COVIDIEN

positive results for life™

Symbotex™ Composite Mesh

For Ventral Hernia Repair

| HERNIA CARE | **MESH** • FIXATION • PERMACOL™ • DISSECTION

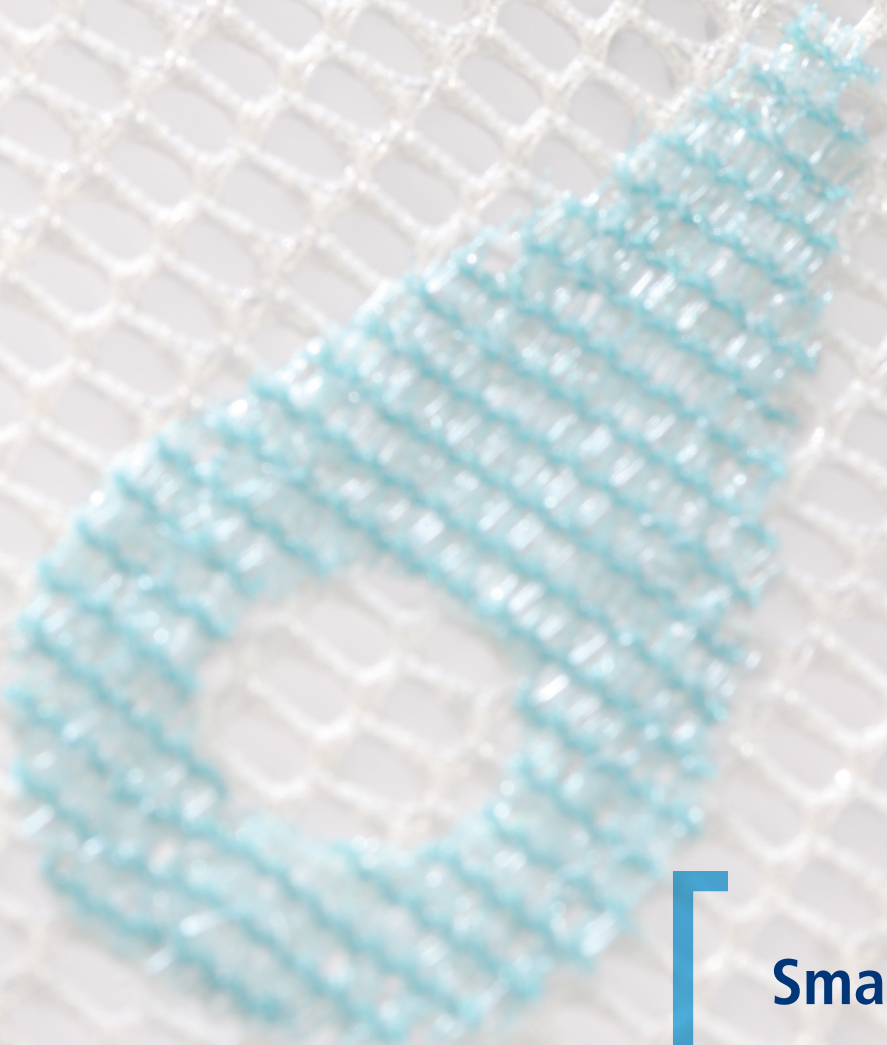
Value Analysis Committee

Product Information Kit

Innovation that matters

SYMBOTEX™ COMPOSITE MESH

Covidien's new Symbotex™ composite mesh provides surgeons improved ease of use, and optimal performance to minimize visceral tissue attachments, for meeting hernia repair solution needs.



Smart Solutions

SYMBOTEX™ COMPOSITE MESH

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SYMBOTEX™ COMPOSITE MESH
Product Overview

PRODUCT INTRODUCTION

Covidien has established itself as the market leader in hernia repair, with innovations that continue to set new standards in quality, ease of use, and value. Drawing on 20 years of cutting-edge biomedical engineering, its mastery of balanced mesh mechanical properties is matched by its understanding of what best serves the needs of surgeons, patients, and hospitals.

Recently launched products include ProGrip™ laparoscopic self-fixating mesh, Parietex™ composite ventral patch and the Accumesh™ positioning system. These products are expanding the frontiers of what's possible in hernia repair.

At the same time, Covidien remains responsive to the needs of hospitals for products that deliver consistent high quality at a justifiable price.

Why should a hospital purchase the Symbotex™ composite mesh?

Surgical Focus	Economic Value Proposition
Symbotex™ composite mesh is designed to match the surgeon's demands for ease of handling, operative efficiency, versatility, and demonstrated equivalent outcomes as Parietex™ composite and Parietex™ optimized composite mesh. It provides mesh transparency for improved anatomy visualization, easy mesh deployment, effective clinging for mesh placement, and excellent tissue integration for durable repair.[1,2,3]	Covidien offers a comprehensive portfolio of mesh products for small, medium, and large defects.[2,10] Its versatile products allow standardization of procedures and help optimize efficiency in the hospital.

SYMBOTEX™ COMPOSITE MESH

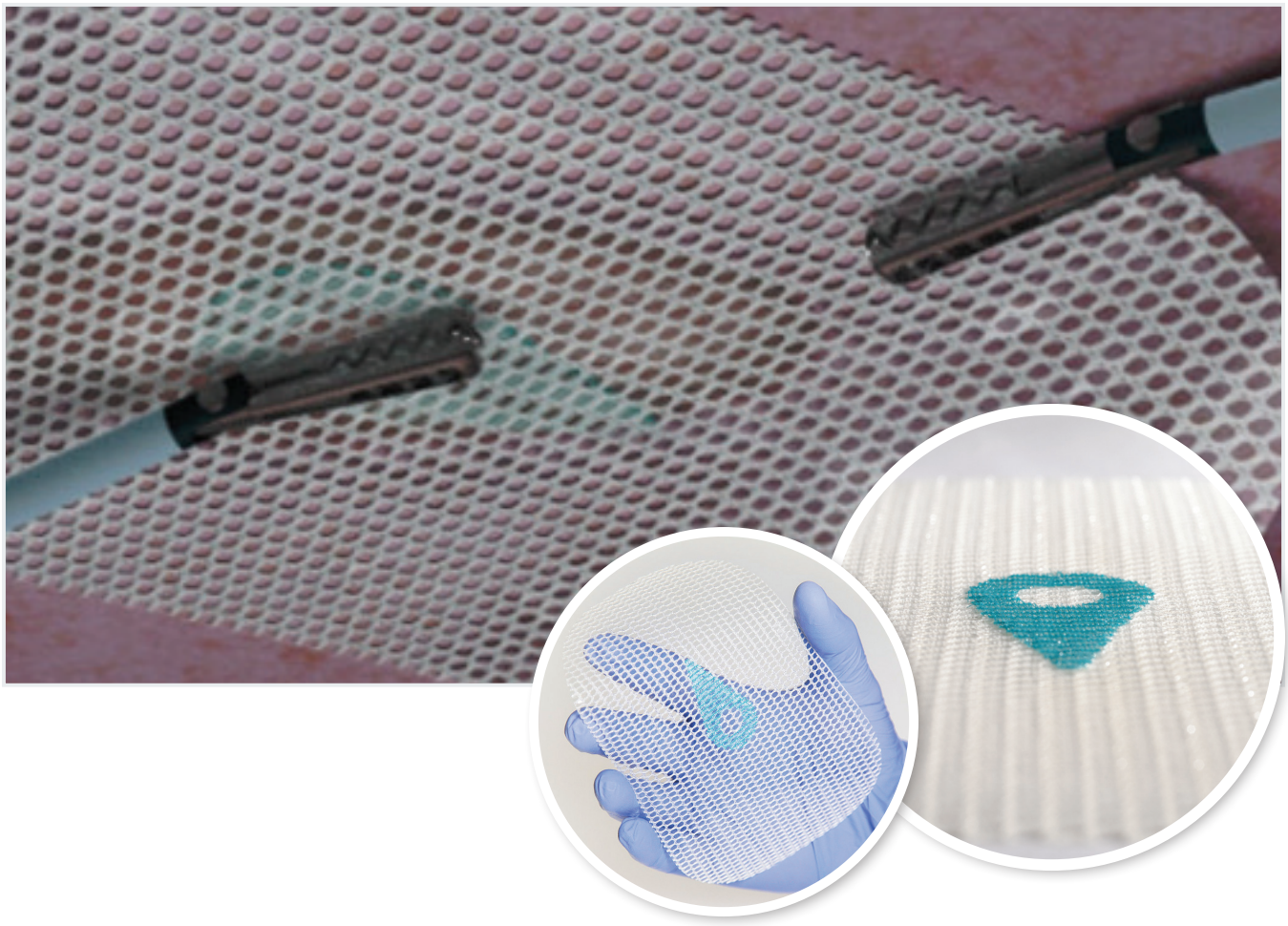
Product Overview

FEATURES AND BENEFITS

SMART DESIGN

Innovative mesh features for streamlined performance

- Exclusive 3D mesh structure delivering reinforced textile strength and significant tissue ingrowth support.[7,8]
- Mesh transparency for improved anatomy visualization during placement.[1]
- Established bioabsorbable film technology with impressive resistance to surgical handling[2,9]
- Comprehensive shape and size portfolio for small, medium, and large defects[2,10]



SYMBOTEX™ COMPOSITE MESH

Product Overview

FEATURES AND BENEFITS

SMART HANDLING

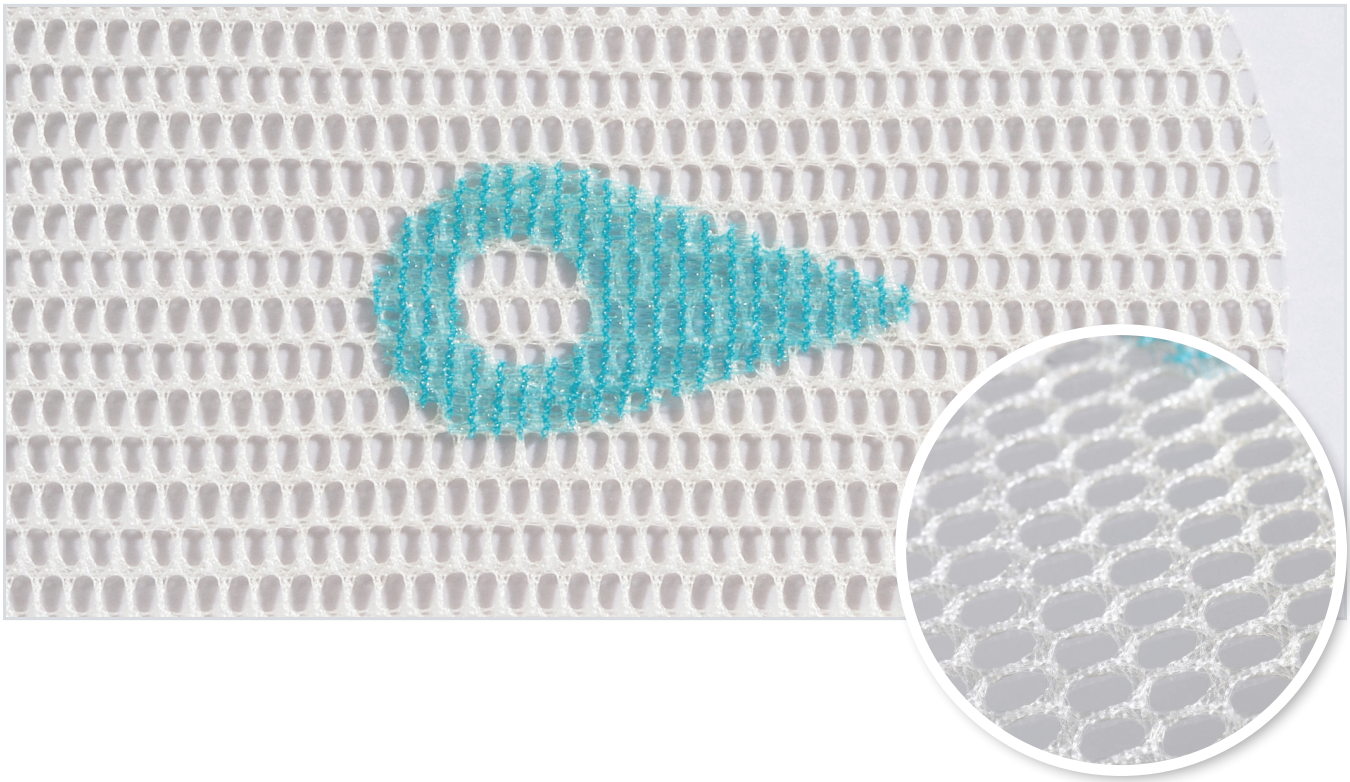
Experience simplicity in hernia repair

- Easy mesh deployment[1]
- Centering and orientation marking for accurate mesh positioning[Ω,1,2]
- Abdominal wall clinging effect for simplified mesh placement[‡,1,3]

SMART REPAIR

Designed to offer patients optimal hernia repair performance

- Excellent tissue integration[4]
- Minimized visceral attachment[5]
- Good level of neoperitonization and better minimizing tissue attachment compared to Physiomesh™* flexible composite mesh and Ventralight™* ST mesh[¥,6]
- Helping to meet physiological needs through balanced mesh mechanical properties[7]



SYMBOTEX™ COMPOSITE MESH

Product Diagram

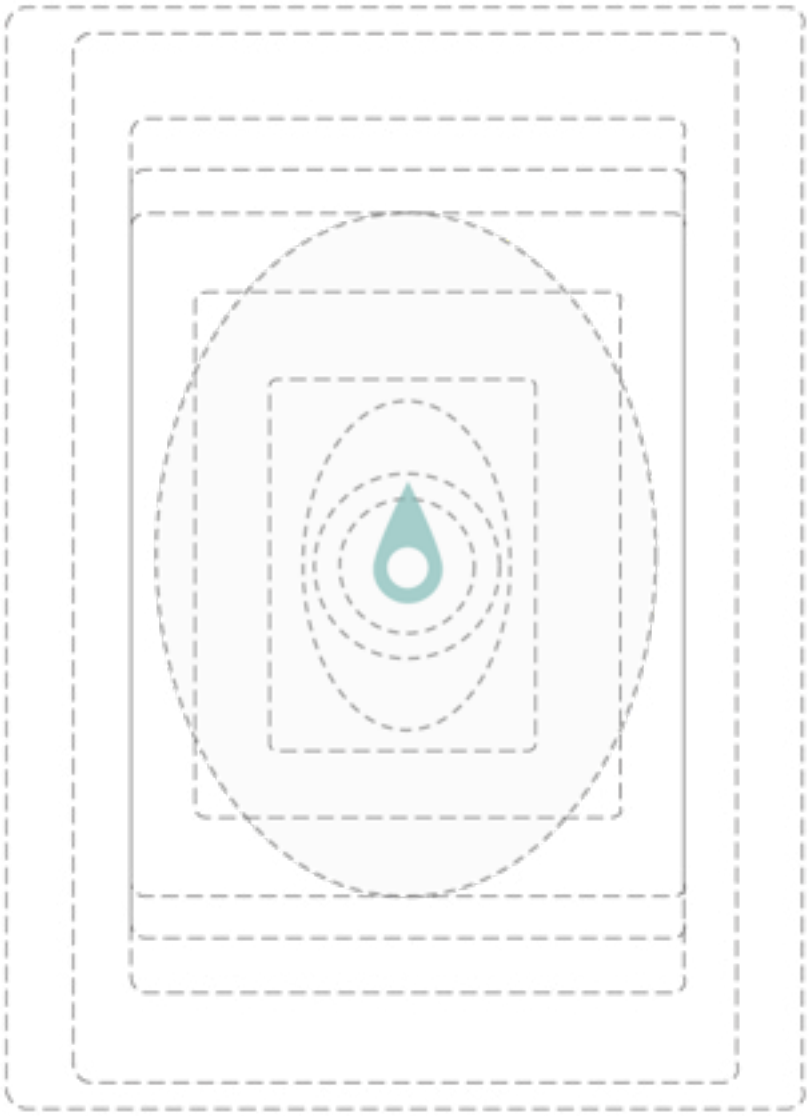
PRODUCT SPECIFICATIONS

Device Classification

Symbotex™ composite mesh is intended for the reinforcement of soft tissue where a weakness exists such as the repair of the primary abdominal wall and incisional hernias.

Material Composition

- Three-dimensional (3D) textile monofilament polyester (PET) (white textile).
- Non-absorbable monofilament polyester (PET) (green textile).
- A bioabsorbable collagen film.



Pore Size
Textile: 3.3 mm x 2.3 mm
Sterilization Method
Gamma Radiation[11]
Shelf Life
3 years[13]

SYMBOTEX™ COMPOSITE MESH

Product Diagram

510(k) CLEARANCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G6(
Silver Spring, MD 20993-0002

August 22, 2013

Sofradim Production
% Clare Santulli
Regulatory Affairs Manager
Surgical devices, a global business unit of Covidien
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K131969
Trade/Device Name: Symbotex™ Composite Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL, OXJ
Dated: June 26, 2013
Received: June 28, 2013

Dear Ms. Santulli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Jiyoung Dang -S

on behalf of
Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYMBOTEX™ COMPOSITE MESH

Product Diagram

INSTRUCTIONS FOR USE

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Symbotex™

Composite Mesh

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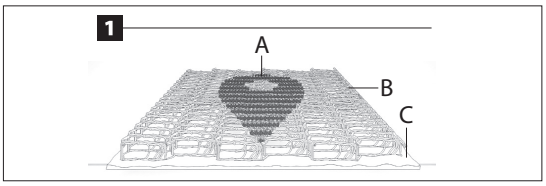

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IMPORTANT!

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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.

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 soft tissue where a weakness exists such as the repair of the primary abdominal wall and incisional hernias.

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, fistula formation, adhesions, infection, inflammation, chronic pain, and/or allergic reactions to the components of the product.

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.

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 !

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.

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 en cas de présence d'une faiblesse, telle que pour la réfection des hernies primaires de la paroi abdominale et des 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, formation de fistules, adhérence, infection, inflammation, douleur chronique, et/ou réactions allergiques aux constituants du produit.

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.

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: 2013

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

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

www.covidien.com

Made in France. 2013/06 - 9

SYMBOTEX™ COMPOSITE MESH

Product Diagram

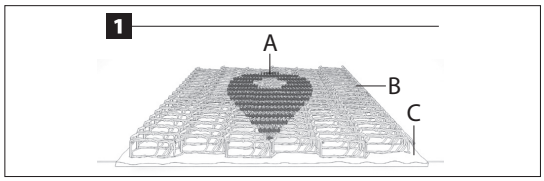
INSTRUCTIONS FOR USE

COVIDIEN™

Symbotex™

Composite Mesh

1061330



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WARNINGS

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4. The effectiveness and safety related to the use of this device in pregnant women have not been established.

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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.

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STERILIZATION TECHNIQUE

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STORAGE

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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.

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 en cas de présence d'une faiblesse telle que pour la réfection des hernies primaires de la paroi abdominale et des 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, formation de fistules, adhérence, infection, inflammation, douleur chronique, et/ou réactions allergiques aux constituants du produit.

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.

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: 2013

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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SYMBOTEX™ COMPOSITE MESH

Product Diagram

INSTRUCTIONS FOR USE

COVIDIEN™

Symbotex™

Composite Mesh

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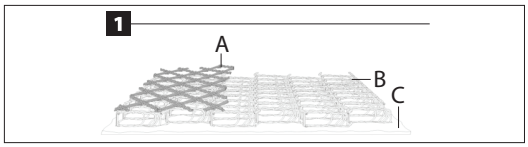

EN

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 collagen from porcine origin and glycerol.

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 soft tissue where a weakness exists such as the repair of the primary abdominal wall and incisional hernias.

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, fistula formation, adhesions, infection, inflammation, chronic pain, and/or allergic reactions to the components of the product.

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.

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 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 !

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.

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 en cas de présence d'une faiblesse telle que pour la réfection des hernies primaires de la paroi abdominale et des 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, formation de fistules, adhérence, infection, inflammation, douleur chronique, et/ou réactions allergiques aux constituants du produit.

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.

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 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: 2013

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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SYMBOTEX™ COMPOSITE MESH

Technical Data

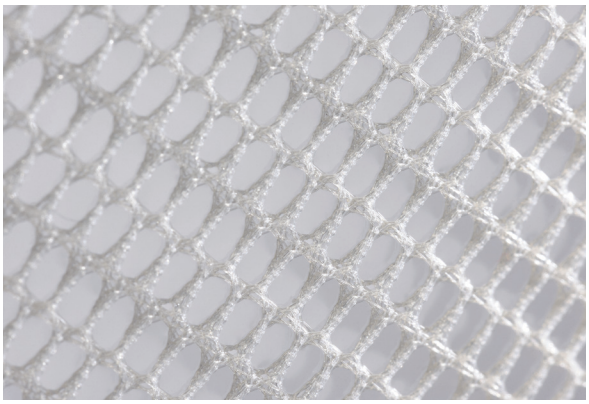
OVERVIEW

Symbotex™ composite mesh was designed to offer patients optimal hernia repair performance. It has a number of versatile properties that make it an appropriate choice for hernia repair.

The dual-sided mesh is designed to help optimize tissue integration and minimize visceral attachments.

The dual-sided three-dimensional mesh features a:

1) non-absorbable, three-dimensional monofilament polyester textile
2) bioabsorbable hydrophilic film made of porcine-based collagen and glycerol[11]

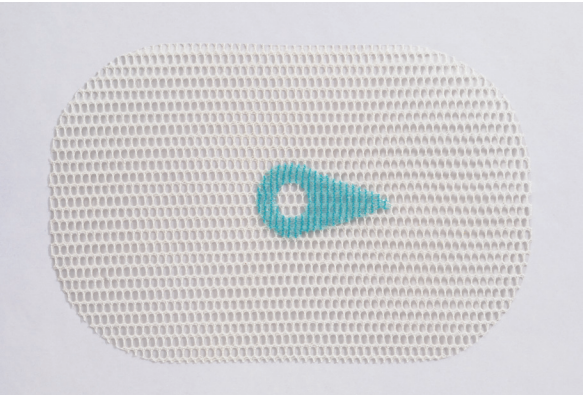


The non-absorbable textile side is placed against the fascia. It provides excellent tissue integration.[4]

The bioabsorbable visceral film side minimizes tissue attachment to the viscera in the event of direct contact, by physically separating the polyester textile of the mesh from organs.

The 3-D structure of the mesh reinforces textile strength[7] and provides significant tissue ingrowth support.[8]

Accuracy of placement is facilitated by a dyed monofilament marking (D&C Green No. 6) on the center of the textile that helps the surgeon center and orient the mesh.[9]



Responding to what matters to surgeons, Covidien leads the way in innovative products for hernia repair.

SYMBOTEX™ COMPOSITE MESH
Technical Data

PRECLINICAL DATA

Clinical Literature

Symbotex™ composite mesh has demonstrated equivalent outcomes as Parietex™ composite mesh and Parietex™ optimized mesh and has been compared favorably to other ventral hernia repair meshes in more than 45 clinical papers worldwide describing studies analyzing Parietex.™ [12]

Intraperitoneal Treatment of Incisional and Umbilical Hernias Using an Innovative Composite Mesh: Four-year Results of a Prospective Multicenter Clinical Trial Hernia: The World Journal of Hernia and Abdominal Wall Surgery, Balique et al (2005)	**Results of a Prospective, Multicenter Clinical Study:** • 80 patients with mean follow-up of 4 years (range, 3.5–4.5) • After 12 months, 86% of the patients were ultrasonically adhesion-free • At 48 months, no occlusion, fistula or mesh sepsis reported in the long-term follow-up	80 patients 48 months
Polyester-based Mesh for Ventral Hernia Repair: Is It Safe? The American Journal of Surgery, Rosen et al (2009)	**Results of a Retrospective Clinical Study:** • 109 complex ventral hernia repairs • Polyester mesh provides distinct advantages for ventral hernia repair, with excellent tissue incorporation and minimal shrinkage • For patients undergoing laparoscopic repair, no delayed mesh infections, fistulas or hernia recurrences at mean follow-up of 14 months	109 patients 14 months
Long-term Results of Laparoscopic Repair of Incisional Hernias Using an Intraperitoneal Composite Mesh Surgical Endoscopy, Moreno-Egea et al (2010)	**Results of a 12-Year Prospective Clinical Study:** • 200 patients with mean follow-up of 6 years (range, 1–12) • Postoperative pain was limited • No mesh infections were detected, including in those who received intestinal injury repair	200 patients 6 years
Eighty-five Redo Surgeries After 733 Laparoscopic Treatments for Ventral and Incisional Hernia: Adhesion and Recurrence Analysis Hernia, Chelala et al (2010)	**Results of a Retrospective Study of Visceral Attachments and Recurrence:** • 89% of patients were free of visceral attachments (47%) or showed only simple attachments of the omentum (42%) • Perfect integration of the polyester layer into the anterior abdominal wall was observed • The mesh was covered with total neoperitoneum and was well vascularized, without any apparent sign of shrinking or wrinkling • 97% of patients in the control group were pain free 3 months postoperatively, with no infection and no residual pain	733 patients, 85 second-look cases 52 months

SYMBOTEX™ COMPOSITE MESH
Technical Data

VALUE PROPOSITION WITH CLINICAL EVIDENCE

Proven Protection With Collagen Barrier[2]

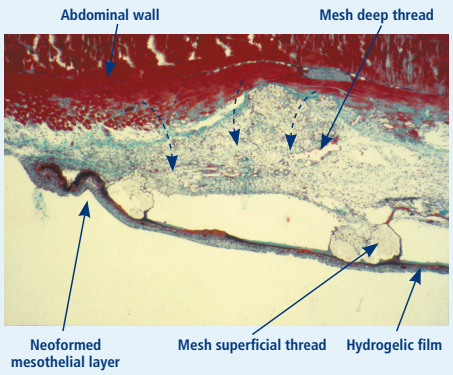
In an animal study comparing meshes with and without a protective barrier

- Collagen-protected meshes had significantly fewer visceral attachments vs. non-protected meshes ($p<0.01$).
- Complete recolonization of the mesh and film resorption occurred in the collagen-protected group after 45 days.
- The anti-adhesion collagen barrier remained intact after 7 days.
- Small bowel adhesion was never observed in all groups receiving the composite mesh.

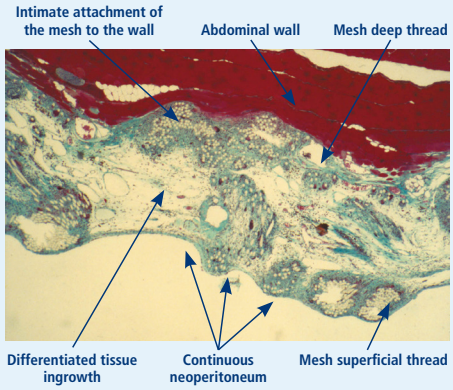
A resorbable collagen barrier limits visceral attachments to the abdominal wall.

After resorption, a neoperitoneum is formed on the visceral surface.[7]

Before resorption of the collagen barrier
Transversal section 1 week after implantation



After resorption of the collagen barrier
Transversal section 6 weeks after implantation



Source: Therin, M., et al. (1998). "Preclinical Evaluation of a New Composite Mesh (collagen-polyester) for Intraperitoneal Hernia Repair With the Selective Property of Tissue Ingrowth on One Side and Adhesion Prevention on the Opposite Side." Paper presented at 14th European Conference on Biomaterials, 15-18 September, The Hague, The Netherlands.

SYMBOTEX™ COMPOSITE MESH
Technical Data

PRECLINICAL RESULTS

Tissue Integration and Neoperitonization; Symbotex™ Composite Mesh Vs. Other Products

Favorable Tissue Integration Vs. Other Meshes[6]

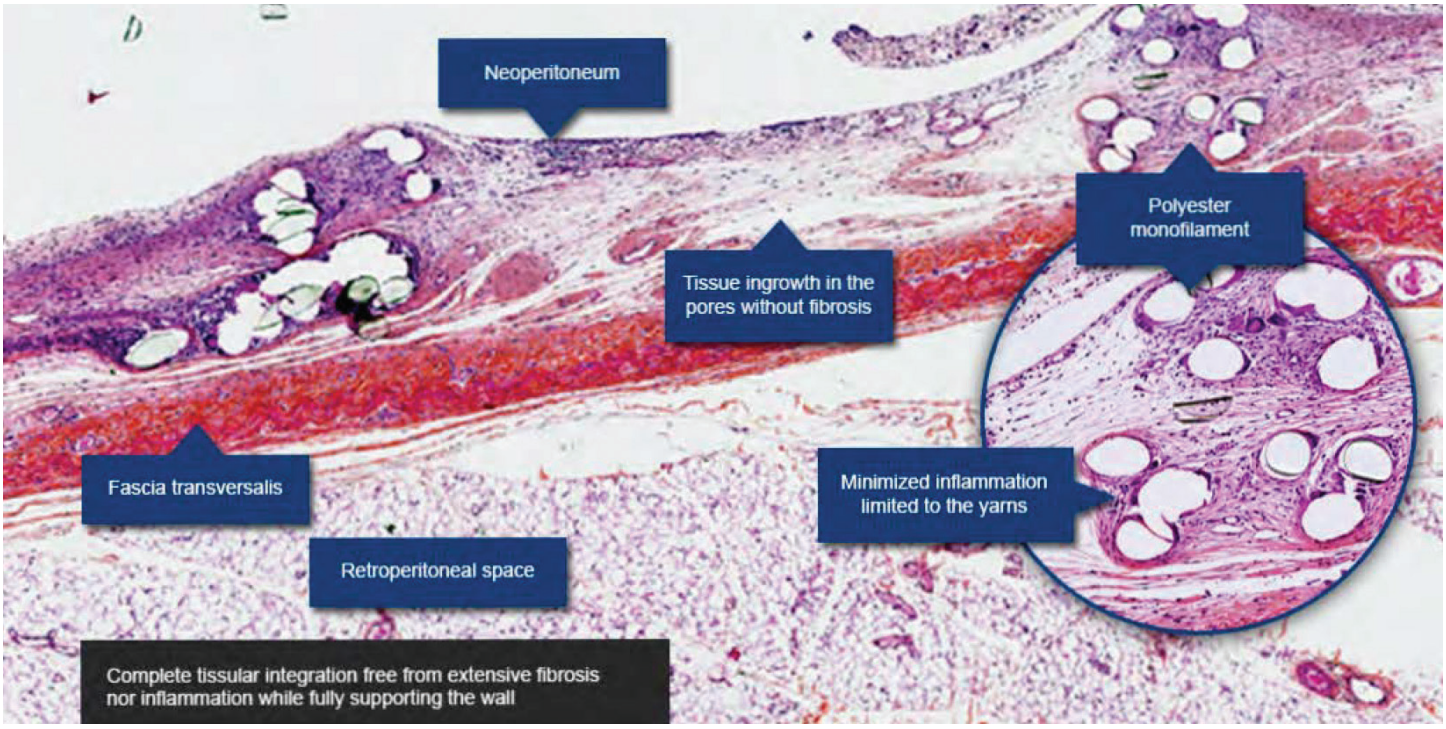
- Bard Ventralight™* Mesh: Marked inflammation and high level of fibrosis
- Ethicon Physiomesh™* Flexible Mesh: Marked inflammation and lack of integration

Neoperitoneum Formation[6]

- Higher level of neoperitoneum formation (at 4 weeks) than Bard Ventralight™* mesh and Ethicon Physiomesh™* flexible mesh

Conclusion[6]

- Symbotex™ composite mesh helps optimize tissue integration and neoperitoneum formation



SYMBOTEX™ COMPOSITE MESH
Technical Data

REIMBURSEMENT

Covidien has developed an online reimbursement resource for hernia and abdominal wall repair. You can reference the interactive U.S. Hernia Reimbursement Guide at *covidien.com/hernia/reimbursement* for the most up-to-date codes and reimbursement rates.

Procedure Codes	
ICD-9-CM Code	Description
53.51	Incisional hernia repair
53.61	Other open incisional hernia repair with graft or prosthesis
53.62	Laparoscopic incisional hernia repair with graft or prosthesis

MS-DRG	Description	Medicare National Average Payment Rate
353	Hernia procedures except inguinal and femoral with MCC	$16,172
354	Hernia procedures except inguinal and femoral with CC	$9,512
355	Hernia procedures except inguinal and femoral without CC/MCC	$6,834

Source: CMS Inpatient Prospective Payment System; 2014 Final Rule
Federal Register, Vol 78, No. 160, August 13, 2013, Pages 50494 – 51040

SYMBOTEX™ COMPOSITE MESH

Competitive Information

COMPETITIVE PRODUCTS OVERVIEW

		Covidien	Bard	Ethicon	Atrium
Features		**Symbotex™ Composite Mesh**	**Ventralight™* ST Mesh**	**Physiomesh™* Flexible Mesh**	**C-QUR™***
Handling properties	clinging effect	✓		✓	
	orientation marking	✓	✓	✓	
	macroporous	✓		✓	✓
	transparent	✓		✓	
Textile for tissue integration	3D	✓			
	polyester/polypropylene	polyester	polypropylene	polypropylene	polypropylene
	monofilament	✓	✓	✓	✓
Film for visceral adhesion prevention	film	collagen film	hydrogel barrier	monocryl film	Omega-3 fatty acid
	resorbable	within one month	30 days	30 days	30 days
	dual-sided mesh	✓	✓		✓

Covidien internal reports:

PhysioMesh™*: TEX022-a
Ventralight™*: TEX024-a

SYMBOTEX™ COMPOSITE MESH

Competitive Information

COMPETITIVE PRODUCTS OVERVIEW

Product/Range	Symbotex™ Composite Mesh		Bard Ventralight™* ST Composite Mesh		Ethicon Physiomesh™* Flexible Mesh		C-QUR™ Mesh
Clinging Effect	✓				✓		
Transparency	✓				✓		✓
Portfolio	From 9 cm to 42*32 cm		From 11.4 to 30.5*35.6 cm		From 7*15 cm to 30*50 cm		From 9 cm to 30.5*47.5 cm
Marking	✓				✓		
Structure	3D macroporous		2D after absorption, not macroporous		2D macroporous		2D macroporous
Textile	PET monofilament		PP monofilament & PGA multifilament		PP monofilament		PP monofilament
Film	Oxidized collagen & glycerol		sodium hyaluronate (HA) + carboxymethylcellulose (CMC) + polyethylene glycol (PEG)		2 layers of polyglecaprone 25 +1 layer of polydiozanone (bond) +1 dyed polydiozanone (marker)		An all-natural Omega-3 gel coating (O3FA coating). BAO (bioabsorbable oil)
Characterization	**After Film Absorption**		**After Film & PGA Yarns Absorption**		**After Film Absorption**		**After Film Absorption**
Direction	Warp	Weft	(becomes 2D)	Weft	Warp	Weft	--
Tensile Breaking Strength (N)	229±9	158±9	327±26	160N	216±12	86±11	--
Burst Strength (kPa)	383±27		659±55		314±35		--
Tear Strength (N)	34±3	32±2	28±2	26±2	34±2	22±6	--
Suture Pull-Out Strength (N)	39±2	44±4	36±3	48±5	27±7	24±4	--
Pore Size (mm)	2.3 x 3.3		0.5 x 0.7 (small pores) 0.6 x 1.0 (large pores)		3.4 x 3.5		--

Covidien internal reports:

PhysioMesh™*: TEX022-a
Ventralight™*: TEX024-a

SYMBOTEX™ COMPOSITE MESH

Material Management Information

Packaging Overview

The Symbotex™ composite mesh is available in a wide range of shapes and sizes to accommodate small, medium, and large defects.[9]

Ordering Information

COVIDIEN PRODUCTS WEBSITE:
www.covidien.com/hernia

Ordering code	Description
SYM9	Symbotex™ Composite Mesh/9 cm diameter, box of 1
SYM12	Symbotex™ Composite Mesh/12 cm diameter, box of 1
SYM15	Symbotex™ Composite Mesh/15 cm diameter, box of 1
SYM1510	Symbotex™ Composite Mesh/15*10 cm, box of 1
SYM2015	Symbotex™ Composite Mesh/20*15 cm, box of 1
SYM2520	Symbotex™ Composite Mesh/15*20 cm, box of 1
SYM3020	Symbotex™ Composite Mesh/30*20 cm, box of 1
SYM3728	Symbotex™ Composite Mesh/37*28 cm, box of 1
SYM4232	Symbotex™ Composite Mesh/42*32 cm, box of 1
SYM2012E	Symbotex™ Composite Mesh/20*12 cm, box of 1
SYM1710E	Symbotex™ Composite Mesh/17*10 cm, box of 1
SYM2515E	Symbotex™ Composite Mesh/25*15 cm, box of 1
SYM3420E	Symbotex™ Composite Mesh/34*20 cm, box of 1
SYM4024E	Symbotex™ Composite Mesh/40*24 cm, box of 1
SYM8OS	Symbotex™ Composite Mesh/8 cm diameter, box of 1
SYM1510OS	Symbotex™ Composite Mesh/15*10 cm, box of 1
SYM2015OS	Symbotex™ Composite Mesh/20*15 cm, box of 1
SYM2520OS	Symbotex™ Composite Mesh/25*20 cm, box of 1
SYM3020OS	Symbotex™ Composite Mesh/30*20 cm, box of 1

SYMBOTEX™ COMPOSITE MESH

References

[1]Demonstrated in a preclinical study sponsored by Covidien, carried out on pigs in May 2013 with 6 surgeons and aiming at validating the design of Symbotex™ composite mesh - Covidien internal report 0901CR252a (June 2013).

[2]Based on the results of the Covidien-sponsored preclinical study carried out on a porcine model to validate the design of Symbotex™ composite mesh - Covidien design validation report 0901CR249a (June 2013).

[3]Definition of the Symbotex™ clinging effect observed during the design validation conducted by Covidien in a porcine model in May 2013 - Covidien internal memorandum 0901CR261a (July 2013).

[4]Assessed in a preclinical study sponsored by Covidien, initiated in May 2013, using a porcine model to evaluate local tissue effects and tissue integration of Symbotex™ Composite mesh vs Parietex™ Optimized composite mesh after laparoscopic ventral repair - Namsa report No.163005 (October 2013).

[5]Assessed in a preclinical study sponsored by Covidien, initiated in April 2013, using a rat caecal abrasion model and evaluating local tissue effects, tissue integration and minimizing tissue attachment performance of Symbotex™ composite mesh vs. Parietex™ Optimized composite mesh - Namsa report No.162750 (May 2013).

[6]Evaluated in a preclinical study sponsored by Covidien, conducted in April 2013, and comparing local tissue effects and integration, collagen film degradation and tissue attachment performance of Symbotex™ composite mesh with Ventralight™* ST mesh and Physiomesh™* flexible composite mesh in a porcine model - Namsa report No.163905 (October 2013).

[7]Comparison of the physical and mechanical properties of Symbotex™ composite mesh to those of Parietex™ optimized composite mesh through a bench study conducted by Covidien in July 2013 - Covidien internal report TEX043 (July 2013).

[8]D. Weyhe, W. Cobb, D. Lomanto et al, Comparative analysis of the performance of a series of meshes based on weight and pore size in a novel mini-pig hernia model - EHS 2013 (SC130037).

[9]Documented in the design verification report issued by Covidien in July 2013 - Covidien design verification report 0901CR247b (July 2013).

[10]Size & shape comparison chart.

[11]Symbotex™ composite mesh Instructions for Use.

[12]Parietex™ Mesh Clinical Studies Compendium (378461c).

[13]Covidien internal stability report STAB1308RP02 (July, 2013).

[14]Symbotex (Type 3DS textile) vs Parietex Optimized Composite Mesh (Type Y50 textile) - Textile comparison- Covidien internal report 0901CR226a (April 2013).

[Ω]If the mesh is not cut, refer to IFU.

[‡]Except in cases where transfacial sutures are used as well as meshes in open approach.

[¥]Four weeks after implantation.

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