur chronique, et/ou réactions allergiques aux constituants du produit.

L'état de l'art des renforts utilisés conformément à l'indication, établie que les évènements suivants peuvent se produire : dommages aux organes (tels que dommages aux intestins et aux viscères), hernies de trocart, occlusion intestinale et rétention urinaire (qui peut se produire lors de l'utilisation d'anesthésiques).

AVERTISSEMENTS

1. Pour prévenir toute blessure, une attention particulière est requise lors de la fixation du dispositif en présence de nerfs ou de vaisseaux.

2. Afin de préserver l'élasticité et la porosité du renfort, il est recommandé de ne pas le tendre exagérément au moment de la pose. La tension doit être modérée et équivalente dans toutes les directions pour fixer le renfort afin de tenir compte de la rétraction de plaie lors de la cicatrisation.

3. Une attention particulière doit être apportée pour ne pas découper le marquage vert. En cas de découpe du renfort, il se peut que le marquage ne soit plus centré et ne conserve pas ses fonctionnalités.

4. L'efficacité et la sécurité relatives à l'utilisation de ce dispositif chez la femme enceinte n'ont pas été établies. Pour les femmes en âge de mener une grossesse, le chirurgien doit être attentif au fait que le dispositif ne s'allongera pas de manière significative lors de la croissance survenant lors de la grossesse.

5. Le dispositif est livré sous emballage stérile. Vérifier l'intégrité de l'emballage avant toute utilisation. Ne pas utiliser le dispositif si l'emballage est ouvert ou endommagé.

6. Le dispositif se présente sous double emballage stérile. Il est recommandé de n'ouvrir le dernier emballage qu'au moment de la mise en place du renfort et de manipuler celui-ci à l'aide de gants et d'instruments non souillés.

PRECAUTIONS D'EMPLOI

Les utilisateurs doivent être familiers des procédures et techniques chirurgicales impliquant l'utilisation de renforts chirurgicaux avant d'utiliser le dispositif. Ce dispositif est réservé aux praticiens spécialistes qui l'utilisent sous leur seule responsabilité.

1 VUE SCHÉMATIQUE

A) MARQUAGE VERT EN TEXTILE POLYESTER

B) TEXTILE TRIDIMENSIONNEL POLYESTER MONOFILAMENT

C) FILM À BASE DE COLLAGÈNE ET DE GLYCÉROL

INTERVENTIONS - MISE EN PLACE

1. Avant toute manipulation, le renfort Symbotex™ composite doit être hydraté dans son emballage d'origine par immersion complète, quelques secondes dans une solution physiologique stérile afin de restituer au renfort sa conformabilité et sa souplesse.

2. Au moment de la mise en place, il est indispensable de repérer parfaitement la face du film de la face poreuse du textile, de façon à correctement l'orienter : la face poreuse du textile contre la paroi pour une intégration tissulaire / la face du film en regard des structures pour lesquelles on souhaite limiter les adhérences tissulaires.

3. Le marquage vert est placé contre la paroi abdominale. Il devrait être visible à travers le renfort composite. La partie circulaire du marquage sera centrée sur l'orifice, la partie triangulaire devra être alignée par rapport à la ligne médiale du corps.

4. Dans le cas d'une utilisation par voie laparoscopique, le renfort Symbotex™ composite doit être roulé après hydratation, face film orientée vers l'intérieur, de façon à protéger le film lors du passage dans le trocart.

5. Les fils de couleur placés sur la face textile aident à la manipulation du renfort une fois déroulé dans la cavité abdominale. Ces fils permettent de repérer plus facilement la face textile du renfort. Ils peuvent servir à la fixation transpariétale du renfort.

6. Le renfort doit déborder d'au moins 5 cm les berges du ou des orifice(s). La technique de fixation du renfort (sutures ou agrafes) est laissée au choix du praticien. Il est recommandé de fixer le renfort à une distance d'environ 1cm du bord du renfort.

7. Le renfort Symbotex™ composite peut être découpé à la taille désirée, sans perte de la propriété de minimisation des adhérences du film.

NOTE : Le marquage vert ne devra pas être découpé. En cas de découpe du renfort, il se peut que le marquage ne soit plus centré et ne conserve pas ses fonctionnalités.

MODE DE STERILISATION

Dispositif stérile à usage unique. Stérilisé par irradiation gamma. Ne pas restériliser.

CONSERVATION

Conditions de stockage recommandées : température ambiante.

Ne pas utiliser le dispositif au-delà du dernier jour du mois d'expiration figurant sur l'étiquette.

A réception du dispositif, s'assurer que le conditionnement n'a été ni ouvert ni endommagé et conserve intègre son scellage. Ne pas utiliser le dispositif si l'emballage présente un défaut d'intégrité pouvant compromettre la stérilité.

TRACABILITE

Une étiquette de traçabilité identifiant le type et le numéro de lot du dispositif est jointe à chaque emballage de dispositif. Cette étiquette est destinée à être collée sur le dossier médical permanent du patient afin de clairement identifier le dispositif implanté.

Marquage CE initial: 2014

Do not use if package is opened or damaged. / Ne pas utiliser en cas d'endommagement ou d'ouverture de l'emballage.

STERILE R

Single use

Rx ONLY

Do not resterilize

Caution, consult accompanying documents

CE 0459

Sofradim Production, 116, avenue du Formans-01600 Trévoux-France.

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APPENDIX C

Quality of Life and patient satisfaction Questionnaire

➢ At 1 month (D30 Follow up)

1- Do you currently feel post-operative discomfort?

-No
-Discomfort
-"Pins and needles"
-Loss of sensation
-Moderate pain
-Severe pain
-Other symptoms (please specify)

2- Where are these symptoms located?

-Several possible answers:
-Operated side
-Scar region
-Other side
-Both sides
-Elsewhere (specify)

3- When exactly do you feel these symptoms?

-Several possible answers:
-During lifting, coughing or pushing
-During others types of effort (please specify)
-After physical effort or and the end of the day
-At any other particular time (please specify)
-At any time

4- How often do you feel them?

-Rarely
-several time a week
-Several time a day
-Throughout the day
-24/24h

5- The symptoms felt:

-Do not hinder your activities
-Allow you to pursue your activities but at a slower pace

-Cause temporary interruption in your activities
-Prevent certain activities (which one?)

6- These symptoms

-Are more of a nuisance than those of the hernia you previously had
-Are less of a nuisance than those of the hernia you previously had

➢ At 1 Year and 2 Year Follow up

1- Since your surgery does your abdomen seems:

-firm
-not firm

2- Do you have a new hernia or bulge?

-No
-yes (if so Operated side; Scar region; other side; both side, elsewhere (specify)

3- Do you currently feel any post-operative discomfort?

-No
-Discomfort
-"Pins and needles"
-Loss of sensation
-Moderate pain
-Severe pain
-Other symptoms (please specify)

4- Where are these symptoms located?

-Several possible answers:
-Operated side
-Scar region
-Other side
-Both sides
-Elsewhere (specify)

5- When exactly do you feel these symptoms?

-Several possible answers:
-During lifting, coughing or pushing
-During others types of effort (please specify)
-After physical effort or and the end of the day
-At any other particular time (please specify)

-At any time

6- How often do you feel them?

-Rarely
-several time a week
-Several time a day
-Throughout the day
-24/24h

7- The symptoms felt:

-Do not hinder your activities
-Allow you to pursue your activities but at a slower pace
-Cause temporary interruption in your activities
-Prevent certain activities (which one?)

8- These symptoms

-Are more of a nuisance than those of the hernia you previously had
-Are less of a nuisance than those of the hernia you previously had

9- Have you had a re-operation on your abdominal wall?

-No
-Yes (if so please specify)

10- Looking back, how do you assess the result of your abdominal hernia operation

-Excellent
-Good
-Medium
-Bad