Value Analysis Committee

PROCEED® Surgical Mesh

Product Information Kit

Create an IPOM mesh optimized for strength and performance

Color sticky note represents customer insight.
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Trusted Solution for Laparoscopic and Open Intraperitoneal/Intra-abdominal Ventral Hernia Repairs

PROCEED® Surgical Mesh is a macroporous, partially absorbable, tissue-separating mesh

- Trusted by surgeons for over 10 years
- Designed for strength and performance
- Supports safe and comfortable healing
- In an in vitro study, PROCEED Mesh demonstrated bacteriostatic properties against bacteria commonly found in surgical site infections (MRSA, MRSE, VRE, and E. coli) *

*An in vitro study (24 hour study with inoculum challenge in the range of 10⁵-10⁶ CFUs) demonstrated bacteriostatic properties of PROCEED Mesh against MRSA, MRSE, VRE, and E. coli
**PROCEED® Surgical Mesh**

**Designed for Strength and Performance**

- Designed to withstand the maximum intra-abdominal pressure in healthy adults²⁴*

- Customizable⁵
  - Can be trimmed based on surgeon’s discretion, while leaving sufficient overlap to help prevent recurrence

- Blue stripes distinguish parietal side from visceral side⁵

- Versatility for both open and laparoscopic repairs⁵
  - Pliable mesh can be rolled for laparoscopic deployment and placement

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*Shown in a preclinical study

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*Open repair

*Laparoscopic repair

Supports Comfortable Healing

**PROCEED® Surgical Mesh** is built on Ethicon’s **Macroporous Partially Absorbable Mesh (MPPAM)** technology

- Macroporous polypropylene layer
  - Promotes host tissue penetration and fibrin fixation of the mesh to the tissue, helping to eliminate dead space and reduce risk of seroma formation
  - Allows patients to heal naturally
- Absorbable tissue-separating barrier
  - Bioresorbable oxidized regenerated cellulose (ORC) layer on visceral side helps minimize tissue attachment to mesh

**In a study from the International Hernia Mesh Registry (IHMR), patients receiving open hernia repair with PROCEED Mesh reported significant improvement in pain and movement limitations from baseline at 12 months postsurgery**

<table>
<thead>
<tr>
<th>Patient Reported Hernia Pain at Baseline and 12-months Post Surgery</th>
<th>CCS Mean Movement Limitation Score and 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>baseline</td>
<td>12 months Post Surgery</td>
</tr>
<tr>
<td>% of Patients</td>
<td>0%</td>
</tr>
<tr>
<td>Time-Point</td>
<td>Pre</td>
</tr>
</tbody>
</table>

**Results from a laparoscopic ventral hernia repair study showed low rates of complications and hernia recurrence at 2-year follow-up**

<table>
<thead>
<tr>
<th>Postoperative Complication</th>
<th>2 Year Follow-Up Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>0%</td>
</tr>
<tr>
<td>Pain or discomfort</td>
<td>4.7%</td>
</tr>
<tr>
<td>Recurrence</td>
<td>5.7%</td>
</tr>
</tbody>
</table>

*Data from an animal study
†PROCEED Mesh has an ORC component that should not be used in the presence of uncontrolled and/or active bleeding as fibrinous exudates may increase the chance of adhesion formation.
‡Data from a prospective, longitudinal study of 82 patients receiving open hernia repair using PROCEED Mesh from the IHMR. 95.1% ventral hernias, 4.9% umbilical hernias; mesh placement: preperitoneal (n=40), intraperitoneal (n=40), retrorectus (n=1), onlay (n=1)
§Data from a multicenter prospective observational cohort study of 210 patients undergoing primary laparoscopic ventral hernia repair (n=97) or incisional hernia repair using intra-abdominal placement of PROCEED Mesh
Device Details

PROCEED® Surgical Mesh is composed of three materials with distinct functions:

- **PROLENE® Soft Polypropylene Mesh** – nonabsorbable layer on the parietal side, as indicated by blue stripes, provides strength and allows for tissue ingrowth.

- **Oxidized regenerated cellulose (ORC) knitted fabric** – plant-based material on the visceral side provides a bioresorbable layer that physically separates the polypropylene mesh from underlying tissue and organ surfaces during wound healing, to minimize tissue attachment; absorbed within 4 weeks.

- **PDS® (polydioxanone) Suture polymer film** – creates a flexible, secure bond between the polypropylene mesh and ORC; absorbed within 6 months.

*An in vitro study (24 hour study with inoculum challenge in the range of $10^5$ to $10^6$ CFU's) demonstrated bacteriostatic properties of PROCEED Mesh against MRSA, MRSE, VRE, and E. coli.*
Available in a Range of Sizes

<table>
<thead>
<tr>
<th>Ordering Code</th>
<th>Mesh Size</th>
<th>Shape</th>
<th>How Supplied</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCDB1</td>
<td>5 cm x 10 cm</td>
<td>Rectangle</td>
<td>Sterile, 1 per box</td>
</tr>
<tr>
<td>PCDR1</td>
<td>7.5 cm x 15 cm</td>
<td>Rectangle</td>
<td>Sterile, 1 per box</td>
</tr>
<tr>
<td>PCDN1</td>
<td>10 cm x 15 cm</td>
<td>Oval</td>
<td>Sterile, 1 per box</td>
</tr>
<tr>
<td>PCDM1</td>
<td>15 cm x 15 cm</td>
<td>Square</td>
<td>Sterile, 1 per box</td>
</tr>
<tr>
<td>PCDD1</td>
<td>10 cm x 20 cm</td>
<td>Rectangle</td>
<td>Sterile, 1 per box</td>
</tr>
<tr>
<td>PCDG1</td>
<td>15 cm x 20 cm</td>
<td>Oval</td>
<td>Sterile, 1 per box</td>
</tr>
<tr>
<td>PCDH1</td>
<td>20 cm x 25 cm</td>
<td>Oval</td>
<td>Sterile, 1 per box</td>
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<tr>
<td>PCDJ1</td>
<td>20 cm x 30 cm</td>
<td>Rectangle</td>
<td>Sterile, 1 per box</td>
</tr>
<tr>
<td>PCDT1</td>
<td>26 cm x 34 cm</td>
<td>Oval</td>
<td>Sterile, 1 per box</td>
</tr>
<tr>
<td>PCDW1</td>
<td>25 cm x 35.5 cm</td>
<td>Rectangle</td>
<td>Sterile, 1 per box</td>
</tr>
<tr>
<td>PCDL1</td>
<td>30.5 cm x 30.5 cm</td>
<td>Square</td>
<td>Sterile, 1 per box</td>
</tr>
</tbody>
</table>

**How supplied**

PROCEED® Surgical Mesh is available in single packets as sterile devices in a variety of sizes and shapes.

**Indications for use**

PROCEED Mesh may be used for the repair of hernias and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.⁵

For complete indications, warnings, precautions, and adverse reactions, see pages 10-12.

See your Ethicon Sales Representative for more information.
# Mesh Conversion Chart

<table>
<thead>
<tr>
<th>PROCEED™ Surgical Mesh</th>
<th>Size / Shape</th>
<th>BARD VENTRALIGHT™ ST Mesh</th>
<th>BARD VENTRALIGHT™ ST Mesh with Echo PS™ Positioning System</th>
<th>MEDTRONIC SYMBOTEX™ Composite Mesh</th>
<th>MEDTRONIC PARIETEX™ Optimized Composite (PCOx) Mesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCDR1</td>
<td>7.5 cm x 15 cm (3&quot; x 6&quot;) Rectangle</td>
<td>5954460 10.2 cm x 15.2 cm</td>
<td>5955460 10.2 cm x 15.2 cm</td>
<td>SYM1510 SYM15100S 15 cm x 10 cm</td>
<td>PC01510X PC01510FX PC015100SX 15 cm x 10 cm</td>
</tr>
<tr>
<td>PCDN1</td>
<td>10 cm x 15 cm (4&quot; x 6&quot;) Oval</td>
<td>5954460 10.2 cm x 15.2 cm</td>
<td>5955460 10.2 cm x 15.2 cm</td>
<td>SYM1510 SYM15100S 15 cm x 10 cm</td>
<td>PC01510X PC01510FX PC015100SX 15 cm x 10 cm</td>
</tr>
<tr>
<td>PCDM1</td>
<td>15 cm x 15 cm (6&quot; x 6&quot;) Square</td>
<td>5954600 15.2 cm</td>
<td>5955600 15.2 cm</td>
<td>SYM15 15 cm</td>
<td>PC015X PC015FX 15 cm</td>
</tr>
<tr>
<td>PCDG1</td>
<td>15 cm x 20 cm (6&quot; x 8&quot;) Oval</td>
<td>5954680 15.2 cm x 20.3 cm</td>
<td>5955680 15.2 cm x 20.3 cm</td>
<td>SYM2015 SYM20150S 20 cm x 15 cm</td>
<td>PC02015X PC02015FX PC020150SX 20 cm x 15 cm</td>
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<tr>
<td>PCDH1</td>
<td>20 cm x 25 cm (8&quot; x 10&quot;) Oval</td>
<td>5954810 20.3 cm x 25.4 cm</td>
<td>5955810 20.3 cm x 25.4 cm</td>
<td>SYM2520 SYM25200S 25 cm x 20 cm</td>
<td>PC02520X PC02520FX PC025200SX 25 cm x 20 cm</td>
</tr>
<tr>
<td>PCDJ1</td>
<td>20 cm x 30 cm (8&quot; x 12&quot;) Rectangle</td>
<td>5954113 25.4 cm x 33 cm</td>
<td>5955113 25.4 cm x 33 cm</td>
<td>SYM3020 SYM30200S 30 cm x 20 cm</td>
<td>PC03020X PC03020FX PC030200SX 30 cm x 20 cm</td>
</tr>
<tr>
<td>PCDT1</td>
<td>26 cm x 34 cm (10&quot; x 13&quot;) Oval</td>
<td>5954113 25.4 cm x 33 cm</td>
<td>5955113 25.4 cm x 33 cm</td>
<td>SYM3728 37 cm x 28 cm</td>
<td>PC03728X PC03728FX 37 cm x 28 cm</td>
</tr>
<tr>
<td>PCDW1</td>
<td>25 cm x 35.5 cm (10&quot; x 14&quot;) Rectangle</td>
<td>5954113 25.4 cm x 33 cm</td>
<td>5955113 25.4 cm x 33 cm</td>
<td>SYM3728 37 cm x 28 cm</td>
<td>PC03728X PC03728FX 37 cm x 28 cm</td>
</tr>
<tr>
<td>PCDL1</td>
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<td>5954124 30.5 cm x 35.6 cm</td>
<td>5955124 30.5 cm x 35.6 cm</td>
<td>SYM4024E 40 cm x 24 cm</td>
<td>PC03728X PC03728FX 37 cm x 28 cm</td>
</tr>
</tbody>
</table>

The third-party trademarks used herein are trademarks of their respective owners.
Ordering Information

Product can be ordered direct through Johnson & Johnson Health Care Systems, Inc. (JJHS) and through distributor channels.

**Electronic ordering options**
Note: Placing orders electronically avoids minimum order fees for hospitals.

**Order 360™**: order360.jnjgateway.com
For questions about your order, visit the website or call 1-866-565-4283.

**Global Healthcare Exchange**: ghx.com
For questions about your order, visit the website or call 1-800-YOUR-GHX.

**Electronic Data Interchange**
Call JJHCS EDI Help Line: 1-800-262-2888.

**Nonelectronic/Manual ordering options**
Call JJHCS at 1-800-255-2500 (option 1) between 8:30 a.m. and 8:00 p.m. eastern time, or fax your order to 1-832-562-2212 or 1-800-997-1122. For more information or product support, call 1-877-ETHICON (384-4266).

**Customer support**
For product use assistance, clinical guidelines, service and repair, emergency assistance, copy of 510(k) clearance letter or complaints, please contact our Customer Support Center at customersupport@eesus.jnj.com or by calling 1-877-ETHICON (384-4266). Our support center is staffed 24 hours a day, 7 days a week by qualified nurses to answer your product-related questions.

For complete product details, see Instructions for Use. For more information, contact your local Ethicon representative or call 1-877-ETHICON (384-4266).
Instructions for Use
**PROCEED™ Surgical Mesh**

**DESCRIPTION**

PROCEED™ Surgical Mesh is a sterile, thin, flexible laminate mesh designed for the repair of hernias and other fascial deficiencies. The mesh product is comprised of an oxidized regenerated cellulose (ORC) fabric, and PROCEED™ Soft Mesh, a nonabsorbable polypropylene mesh, which is encapsulated by a polydioxanone polymer. The polypropylene mesh side of the product allows for tissue ingrowth, while the ORC side provides a biocompatible layer that physically separates the polypropylene mesh from underlying tissue and organ surfaces during the wound healing period to minimize tissue attachment to the mesh. The polydioxanone provides a bond to the ORC layer.

The PROCEED Soft Mesh component is constructed of interlocked filaments of extruded polypropylene identical in composition to that used in PROLINE™ Polypropylene Suture, Nonabsorbable Surgical Suture, U.S.P. (Ethicon, Inc.). This material, when used as a suture, has been reported to be reabsorbed and to retain its strength indefinitely in clinical use. The PROCEED™ Soft Mesh affords excellent strength, durability and surgical adaptability, with a porous structure to enable mesh incorporation into surrounding tissues.

The ORC component is an absorbable off-white knitted fabric prepared by the controlled oxidation of regenerated cellulose. The ORC layer is absorbed from the site of implantation within four (4) weeks. Absorption rate depends upon several factors, including the amount used and implantation site.

The polydioxanone components are made from the polyester, poly (dioxanone) polymer that is identical to the polymer used in PROLINE™ Polypropylene Suture, Synthetic Absorbable Suture, U.S.P. (Ethicon, Inc.). The polydioxanone polymer has been found to be nonantigenic, nonpyrogenic and to elicit only a mild tissue reaction during absorption. The polydioxanone component is absorbed within six (6) months.

**ACTIONS/PERFORMANCE**

PROCEED™ Mesh is a laminate mesh, whose PROCEED™ Soft Mesh component is included with nonabsorbable fibers, used to reinforce or bridge traumatic or surgical wounds to provide extended support during and following wound healing. The ORC is intended to physically separate the mesh from underlying tissue and organ surfaces during the critical wound-healing period, thereby reducing the severity and extent of tissue attachment to the mesh.

Animal studies show that implantation of PROCEED™ Mesh elicits a transient inflammatory reaction that does not interfere with integration of the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The ORC and polydioxanone components are essentially absorbed within six (6) months, whereas the polypropylene material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

Minimal visceral tissue attachment has been demonstrated in animal studies that show reduction in the extent and severity of adhesions to the mesh.

**INDICATIONS**

PROCEED™ Mesh may be used for the repair of hernias and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

**CONTRAINDICATIONS**

None known.

**WARNINGS**

When this mesh is used in infants, children, pregnant women or women planning pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

In animal studies, PROCEED™ Mesh did not potentiate infections. However, it is recommended that the mesh not be used following planned intraoperative or accidental opening of the gastro-intestinal tract. If the mesh is used in a contaminated field, contamination of the mesh may lead to infection that may require removal of the mesh.

PROCEED™ Mesh is provided by Ethicon, Inc. as a single-use, sterile product.

Do not resterilize/reuse. Recycle of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users. Do not use if packaging is opened or damaged. Discard opened unsterile products.

Users should be familiar with surgical procedures and techniques involving nonabsorbable meshes before using PROCEED™ Mesh.
Instructions for Use

PROCEED™ Mesh has an ORC component that should not be used in the presence of uncontrolled and/or active bleeding as fibrous exudates may increase the chance of adhesion formation. Foreign body reactions may occur in some patients.

PRECAUTIONS

The mesh should be shaped using sharp cutting instrumentation and in such a way that sufficient overlap of the fascial defect on all sides is achieved, thereby allowing adequate stabilization of each of the fascial borders. When cutting or shaping, use caution to avoid damaging the mesh. Do not soak or stretch PROCEED™ Mesh.

The safety and effectiveness of PROCEED™ Mesh in combination with solutions other than saline (such as peritoneal instillates, and/or medications) have not been studied.

ADVERSE REACTIONS

Potential adverse reactions with PROCEED™ Mesh implantation are those typically associated with surgically implantable materials, including infection, inflammation, seroma formation, acute or chronic pain, foreign body reaction, herniation, nerve damage, soft tissue injury, adhesion formation, fistula formation, extrusion/resection, excessive contraction or shrinkage of the tissue surrounding the mesh, and mesh failure/hernia recurrence.

INSTRUCTIONS FOR USE

Correct surface orientation is critical for PROCEED™ Mesh to function as intended. The polypropylene mesh side (side with the blue stripes) of the product should be placed adjacent to these tissues where tissue ingrowth is desired. The other surface, the ORC side, should be placed adjacent to these tissues where minimal tissue attachment is desired (i.e. visceral surfaces). This orientation is essential.

Uncontrolled and/or active bleeding should be controlled prior to placement of the PROCEED™ Mesh.

The mesh should be shaped in such a way that sufficient overlap of the fascial defect on all sides is achieved, thereby allowing adequate stabilization of each of the fascial borders.

To avoid distorting, crinkling or cutting of the edges, adequate mesh fixation is required to minimize post-operative complications and recurrence. The fixation technique, method and products used should follow the current standard of care. Careful attention to fixation and spacing will help prevent excessive tension or disruption between the mesh materials and connective tissue.

It is recommended that points of fixation be placed 6.5 mm to 12.5 mm (1/4” to 1/2") apart at a distance approximately 6.5 mm (1/4") from the edge of the mesh.

STORAGE

Store at or below 25°C. Do not use after expiry date.

HOW SUPPLIED

PROCEED™ Mesh is available in single packets as sterile, undyed sheets with blue stripes in a variety of sizes.

CAUTION

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

SYMBOLS USED ON LABELING

[Symbol explanations and instructions for use]
SEP 17 2003

Mr. Rey Librojo
Senior Project Manager, Regulatory Affairs
Ethicon, Inc.
Rt. #22 West
Somerville, New Jersey 08876-0151

Re: K031925
Trade/Device Name: PROCEED* Triaminate Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Polymeric surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: June 20, 2003
Received: June 27, 2003

Dear Mr. Librojo:

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 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/dome/dsmain.html

Sincerely yours,

Muriel Provost

Celia 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
510(k) Clearance Letter

INDICATIONS FOR USE

510(k) Number (if known): K#31925

Device Name: PROCEED* Trilaminate Surgical Mesh

Indications for Use: PROCEED Mesh may be used for the repair of hernias and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ❌ OR Over-The Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-9G)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K#31925

* Trademark
Clinical Evidence

The Global Evidence Database and the Clinical Evaluation Report: PROCEED® Surgical Mesh (December 4, 2014) were searched for published and unpublished clinical studies of PROCEED Mesh use for hernia repair. The 15 studies identified are summarized below.

Global Evidence Database

Laparoscopic Ventral Hernia Repair


Summary

This multi-center, prospective, non-controlled study evaluated the results of 210 patients undergoing primary laparoscopic ventral hernia repair or incisional hernia repair using an intra-abdominal placement of the PROCEED Mesh (Ethicon Inc., Johnson & Johnson, Somerville, NJ, USA).

At one year, the cumulative incidence of recurrence was 10 cases (n=192, 5.2%), and chronic discomfort or pain was observed in 4.7% of patients. There were no incidences of conversion to open repair, enterotomy, mesh infection or mortality. At two years, there was one additional recurrence.

The authors concluded that they had a favorable experience with the PROCEED Mesh in laparoscopic ventral hernia repair.

Objectives

To evaluate the efficacy and safety of the PROCEED Mesh in laparoscopic ventral hernia repair

Design

This was a multi-center, prospective, non-controlled study.

The primary endpoint was the recurrence rate at 1 year, where recurrence was defined as “any abdominal wall gap with or without bulge in the area of the midline scar perceptible or palpable by clinical examination.”

Secondary endpoints included postoperative morbidity, including seroma formation, mesh infections and recurrence after two years.

Subjects

Adult patients undergoing primary laparoscopic ventral hernia repair or incisional hernia repair between January 2008 and March 2009 in nine centers in Belgium.

Exclusion criteria were hostile abdomen with conversion from a laparoscopic to an open approach, emergency surgery and repair of a parastomal hernia.
Clinical Evidence

(Continued)

Procedures

Patients underwent primary laparoscopic ventral hernia repair or incisional hernia repair using an intra-abdominal placement of the PROCEED® Surgical Mesh (Ethicon Inc., Johnson & Johnson, Somerville, NJ, USA).

Follow-up was performed 3-6 weeks after surgery and 1 year and 2 years postoperatively.

Results

210 patients were included in the study (113 men and 97 women), of which there were 97 primary ventral and 103 incisional hernias after prior abdominal surgery, and 28 patients (13.3%) were treated for a recurrent incisional hernia. The mean age was 60 years.

At 3-6 weeks follow-up, there were 14 clinically palpable seromas without need for treatment.

There were no incidences of conversion to open repair, enterotomy, mesh infection or mortality.

At one year, the cumulative incidence of recurrence was 10 cases (n=192, 5.2%), and chronic discomfort or pain was observed in 4.7% of patients. At two years, there was one additional recurrence.

Twelve patients were re-operated during the first year due to recurrence (n=7), acute cholecystitis (n=2), trocar site hernia after gastric bypass (n=1) and pain (n=2).

Conclusions

The authors concluded that they experienced a favorable experience with the PROCEED Mesh in laparoscopic ventral hernia repair.
Clinical Evidence

Clinical Evaluation Report – PROCEED® Surgical Mesh (December 4, 2014)

Laparoscopic Ventral Hernia Repair


In a retrospective review with 27 patients followed for 23 months, Hussain (2012) evaluated postoperative complications after laparoscopic ventral hernia repair. In this study, transfixeding sutures and additional tacks were used for fixation. Primary hernia was diagnosed in 23 patients while 4 patients had recurrent hernias, with a mean duration of symptoms being 10 ± 11 months (range: 2-48 months). Seven of the 27 patients had risk factors of hypertension, and three were diabetic. Four additional patients were obese and had ischemic heart disease as pre-existing comorbidities. After surgery, 3 patients had seromas/hematomas, which resolved with conservative treatment. No recurrence or wound infections were observed. Pain was reported in 4 patients who improved after analgesic administration. The authors concluded that laparoscopic repair with PROCEED Mesh was an appropriate approach resulting in good quality repair and low complication rates.


Khalil (2012) reported a retrospective review including 27 patients followed for 13 months (mean) who underwent laparoscopic incisional ventral hernia repair. Mesh was fixated with an endoscopic stapler. The objective was to measure both short- and intermediate-term outcomes, which were evaluated postoperatively by clinical examination as well as ultrasound for complications or recurrence. No bowel injury or other intraoperative complication occurred. Seromas (n=5), wound infection (n=1), chest infections (n=2), and recurrence (n=1) were observed. Three of the seromas were treated conservatively and resolved spontaneously within 2 weeks. The remaining 2 cases required aspiration and improved after 5 weeks. Though ileus did occur in 2 patients, recovery was achieved with "simple measures" after 3 days. Seven patients were lost to follow-up after the first two visits at one and weeks post-discharge. There were no cases of mesh removal due to infection, and the single case of recurrence occurred in a high-risk morbidly obese patient with pre-existing chronic obstructive airway disease. The authors concluded that laparoscopic ventral hernia repair with PROCEED Mesh permitted rapid recovery and a low recurrence in short- and intermediate-term follow-up.


A retrospective analysis was conducted by Tollens (2011) in 86 obese and non-obese patients using PROCEED Mesh to laparoscopically repair incisional hernias to compare the recurrence rate in these two patient groups. Obesity was defined as Body Mass Index (BMI) ≥30 kg/m². Laparoscopic technique was used in 31 obese and 47 non-obese subjects. Two obese patients and 6 non-obese patients underwent hernia repair with the open technique. A variety of fixation methods were employed including EMS tackers, PROLENE® Polypropylene Suture, AbsorbaTack™ Fixation Device, SorbaFix™ Absorbable Fixation System, and ETHICON SECURESTRAP® Absorbable Strap Fixation Device. Mean follow-up was 14 months, ranging from 7.4 months to 22 months. Tollens and colleagues reported no wound or mesh infections but did note 4 recurrences among 78 retrospective cases. The postoperative stay ranged from 0-5 days, and the mean was 2 days. Overall, 12 patients (14%) developed seromas, 1 (1.2%) cellulitis of the abdominal wall, 1 (1.2%) ileus, and 1 (1.2%) persistence of pain at 1-year follow up. There were 4 (4.46%) recurrences (2 in patients with ≥30 kg/m² BMI and 2 in patients with <30 kg/m² BMI). No wound or mesh infections, bowel obstruction, or enteric fistulas occurred. The study demonstrates the utility of PROCEED Mesh in ventral hernia repair by a standardized laparoscopic technique or open technique. The equivalent recurrence rates between the obese and non-obese populations in this study indicated this mesh possesses adequate strength for use in obese patients.
Clinical Evidence


Bucher (2011) examined the use of PROCEED® Surgical Mesh on a new laparoscopic technique with a single-port access (SPA) for incisional and primary ventral hernia repair in an uncontrolled, prospective trial including 52 patients. The method of fixation used in this study was absorbable tacks (AbsorbaTack™ Fixation Device) and absorbable sutures. Patients with umbilical hernias (n=32), incisional hernias (n=14), inguinal hernia (n=1) and those with hernia of the linea alba (n=1) were included in this study. Follow-up was a mean of 16 months, ranging from the 3-28 months. SPA repair of primary and incisional ventral hernia was completed in all cases without conversion to standard laparoscopy. The median (range) hospital stay was 1 day (1-5 days). No intra-operative complications were noted. Notably, there were no cases of recurrence, 2 cases of seroma (treated conservatively), and 1 case of pain that resolved spontaneously after 3 months. Per the authors’ conclusions, SPA ventral hernia repair appears to be safe for experienced SPA surgeons.


Berrevoet (2009) conducted a multicenter, observational, single cohort study in 114 subjects using PROCEED Mesh fixed with tacks and transfascial sutures per the surgeon’s preference to evaluate outcomes of laparoscopic ventral hernia repair of primary hernia defects (umbilical, epigastric, and Spigel). Direct follow-up was done at 3 weeks, 3 months, and 6 months postoperatively and then by telephone using a standardized checklist at 12 months and yearly thereafter. The patients were followed for a mean of 27 months (range: 12-38 months) with outcomes including chronic pain (by oral analgesic use at 6 months), and the incidence of seroma, hematoma, wound or mesh infection, and recurrence. Four (3.5%) recurrences occurred with 3 of the 4 patients being reoperated. Twelve (10.5%) patients developed seromas or hematomas, with 4 of the 12 requiring treatment. Pain lasting greater than 6 months was reported in 2 patients (1.8%). One of these patients had pain at the tack fixation level and was treated with infiltrations of long-acting anesthetics while the other patient had pain due to adhesions, which were addressed in re-laparoscopy. An additional patient had urinary retention postoperatively (no treatment specified). The authors concluded that this study documented a favorable experience using a large-pore mesh in laparoscopic ventral hernia repair with no major complications related directly to the mesh.


Sodergren (2010) conducted a retrospective case series with 50 patients and 55 cases treated laparoscopically with PROCEED Mesh or Composix™ Mesh (Bard) fixated by a helical stapling device (ProTack™ 5 mm Fixation Device). Hernia types treated included epigastric (n=1), lumbar (n=1), umbilical (n=2), parastomal (n=8), and incisional (n=44). The median operating time was 50 minutes (range 30-120), and the median length of stay was 1 day (range 1-14). One procedure was abandoned due to the size of the hernia. Two (2) patients (36%) converted to open repair, and operative complications were reported in 2 patients (3.6%). Postoperatively, 12 patients (21.8%) developed minor morbidity, 2 (3.6%) wound infections, 1 (1.8%) was re-admitted due to pain, and 8 (14.5%) developed seromas. The seromas all resolved with conservative treatment. Six patients (10.9%) had recurrence; however, the authors note that all recurrences were associated with obese patients (mean BMI 37 kg/m²) and potential inadequate stapling – known risk factors. Two of the 6 recurrences were reported in one patient.
Clinical Evidence


Eriksen (2009) conducted a single-arm prospective, multicenter study in 35 patients with ventral hernias to evaluate pain and other recovery parameters post-laparoscopic hernia repair. PROCEED® Surgical Mesh was used in all patients. Mesh was fixated laparoscopically by the use of tacks (ProTack™ 5 mm Fixation Device). Discharge was planned for all patients on postoperative Day 2 with return to normal daily activities/work without risk. Self-assessment of pain, general wellbeing, fatigue, and quality of life were measured via SF-36 questionnaires. Patients were also asked to self-report nausea and overall bowel function. All assessments were made on the day of surgery, and again at Days 17, Day 30, and finally at the 6-month time point. All patients were also seen in the clinic at Day 30 and again at study end where physical examination was made and ultrasound performed. After one month, 23% of the patients developed seromas, 10% had superficial wound infections, and 6% reported hematomas. By study end, there was no reported recurrence, and all other complications resolved. The investigators concluded that laparoscopic ventral hernia repair was associated with considerable postoperative pain and fatigue in the first postoperative month, prolonging the time of convalescence and significantly affecting patients’ quality of life up to 6 months postoperatively. Mesh fixation with fibrin glue or other non-invasive/degradable products seems promising for reducing pain, and it should be investigated in future randomized trials.


Datta (2008) evaluated the clinical outcomes of laparoscopic ventral hernia repair after antecolic laparoscopic gastric bypass in this retrospective analysis of 26 patients (PROCEED Mesh: n=10; primary repair, n=8; hernia left in situ, n=8). The fixation method for the mesh implant was unspecified tacks. Outcomes were measured by the incidence of recurrence and other complications. Patients were followed for an average of 14 months (range: 4-30 months). No complications in the in situ group were noted. Two patients in the primary repair group developed small bowel obstruction, and both underwent laparoscopic bowel resection and ventral hernia repair without postoperative complications using PROCEED Mesh. No bowel obstruction, clinical evidence of recurrence or infection was reported in the original 10 PROCEED Mesh patients. One PROCEED Mesh patient reported chronic pain at 3 months postoperatively, which was resolved with transection of a single adhesive band attached to one of the tacks with no adhesions noted to the mesh itself.


Rosenberg (2008) conducted a retrospective study in 49 patients using PROCEED Mesh fixated with ProTack™ 5 mm Fixation Device to determine the feasibility of use in laparoscopic ventral hernia repair. Higher-risk patients were included in this with 16 patients being obese, 15 were smokers, and 7 had chronic obstructive pulmonary disease. Hernia types repaired in this study were Spigelian, umbilical, paraomental, incisional, and linea alba. The incidence of recurrence and postoperative complications constituted the measured outcomes. Patients were followed for a median of 17 months (range: 3-27 months). The median hospital stay was 1 day. Of the 49 patients, five developed postoperative complications. One patient developed a pulmonary embolism extending hospital stay to 37 days, one patient was diagnosed with uncomplicated pneumonia and recovered quickly, an additional patient developed respiratory unspecified respiratory complications and was hospitalized for 54 days; one patient had a small bowel perforation during repair of a stomal hernia necessitating re-laparotomy and mesh removal; the last of the five patients with postoperative complications developed an uncomplicated wound infection at the trocar site. There were no mesh infections or seromas observed. As there were no mesh infections or other mesh-related complications, the authors concluded that the use of PROCEED Mesh in laparoscopic ventral hernia repair was safe and effective even in some of the higher-risk patients who were obese or who had pulmonary disease.
Clinical Evidence

Laparoscopic and Open Ventral Hernia Repair


Moreno-Egea (2009) investigated PROCEED® Surgical Mesh, both in open (20 cases) and laparoscopic (30 cases) ventral repair with excellent safety results. Tacks (ProTack™ 5 mm Fixation Device) were used to fixate the mesh. The authors encountered one case of reintervention due to hemoperitoneum caused by a trocar, and no infections, no seroma, no intestinal occlusion, and no recurrence after 12 months follow-up. PROCEED Mesh was judged by the authors to be safe and well tolerated during incisional hernia repair.

Open Ventral Hernia Repair


Liu (2011) reported the use of PROCEED Mesh fixated by the use of interrupted 0 polypropylene sutures in 36 patients undergoing open surgery for large abdominal wall defects. This study included 22 patients with incisional hernia, 4 with recurrent incisional hernia, 2 with incarcerated incisional hernia, 2 with abdominal wall defects secondary to metastasized cancer, and 6 with desmoids tumor resections. Assessment was made at 3 weeks, 3 months, and finally at 6 months in the outpatient clinic. The mean total follow-up time was 28 months. Postoperatively, it was reported that 11 patients (30.6%) developed complications: 6 seromas, 1 minor wound infection, 1 wound sinus, 2 pulmonary infections, and 1 urinary tract infection. There were no instances of intestinal fistulas, problems related to intestinal adhesion, chronic wound pain, or mesh infections. No adhesion-related complications, recurrences, or mesh infections occurred. Liu and colleagues demonstrated that the intra-peritoneal repair technique for a large abdominal wall defect using PROCEED Mesh was a feasible and safe method in these patients with no report of major complications.


El-Shafei (2009) examined the use of PROCEED Mesh for the repair of abdominal wall defects in infants. In this study, there were 6 infants with major omphalocele, 5 with ventral hernia, 4 with burst abdomen, and 3 cases of incisional hernia. A fixation method of continuous PROLENE® Polypropylene Suture or interrupted ETHIBOND EXCEL® Polyester Suture was used. Outcomes were measured by the incidence of postoperative complications in this higher-risk population. The follow-up period was a mean of 14.7 months (range: 2-21 months). Complications included wound infection (4 cases, 2 of which were in cases with burst abdomen), stitch sinus (2), and seroma (8). The stitch sinus cases responded well to simple excision, and the seromas were successfully evacuated via drain resulting in complete resolution. All wound infections were managed conservatively and resolved with regular irrigation and dressing. One patient had skin necrosis, and one died due to a major heart anomaly; neither case attributed to the mesh device. Based on the study results, the authors concluded that PROCEED Mesh was an excellent alternative for bridging major congenital and acquiring abdominal wall defects in infants, in which direct closure could not be achieved, and direct contact between the mesh and the bowel cannot be avoided.*

*Warning* When this mesh is used in infants, children, pregnant women or women planning pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows. For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full instructions for use.
Clinical Evidence


Berrevoet (2013) captured 12-month patient-reported outcomes following implantation with PROCEED Mesh. The results included 82 patients who underwent open repair (preperitoneal, n=40; intraperitoneal, n=40; retrorectus, n=1; onlay, n=1). Of these, 4.9% were umbilical, and 95.1% were ventral; 82.9% were fixated with sutures. At 12 months post-op, 30.9% of patients reported symptomatic pain compared to 62.3% pre-surgery. The overall mean pain and movement limitation scores at 12 months had significantly decreased compared to pre-surgery. Complications at 12 months included recurrence (3.7%), seroma (6.1%), and hematoma (4.9%). No mesh infections were reported. Longitudinal data provided by the IHMR showed a low recurrence rate for open hernia repair using PROCEED Mesh. The 12-month post-surgery patient-reported Carolinas Comfort Scale™ data indicated a statistically significant improvement in pain and movement availability, thereby suggesting the success of open hernia repair using this mesh.

**Laparoscopic Inguinal Hernia Repair**


Wenbin (2010) investigated a modified trans-abdominal pre-peritoneal technique, also laparoscopic, for inguinal hernia repair in a large, prospective uncontrolled trial including 1,100 patients. This technique, using PROCEED® Surgical Mesh fixated by absorbable sutures and an endostapler, was shown to be safe with 0.9% recurrence rate, no infections, no migrations, and no adhesive ileus. A total of 1,002 (95%) patients were discharged within 48 hours and back to normal activity within 3 days. Other patients were all back to normal activities within 14 days. The authors reported that 902 (82%) of patients required only over-the-counter analgesics postoperatively with 198 patients (18%) requiring oral analgesics for 2 to 21 days, and 10 (0.9%) patients requiring analgesic medication for chronic pain. Two (2) cases of seroma and 10 cases of urinary retention were noted. Wenbin and colleagues posited that the modified laparoscopic hernioplasty is a safe and efficacious treatment option for primary inguinal hernia. The technique shows less operative time, rapid rehabilitation, less overall complications and discomfort, which lead to lower costs in this patient population.


Finley (2007) evaluated the use of 3 types of meshes (PROCEED Mesh, n=10; Marlex® Mesh, n=19; polypropylene cone mesh plug, n=19) in inguinal herniorrhaphy procedures concurrent with robot-assisted laparoscopic radical prostatectomies (RALP) versus historical controls. Fixation devices included DEXON™ S Suture or Tevdek® Non-Absorbable Suture (PROCEED Mesh, Marlex® Mesh) and ProTack™ 5 mm Fixation Device followed by suture in the case of the polypropylene cone mesh plug. Patients were assessed for postoperative complications for a median of 15.3 months (range: 1 week to 4.3 years). During the study, no recurrence was noted. One patient developed postoperative urine leakage and underwent subsequent revision (mesh product unidentified). No significant between-group differences in smoking history, analgesic use, blood loss, duration of hospital stay, or complications was found between the historic controls and mesh groups. The authors concluded that simultaneous repair of inguinal hernias during transperitoneal RALP was not only technically feasible but also effective without increased complications attributable to its application.

**Open Inguinal Hernia Repair**

No studies were found.
References