IMPORTANT
Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

For more information or to set up a product demonstration, contact your local Covidien Surgical Device Representative or call Customer Service at 1-800-722-8772.
**Parietex™ Mesh**

**Innovation in Your Hands**

Parietex™ polyester mesh, with its unique balance of properties, is designed to provide fast and true tissue ingrowth with a reduced foreign material reaction.1 Parietex™ mesh is a macroporous mesh that is more hydrophilic than polypropylene,1 providing improved biocompatibility and superior cellular proliferation in vitro.2

The proprietary weave of Parietex™ mesh is designed to support patient comfort and mobility. The Parietex™ family of synthetic mesh features a comprehensive line of products designed to combine superior economic efficiency with positive clinical outcomes for your patients, putting innovation in your hands.

Our complete line of synthetic mesh supports surgeon-preferred techniques for both inguinal and ventral hernia repairs.

---

**Parietex™ Composite (PCO) Mesh**

AHEAD OF ITS TIME. AND STILL AHEAD OF THE CURVE.

Magenta shows area covered by pocket
# Table of Contents

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Product Introduction

**Product Overview**

**Parietex™ Composite (PCO) Mesh:**
**AHEAD OF ITS TIME. AND STILL AHEAD OF THE CURVE.**

Introduced in 1999, Parietex™ composite (PCO) mesh is proven effective in advanced treatment for complex ventral hernias. It was the first mesh to offer a resorbable collagen barrier on one side to limit visceral attachments, and a three-dimensional polyester knit structure on the other to promote differentiated tissue ingrowth. Its unique polyester material works with the body’s natural systems for true tissue integration, and it is optimized to minimize shrinkage. Parietex™ PCO mesh was ahead of its time and remains the standard that others strive to reach.

**Why should a hospital purchase Parietex™ Composite (PCO) Mesh?**

<table>
<thead>
<tr>
<th>Optimal Patient Outcomes</th>
<th>Operational Efficiencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 12 months, the recurrence rate with Parietex™ PCO mesh is only 2.5%; Only 1.8% at 4 years; no other long-term complications observed. In outpatient procedures, transactional data shows Parietex™ PCO mesh had the lowest recurrence rate (1%) at 12 months when compared to Composix™ (4%) and Sepalmesh™ (5%).</td>
<td>A comprehensive portfolio of mesh products offers opportunity for standardization and hospital efficiencies. Covidien partners with customers to offer versatile contracting options.</td>
</tr>
</tbody>
</table>

**What are the competitive advantages of Parietex™ Composite (PCO) Mesh?**

<table>
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<tr>
<th>Clinically Proven Protection</th>
<th>Clinically Proven Integration</th>
<th>Ease of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Parietex™ PCO mesh is proven effective, with more than 10 years of documented success.</td>
<td>• Parietex™ PCO mesh provides strong incorporation into the abdominal wall in prospective and comparative animal studies.</td>
<td>• Larger sizes can be rolled up and are easily inserted through a standard trocar.</td>
</tr>
<tr>
<td>• Parietex™ PCO mesh is proven safe, based on a mean clinical follow up of four years in a prospective, multicenter human trial. 86% of studied PCO patients were attachment-free at 12 months post-surgery.</td>
<td>• Incites true tissue integration rather than inflammatory encapsulation and is optimized to minimize shrinkage.</td>
<td>• Polyester mesh is easy to place and manipulate.</td>
</tr>
<tr>
<td>• Parietex™ PCO mesh features a resorbable hydrophilic film that minimizes visceral attachments.</td>
<td>• It is proven to develop a stronger attachment to the anterior abdominal wall than polypropylene mesh.</td>
<td></td>
</tr>
</tbody>
</table>

---

**Product Diagram**

- 3D portion fully coated to protect the viscera
- Optimal memory to facilitate placement
- Resorbable collagen barrier/hydrophilic film designed to limit attachments
- 3D polyester knit promotes fast tissue ingrowth

---

**Parietex™ Composite (PCO) Mesh**

- Parietex™ Composite Open Skirt (PCO OS) Mesh
- Parietex™ Composite Parastomal (PCO PM) Mesh
- Parietex™ Composite Hiatal (PCO 2H) Mesh
Introduction

Specialty Configurations

Procedure-Specific Options for Hernia Repair

The Parietex™ family of synthetic mesh products supports surgeon-preferred techniques, allowing surgeons to provide patient-specific repairs.

**LAPAROSCOPIC VENTRAL**

Parietex™ Composite (PCO) Mesh
- Proven effective, with more than 10 years of documented success
- Stronger incorporation into the abdominal wall in prospective and comparative animal studies
- Larger sizes can be rolled up and inserted through a standard trocar

**OPEN VENTRAL**

Parietex™ Composite Open Skirt (PCO OS) Mesh
- Based on PCO mesh, which is proven effective, with more than 10 years of documented success
- Stronger incorporation into the abdominal wall in prospective and comparative animal studies
- Skirt on the parietal side allows for mechanical fixation, which can reduce procedure time

**HIATAL**

Parietex™ Composite Hiatal (PCO 2H) Mesh
- Allows for easy placement and manipulation around the esophagus
- Resorbable barrier with more than 10 years of documented success for clinically proven protection
- Stronger incorporation into the abdominal wall in prospective and comparative animal studies

**PARASTOMAL**

Parietex™ Composite Parastomal (PCO PM) Mesh
- Designed for direct and modified Sugarbaker techniques
- Resorbable barrier with more than 10 years of documented success for clinically proven protection
- Stronger incorporation into the abdominal wall in prospective and comparative animal studies

†Parietex™ Composite (PCO) mesh is also indicated for use in open ventral repairs.

**510(k) Summary for PARIETEX® COMPOSITE Mesh**

1. **SPONSOR**
   Sofradim Production
   116 Avenue du Forum
   01600 Treoux
   France
   Contact: Christophe COSSON
   Telephone: 33 (0)4 74 08 90 00
   Facsimile: 33 (0)4 74 08 90 02

2. **DEVICE NAME**
   Proprietary Name: PARIETEX® COMPOSITE Mesh
   Common/Usual Name: Surgical Mesh
   Classification Name: Surgical Mesh

3. **PREDICATE DEVICES**
   Sofradim PARIETEX®COMPOSITE Meshes, K002699
   Sofradim UGYTEX™, K093376

4. **DEVICE DESCRIPTION**

   The PARIETEX® COMPOSITE Mesh is a surgical mesh used during open (laparotomy) procedures or during laparoscopic procedures. The PARIETEX® COMPOSITE Mesh is made from polyethylene terephthalate (polyester) and a collagen-based hydrogel component. The hydrophilic collagen film does not affect the physical performance characteristics of the mesh but serves to separate the coated side of the mesh from underlying tissues to minimize tissue attachment and ingrowth. The PARIETEX® COMPOSITE Mesh is offered in several sizes and shapes to accommodate the type and approach of the surgical procedure.

Additional 510(k)s available upon request.
5. INTENDED USE

The PARTEX® COMPOSITE Mesh is used for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair, and partial (i.e., pertaining to the walls) reinforcement of tissues. The non-resorbable three-dimensional polyester mesh provides long-term reinforcement of soft tissues. On the opposite side, the resorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscer.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Sofradim PARTEX® COMPOSITE (PCO) meshes are identical to the current PARTEX® COMPOSITE (PCO) (K002699) meshes with the exception of a modification in the origin of the collagen of the hydrophilic film. In the current PCO meshes, the oxidized collagen is obtained from bovine dermis. In the proposed PCO meshes, the collagen is obtained from porcine dermis.

7. PERFORMANCE TESTING

The polyester mesh material used is not modified and remains the same as that described in the current PCO file (K002699). A study was conducted and demonstrated that there was no statistically significant difference between the test groups in tissue attachment. Both the porcine and bovine products were successful at minimizing tissue attachment. A histological analysis was also performed using randomly selected animals. Additionally, there was no difference in the cellular inflammatory reaction for the two products.

Sofradim Production Special 510(k)  
A416, 2004  
Sofradim PARTEX® COMPOSITE (PCO) Mesh  
Appendix E - Page 2

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
9500 Corporate Boulevard
Rockville, MD 20850

APRIL 29, 2004

Sofradim Production
n.c. Ms. McNamara-Cullinan, RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K040998
Trade/Device Name: Sofradim PARTEX® COMPOSITE (PCO) Mesh
Regulation Number: 21 CFR 888.3390
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: 571

Dated: April 16, 2004
Received: April 19, 2004

Dear Ms. McNamara-Cullinan:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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 1006-1010).

Sofradim Production Special 510(k)  
April 16, 2004  
Sofradim PARTEX® COMPOSITE (PCO) Mesh  
Appendix E - Page 2

Additional 510(k)s available upon request.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dms/dsonline.html

Sincerely yours,

Mary C. Parrott
Cella M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

KO40998

Indications for Use

510(k) Number (if known):

Device Name: Soffradix PARIOTEX® COMPOSITE (PCO) Mem

Indications for Use:

The PARIOTEX® Composite Mem is used for the reinforcement of interprosthesis surgical repairs. It is indicated for the treatment of incisor, bicuspid, and molar teeth. Its extendable, three-dimensional polyester mesh provides long-term reinforcement of soft tissue. On the opposite side, the reversible hydrophilic film minimizes tissue adhesion to the mesh in case of direct contact with the viscera.

Prescription Use ___ AND OR Over-The-Counter Use ___
(Please do not write below this line. Continue on יווחט plan at end.)

(Conformance of COBE, Office of Device Evaluation (ODE))

Soffradix Production Spec(s) 510(k) April 16, 2004
Soffradix PARIOTEX® COMPOSITE (PCO) Mem

Additional 510(k)s available upon request.
PARIETEX® Composite
DUAL-FACING MESH COMBINING REHABILITATIVE PERMANENT RENFORCEMENT AND RESORBABLE HYDROPHILIC FILM

10000-37787

< Product Introduction—Instructions for Use >

MATERIAL
PARIETEX® Composite is provided in a sterile packaging. The packaging is to be checked for any damage before use. The mesh is bedded in a biocompatible manner, so it can be used in the peritoneum or the pericardium without the need for a second peritoneal cavity wall.

1. PARIETEX™ Composite is furnished in a sterile packaging. The packaging shall be checked for any damage before use.

PRECAUTIONS
- Since this product is a medical device, it is recommended to check the product before use.

INDICATIONS
- PARIETEX™ Composite is a three-dimensional multifilament polyethylene mesh designed for reinforcing the peritoneum or the pericardium. It is intended for use in the treatment of abdominal wall defects and weak hernia.

CONTRAINDICATIONS
- The use of PARIETEX™ Composite is contraindicated in the case of having a known or suspected allergy to its components.

STORAGE
- The product is intended for a single-use device. It is not recommended to store the product for an extended period. The product should be used within 2 years of expiration.

B. PACKAGE CONTENTS
- The package shall contain a sheet of instructions for use and a label with the manufacturer’s contact information.

C. EXTRACTION FROM PACKAGING
- The mesh can be extracted from the packaging by cutting through the label and the outer wrapping.

D. HANDLING OF THE PRODUCT
- The product is a medical device and should be handled with care. It is recommended to wear disposable gloves when handling the product.

E. USE
- The product should be used by medical practitioners who have been trained in its use.

F. DISPOSAL
- The product should be disposed of in accordance with local and national regulations for medical waste.

G. GROSS DEFECTS
- The product may have defects, such as holes or tears, which are expected during the manufacturing process.

H. FURTHER INFORMATION
- For further information, please contact the manufacturer.

I. SALES AND DISTRIBUTION
- The product is manufactured and distributed by a reputable company.

J. QUALITY ASSURANCE
- The product is manufactured under strict quality control procedures.

K. GUARANTEE
- The manufacturer offers a guarantee for the product. The guarantee period is 2 years from the date of manufacture.

L. AUTHORIZATION AND REGISTRATION
- The product is authorized and registered with the appropriate regulatory body.

M. MARKETING AND DISTRIBUTION
- The product is marketed and distributed by a reputable company.

N. MEDICAL DEVICE REGISTRATION
- The product is registered as a medical device.

O. MEDICAL DEVICE CONFORMITY
- The product is conformity assessed under the applicable medical device regulations.

P. MEDICAL DEVICE SAFETY
- The product is designed to be safe for use.

Q. MEDICAL DEVICE PERFORMANCE
- The product is designed to perform as intended.

R. MEDICAL DEVICE COMPLIANCE
- The product is compliant with all applicable medical device regulations.

S. MEDICAL DEVICE USE
- The product is intended for use by medical practitioners.

T. MEDICAL DEVICE STERILIZATION
- The product is sterilized by gamma irradiation.

U. MEDICAL DEVICE REPROCESSING
- The product is not intended for reprocessing.

V. MEDICAL DEVICE DISPOSAL
- The product should be disposed of in accordance with local and national regulations for medical waste.

W. MEDICAL DEVICE TRAINING
- Training is provided for medical practitioners who will use the product.

X. MEDICAL DEVICE DOCUMENTATION
- Documentation is provided with the product.

Y. MEDICAL DEVICE AUDITS
- Audits are conducted to ensure compliance with medical device regulations.

Z. MEDICAL DEVICE CONSTRUCTION
- The product is constructed from high-quality materials.

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Technical Data

Clinical Literature

Parietex™ composite (PCO) mesh has demonstrated positive patient outcomes and has been compared favorably to other ventral hernia repair meshes in more than 45 clinical papers worldwide.

Intraperitoneal Treatment of Inguinal 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 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

Intraperitoneal Treatment of Incisional and Umbilical Hernias Using an Innovative Composite mesh: four-year 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

Polyester-based mesh for Ventral Hernia Repair: Is It Safe?

The American Journal of Surgery 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 2009

- 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 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 neoaperitoneum 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

Clinically Proven Protection

- In an animal study comparing meshes with and without a protective barrier, collagen-protected meshes had significantly fewer visceral attachments than did the non-protected meshes (p<0.01), with complete recolonization of the mesh and film resorption after 45 days.
- Small bowel adhesion was never observed in all groups receiving the composite mesh.
- The anti-adhesive collagen barrier was intact after 7 days.


Parietex™ Composite mesh significantly reduced the risk of postsurgical visceral attachments compared to conventional meshes and could be a valuable solution for intraperitoneal incisional hernia repair.
Clinically Proven Effectiveness

In a retrospective review of visceral attachments and recurrence in 85 re-operated patients with a mean follow up time of 52 months, Parietex™ composite (PCO) mesh proved effective with nearly 90% of patients developing no or only mild visceral attachments.

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.

Ninety-seven percent of patients in the control group were pain-free 3 months postoperatively, with no infection and no residual pain.

The major improvement observed in this method of laparoscopic incisional and ventral hernia repair (LIVHR) is highlighted by the absence of prosthesis migration, limited visceral attachments, and a low recurrence rate.

<table>
<thead>
<tr>
<th>Observations on mesh-related visceral attachments</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adhesion-free</td>
<td>40</td>
<td>47.05</td>
</tr>
<tr>
<td>Minor adhesion (Mueller I)</td>
<td>36</td>
<td>42.35</td>
</tr>
<tr>
<td>Serosal adhesion (Mueller II)</td>
<td>9</td>
<td>10.58</td>
</tr>
<tr>
<td>Mean follow-up</td>
<td>52 months (range 3–101 months)</td>
<td></td>
</tr>
</tbody>
</table>

Clinically Proven Integration

<table>
<thead>
<tr>
<th>Cell Quantification at Day 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cell/Mesh (2cm²)</td>
</tr>
<tr>
<td>Day 2</td>
</tr>
<tr>
<td>Polypropylene</td>
</tr>
<tr>
<td>Polyester</td>
</tr>
</tbody>
</table>

In vitro polyester showed 58% greater cell quantification than polypropylene at day 2.

<table>
<thead>
<tr>
<th>Cell Quantification at Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cell/Mesh (2cm²)</td>
</tr>
<tr>
<td>Day 7</td>
</tr>
<tr>
<td>Polypropylene</td>
</tr>
<tr>
<td>Polyester</td>
</tr>
</tbody>
</table>

In vitro polyester showed 57% greater cell quantification than polypropylene at day 7.

- Study compared cell behavior in contact with polyester and polypropylene mesh over 2 hours, as well as 3, 6, and 10 days.
- Cell staining and SEM observation of incubated meshes showed good cell viability, adhesion and proliferation on polyester meshes, but poor proliferation on polypropylene meshes despite good cell viability.
- Polyester meshes favor cell colonization as compared with polypropylene meshes under in vitro conditions.

A Second Look Case Report

- 65-year-old patient presented with a ventral hernia that was repaired with Parietex™ Composite (PCO) mesh.
- 2 years, 10 months later, patient underwent a laparoscopic procedure that provided a second look at the hernia repair.
- Minimal attachments were observed and easily taken down.
- Revascularization and neoperitoneum were present.

At Day 2 and Day 7, cell proliferation on the polyester mesh was more than twice as robust as that on the polypropylene mesh.
Covidien has developed online reimbursement resources for hernia and abdominal wall repair. You can reference the interactive US Hernia Reimbursement Guide at covidien.com/hernia/reimbursement for the most up-to-date codes and reimbursement rates.

**Competitive Products Overview**

Parietex™ Composite (PCO) mesh enables advanced treatment for complex ventral hernias. The clinically proven PCO mesh combines Parietex™ three-dimensional polyester mesh with a resorbable collagen film to limit visceral attachments. In more than 10 years of market data, Parietex™ Composite mesh has demonstrated less shrinkage, fewer and less-dense visceral attachments, and significantly stronger abdominal wall adherence and tissue ingrowth than competitive polypropylene meshes.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>COVIDIEN PARIETEX™ COMPOSITE (PCO) MESH</th>
<th>ETHICON PROCEED™</th>
<th>BARD SEPRAMESH™ IP</th>
<th>BARD COMPOSIX™</th>
<th>ATRIUM C-QUR™</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPECIFICATIONS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MATERIAL</td>
<td>3-D PET + collagen, PEG, glycerol</td>
<td>PROLENE™ PP + PDS (polydioxanone)+ ORC (Oxidized regenerated cellulose)</td>
<td>PP+PGA Coating HA+CMC+PEG</td>
<td>PP + PTFE</td>
<td>HA + CMC + PEG</td>
</tr>
<tr>
<td>POROSITY</td>
<td>2.5 x 1.7 mm</td>
<td>3 - 4 mm</td>
<td>-</td>
<td>NA</td>
<td>0.8 mm</td>
</tr>
<tr>
<td>DENSITY</td>
<td>78 g/m²</td>
<td>45 g/m²</td>
<td>-</td>
<td>NA</td>
<td>85 g/m²</td>
</tr>
<tr>
<td>THICKNESS</td>
<td>1.5 - 2 mm</td>
<td>0.7 mm</td>
<td>-</td>
<td>-</td>
<td>0.48 mm</td>
</tr>
<tr>
<td>TRANSPARENCY</td>
<td>+++</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>ELASTICITY</td>
<td>21/42%</td>
<td>NA</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>RESISTANCE</td>
<td>22/15 daN</td>
<td>66 N/cm²</td>
<td>-</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>RESORPTION DELAY</td>
<td>2 weeks</td>
<td>2 weeks</td>
<td>14 days ORC 90 days PDS</td>
<td>14 days PGA 28 days*</td>
<td>NA</td>
</tr>
<tr>
<td>PERFORMANCE</td>
<td>ADHESION SURFACE AT 30 DAYS¹</td>
<td>11.2%</td>
<td>38.5%</td>
<td>10.4%</td>
<td></td>
</tr>
</tbody>
</table>

¹ Includes all adhesion parameters, not just seroma.
Competitive Information

Ethicon: Proceed™ Surgical Mesh

MATERIAL COMPOSITION
Comprised of an oxidized regenerated cellulose (ORC) fabric and PROLENE™ Soft Mesh, a monofilament, nonabsorbable polypropylene encapsulated with polydioxanone (PDS)

PARIETEX® COMPOSITE (PCO) MESH VS. ETHICON PROCEED™ SURGICAL MESH

<table>
<thead>
<tr>
<th>Bioabsorbable Component</th>
<th>Proceed™ Mesh</th>
<th>Parietex™ Composite (PCO) Mesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradable collagen barrier on one side to limit visceral attachments</td>
<td>Oxidized regenerated cellulose (ORC) fabric physically separates the polypropylene mesh from underlying tissue and organ surfaces12</td>
<td></td>
</tr>
<tr>
<td>Comprised of porcine collagen, polyethylene glycol and glycerol</td>
<td>PROLENE™ soft mesh component constructed of knitted filaments of extruded polypropylene10</td>
<td></td>
</tr>
<tr>
<td>More than 10 years of documented clinical effectiveness</td>
<td>Meticulous hemostasis must be achieved (if not, mesh turns dark and tends to adhere to tissue)9</td>
<td></td>
</tr>
</tbody>
</table>

Flexible Material
Polyester, with a three-dimensional weave, is flexible and soft, whereas PROCEED™ surgical mesh is made of a unique polyester material optimized to minimize shrinkage

Shrinkage
Unique polyester material optimized to minimize shrinkage, with less than 10% shrinkage at 30 days; whereas PROCEED™ surgical mesh demonstrated a contraction of PROLENE™ Soft Polypropylene mesh by 34% within 4 weeks11

Interaction with Blood
Transparent barrier for visualization, whereas PROCEED™ surgical mesh is said to have a very smooth surface designed to prevent adhesion formation; however, it is less smooth than other composite meshes12

Surface Properties
Very smooth and continuous barrier, whereas PROCEED™ surgical mesh is said to have a very smooth surface designed to prevent adhesion formation; however, it is less smooth than other composite meshes12

Protection
Collagen barrier extends 5 mm beyond mesh edge; whereas PROCEED™ surgical mesh attachment was the only mesh that showed no visceral attachments at both 7 days and 30 days. PROCEED™ surgical mesh: 5 of 6 at 7 days, 5 of 3 at 30 days

IFU Warning
“PROCEED™ Mesh has an ORC component that should not be used in the presence of uncontrollable and/or active bleeding, as fibrinous exudates may increase the chance of adhesion formation.”

Proceed™ Surgical Mesh—Instructions for Use
**Davol: Bard Sepramesh™ IP Composite (2nd generation, 2005)**

**MATERIAL COMPOSITION**
Polypropylene and polyglycolic acid (PGA) mesh with hydrogel safety coating

**PARİETEX™ COMPOSITE (PCO) MESH VS. BARD SEPRAMESH™ IP COMPOSITE**

<table>
<thead>
<tr>
<th>Clinical Proof</th>
<th>Parıetex™ Composite (PCO) Mesh</th>
<th>Sepramesh™ IP</th>
</tr>
</thead>
<tbody>
<tr>
<td>More than 10 years of documented clinical effectiveness</td>
<td>No human clinical data</td>
<td></td>
</tr>
<tr>
<td>Inconsistent animal clinical results</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bioreable Component</th>
<th>Parıetex™ Composite (PCO) mesh with hydrogel safety coating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resorbable collagen barrier on one side to limit visceral attachments</td>
<td></td>
</tr>
<tr>
<td>Comprised of oxidized atelocollagen type I Polyethylene glycol Glycerol</td>
<td></td>
</tr>
<tr>
<td>Hydrogel barrier minimizes tissue attachment to the prosthesis18</td>
<td></td>
</tr>
<tr>
<td>Comprised of sodium hyaluronate (HA), carboxymethylcellulose (CMC) and polyethylene glycol (PEG) based hydrogel18</td>
<td></td>
</tr>
<tr>
<td>Bioreorbable fibers reinforce mesh strength and bind the mesh to the hydrogel coating18</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tissue Integration</th>
<th>Parıetex™ Composite (PCO) mesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incites excellent fibrous ingrowth and neoperitoneum18</td>
<td></td>
</tr>
<tr>
<td>Deep tissue incorporation</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Handling Properties</th>
<th>Parıetex™ Composite (PCO) mesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimized to minimize shrinkage</td>
<td></td>
</tr>
<tr>
<td>Larger sizes can be rolled up and inserted through a standard 12 mm trocar (37 cm x 28 cm)</td>
<td></td>
</tr>
<tr>
<td>Requires minimum:18</td>
<td></td>
</tr>
<tr>
<td>- 12 mm trocar for 15.2 cm x 7.6 cm and larger</td>
<td></td>
</tr>
<tr>
<td>- 15 mm trocar for 20.3 cm x 15.2 cm and larger</td>
<td></td>
</tr>
<tr>
<td>- 18 mm trocar for 35.6 cm x 30.5 cm</td>
<td></td>
</tr>
</tbody>
</table>

**EVIDENCE-BASED MEDICINE**

**PARİETEX™ COMPOSITE (PCO) MESH VS. BARD SEPRAMESH™ IP COMPOSITE**

<table>
<thead>
<tr>
<th>Transcational Procedure Data, 2005-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrence Rate</td>
</tr>
<tr>
<td>Parıetex™ Composite (PCO) mesh</td>
</tr>
<tr>
<td>1.4%</td>
</tr>
<tr>
<td>3.5%</td>
</tr>
<tr>
<td>4.5%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parıetex™ Composite (PCO) mesh</th>
<th>Bard Sepramesh™* (% Patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.4%</td>
<td>12.7%</td>
</tr>
</tbody>
</table>

• The ventral hernia recurrence rate with Parıetex™ mesh was 3x less than Bard Sepramesh™* IP in the outpatient setting

• The amount of postoperative surgery pain medication with Parıetex™ mesh was half of Bard Sepramesh™* IP for Ventral Hernia Repair.

**Abdominal Wall Hernia Repair: A Comparison of Sepramesh™ and Parıetex™ Composite mesh in a Rabbit Hernia Model**

Journal of the American College of Surgeons 2007
Davol: Bard Composix™

MATERIAL COMPOSITION
Polypropylene mesh and sub-micronic ePTFE, stitched with PTFE monofilament

Parietex™ Composite (PCO) Mesh vs. Bard Composix™ Mesh

<table>
<thead>
<tr>
<th>Barrier Composition</th>
<th>Composix™ Mesh</th>
<th>Parietex™ Composite (PCO) Mesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resorbable collagen barrier on one side to limit visceral attachments</td>
<td>Polypropylene Bard Mesh on one side to promote tissue ingrowth and sub-micronic ePTFE on the other side to minimize visceral attachments to the prosthesis</td>
<td></td>
</tr>
<tr>
<td>Comprised of oxidized atelocollagen type I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polyethylene glycol Glycerol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>More than 10 years of documented clinical effectiveness</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Protection                                                        |                                                                           |                                                                                             |
| Collagen barrier extends 5 mm beyond mesh edge                   |                                                                           |                                                                                             |
| Sealed edge prevents exposure of the polypropylene mesh side from contact with the bowel, thus potentially reducing the chances of visceral attachments around the edge of the prosthesis20 |                                                                                             |
|                                                                 |                                                                           |                                                                                             |
| Tissue Integration                                                |                                                                           |                                                                                             |
| Incites excellent fibrous ingrowth and neoperitoneum7            |                                                                           |                                                                                             |
| Deep tissue incorporation                                         |                                                                           |                                                                                             |

| Handling Properties                                               |                                                                           |                                                                                             |
| Optimized to minimize shrinkage                                   |                                                                           |                                                                                             |
| Larger sizes can be rolled up and inserted through a standard 12 mm trocar (37 cm x 28 cm) |                                                                           |                                                                                             |
| Cannot be cut, as the polypropylene layer will be widely exposed  |                                                                           |                                                                                             |

EVIDENCE-BASED MEDICINE
Parietex™ Composite (PCO) Mesh vs. Bard Composix™ Mesh

| Transactional Procedure Data, 2005-20086                          |                                                                           |                                                                                             |
| Use of Pain Medication                                             |                                                                           |                                                                                             |
| Recurrence Rate                                                    |                                                                           |                                                                                             |

Case Reports24

Patient Exploratory Laparotomy

Surgical Repair
- Ventral hernia repair with Bard Composix™ four years postop
- Ventral hernia repair with Parietex™ Composite (PCO) mesh two years postop

Clinical Result
- Parietex™ Composite (PCO) Mesh
  - No visible contraction
  - No visceral attachments to mesh
  - Minimal visceral attachments to tacks
- Bard Composix™ Mesh
  - Experienced significant shrinkage
  - Numerous grade I visceral attachments (Mueller scale)

Surgeon noted that when running a grasper over both repairs the Bard Composix™ mesh was very rigid and hard while the Parietex™ Composite (PCO) mesh was soft and compliant.
**Comparison of Two Composite Meshes Using Two Fixation Devices in a Porcine Laparoscopic Ventral Hernia**

Hernia: The World Journal of Hernia and Abdominal Wall Surgery 2004

**Comparative Results In Vivo: Fewer Less-Dense Visceral Attachments**

<table>
<thead>
<tr>
<th>Percentage Area of Visceral Attachments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parietex™ Composite (PCO) Mesh</td>
</tr>
<tr>
<td>0.1%</td>
</tr>
</tbody>
</table>

**% Area of Attachments**

| Attachment Density | 14.5 ± 12.4% | 53.4 ± 9.8% |

**Resistance to Adhesion Formation: A Comparative Study of Treated and Untreated Mesh Products Placed in the Abdominal Cavity**

Hernia: The World Journal of Hernia and Abdominal Wall Surgery 2004

**Comparative Results In Vivo: Fewer Attachments**

<table>
<thead>
<tr>
<th>Presence of Visceral Attachments (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parietex™ Composite (PCO) Mesh</td>
</tr>
<tr>
<td>8%</td>
</tr>
</tbody>
</table>

**Barrier Composition**

- Resorbable collagen barrier on one side to limit visceral attachments
- Comprised of oxidized collagen type I and polyethylene glycol glycerol
- More than 10 years of documented clinical effectiveness

**Tissue Integration**

- Incites excellent fibrous ingrowth and neoperitoneum
- No tissue integration at 30 days
- Two-sided fatty acid coating creates a barrier on both sides of the mesh

**Protection**

- Resorbable collagen barrier on one side to limit visceral attachments
- C-Qur™ showed higher adhesion score than Parietex™ composite (PCO) mesh

**Material Properties**

- Larger sizes can be rolled up and inserted through a standard 12 mm trocar (37 cm x 28 cm)
- Thick material is difficult to roll and insert into trocar

**Animals with Visceral Attachments at 30 Days**

| Incorporation Score at 30 Days | 2 (1-4) | 1.5 (1-3) |

**Atrium Medical Corporation: C-Qur™ Mesh**

Polypropylene mesh with Omega-3 fatty acid bioabsorbable coating

**Material Composition**

- All-natural coating significantly improves anatomical conformance by reducing aggressive, dense acellular collagen formation during material healing

**PARIETEX™ COMPOSITE (PCO) MESH VS. ATRIUM C-QUR™ MESH**

Packaging Overview

Box Dimensions
Sizes will vary depending on order code. Each box contains a single, individually packaged mesh.

Ordering Information

COVIDIEN PRODUCTS WEBSITE: www.covidien.com/hernia
CUSTOMER SERVICE: 1-800-722-8772

| Box Dimensions | Sizes will vary depending on order code. Each box contains a single, individually packaged mesh. |

Product Order Codes

Laparoscopic Ventral Hernia Repair: Parietex™ Composite (PCO) Mesh

<table>
<thead>
<tr>
<th>Order Code</th>
<th>Description</th>
<th>Order Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCO9</td>
<td>9cm Round</td>
<td>PCO2015</td>
<td>20cm x 15cm</td>
</tr>
<tr>
<td>PCO12</td>
<td>12cm Round</td>
<td>PCO2520</td>
<td>25cm x 20cm</td>
</tr>
<tr>
<td>PCO15</td>
<td>15cm Round</td>
<td>PCO3020</td>
<td>30cm x 20cm</td>
</tr>
<tr>
<td>PCO20</td>
<td>20cm Round</td>
<td>PCO3728</td>
<td>37cm x 28cm</td>
</tr>
<tr>
<td>PCO1510</td>
<td>15cm x 10cm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Open Ventral Hernia Repair: Parietex™ Composite Open Skirt (PCO OS) Mesh

<table>
<thead>
<tr>
<th>Order Code</th>
<th>Description</th>
<th>Order Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCO8OS</td>
<td>Skirted 8cm Round</td>
<td>PCO2520OS</td>
<td>Skirted 25cm x 20cm</td>
</tr>
<tr>
<td>PCO1510OS</td>
<td>Skirted 15cm x 10cm</td>
<td>PCO3020OS</td>
<td>Skirted 30cm x 20cm</td>
</tr>
<tr>
<td>PCO2015OS</td>
<td>Skirted 20cm x 15cm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Parastomal Hernia Repair: Parietex™ Composite Parastomal (PCO PM) Mesh

<table>
<thead>
<tr>
<th>Order Code</th>
<th>Description</th>
<th>Order Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCOPM15</td>
<td>Parastomal 15cm Round NO HOLE</td>
<td>PCOMP15H35</td>
<td>Parastomal 15cm Round HOLE 35mm</td>
</tr>
<tr>
<td>PCOPM20</td>
<td>Parastomal 20cm Round NO HOLE</td>
<td>PCOMP15H50</td>
<td>Parastomal 15cm Round HOLE 50mm</td>
</tr>
</tbody>
</table>

Hiatal Hernia Repair: Parietex™ Composite Hiatal (PCO 2H) Mesh

<table>
<thead>
<tr>
<th>Order Code</th>
<th>Description</th>
<th>Order Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCO2H1</td>
<td>Hiatal Heart-Shaped Mesh 8cm x 8cm</td>
<td>PCO2H3</td>
<td>Hiatal Horseshoe-Shaped Mesh 9cm x 8cm</td>
</tr>
</tbody>
</table>
We hope that this comprehensive information packet has been helpful to you in facilitating your decision-making process. If you have any questions or concerns, please contact your Covidien Sales Representative.