Symbotex™ Composite Mesh
For Ventral Hernia Repair

Value Analysis Committee
Product Information Kit

Innovation that matters
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.
1. Product Overview
   - Product Introduction
   - Features and Benefits

2. Product Diagram
   - Products Specifications
   - 510(k) Clearance
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   - Overview
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   - Value Proposition
   - Preclinical Results
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   - Competitive Products Overview

5. Material Management Information

6. References
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?

<table>
<thead>
<tr>
<th>Surgical Focus</th>
<th>Economic Value Proposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symbotex™ composite mesh is designed to match the surgeon’s demands for ease of handling, operative efficiency, versatility, and demonstrated equivalent performance as Parietex™ composite and Parietex™ optimized composite mesh.</td>
<td>Covidien offers a comprehensive portfolio of mesh products for small, medium, and large defects. Its versatile products allow standardization of procedures and help optimize efficiency in the hospital.</td>
</tr>
<tr>
<td>It provides mesh transparency for improved anatomy visualization, easy mesh deployment, effective clinging for mesh placement, and excellent tissue integration for durable repair.</td>
<td></td>
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</tbody>
</table>
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\(^2,10\)
SYMBOLEX™ COMPOSITE MESH
Product Overview

FEATURES AND BENEFITS

SMART HANDLING
Experience simplicity in hernia repair

- Easy mesh deployment¹
- Centering and orientation marking for accurate mesh positioning²,³,⁴
- Abdominal wall clinging effect for simplified mesh placement²,³,⁴

SMART REPAIR
Designed to offer patients optimal hernia repair performance

- Excellent tissue integration⁴
- Minimized visceral attachment⁵
- Good level of neoperitonization and better minimizing tissue attachment compared to Physiomesh™ flexible composite mesh and Ventralight™ ST mesh⁶,⁷
- Helping to meet physiological needs through balanced mesh mechanical properties⁷
**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.

<table>
<thead>
<tr>
<th>Pore Size</th>
<th>Textile: 3.3 mm x 2.3 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization Method</td>
<td>Gamma Radiation¹¹</td>
</tr>
<tr>
<td>Shelf Life</td>
<td>3 years¹³</td>
</tr>
</tbody>
</table>
August 22, 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 (as 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 899. 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 Part 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 www.fda.gov/MedicalDevices/Industry/Reports_Problems/default.htm. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR 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/Reports/Problem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from 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 www.fda.gov/MedicalDevices/Industry/default.htm.

Sincerely yours,

Jyoung Dang -S
on behalf of
Mark N. Melkonian
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
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

Recommended storage conditions: room temperature.

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

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 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

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
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.

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

A) GREEN COLORED POLYESTER MARKING

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

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.

The use of this device is contraindicated in cases of allergy to polyesters, cellulose, or glycerol. This device is not designed for use in the head, neck,
or endocardium.

A) Renforcement Composite

Symbotex™ Composite Mesh

1061329


The technique described and shown in this product is not to be referenced in local techniques. The device was designed, tested and manufactured for

Recommended storage conditions: room temperature.

5. The films of different colors placed on the face textile help identifying the device once placed in the abdominal cavity. The films are then

PRECAUTIONS D’EMPLOI

Les utilisateurs doivent être familiers des procédures et techniques chirurgicales impliquant l’utilisation de renforts chirurgicaux avant d’utiliser l’ dispositif. Ces procédures et techniques incluent l’utilisation de pincettes qui facilitent l’autopsie morcelée.

The 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

It is essential to ensure that the mesh is not stretched more than 5% during placement in order to prevent any tissue damage.

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

The device is to be used in the abdominal cavity only. It is not designed for use in the head, neck, or endocardium.

The device is intended for use in adults for the following indications:

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

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

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Posed complications associated with the use of Symbotex™ composite mesh are those normally associated with surgically implantable mesh: seroma,
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Precautions

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STORAGE

Recommended storage conditions: room temperature.

Do not use the device for the placement of the last layer of mucosa.

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 physical

CONTRAINDICATIONS

Les utilisateurs doivent être familiers des procédures et techniques chirurgicales impliquant l’utilisation de renforts chirurgicaux avant d’utiliser l’ dispositif. Ces procédures et techniques incluent l’utilisation de pincettes qui facilitent l’autopsie morcelée.

6. Le dispositif est fourni sous double emballage stérile. Il est recommandé de le dérouler dans une solution physiologique stérile afin de restituer au renfort sa conformabilité et sa souplesse.

TOXICITY

Cette indication est applicable pour l’utilisation du dispositif. Elle est en revanche non applicable en matière de techniques chirurgicales. Le dispositif est fourni au

DESCRIPTION

Symbotex® composite mesh is made out of three-dimensional monofilament polyester textile, which is covered on both absorbable, continuous and

STERILITY

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Ce dispositif est réservé aux praticiens spécialistes qui l’utilisent sous leur seule responsabilité.

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3. Autre attention particulière doit être portée au fait que le dispositif est à usage unique.

C) FILM À BASE DE COLLAGÈNE ET DE GLYCÉROL

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C) Traceability identification label is joint to every device package which identifies the type and lot number of the device. This label should be affixed to the patient’s

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**SYMBOTEX™ COMPOSITE MESH**

**Product Diagram**

**INSTRUCTIONS FOR USE**

**Symbotex™ Composite Mesh**

1061330

**EN**

**DESCRIPTION**

Symbotex™ composite mesh est un matériau tridimensionnel monofilament léger, qui est conçu avec une absorptivité centrale et hydrophile, idéal pour le soutien des tissus mous.

Il est recommandé que le mât du renfort Symbotex™ composite ne soit pas à l'endroit de la cicatrisation. Par conséquent, la main doit être soignée et le matériel doit être conservé dans un sac ou une boîte.

**INDICATIONS**

Le mât Symbotex™ composite est utilisé pour le renforcement des tissus mous en cas de graisse d'origine inesthétique ou pour la correction des infections et douleurs musculaires. Il est également recommandé pour la correction de l'adénopathie et l'inflammation locale.

**PRECAUTIONS D'EMPLOI**

Le mât composite ne devrait pas être découpé à la taille désirée. Dans le cas de la reconstruction d'un abord chirurgical ou d'une intervention chirurgicale, il est recommandé de décider préalablement de la position à adopter par rapport à l'os et au tissu mous. L'orientation de l'outil est également importante pour assurer une réduction de la douleur et une meilleure efficacité.

La mise en œuvre de la technique chirurgicale doit être réalisée de manière précise et minutieuse. Les zones à risque doivent être soignées avec des antiseptiques appropriés et les patients doivent être mis en position stable pour assurer un meilleur confort et une meilleure sécurité.

**CONSERVATION**

Le mât composite Symbotex™ doit être conservé dans un emballage stérile et exempt d'humidité afin de prévenir les dégradations et la contamination. Il est également recommandé de le stocker dans un endroit sec et frais.

**MODE DE STÉRILISATION**

Le mât composite Symbotex™ est stérilisé par irradiation gamma et peut être réutilisé après une stérilisation appropriée.

**INTERNEMENTS - MODE D'EMPLOI**

1. L'utilisation de la technique chirurgicale doit être réalisée le plus rapidement possible après la désinfection de la zone d'intervention.

2. La technique chirurgicale doit être réalisée de manière précise et minutieuse, en s'assurant de respecter les lignes de cicatrisation et de minimiser les risques de complications. Les zones à risque doivent être soignées avec des antiseptiques appropriés et les patients doivent être mis en position stable pour assurer un meilleur confort et une meilleure sécurité.

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**STERILE**

Dispositif stérile à usage unique. Ne pas utiliser dans un conditionnement ou un emballage stérile pré préparé.

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INSTRUCTIONS FOR USE

**SYMBOTEX™ COMPOSITE MESH**

**Product Diagram**

**INFORMATION FOR THE DOCTOR**

**PRODUCT**

*SymboTEX™ Composite Mesh*

**DESCRIPTION**

SymboTEX™ composite mesh is constituted of a three-dimensional polymer polypropylene knitted and coated with a two-dimensional polyester green flap. The device is provided in double sterile packaging. It is recommended to open the last packaging only for the placement of the mesh and to handle the mesh in a sterile way.

**APPLICATIONS**

This device is intended for the reinforcement of soft tissue where a weakness exists such as the repair of the primary abdominal wall and hernias.

**INTERVENTIONS - MISE EN PLACE**

1. The user should familiarize himself with the procedure to be followed and must be aware of possible complications and contraindications.
2. The device should be placed in the area to be reinforced. The mesh should be used in the form in which it is provided without being cut.
3. The mesh should be placed so that it does not interfere with the blood supply to the tissues.
4. The mesh should be placed so that it does not interfere with the blood supply to the tissues.
5. The mesh should be placed so that it does not interfere with the blood supply to the tissues.
6. The mesh should be placed so that it does not interfere with the blood supply to the tissues.

**PRECAUTIONS**

- The device should be handled carefully to avoid any trauma to the skin or tissues.
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**DISPOSITION**

The user should familiarize himself with the procedure to be followed and must be aware of possible complications and contraindications.

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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

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

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 and provides significant tissue ingrowth support.

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.

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

<table>
<thead>
<tr>
<th>Clinical Data</th>
<th>Adhesions Results of a Prospective, Multicenter Clinical Study:</th>
</tr>
</thead>
</table>
| Intraperitoneal Treatment of Incisional and Umbilical Hernias Using an Innovative Composite Mesh: Four-year Results of a Prospective Multicenter Clinical Trial | • 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  
• 1 direct recurrence (1.8%) + 6* indirect recurrence (10%)  
  *Only one necessitated new surgery |
| 80 patients  
48 months |

<table>
<thead>
<tr>
<th>Polyester-based Mesh for Ventral Hernia Repair: Is It Safe?</th>
<th>Results of a Retrospective Clinical Study:</th>
</tr>
</thead>
</table>
• Polyester mesh provides distinct advantages for ventral hernia repair, with excellent tissue incorporation and minimal shrinkage  
• Open repair group, 3 wound infections (13%) occurred  
• For patients undergoing laparoscopic repair, no delayed mesh infections, fistulas or hernia recurrences at mean follow-up of 14 months |
| 109 patients  
14 months |

<table>
<thead>
<tr>
<th>Long-term Results of Laparoscopic Repair of Incisional Hernias Using an Intraperitoneal Composite Mesh</th>
<th>Results of a 12-Year Prospective Clinical Study:</th>
</tr>
</thead>
</table>
| Surgical Endoscopy, Moreno-Egea et al (2010)                                                        | • 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  
• 11 recurrences (6.2%) were diagnosed |
| 200 patients  
6 years |

<table>
<thead>
<tr>
<th>Eighty-five Redo Surgeries After 733 Laparoscopic Treatments for Ventral and Incisional Hernia: Adhesion and Recurrence Analysis</th>
<th>Results of a Retrospective Study of Visceral Attachments and Recurrence:</th>
</tr>
</thead>
</table>
| Hernia, Chelala et al (2010)                                                                                            | • 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  
• A recurrence rate of 4.1% (25/608).  
  * This was due to the inappropriate use of small mesh size in a high BMI patient  
• 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 |
Proven Protection With Collagen Barrier\textsuperscript{15}

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.\textsuperscript{7}
Tissue Integration and Neoperitonization; Symbotex™ Composite Mesh Vs. Other Products

Favorable Tissue Integration Vs. Other Meshes
- Bard Ventralight™ Mesh: Marked inflammation and high level of fibrosis
- Ethicon Physiomesh™ Flexible Mesh: Marked inflammation and lack of integration

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

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

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>53.51</td>
<td>Incisional hernia repair</td>
</tr>
<tr>
<td>53.61</td>
<td>Other open incisional hernia repair with graft or prosthesis</td>
</tr>
<tr>
<td>53.62</td>
<td>Laparoscopic incisional hernia repair with graft or prosthesis</td>
</tr>
</tbody>
</table>

### MS-DRG

<table>
<thead>
<tr>
<th>MS-DRG</th>
<th>Description</th>
<th>Medicare National Average Payment Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>353</td>
<td>Hernia procedures except inguinal and femoral with MCC</td>
<td>$16,172</td>
</tr>
<tr>
<td>354</td>
<td>Hernia procedures except inguinal and femoral with CC</td>
<td>$9,512</td>
</tr>
<tr>
<td>355</td>
<td>Hernia procedures except inguinal and femoral without CC/MCC</td>
<td>$6,834</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Handling properties</th>
<th>Covidien</th>
<th>Bard</th>
<th>Ethicon</th>
<th>Atrium</th>
</tr>
</thead>
<tbody>
<tr>
<td>clinging effect</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>orientation marking</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>macroporous</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>transparent</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

### Textile for tissue integration

<table>
<thead>
<tr>
<th>polyest./polypropylene</th>
<th>Covidien</th>
<th>Bard</th>
<th>Ethicon</th>
<th>Atrium</th>
</tr>
</thead>
<tbody>
<tr>
<td>polyester/polypropylene</td>
<td>polyester</td>
<td>polypropylene</td>
<td>polypropylene</td>
<td>polypropylene</td>
</tr>
<tr>
<td>monofilament</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

### Film for visceral adhesion prevention

<table>
<thead>
<tr>
<th>film</th>
<th>Covidien</th>
<th>Bard</th>
<th>Ethicon</th>
<th>Atrium</th>
</tr>
</thead>
<tbody>
<tr>
<td>collagen film</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>hydrogel barrier</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>monocryl film</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Omega-3 fatty acid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>resorbable</td>
<td>within one month</td>
<td>30 days</td>
<td>30 days</td>
<td>30 days</td>
</tr>
<tr>
<td>dual-sided mesh</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Covidien internal reports:
PhysioMesh™*: TEX022-a
Ventralight™*: TEX024-a
## SYMBOTEX™ COMPOSITE MESH

### Competitive Information

<table>
<thead>
<tr>
<th>Product/Range</th>
<th>Symbotex™ Composite Mesh</th>
<th>Bard Ventralight™ ST Composite Mesh</th>
<th>Ethicon Physiomesh™ Flexible Mesh</th>
<th>C-QUR™ Mesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinging Effect</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Transparency</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Portfolio</td>
<td>From 9 cm to 42*32 cm</td>
<td>From 11.4 to 30.5*35.6 cm</td>
<td>From 7<em>15 cm to 30</em>50 cm</td>
<td>From 9 cm to 30.5*47.5 cm</td>
</tr>
<tr>
<td>Marking</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structure</td>
<td>3D macroporous</td>
<td>2D after absorption, not macroporous</td>
<td>2D macroporous</td>
<td>2D macroporous</td>
</tr>
<tr>
<td>Textile</td>
<td>PET monofilament</td>
<td>PP monofilament &amp; PGA multifilament</td>
<td>PP monofilament</td>
<td>PP monofilament</td>
</tr>
<tr>
<td>Film</td>
<td>Oxidized collagen &amp; glycerol</td>
<td>sodium hyaluronate (HA) + carboxymethylcellulose (CMC) + polyethylene glycol (PEG)</td>
<td>2 layers of polyglecaprone 25 +1 layer of polydiozanone (bond) +1 dyed polydiozanone (marker)</td>
<td>An all-natural Omega-3 gel coating (O3FA coating). BAO (bioabsorbable oil)</td>
</tr>
</tbody>
</table>

Covidien internal reports:

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

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

References

1Demonstrated 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).

2Based 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).

3Definition 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).

4Assessed 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).

5Assessed 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).

6Evaluated 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).

7Comparison 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).


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

10Size & shape comparison chart.

11Symbotex™ composite mesh Instructions for Use.

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

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

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


©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.