Parietex™ Composite Ventral Patch for Small Ventral Hernia Repair
Parietex™ composite ventral patch is a mesh specifically designed for small ventral hernia repair. The shape, size, and specific fixation and deployment system have been designed for optimal abdominal wall conformability and easy deployment and fixation.\textsuperscript{1-3,†}

In addition to these technical features, Parietex™ composite ventral patch has been designed to support tissue integration while minimizing tissue attachments with collagen.\textsuperscript{1,2,4,‡}

The Parietex™ composite ventral patch is offered in a complete range of product sizes, in diameters of 4.6 cm, 6.6 cm, and 8.6 cm.

\textsuperscript{†} Based on preclinical animal and/or benchtop studies
\textsuperscript{‡} Animal data is not necessarily indicative of human clinical outcomes
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PRODUCT OVERVIEW

As the market leader in hernia care, we have demonstrated innovation and excellent leadership over the last 20 years by developing and establishing a comprehensive hernia care range of products.

With innovations such as Parietex™ composite collagen-based film and ProGrip™ mesh technology (a combination of mesh and fixation in one device), we have built an extensive track record of innovation, performance, and value.

Parietex™ composite ventral patch has been developed with the same idea: **Innovation must provide significant benefits to the surgeon and patient, while offering a justifiable price to the hospital.**

**Why would a hospital purchase Parietex™ composite ventral patch?**

**Surgical focus**

Parietex™ composite ventral patch has been designed to ensure efficiency on critical points such as easy and balanced fixation of the mesh, good abdominal wall conformability, and consistent tissue integration.

**Economic value proposition**

According to clinical studies of the current field of competitive patches, some technical points may be improved to decrease the rate of recurrence. Parietex™ composite ventral patch has been technically developed with an accurate focus on these points aimed at decreasing this rate of recurrence.
What are the main advantages of Parietex™ composite ventral patch?

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy and optimal deployment</td>
<td>According to the literature, the success of a ventral patch is often linked to the ability to deploy well within the abdominal cavity. Parietex™ composite ventral patch has been specifically designed to open easily and stay flat against the abdominal wall thanks to the specific rigid and absorbable expanders.</td>
</tr>
<tr>
<td>Balanced fixation</td>
<td>The unique design of the system enables fixation on the four cardinal points, bringing a balanced and strong fixation of Parietex™ composite ventral patch. This unique fixation system reduces the risk of cupping effect and visceral entrapment that may lead to recurrence.</td>
</tr>
<tr>
<td>Minimized visceral attachment</td>
<td>Introduced in 1999, Parietex™ composite mesh was the first mesh to offer an absorbable collagen film on one side to minimize visceral attachments and a three-dimensional (3-D) polyester knit structure on the other side to support tissue integration. Based on this long experience, we adapted the collagen technology to Parietex™ composite ventral patch to attain consistent tissue integration, while at the same time minimizing tissue attachment with the collagen film.</td>
</tr>
</tbody>
</table>

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1 Based on preclinical animal and/or benchtop studies
2 Animal data is not necessarily indicative of human clinical outcomes
PRODUCT SPECIFICATIONS

Indications for Use
Parietex™ composite ventral patch is used for the reinforcement of soft tissues during surgical repair. It is indicated for the treatment of ventral defects (primary and incisional hernias).

Material Composition
- Three-dimensional non-absorbable monofilament polyester textile (PET), white textile
- Two-dimensional non-absorbable monofilament polyester textile (PET), green textile (green dye: D&C Green No. 6)
- A bioabsorbable collagen-based film
- Two violet absorbable polyglycolide-co-L-lactide (PGLA) expanders with coloration agent (violet dye: D&C Violet No. 2)
- Two removable handles composed of colored tubes and yarn

Diameter

| Diameter | 4.6 cm | 6.6 cm | 8.6 cm |

Supports tissue integration while minimizing visceral attachment with collagen film†,‡,†

Easy deployment and fixation system†,‡

Pore Size
- Green textile: 1.2 x 1.6 mm
- White textile: 1.4 x 1.7 mm

Sterilization Method
Ethylene Oxide (EtO)

Shelf Life
5 years

† Based on preclinical animal and/or benchtop studies.
‡ Animal data is not necessarily indicative of human clinical outcomes
510 (k) CLEARANCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

1430 M Street, N.W.
Washington, D.C. 20204-3000

Sofradim Production

15 Crosby Drive
Bedford, Massachusetts 01730

Mr. James McMahon
Senior Manager, Regulatory Affairs

Re: K120506

Trade/Device Name: PARIETEX™ Composite Ventral Patch
Regulation Number: 21 CFR R7.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: F1L, OXJ

Dated: May 11, 2012
Received: May 14, 2012

Dear Mr. McMahon:

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 waivers. 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.

Page 2 – Mr. James McMahon

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 all 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 system (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 511-512 of the Act); 21 CFR 1006-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Part 807), please go to http://www.fda.gov/AboutFDA-CenterOfficesComplianceOfficeofCompliance/forIndustry/ucm112889.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.95). 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.

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) 638-2841 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/StartupsforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Parietex™ composite ventral patch is a dual-facing mesh composed of a non-absorbable 3-D monofilament polyester textile for abdominal wall reinforcement covered by a bioabsorbable hydrophilic collagen film to minimize visceral attachment. A fixation system composed of four flaps made out of monofilament polyester textile and two removable handles completes the device. This fixation system and the 3-D reinforcement textile are assembled with absorbable poly(glycolide-co-L-lactide) (PGLA) expanders. This system was designed to facilitate placement and fixation of the mesh.³

The fascial side of the mesh ensures abdominal wall reinforcement, enabling consistent tissue ingrowth.¹,² The visceral side of the mesh is composed of porcine origin collagen film, polyethylene glycol, and glycerol. The film is absorbable, continuous, and hydrophilic, and juts out over the edge of the textile. This side physically separates the polyester textile from the tissues and organs to minimize tissue attachment to the mesh in case of direct contact with viscera, as demonstrated in a preclinical study.³,⁴,†,‡

The four flaps of the Parietex™ composite ventral patch that provide a dedicated fixation surface area are composed of a dyed (D&C Green No. 6) bidimensional monofilament polyester textile. These flaps also facilitate visualization during the semi-peripheral suture fixation.³

† Animal data is not necessarily indicative of human clinical outcomes
‡ Based on preclinical animal and/or benchtop studies
Two dyed (D&C Violet No. 2) PGLA expanders provide shape memory to the mesh and offer stability to facilitate insertion and proper deployment of the mesh through the defect.\(^3\) The PGLA component is completely absorbed within one year.

The device also presents two removable handles (composed of colored tubes and yarns) that are attached to the extremity of the flaps to provide a means for proper positioning of the mesh. They are kept extracorporeally during the procedure and discarded after the surgery.

The PGLA component and the hydrophilic film are fully absorbable, which provide less long-term foreign material in the body.

Among the large and innovative range of synthetic meshes we provide to surgeons, Parietex™ composite ventral patch has been developed with the idea that products have to be adapted to surgeons’ real needs while ensuring patient comfort after operation.
Why use a patch for small ventral hernia repair?

An evolution in small ventral hernia repair has appeared on the market with the introduction of ventral patches. The two techniques (intraperitoneal ventral patch usage versus flatsheet in retromuscular placement) have been evaluated in a prospective study that included 116 patients. The results have been published in the American Journal of Surgery (2011).

### Use of a ventral patch found to bring benefits to the patient:

Pain has been highly decreased at discharge, after one week and after 21 days.

<table>
<thead>
<tr>
<th></th>
<th>Retromuscular mesh repair (n = 56)</th>
<th>Intraperitoneal (n = 60)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS Score Day 1</td>
<td>Mean 77.1 Standard Error 1.5</td>
<td>Mean 49.8 Standard Error 1.21</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>VAS Score Day 7</td>
<td>Mean 56.7 Standard Error 2.01</td>
<td>Mean 25.4 Standard Error 1.82</td>
<td></td>
</tr>
<tr>
<td>VAS Score Day 21</td>
<td>Mean 23.63 Standard Error 2.18</td>
<td>Mean 3.3 Standard Error 0.70</td>
<td></td>
</tr>
</tbody>
</table>

*Between-groups difference evaluated with repeated-measures analysis of variance.

### Use of a ventral patch was found to bring economic value:

Operative time and hospital stay have been decreased with intraperitoneal patch placement.

<table>
<thead>
<tr>
<th></th>
<th>Retromuscular mesh repair (n = 56)</th>
<th>Intraperitoneal (n = 60)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation time (min)</td>
<td>Mean 79.9 Standard Error 1.73</td>
<td>Mean 33.9 Standard Error 0.74</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hospital stay (days)</td>
<td>Mean 3.8 Standard Error 0.17</td>
<td>Mean 2.1 Standard Error 0.07</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
ISSUES AND RESULTS WITH AVAILABLE PATCHES
BASED ON A SELECTION OF RELEVANT LITERATURE

HIGH RECURRENCE RATE REPORTED
FROM 8.9% \(^5,\dagger\) UP TO 14.8% \(^6,\dagger\)

- IMPROPER DEPLOYMENT of the mesh \(^6\)
- EXTENSIVE SHRINKAGE of the mesh \(^6\)
- STRONG ADHESIONS \(^5\)
- LACK OF STRENGTH with the memory ring \(^6\)

<table>
<thead>
<tr>
<th>Reintervention Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Stay</td>
</tr>
<tr>
<td>Procedure</td>
</tr>
<tr>
<td>New Device</td>
</tr>
</tbody>
</table>

\(\dagger\) Median follow-up of 25 months.
\(\dagger\) Mean follow-up of 49 months.
# Economic Value Proposition

## Identified Issues on Existing Competitive Products

<table>
<thead>
<tr>
<th>Identified Issues</th>
<th>Technical Solutions</th>
<th>Medtronic Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improper deployment of the mesh(^7)</td>
<td></td>
<td>Provides easy deployment and fixation system(^3)</td>
</tr>
<tr>
<td>Insufficient flatness of the mesh against the abdominal wall (potato-chip-like)(^6)</td>
<td></td>
<td>Designed for optimal wall conformability(^3)</td>
</tr>
<tr>
<td>Visceral attachments(^5)</td>
<td></td>
<td>Supports tissue integration while minimizing visceral attachment with collagen film(^4,!)</td>
</tr>
</tbody>
</table>
PRODUCT CLAIMS DATA

Designed for optimal abdominal wall conformability:1-3,†

- Mesh conforms to the abdominal cavity thanks to expander, positioning and fixation system (handles and peripheral fixation).
- The peripheral fixation enables the mesh to conform to the abdominal wall during the tissue integration process.
- The rigid and absorbable expanders enable the mesh to flatten against the abdominal wall.

† Based on preclinical animal and/or benchtop studies
PRODUCT CLAIMS DATA

Provides easy deployment and fixation system\textsuperscript{1-3,1}:

- Pulling on the handles will help the user to position the mesh in the center of the defect.
- Colored textile of the fixation system enhances visibility during a procedure.
- The innovative fixation system based on four semi-peripheral points provides a balanced fixation on healthy tissue away from the center of the defect.

\textsuperscript{1} Based on preclinical animal and/or benchtop studies
Supports tissue integration while minimizing visceral attachment with collagen film:¹,²,⁴,†‡

- 3-D monofilament polyester textile with large pores (1.4 x 1.7 mm) for a consistent tissue integration.
- Hydrophilic absorbable collagen film to minimize tissue attachment.

Macroporous 3-D textile enabling consistent tissue integration:¹,²,⁴,†

Resorbable expander PGLA resorption < 12 months

Minimizing tissue attachment barrier:⁴,†

¹Based on preclinical animal and/or benchtop studies
‡ Animal data is not necessarily indicative of human clinical outcomes
## COMPETITIVE PRODUCTS OVERVIEW

### Comparative Results of Internally Sponsored Preclinical Study$^{1,2,†}$

<table>
<thead>
<tr>
<th></th>
<th>Parietex™ composite ventral patch</th>
<th>Bard Ventralex™ hernia patch</th>
<th>Ethicon Proceed™ ventral patch</th>
</tr>
</thead>
<tbody>
<tr>
<td>The mesh is well deployed within the abdominal wall</td>
<td>Sufficient</td>
<td>Sufficient</td>
<td>Sufficient</td>
</tr>
<tr>
<td>The mesh is conformable to the abdominal wall</td>
<td>Sufficient</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td>No retraction of the mesh has been observed</td>
<td>Sufficient</td>
<td>Sufficient</td>
<td>Low</td>
</tr>
<tr>
<td>No migration of the mesh has been observed</td>
<td>Sufficient</td>
<td>Sufficient</td>
<td>Low</td>
</tr>
<tr>
<td>The mesh is well integrated after 4 weeks</td>
<td>Sufficient</td>
<td>Sufficient</td>
<td>Low</td>
</tr>
</tbody>
</table>

Ventral Patch Product Codes:

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Parietex™ composite ventral patch</th>
<th>Ventralex™ Hernia Patch</th>
<th>Ventralex™ ST Hernia Patch</th>
<th>Proceed™ Ventral Patch</th>
<th>C-Qur™ V-patch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Medtronic</td>
<td>Bard</td>
<td>Bard</td>
<td>Ethicon</td>
<td>Atrium</td>
</tr>
<tr>
<td>Small size</td>
<td>PCO4VP</td>
<td>0010301</td>
<td>5950007</td>
<td>PVPS</td>
<td>31200</td>
</tr>
<tr>
<td>Medium size</td>
<td>PCO6VP</td>
<td>0010302</td>
<td>5950008</td>
<td>PVPM</td>
<td>31201</td>
</tr>
<tr>
<td>Large size</td>
<td>PCO8VP</td>
<td>0010303</td>
<td>5950009</td>
<td></td>
<td>31202</td>
</tr>
</tbody>
</table>

$^{†}$ Animal data is not necessarily indicative of human clinical outcomes
### COMPETITIVE PRODUCTS OVERVIEW

<table>
<thead>
<tr>
<th>Features</th>
<th>Medtronic</th>
<th>Bard</th>
<th>Bard</th>
<th>Ethicon</th>
<th>Atrium</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Deployment system</strong></td>
<td>Medtronic</td>
<td>Bard</td>
<td>Bard</td>
<td>Ethicon</td>
<td>Atrium</td>
</tr>
<tr>
<td>Rigid and absorbable PGLA expanders combined with removable handles for easy deployment</td>
<td>Non-absorbable PET recoil ring</td>
<td>SorbaFlex™ technology</td>
<td>Non-absorbable positioning ring and polydioxanone polymer reinforcement film</td>
<td>O3FA-coated reinforcement washer</td>
<td></td>
</tr>
<tr>
<td><strong>Fixation</strong></td>
<td>Medtronic</td>
<td>Bard</td>
<td>Bard</td>
<td>Ethicon</td>
<td>Atrium</td>
</tr>
<tr>
<td>Semi-peripheral fixation on four cardinal points</td>
<td>Two or four U-stitches (depending on patchsize) on the anterior mesh pocket, plus two sutures on straps</td>
<td>Lateral fixation with polypropylene straps and pocket</td>
<td>Central fixation with polypropylene straps; fixation on the edges of the defect</td>
<td>Central fixation with polypropylene straps; fixation on the edges of the defect</td>
<td></td>
</tr>
<tr>
<td><strong>Minimizing tissue attachment</strong></td>
<td>Medtronic</td>
<td>Bard</td>
<td>Bard</td>
<td>Ethicon</td>
<td>Atrium</td>
</tr>
<tr>
<td>Absorbable collagen film</td>
<td>Non-resorbable e-PTFE layer</td>
<td>Absorbable hydrogel barrier</td>
<td>Absorbable ORC layer</td>
<td>O3FA-bioabsorbable coating</td>
<td></td>
</tr>
<tr>
<td><strong>Size</strong></td>
<td>Medtronic</td>
<td>Bard</td>
<td>Bard</td>
<td>Ethicon</td>
<td>Atrium</td>
</tr>
<tr>
<td>4.6 cm, 6.6 cm, 8.6 cm</td>
<td>4.3 cm, 6.4 cm, 8 cm</td>
<td>4.3 cm, 6.4 cm, 8 cm</td>
<td>4.3 cm, 6.4 cm</td>
<td>4.6 cm, 6.4 cm, 8 cm</td>
<td></td>
</tr>
</tbody>
</table>
Medtronic has developed comprehensive online reimbursement resources for hernia and abdominal wall repair. You can reference the interactive U.S. Hernia Reimbursement Guide at medtronic.com/covidien for the most up-to-date codes and reimbursement rates.

### HCPCS Supply Code

| Mesh          | C1781 | Mesh, implantable |

### ICD - 10 Procedure Codes (Hospital Inpatient Procedures)

| Umbilical Hernia (Open Approach) | 0WUF0JZ | Repair abdominal wall, open approach with mesh |

### CPT Procedure Codes (Physician, Hospital Outpatient, Ambulatory Surgical Center)

| Umbilical Hernia (Open Approach) | 49585 | Repair umbilical hernia, age 5 years or older; reducible |
|                                | 49587 | Repair umbilical hernia, age 5 years or older; incarcerated or strangulated |

### DRG Classification (Inpatient Procedures)

| DRG Classification Dependent on Combination of ICD 10 Procedure and ICD - 10 Diagnostic Codes (Determines Hospital Payment) | 353 | Hernia procedures except inguinal & femoral w/ major complications and comorbidities (MCC) |
|                                                                                                                | 354 | Hernia procedures except inguinal & femoral w/ complications and comorbidities (CC) |
|                                                                                                                | 355 | Hernia procedures except inguinal & femoral w/o complications or comorbidities (w/o CC or MCC) |

No Lap / Open distinction
PACKAGING OVERVIEW

Product Order Codes

<table>
<thead>
<tr>
<th>Order Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCO8VP</td>
<td>Parietex™ composite ventral patch 8.6 cm diameter, box of 1</td>
</tr>
<tr>
<td>PCO4VP</td>
<td>Parietex™ composite ventral patch 4.6 cm diameter, box of 1</td>
</tr>
<tr>
<td>PCO6VP</td>
<td>Parietex™ composite ventral patch 6.6 cm diameter, box of 1</td>
</tr>
</tbody>
</table>

Ordering Information

medtronic.com/covidien
800-722-8772
HERNIA CARE
Our comprehensive product portfolio can enhance your hernia repair procedures.

1. Based on internal preclinical study 0506-141814. Report 10 days and 4 weeks implantation study. March 2012
2. Based on internal preclinical study 0506-141814. Report 10 days and 4 weeks implantation study - Amendment 1. June 2012
4. Based on internal preclinical study 0506-140983. Evaluation of the local tissue effects and tissue attachment minimization of a Parietex™ Composite ventral patch in a rat caecal abrasion model – Amendment 1. February 2012

For detailed information, please refer to the Instructions For Use.

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