Parietex ProGrip™ Self-Fixating Mesh

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

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.
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Product Overview

**Parietex ProGrip™ Self-Fixating Mesh: THE FASTEST WAY TO PATIENT COMFORT**

In hernia repair, surgeons want to balance security and patient comfort with ease of use; in partnership with surgeons, Covidien developed Parietex ProGrip™ self-fixating mesh to deliver all three. It is the only bicomponent mesh consisting of monofilament polyester with a resorbable polylactic acid (PLA) microgrip technology that is designed to provide a secure and durable repair and the potential for greater patient comfort. The combination of mesh and microgripping technology provides immediate tension-free fixation3 that offers surgical efficiencies and patient advantages.

**Why should a hospital purchase Parietex ProGrip™ Self-Fixating Mesh?**

<table>
<thead>
<tr>
<th>Improved Patient Outcomes</th>
<th>Surgical Efficiencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients experienced less pain on the first postoperative day and they required fewer analgesics during the length of their hospital stay.4</td>
<td>Operative times are improved by 19%, providing economic efficiencies for facilities.4</td>
</tr>
</tbody>
</table>

**What are the competitive advantages of Parietex ProGrip™ Self-Fixating Mesh?**

<table>
<thead>
<tr>
<th>Enhanced Security</th>
<th>Designed to Improve Patient Comfort</th>
<th>Ease of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exhibits 100% stronger peel strength than suture fixation at four weeks.39</td>
<td>Patients report a lower postoperative pain score and require a reduced dose of analgesics.4</td>
<td>Parietex ProGrip™ self-fixating mesh can be positioned and placed in less than 60 seconds6 as in a standard open repair, without requiring the use of additional fixation.7</td>
</tr>
<tr>
<td>Provides substantially stronger incorporation than fibrin glue, and equivalent incorporation to hernia stapler fixation at five days, with higher retention force than hernia staplers at two months.57</td>
<td>It reduces the potential of chronic groin pain from sutures entrapping nerves.</td>
<td></td>
</tr>
</tbody>
</table>

3Study conducted in an animal model.
Parietex ProGrip™ Self-Fixating Mesh

Adjustable Fixating Flap
Tailor opening around the cord

Elliptic Shape
Fits perfectly to groin anatomy

Resorbable Microgrips
Provide immediate fixation

Semi Resorbable Mesh
50% of material left after PLA absorption

Flat Sheet Design
Anatomical Design

**Product Specifications**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device Classification:</strong></td>
<td>Surgical mesh used in inguinal and incisional hernia repair</td>
</tr>
<tr>
<td><strong>Material Composition:</strong></td>
<td>Bicomponent mesh constructed of hydrophilic monofilament polyester (PET) knit with resorbable polylactic acid (PLA) microgrips</td>
</tr>
<tr>
<td><strong>Fixation:</strong></td>
<td>Self-fixating over 100% of surface area (may not require sutures)</td>
</tr>
<tr>
<td><strong>Pore Size:</strong></td>
<td>1.1 mm to 1.7 mm</td>
</tr>
<tr>
<td><strong>Weight:</strong></td>
<td>73.0 g/m² (before PLA resorption)</td>
</tr>
<tr>
<td></td>
<td>38.0 g/m² (after PLA resorption)</td>
</tr>
</tbody>
</table>
Sofradim Production
% Covidien
Ms. Sharon Alexander
Senior Associate, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K081050
Trade/Device Name: PARIETEX™ PROGRIP™ Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: April 10, 2008
Received: April 14, 2008

Dear Ms. Alexander:

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 1000-1050.

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 Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH’s Office of Surveillance and Biometric’s (OSB’s) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure
Indications For Use

510(k) Number (if known): K081050

Device Name: PARIETEX™ PROGRIP™ Mesh

Indications for Use:

PARIETEX™ PROGRIP™ Mesh is indicated for inguinal and incisional hernia repair.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K081050
PARIETEX™ PROGRIP™
Polyester and polyactic acid mesh

ENGLISH

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT:
This booklet is designed to assist in using this product. It is not a reference to surgical techniques.
This device was designed, tested, and manufactured for single patient use only. Reuse or repackaging of this
device may lead to infection and subsequent patient injury. Repackaging and/or sterilization of the device
may enter the risk of contamination and patient injury. Do not reuse, reprocess or sterilize the device.

DESCRIPTION
PARIETEX™ PROGRIP™ mesh is available in 2 forms:
- Rectangular simple mesh
- Pre-cut, elliptic, with self-grasping overlapping flap. Right or left side.

These meshes and the overlapping flaps of the pre-cut versions are made of a multifilament polyester and
have polyactic acid monofilament barbs on one of the sides. These pre-cuts facilitate gluing, positioning and
fixation of the overlapping flap and the mesh to the surrounding tissue. A colored yarn marker on the
medial edge of the pre-cut mesh helps orientation.

The monofilament polyactic acid barbs are biomechanically and contribute to the fixation of the mesh to
surrounding tissue during at least 9 weeks. The polyactic acid pins degrade and mesh is ever by hydrolysis
and are metabolised by the body into CO₂ and H₂O.

INDICATIONS
Regional and internal hernia repair.

CONTRAINdications
All the usual contraindications for the use of wall reinforcing materials apply to the use of PARIETEX™ PROGRIP™
mesh. These include, but may not be limited to:
- Patients in a period of growth, the mesh may not stretch significantly as the patient grows,
- Surgery in an infected or contaminated site.

ADVERSE REACTIONS
The complications arising from wall reconstruction with mesh can be seen after PARIETEX™ PROGRIP™ mesh
has been used. These complications include, but may not be limited to, infection, hematoma, seroma,
inflammation, chronic pain, irritation, allergic adherence, adhesion reactions to the components of the product.

PRECAUTIONS
- Excessive tension should be avoided on the PARIETEX™ PROGRIP™ mesh and suture attachment points to
account for wound shrinkage during the healing process.
- The mesh is provided in double-stripe packaging. It is recommended to open the first packaging only
for the placement of the mesh and to handle the latter using clean gloves and instruments.
- These meshes should only be used by experienced surgeons who do not undertake the own responsibility.

PRODUCT Introduction—Instructions for Use

1. OPERATING STEPS

Example of a pre-cut mesh with flap:
1. The mesh should be positioned, slit upwards, flap open, colored barbs facing toward the pubis, per side
facing the deep muscular plane.
2. In the slit around the cord (fig. 1).
3. Internal oblique muscle
4. External oblique muscle
5. Cutaneous incision
6. Symphysis cord
7. Large curve
8. Fold the flap back onto the mesh. Grasping is reversible to allow side closure to be adjusted several times.

Example of a rectangular mesh:
– This mesh can be used when no cut to the required dimensions. It can be fixed to the Cooper’s ligament
and/or to the anterior muscular plane. It can also be used between the posterior muscular plane and the
anterior aponeurotic one (external oblique muscle).

STERILIZATION

STORAGE
Recommended storage conditions: Room temperature, out of light.
Do not use the device past the last day of the labelled month of expiration.
Upon receipt of shipment, ensure the packaging is not open or damaged and retains its sealed
appearance. Do not use the device if the integrity of the packaging appears compromised.

GUARANTEE
SOFRADIM PRODUCTION certifies that all precautions have been taken in the choice of materials and
manufacturing methods for this product. SOFRADIM PRODUCTION disclaims all liability in case of loss, damage
arising from the device or indirectly linked to the use of the product. The guarantee terms and conditions listed above
cannot and do not replace any guarantee which may appear in the present document, whether express or tacit
by means of legislation or any other means of enforcement. SOFRADIM PRODUCTION is not liable for any other action
taken in its behalf by any party with regard to the product and firmly holds any party to do so.
Technical Data

Excellent Tissue Integration

Microgrip technology is comparable in strength to hernia stapling at 5 days.

Microgrip technology is superior in strength to hernia stapling at 2 months.

At two months, microgrip technology demonstrated:

- Superior peel strength to hernia staplers
- Superior peel strength to fibrin glue
- Superior peel strength to unfixed mesh

"ProGrip™ is a safe and effective mesh for open hernia repair that is easy for surgeons to use and provides better outcomes for patients than other fixation methods. These factors have combined to ensure that ProGrip™ is the first choice of mesh in our clinic."

Superior Peel Strength to Suture Fixation

100% stronger peel strength than absorbable fixation at 4 weeks.

Peak Peel Strength

<table>
<thead>
<tr>
<th>Week</th>
<th>Force</th>
<th>Median Peak Peel Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>4.7 lbs</td>
<td>20.9 N (Parietex ProGrip™)</td>
</tr>
<tr>
<td></td>
<td>3.9 lbs</td>
<td>17.3 N (Parietex™ with Polysorb™ Sutures)</td>
</tr>
<tr>
<td>Week 4</td>
<td>5.6 lbs</td>
<td>24.9 N (Parietex ProGrip™)</td>
</tr>
<tr>
<td></td>
<td>2.6 lbs</td>
<td>11.6 N (Parietex™ with Polysorb™ Sutures)</td>
</tr>
<tr>
<td>Week 8</td>
<td>4.6 lbs</td>
<td>20.5 N (Parietex ProGrip™)</td>
</tr>
<tr>
<td></td>
<td>3.3 lbs</td>
<td>14.8 N (Parietex™ with Polysorb™ Sutures)</td>
</tr>
</tbody>
</table>

Week 1
Median-peak peel strength of Parietex ProGrip™ self-fixating mesh is higher than the median-peak peel strength of Parietex™ fixed by absorbable sutures. (P=0.810)

Week 4
Median-peak peel strength of Parietex ProGrip™ self-fixating mesh is significantly higher than the median-peak peel strength of Parietex™ fixed by absorbable sutures. (P=0.001)

Week 8
Median-peak peel strength of Parietex ProGrip™ self-fixating mesh is higher than the median-peak peel strength of Parietex™ fixed by absorbable sutures. (P=0.041)

*A revolutionary idea has been developed which provides secure fixation of the entire surface of the prosthetic mesh to the posterior inguinal wall through resorbable microgrips. This provides self-gripping properties to the mesh the moment the mesh is applied."

### Reduced Patient Pain

Postoperatively patients with microgrip fixation reported 45% lower pain scores than patients with suture fixation.

At 6 months patients with microgrip fixation reported 70% lower pain scores than patients with suture fixation.

Findings of a double-blinded randomized study evaluating postoperative pain and the use of analgesics for a self-fixating mesh with microgrip technology vs. traditional suture-fixating Lichtenstein repair found:

- During traditional Lichtenstein repair (suture fixating) patients reported a significantly higher pain score on the first postoperative day
- The differences in pain (scores) were clear and remained consistent during the 6-month follow-up period


**Parietex ProGrip™ self-fixating mesh offers surgical efficiencies by combining the steps of placing and positioning the mesh with the actual fixation of mesh. In initial studies, positioning and fixating the mesh were completed in less than 60 seconds.**

Technical Data

Reduced Dosage of Analgesics

Patients with microgrip fixation were administered 48% less analgesics during their hospital stay.

Patients with microgrip fixation were administered a total of 42% less analgesics during and after their hospital stay.

Findings of a double-blinded randomized study evaluating postoperative pain and the use of analgesics for a self-fixating mesh with microgrip technology vs. traditional suture-fixating Lichtenstein repair found:

- Immediately after surgery the traditional suture fixing Lichtenstein repair patients required cumulatively higher analgesic doses
- The results remained consistent during the 6-month follow-up period


“This is the first randomized study to show a beneficial effect of the new self-fixating mesh on pain score. According to our investigations, operative time is reduced, which is a considerable fact with regard to economic aspects as well as the beneficial aspects for the patients.”

This study was conducted with Parietene ProGrip™.
An Effective and Durable Hernia Repair

Patients reported the following complication results at 2 years:

<table>
<thead>
<tr>
<th>Complications</th>
<th>Number of patients reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean pain (VAS/10)</td>
<td>Only one patient reported pain evaluated at 2/10</td>
</tr>
<tr>
<td>Seroma</td>
<td>0</td>
</tr>
<tr>
<td>Induration</td>
<td>0</td>
</tr>
<tr>
<td>Testicular pain</td>
<td>0</td>
</tr>
<tr>
<td>Recurrence</td>
<td>0</td>
</tr>
<tr>
<td>Mesh sepsis</td>
<td>0</td>
</tr>
</tbody>
</table>

(52 patients/70 hernias)

At 2 years patients showed no recurrence or complications.

A 24-month study following 52 patients who underwent inguinal hernia repair surgery reported an average low procedure time and no complications or recurrences at two years.

- No complications, with mean VAS score of 1.2 (out of 10) at discharge; only 44% of patients required analgesics
- At two years, there were no complications or recurrences; only one patient reported pain


"Dr. Philippe Chastan has produced data from a cohort of patients whose hernias have been repaired with ProGrip mesh and reported ease of surgery, short surgical time, low complications and excellent short-term outcomes."

Covidien has developed comprehensive online reimbursement resources for hernia and abdominal wall repair. You can reference the interactive US Hernia Reimbursement Guide at covidien.com/hernia for the most up-to-date codes and reimbursement rates.
Parietex ProGrip™ self-fixating mesh is a truly unique product that crosses the categories of synthetic mesh and fixation. The microgrip technology provides immediate, effective, tension-free fixation, leaving the use of additional fixation at the surgeon’s discretion. ProGrip™ is designed to provide a unique combination of surgical efficiency and patient benefits.

**Competitive Products Overview**

**TRADITIONAL HERNIA REPAIR METHOD REQUIRES MESH AND ADDITIONAL FIXATION.**

- Flat Sheet Mesh

**HERNIA REPAIR WITH MICROGRIP TECHNOLOGY.**

- Parietex ProGrip™ Self-Fixating Mesh

**Additional Fixation Optional**

- Suture
- OR
- Tack
- OR
- Glue†

†Not indicated for use in hernia repair; image representative of glue fixation with appropriate indications for use.
Packaging Overview

Box Dimensions:
215 mm x 20 mm x 310 mm

Each box contains a single, individually packaged mesh.

Product Order Codes

<table>
<thead>
<tr>
<th>Ordering Code</th>
<th>Size</th>
<th>Left Side</th>
<th>Right Side</th>
<th>Shape</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEM1208GL</td>
<td>12 x 8 cm (4.7”x 3”)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TEM1208GR</td>
<td>12 x 8 cm (4.7”x 3”)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TEM1409GL</td>
<td>14 x 9 cm (5.5”x 3.5”)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TEM1409GR</td>
<td>14 x 9 cm (5.5”x 3.5”)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>TEM1509G</td>
<td>15 x 9 cm (6”x 3.5”)</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>TEM1515G</td>
<td>15 x 15 cm (6”x 6”)</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

Ordering Information

COVIDIEN PRODUCTS WEBSITE: www.covidien.com/hernia

CUSTOMER SERVICE: 1-800-722-8772
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 or if you would like additional information, please contact your Covidien Sales Representative.
Parietex ProGrip™ Self-Fixating Mesh: THE FASTEST WAY TO PATIENT COMFORT
IMPORTANT
Please refer to the package insert for complete instructions, contraindications, warnings and precautions.