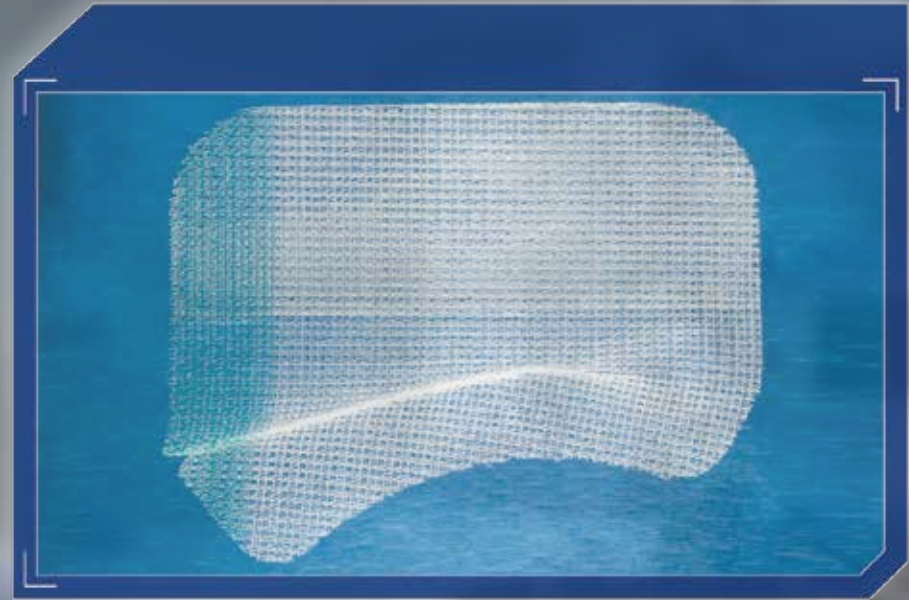


At Covidien, Hernia Care means

# LEADING THE FUTURE OF FIXATION

[ Innovation that matters ]

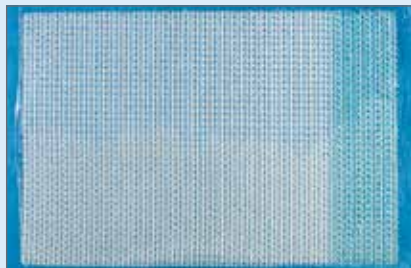
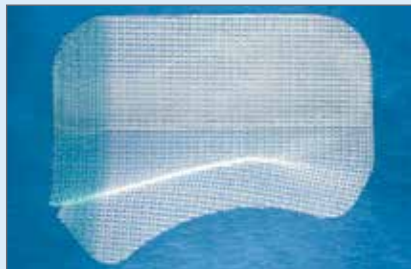
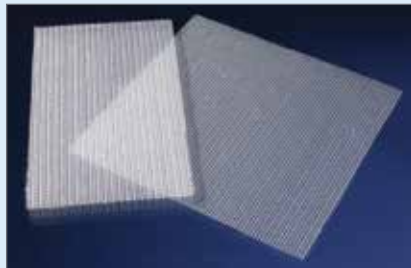


## ProGrip™ Laparoscopic Self-Fixating Mesh Value Analysis Committee — Product Information Kit

| HERNIA CARE | MESH • FIXATION • PERMACOL™ • DISSECTION

# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation



As a leader in hernia care, Covidien is defining the future of hernia mesh fixation with the ProGrip™ mesh family.

ProGrip™ mesh revolutionizes hernia repair by seamlessly combining mesh and fixation into one device, which potentially eliminates the need for additional tacks, sutures or glue.<sup>‡</sup> Unlike any other implant, the ProGrip™ mesh family of products features thousands of resorbable polylactic acid microgrips<sup>‡</sup> that provide immediate fixation over the entire anatomy.<sup>‡,Ω,†,1,2</sup> The atraumatic microgrips<sup>‡</sup> resorb over approximately 18 months leaving a lightweight, macroporous, hydrophilic polyester mesh that incorporates into the tissue more strongly than polypropylene mesh with tacks or glue.<sup>†,3,4</sup>

ProGrip™ self-gripping mesh for open inguinal hernia repair has been used and studied extensively and has shown to reduce patient pain as well as to shorten procedural times when compared to standard suturing techniques.<sup>5,6,7</sup> Designed specifically for ease of use in laparoscopic inguinal hernia repair, ProGrip™ laparoscopic self-fixating mesh extends the ProGrip™ mesh family. Combining the resorbable polylactic acid microgrip<sup>‡</sup> technology to a fast-resorbing film on the posterior side of the mesh, ProGrip™ laparoscopic self-fixating mesh delivers tack-free fixation over the entire anatomy<sup>‡</sup> thus eliminating the pain<sup>8,9</sup> and cost<sup>10</sup> associated with traditional fixation.

The ProGrip™ mesh family is available in a wide range of sizes and shapes for open incisional, open and laparoscopic inguinal hernia repairs.

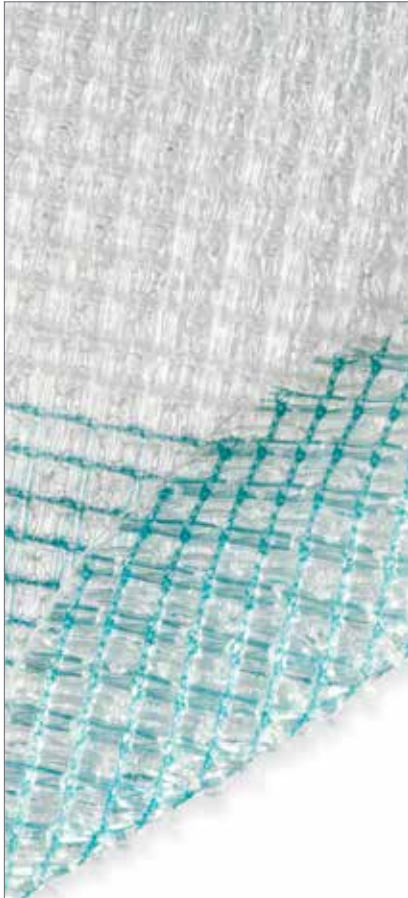


*positive results for life™*

# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

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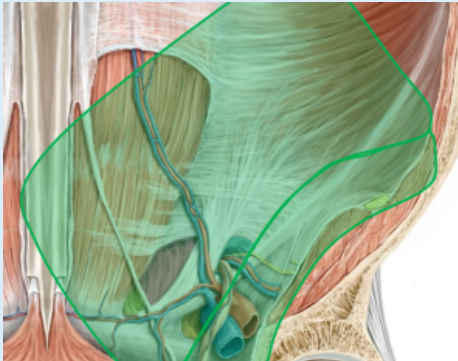
#### **MATERIALS MANAGEMENT INFORMATION**

- Packaging Overview
- Product Order Codes
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# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### PRODUCT OVERVIEW



Laparoscopic inguinal hernia repair is a well-established alternative to open inguinal repair with comparable outcomes. However, the use of tacks for mesh fixation can **increase the risk of chronic post-operative pain**.<sup>11</sup>

Designed to address key issues in laparoscopic inguinal hernia repair, ProGrip™ laparoscopic self-fixating mesh eliminates the pain<sup>8,9</sup> and cost<sup>10</sup> associated with tack fixation and provides tack-free fixation over the entire anatomy, including below the inguinal ligament where traditional tacks cannot be placed.<sup>†,Ω,2</sup>

#### LIHR — Laparoscopic Inguinal Hernia Repair

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## Why Should a Hospital Purchase ProGrip™ Laparoscopic Self-Fixating Mesh?

| Key Issues   | Traditional Tack and Mesh  | ProGrip™ Laparoscopic Mesh   |
|--|--|--|
| Overall, moderate to severe <b>chronic pain</b> experienced by 10-12% of LIHR patients <sup>12, 13</sup>         | Tack fixation can cause <b>trauma to the tissue</b> <sup>14</sup> <ul style="list-style-type: none"> <li>Increased post-operative pain</li> <li>Longer hospital stays</li> </ul>       | <b>Eliminates the pain</b> associated with traditional tack fixation <sup>8,9</sup>  |
| <b>Increasing cost pressure</b> on equipment, especially in laparoscopic procedures                              | US hospitals pay <b>upwards of \$720 per case</b> for tack fixation and mesh <sup>15</sup>   | Combines the functionality of <b>mesh and fixation into one product</b> <ul style="list-style-type: none"> <li>Reduces cost associated with traditional tack fixation and/or glues<sup>10</sup></li> </ul> |
| <b>Up to 2.84% recurrence rate in LIHR</b> and often occurring along the inferior edge of the mesh <sup>13</sup> | Tacking <b>below the inguinal ligament</b> is contraindicated <sup>16</sup> <ul style="list-style-type: none"> <li>Medially due to vessels</li> <li>Laterally due to nerves</li> </ul> | Delivers <b>tack-free fixation over the entire anatomy</b> , including below the inguinal ligament where tacks cannot be placed <sup>†,Ω,2</sup>   |

The future of laparoscopic inguinal fixation will reduce pain and provide fixation of the entire surface while lowering the cost of the procedure.

# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

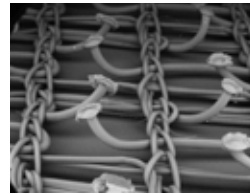
### PRODUCT OVERVIEW

#### ProGrip™ laparoscopic self-fixating mesh:

- **Increases the security** of the laparoscopic inguinal hernia repair<sup>†,Ω,1,2,3</sup>
- **Eliminates the pain** associated with traditional tack fixation<sup>Ω,8,9</sup>
- Is **easy to use** and **faster** than tacks<sup>†,18,20</sup>
- **Lowers the cost** of the laparoscopic inguinal procedure by combining the functionality of mesh and fixation into one device<sup>10,15</sup>

### What are the Competitive Advantages of ProGrip™ Laparoscopic Self-Fixating Mesh?

#### Self-Fixating



- More than 5,000 microgrips<sup>Σ</sup> eliminate the need for traditional tack fixation or glue<sup>†,1,1,17</sup>
- Superior fixation strength compared to Bard 3DMax™ light textile with SorbaFix™ tacks or fibrin sealant<sup>†,3</sup>
- Equivalent recurrence rate compared to laparoscopic repair with fixation<sup>Ω,†,8,9,10</sup>
- Tack-free fixation over the entire anatomy, including below the inguinal ligament where tacks cannot be placed<sup>†,Ω,2</sup>

#### Less Pain



- Eliminates the pain associated with traditional tack fixation<sup>Ω,8,9</sup>
- Low post-operative pain and fast recovery in laparoscopic inguinal hernia repair<sup>Ω,8,9,10,18</sup>
- 40% of the mesh weight resorbs reducing foreign material presence in patient over time<sup>†,19</sup>
- Resorbable, atraumatic microgrips<sup>Σ</sup> preserve cord and nerve structures<sup>†,Ω,2</sup>

#### Easy to Use



- Doesn't stick to itself making it easy to handle and unfold laparoscopically<sup>†,20</sup>
- Faster than tacks or glue<sup>18</sup>
- Easy to orient with green medial marking

#### Lower Cost<sup>15</sup>



- Combines the functionality of mesh and fixation into one device
- Reduces the cost associated with traditional tack fixation and/or glues<sup>10</sup>
- Less post-operative pain may result in lower cost of pain management therapy<sup>Ω,21</sup>

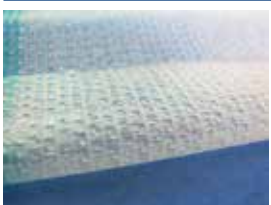


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# ProGrip™ Laparoscopic Self-Fixating Mesh

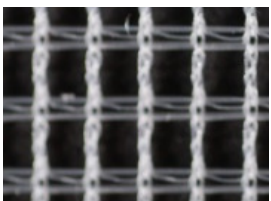
## The Future of Fixation

### PRODUCT DIAGRAM



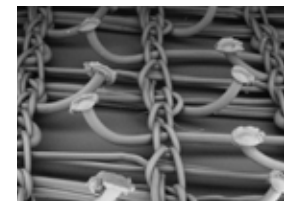
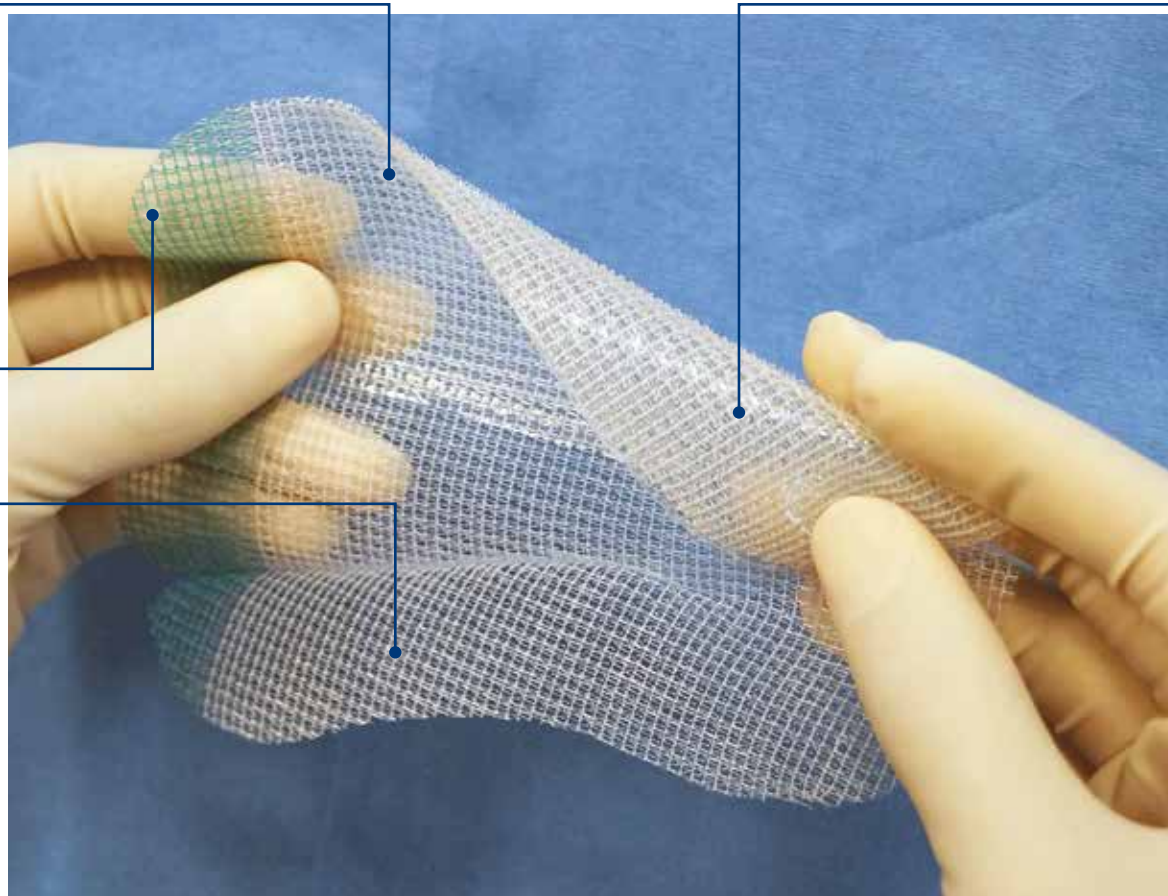
Fast resorbing film on posterior side for easy deployment<sup>†,20</sup>

Green medial marking to aid in orientation



Lightweight, semi-resorbable construction reduces foreign material in patient<sup>†,19</sup>

Macroporous, hydrophilic textile promotes rapid tissue integration<sup>†,22</sup>



More than 5,000 resorbable PLA microgrips<sup>‡</sup> eliminate the need for traditional fixation<sup>†,1,17</sup>

Tack-free fixation over the entire anatomy, even in places where traditional fixation cannot be placed<sup>†,0,2</sup>



3D shape conforms to the anatomy

Available in flat as well as left and right anatomical configurations for versatility

# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### PRODUCT FEATURES

#### Device Classification

Surgical mesh used for the reinforcement of soft tissues during surgical repair and more specifically indicated in the treatment of laparoscopic inguinal hernia repair.

#### Flat Sheet Design



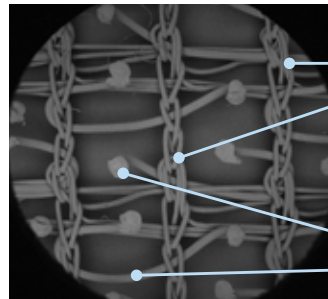
#### Anatomical Design



#### Technical Specifications<sup>†,1,19,20,23,24</sup>

|  |   |
|--|---|
| Textile Material                             | Monofilament Polyethylene Terephthalate (PET) |
| Microgrip Material                           | Monofilament Polylactic Acid (PLA)            |
| Microgrips/cm <sup>2</sup>                   | 36  |
| Microgrip Absorption Time                    | >18 Months                                    |
| Fast Resorbing Film Composition              | 70% Collagen, 30% Glycerol                    |
| Fast Resorbing Film Dissolution Time         | <1 Day  |
| Weight Before Absorption (g/m <sup>2</sup> ) | 82  |
| Weight After Absorption (g/m <sup>2</sup> )  | 49 (lightweight)                              |
| Pore Size (mm) (height by width)             | 1.8 x 1.8 (macroporous)                       |
| Sterilization Method                         | Ethylene Oxide                                |
| Shelf-Life                                   | 18 Months                                     |

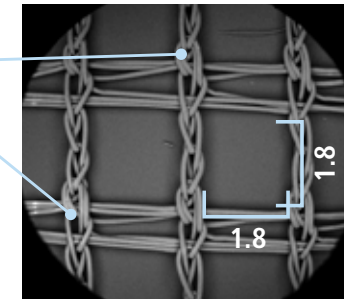
#### Pre-PLA Absorption



Monofilament  
Non-Resorbable  
PET textile

Monofilament  
Resorbable PLA  
Microgrips

#### Post-PLA Absorption




# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

510(K) CLEARANCE

DEC. 12. 2012 11:06AM NO. 1766 P. 1/3

 DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service  
Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - W066-0009  
Silver Spring, MD 20993-0002

Sofradim Production  
% Covidien LLC, Soft Tissue Implants  
Mr. James McMahon  
Associate Director, Regulatory Affairs  
15 Crosby Drive  
Bedford, Massachusetts 01730  
December 11, 2012

Re: K123479  
Trade/Device Name: PROGRIP™ Laparoscopic Self-Fixating Mesh  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: II  
Product Code: FTL  
Dated: November 09, 2012  
Received: November 19, 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: CDHRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (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.

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

DEC. 12. 2012 11:06AM NO. 1766 P. 2/3

Page 2 - Mr. James McMahon

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 systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffice/ucm115809.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 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/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) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Peter D. Rumm -S  
Mark N. Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

DEC. 12. 2012 11:07AM NO. 1766 P. 3/3

INDICATION FOR USE STATEMENT

510(k) Number (if known): K123479

Device Name: PROGRIP™ Laparoscopic Self-Fixating Mesh

Indications for Use:

PROGRIP™ Laparoscopic Self-Fixating Mesh is indicated for the reinforcement of soft tissues during repair of inguinal hernia defects by laparoscopic approach.

Prescription Use X AND/OR Over-the-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDHR, Office of Device Evaluation (ODE)

David Krause  
(Division Sign-Off)  
Division of Surgical Devices  
510(k) Number: K123479



# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### INSTRUCTIONS FOR USE\*

## ProGrip™ Laparoscopic Self-Fixating Mesh

EN

#### 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 reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or re-sterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or re-sterilize this device.

##### DESCRIPTION

ProGrip™ laparoscopic self-fixating mesh is available in 2 forms:

- Anatomical mesh
- Rectangular mesh

The mesh is made of knitted monofilament polyester with monofilament polylactic acid resorbable grips on one side and a resorbable film made of collagen from porcine origin and glycerol, on the other side. The grips allow positioning and fixation of the mesh to the surrounding tissue, while the collagen film facilitates mesh handling and deployment. The mesh presents a green band (polyester dyed with D&C green no. 6) to facilitate their orientation.

The monofilament polylactic acid grips are bioresorbable and provide the fixation of the mesh to surrounding tissue for at least 8 weeks. The polylactic acid grips degrade and resorb in vivo by hydrolysis and are metabolized by the body into CO<sub>2</sub> and H<sub>2</sub>O.

##### INDICATIONS

ProGrip™ laparoscopic self-fixating mesh is indicated for the reinforcement of soft tissues during repair of inguinal hernia defects by laparoscopic approach.

##### CONTRAINDICATIONS

- As ProGrip™ laparoscopic self-fixating mesh will not stretch to accommodate growth, its use may not be appropriate in patients in a period of growth.
- Any foreign material may potentiate or prolong infection in the presence of bacterial contamination, and as such, the use of ProGrip™ laparoscopic self-fixating mesh may not be appropriate in infected or contaminated sites. Furthermore, this product should be used with the understanding that infection may require removal of the mesh.
- The collagen film is not intended to minimize tissue attachment, thus this product cannot be used intraperitoneally.

##### ADVERSE REACTIONS

The possible complications associated with the use of ProGrip™ laparoscopic self-fixating mesh are those typically associated with surgically implantable materials: seroma, hematoma, recurrence, inflammation, chronic pain, infection, allergic reactions to the components of the product.

##### WARNINGS

- The mesh can be re-cut to size provided a sufficient overlap is kept on all sides of the defect. If the mesh is re-cut, the use of additional fixation should be considered depending on size and type of hernia and patient's condition to limit the risk of recurrence.
- To avoid injury, careful attention is required if fixating the device in the presence of nerves or vessels.
- If an anatomical mesh is re-cut, special care should be taken to preserve the sewing to limit the risk of recurrence.
- To limit the risk of recurrence, excessive tension should be avoided on the ProGrip™ laparoscopic self-fixating mesh and on the fixation points if any, to account for wound shrinkage during the healing process.
- The effectiveness and safety related to the use of this device in pregnant women have not been established.

##### PRECAUTIONS

- The mesh should only be used by experienced practitioners who do so under their own responsibility.
- The mesh is provided in a double sterile packaging. It is recommended to open the last packaging only for the placement of the mesh and to handle the latter using clean gloves and instruments.
- The mesh must be hydrated for a few seconds in a sterile saline solution before use.

##### OPERATING STEPS

1. For the anatomical mesh, the right and left mesh are identified on the labels as such: "RIGHT" means the right side of patient and "LEFT" means left side of patient.
2. ProGrip™ laparoscopic self-fixating mesh needs to be hydrated for a few seconds in a sterile saline solution before use.
3. Rolling/folding of the mesh:
  - a. For the rectangular mesh, it is recommended to roll the mesh in the length-wise direction.
  - b. For the anatomical mesh, it is recommended to fold the mesh on itself, grips outside, length-wise, starting at the anatomical flap seam.
4. Grasp the mesh at either end and insert it through the trocar of a minimum of 10mm in size.
5. Deploy the mesh in the inguinal area.
6. Place the green band towards the pubic zone and the polylactic acid grips in contact with the surrounding tissue.
7. The textile self-fixating feature allows positioning of the mesh without

##### STERILIZATION

Single-use device. Sterilized by ethylene oxide. Do not re-sterilize.

\*Full IFU available, part #1036353

# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### INSTRUCTIONS FOR USE

#### STORAGE

Store at room temperature.

AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES: DO NOT USE PRODUCT IF TEMPERATURE DOT (111°F / 44°C) ON PACKAGE IS BLACK.

Do not use the device past the last day of the labeled month of expiration.

Upon receipt of shipment, ensure that the packaging is not open or damaged and retains its sealed integrity. Do not use the device if the integrity of the packaging appears compromised.

#### TRACEABILITY

A traceability label is attached to every device package which identifies the type and lot number of the device. This label should be affixed to the patient's permanent medical record to clearly identify the device which was implanted.



Do not use if package is opened or damaged. / Ne pas utiliser en cas d'endommagement ou d'ouverture de l'emballage. / Bei geöffnet oder beschädigter Verpackung nicht verwenden. / Non utilizzare se la confezione è aperta o danneggiata. / No usar el dispositivo si la envoltura está abierta o dañada. / Não utilizar se a embalagem estiver aberta ou danificada. / Niet gebruiken als de verpakking beschadigd of geopend is. / Får ej användas om förpackningen är öppnad eller skadad. / Må ikke anvendes, hvis emballagen er åbnet eller beskadiget. / Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut. / Μη χρησιμοποιείτε αν η συσκευασία έχει ανοιχτεί ή υποστεί ζημιά. / Nie stosować, jeżeli opakowanie zostało otwarte lub uszkodzone. / Ambalaj açılmış ya da zarar görmüşse kullanmayın. / Не использовать изделие, если упаковка вскрыта или повреждена. / Pokud je balení otevřené nebo poškozené, produkt nepoužívejte. / Tilos felhasználni, ha a csomagolás kinyílt vagy megsérült. / Nepoužívajte, ak je obal otvorený alebo poškodený. / Skal ikke brukes hvis emballasjen er åpnet eller skadet. / Ne uporabljajte, če je embalaža odprta ali poškodovana. / 如果包装已打开或破损，请勿使用。 / 如果包装已開啟或損毀，則請勿使用。 / 포장 이 개봉되어 있거나 손상된 경우에는 사용하지 마십시오. / Не използвайте, ако опаковката е отворена или повредена. / A nu se utiliza în cazul în care ambalajul este deschis sau deteriorat. / Arge kasutage, kui pakend on avatud või kahjustatud. / Nelietot, ja iepakojums ir atvērts vai bojāts. / Ne koristite ako je pakiranje otvoreno ili oštećeno. / Ne koristiti ako je pakovanje otvoreno ili oštećeno. / Nenaudokite, jei pakuotė atidaryta arba pažeista.

STERILE EO



Single use

Rx  
ONLY



Do not  
resterilize



Caution, consult  
accompanying  
documents



Upper temperature  
limit

CE  
0459

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Made in France. 2012/11 - 1

\*Full IFU available, part #: 1036353



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# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### TECHNICAL DATA

#### Superior Fixation Strength Compared to Bard 3DMax™ Light Mesh†,3,4

##### Immediate Fixation†,4

- ProGrip™ laparoscopic self-fixating mesh vs Bard 3DMax™ light mesh with Baxter Tisseel™ fibrin sealant vs Bard 3DMax™ light mesh with SorbaFix™ tacks
- 6x6 cm mesh implanted in a porcine model (8 pigs)
- Samples explanted at 24 hours postoperatively, peritoneum removed, 3 cm defect created, peritoneum replaced
- Displacement, contact area and return to initial position recorded

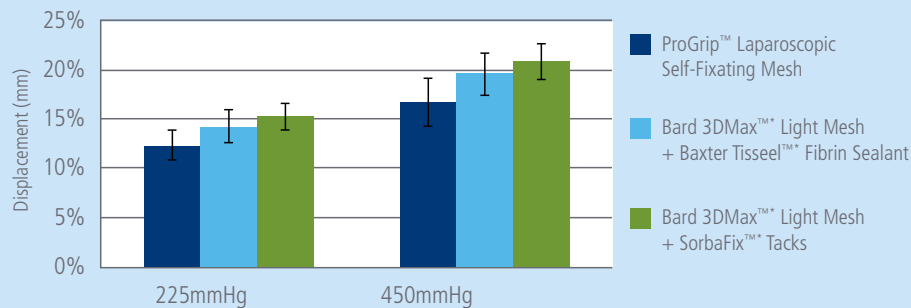


##### Long-term Fixation Strength†,3

- ProGrip™ laparoscopic self-fixating mesh vs Bard 3DMax™ light mesh with Baxter Tisseel™ fibrin sealant vs Bard 3DMax™ light mesh with SorbaFix™ tacks
- 5x10 cm mesh implanted in a porcine model
- Samples explanted at 4 and 8 weeks
- Peel strength test to measure fixation strength

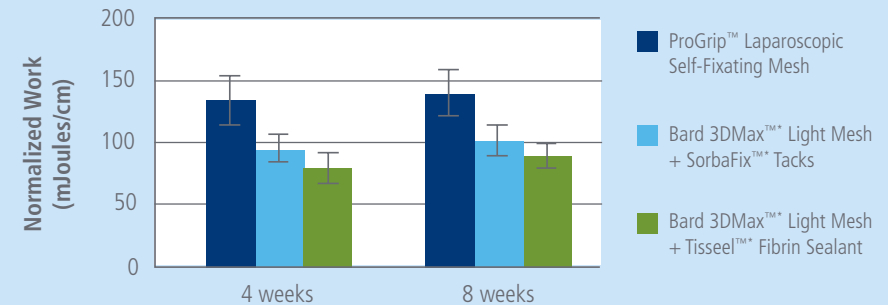


#### Mesh Displacement†



- ProGrip™ laparoscopic self-fixating mesh exhibited the lowest displacement through the defect and the highest contact area at any pressure step.
- Bard 3DMax™ light mesh with SorbaFix™ tacks and Baxter Tisseel™ fibrin sealant fail under physiological pressure (<250 mmHg); no dislocation was recorded for ProGrip™ laparoscopic self-fixating mesh even at high pressures (up to 450 mmHg).

#### In-Vivo Fixation Comparison†

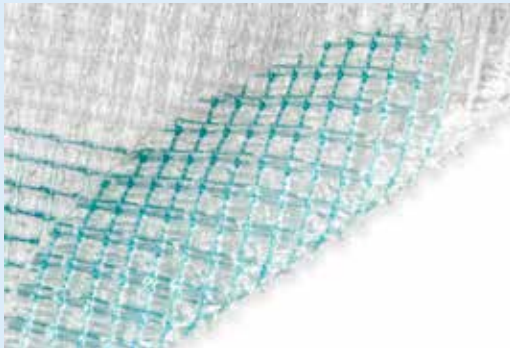


- At 4 and 8 weeks, ProGrip™ laparoscopic self-fixating mesh has statistically superior fixation strength than Bard 3DMax™ light mesh with tacks and glue.

# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### TECHNICAL DATA



ProGrip™ self-gripping mesh has been used extensively in Open Inguinal Hernia Repair and has also been successfully tested in laparoscopic procedures.

LIHR — Laparoscopic Inguinal Hernia Repair

<sup>o</sup>ProGrip™ laparoscopic self-fixating mesh and ProGrip™ self-gripping mesh have equivalent gripping and mechanical properties

## Low Complication and Recurrence Rates in Laparoscopic Inguinal Hernia Repair<sup>o,t,9,10,18</sup>

| ProGrip™ Self-Gripping Mesh in LIHR |                       |
|-------------------------------------|-----------------------|
| Trials/Patients                     | 3/130                 |
| Follow-up (months)                  | 6.2 – 24 (mean: 20.8) |
| Wound Infection (%)                 | 0                     |
| Seroma (%)                          | 3.9 (0 – 6.7)         |
| Hematoma (%)                        | 2.1 (0 – 3.3)         |
| Chronic Pain Rate (%)               | 0                     |
| Testicular Problem (%)              | 0                     |
| Urinary Retention (%)               | 2.3 (0 – 16.7)        |
| Recurrence (%)                      | 1.3                   |

ProGrip™ self-gripping mesh used in laparoscopic inguinal hernia repair has demonstrated less complications and recurrences than traditional meshes.<sup>o,t,9,10,18</sup>



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# ProGrip™ Laparoscopic Self-Fixating Mesh

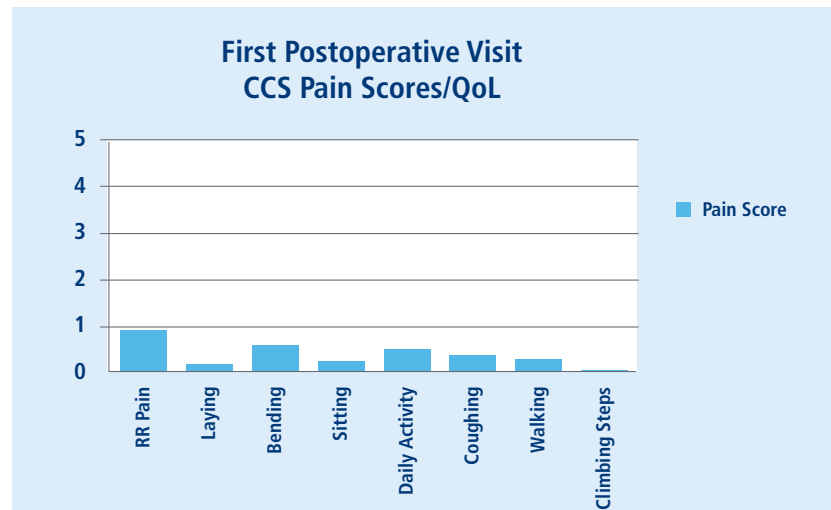
## The Future of Fixation

### TECHNICAL DATA

## Low Postoperative Pain and Fast Recovery in Laparoscopic Inguinal Hernia Repair<sup>2,8,9</sup>

### Totally ExtraPeritoneal (TEP) Procedure<sup>8</sup>

- On-going prospective study — Dr. Jacob and Dr. Laxa (USA)
- 64 hernias (34 patients) repaired with ProGrip™ self-gripping mesh
- 3 – 6 month follow-up



### Interim Results

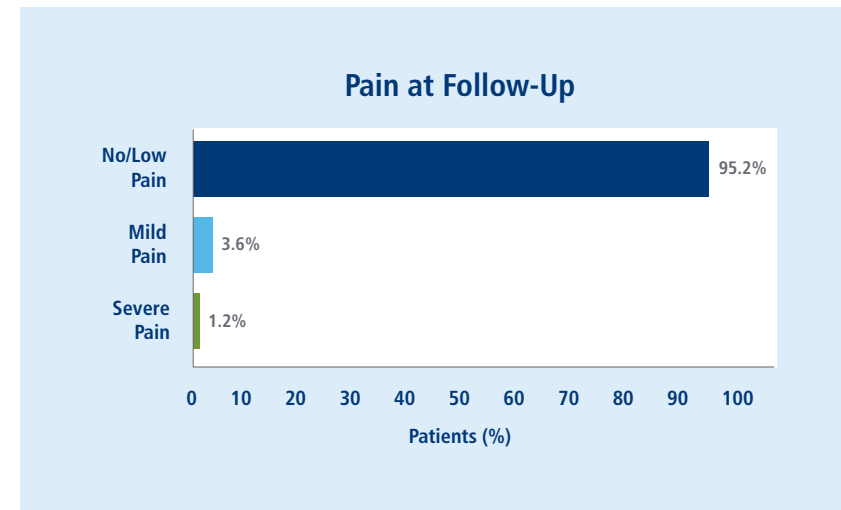
- Excellent early outcomes with no recurrence
- Very low pain scores at discharge and at the first postoperative visit (7.7% of patients had mean CCS scores > 1 at the initial postoperative visit)
- Return to full activity was 2.1 days and to work 4.5 days

CCS — Carolinas Comfort Scale

<sup>9</sup>ProGrip™ laparoscopic self-fixating mesh and ProGrip™ self-gripping mesh have equivalent gripping and mechanical properties

### TransAbdominal PrePeritoneal (TAPP) Procedure<sup>9</sup>

- Retrospective/prospective study — Dr. Birk et al (Germany)
- 220 hernias (169 patients) treated with ProGrip™ self-gripping mesh
- 22.8 month (14.5 – 36.2) follow-up



### Final Results

- Safe and effective with 1.78% recurrence rate
- Low pain rates: 98.8% of patients had no/low to mild pain
- “Cost effective” approach (Dr. Birk)

# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### TECHNICAL DATA

#### Low Postoperative Pain Through ProGrip™ Technology<sup>Ω,5,6,7</sup>

ProGrip™ self-gripping mesh has been used and studied extensively and has demonstrated low patient pain rates in Open Inguinal Hernia Repair.<sup>Ω,5,6,7</sup>

| Author                     | Pain Chapter I |
|----------------------------|----------------|
| Kingsnorth <sup>5</sup>    | •              |
| Chastan <sup>25</sup>      | •              |
| Hollinsky                  |                |
| Kolbe                      |                |
| Kapischke <sup>6</sup>     | •              |
| Quyn <sup>7</sup>          | •              |
| Pedano <sup>26</sup>       | •              |
| Justinger                  |                |
| Garcia Ureña <sup>27</sup> | •              |
| Nienhuijs <sup>28</sup>    | •              |
| Pierides <sup>29</sup>     | •              |
| Esteban                    |                |
| Anadol <sup>30</sup>       | •              |

#### Early Postoperative Pain (1 to 7 days)

| Author (Oxford Classification)  | ProGrip™ Mesh   | Flat Mesh  | p-Value                 | Measurement Scale <sup>Ω</sup>   |
|---------------------------------|---|--|-------------------------|--|
| Kingsnorth <sup>5</sup> (1b)    | -10% at discharge<br>-13% at 7 days                                   | + 39% at discharge<br>+21% at 7 days                                 | 0.007<br>0.039          | 0 – 15 cm VAS™<br>(% Reduction)  |
| Chastan <sup>25</sup> (2b)      | 1.3 at discharge  | NA (Obs.)  | -                       | 0 – 10 cm VAS™   |
| Kapischke <sup>6</sup> (2b)     | 1.79 at 1 day   | 3.23 at 1 day  | 0.031                   | 0 – 10 cm VAS™   |
| Garcia Ureña <sup>27</sup> (2b) | 2.5 ± 1.8 at 7 days   | NA (Obs.)  | <0.001                  | 0 – 10 cm VAS™<br><small>The statistical significance is calculated on the difference of pain compared to baseline after 7 days.</small> |
| Anadol <sup>30</sup> (2a)       | 2.73 ± 1.72 at 12 hrs<br>1.23 ± 1.25 at 24 hrs<br>1.1 ± .92 at 7 days | 4.4 ± 1.65 at 12 hrs<br>1.9 ± 1.09 at 24 hrs<br>1.8 ± 1.42 at 7 days | 0.843<br>0.545<br>0.131 | 0 – 10 cm VAS™   |

#### Chronic Pain (beyond 3 months)

| Author (Oxford Classification)           | ProGrip™ Mesh                      | Other Mesh                         | p-Value        | Measurement Scale <sup>Ω</sup>   |
|--|------------------------------------|------------------------------------|----------------|--|
| Chastan <sup>25</sup> (2b)               | 0 at 1 year<br>0 at 2 year         | NA (Obs.)                          | -              | 0 – 10 cm VAS™   |
| Kapischke <sup>6</sup> (2b) <sup>6</sup> | 0.38                               | 1.26                               | 0.07           | 0 – 10 cm VAS™   |
| Quyn <sup>7</sup> (2b) <sup>7</sup>      | 7.9% at 6 months<br>6.3% at 1 year | 21% at 6 months<br>18.8% at 1 year | <0.05<br><0.05 | SF36 questionnaire<br>% of patients reporting pain   |
| Pedano <sup>26</sup> (2a)                | 4% at 17 months                    | NA (Obs.)                          | -              | Collection methodology not specified   |
| Garcia Ureña <sup>27</sup> (2b)          | 0.4 ± 0.9 at 6 months              | NA (Obs.)                          | <0.001         | 0 – 10 cm VAS™<br><small>The statistical significance is calculated on the difference of pain compared to baseline after 6 months.</small> |

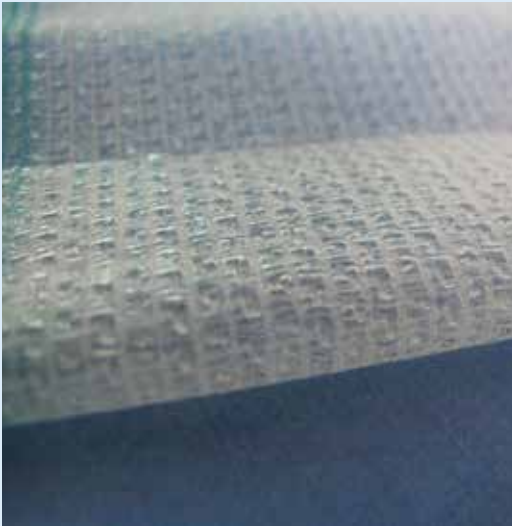
The physical and mechanical properties of ProGrip™ self-gripping polypropylene mesh are at least equivalent to those of ProGrip™ self-gripping polyester mesh.<sup>†,31</sup>

<sup>Ω</sup>The pain scores are expressed in variation compared to the baseline, ie. the pain just before surgery.

# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### TECHNICAL DATA



Thanks to the fast-resorbing film on the posterior side, ProGrip™ laparoscopic self-fixating mesh:

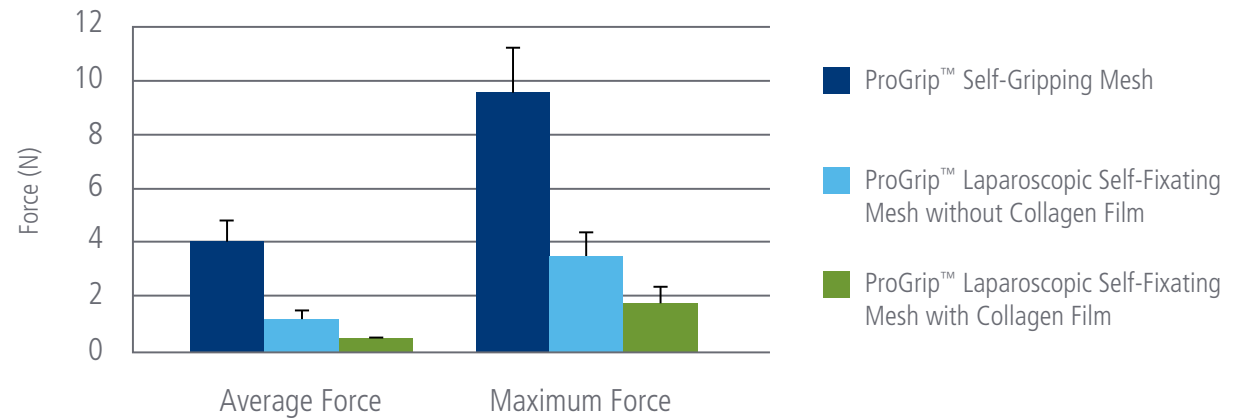
- ☑ Is **10x easier to deploy** than ProGrip™ self-gripping mesh<sup>1,20</sup>
- ☑ Requires **90% less force to unroll** than ProGrip™ self-gripping mesh<sup>1,20</sup>
- ☑ Provides **equivalent tissue engagement** compared to ProGrip™ self-gripping mesh<sup>1,1</sup>

### Easy to Handle and Unfold Laparoscopically<sup>†,20</sup>

#### Test Protocol:

- 3 samples (5 x 10 cm):
  - ProGrip™ self-gripping mesh
  - ProGrip™ laparoscopic self-fixating mesh with collagen film
  - ProGrip™ laparoscopic self-fixating mesh without collagen film
- Sample rolled, inserted into a trocar and submitted to elongation using a tension machine
- Average and maximum forces recorded

### Force Required to Unroll the Mesh<sup>†</sup>



# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### ECONOMICS AND REIMBURSEMENT



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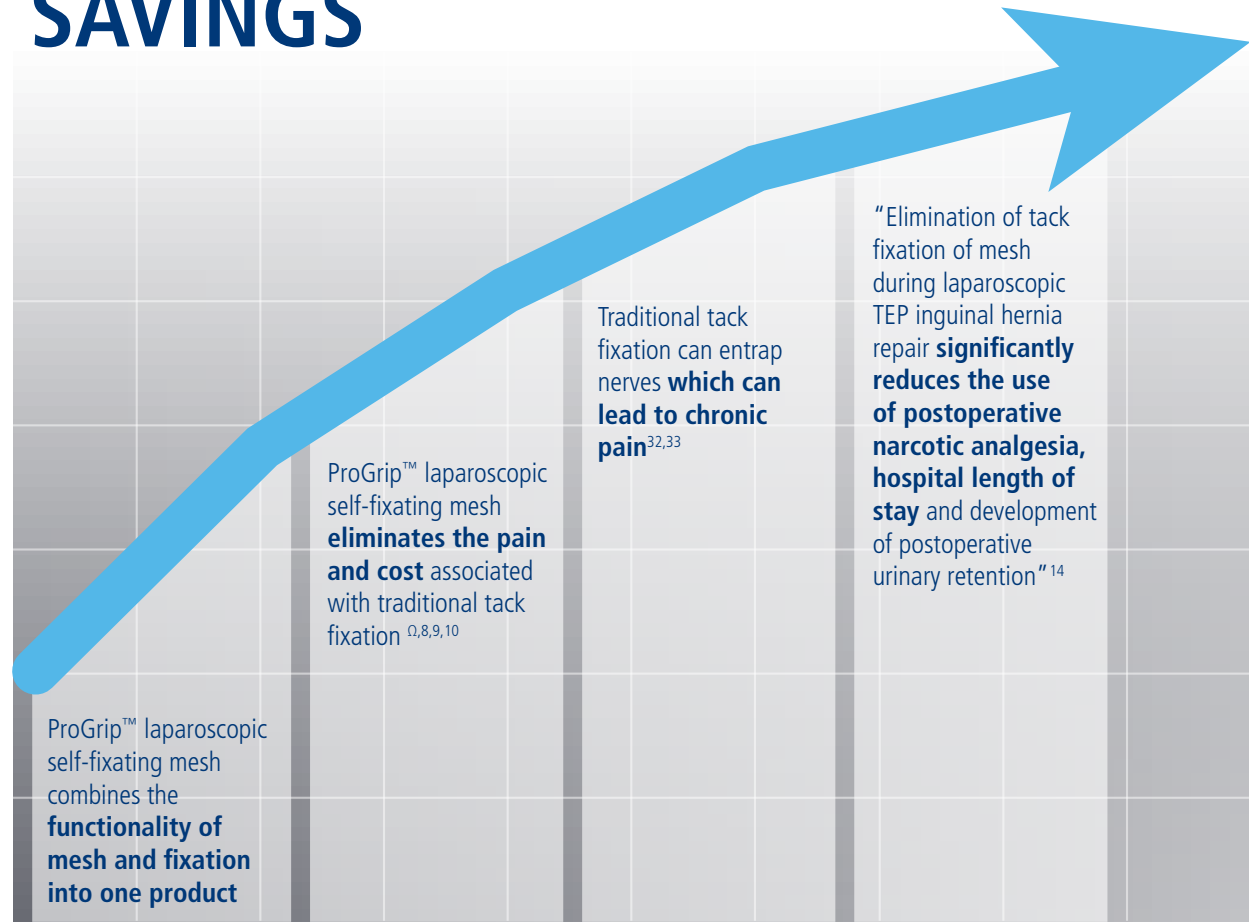


+



## A Cost Effective Alternative for Laparoscopic Inguinal Hernia Repair<sup>15</sup>

# SAVINGS



TEP - Totally ExtraPeritoneal



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# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### ECONOMICS AND REIMBURSEMENT

#### Savings Worksheet (extracted from the cost calculator tool)

The following worksheet is designed to help hospitals estimate the economic savings of ProGrip™ laparoscopic self-fixating mesh. Economic savings may come from reductions in equipment, length of stay and pharmacy costs. Equipment, length of stay and pharmacy reductions and costs are all specific to the hospital and should be inputted by the hospital. The third column is provided as possible guidance based on the available literature.

| Category               | Calculations                    | Possible Savings based on Literature  |
|------------------------|---------------------------------|---|
| Equipment              | Cost of Current Mesh            | Traditional repair requires a mesh which costs \$211 and a tacker which can cost \$511 (Average and illustrative US prices based on IMS data for Ethicon SecureStrap™* fixation system and Bard 3DMax™* light mesh) <sup>15</sup> |
|                        | + Cost of Current Tacks or Glue |   |
|                        | - Cost of ProGrip™ laparoscopic |   |
|                        | <b>= SAVINGS</b>                |   |
| Length of Stay (hours) | Hours Reduced                   | Eliminating tack fixation can reduce length of stay by almost 8 hours <sup>14</sup>   |
|                        | x Cost per Hour                 |   |
|                        | <b>= SAVINGS</b>                |   |
| Pharmacy               | Fewer Doses                     | 3 unit reduction in morphine equivalents in PACU <sup>14</sup>  |
|                        | x Cost per Dose                 |   |
|                        | <b>= SAVINGS</b>                |   |
| Other (if applicable)  | + SAVINGS                       | Reduction in on-going pain management costs which can be as much as \$989 in first year <sup>21</sup>   |
|                        | + SAVINGS                       | Reduction in pain management visits which can be as high as 16.5 in first year <sup>21</sup>  |
|                        | + SAVINGS                       | Other tack-related costs/complications  |
| <b>Savings/Case</b>    | <b>= SAVINGS PER CASE</b>       | <b>Equipment + Length of Stay + Pharmacy + Other</b>  |
| Cases/Year             | x                               | Total number of laparoscopic inguinal procedures in one year  |
| <b>Annual Savings</b>  | <b>= TOTAL SAVINGS</b>          | <b>(SAVINGS/CASE) x (CASES/YEAR)</b>  |

# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### ECONOMICS AND REIMBURSEMENT

#### Reimbursement Information

| Hospital Outpatient |   |   |                                   |            |                        |
|---------------------|---|---|-----------------------------------|------------|------------------------|
| Code Type           | Code  | Procedure Description                                   | National Average Medicare Payment | APC (OPPS) | APC Description (OPPS) |
| CPT                 | 49650   | Laparoscopy, surgical; repair initial inguinal hernia   | \$3,357                           | 0131       | Level II Laparoscopy   |
| CPT                 | 49651   | Laparoscopy, surgical; repair recurrent inguinal hernia | \$3,357                           |            |                        |
| <b>HCPCS</b>        | <b>HCPCS Product Codes associated with the Procedures</b> |   |                                   |            |                        |
| HCPCS               | C1781   | Mesh (implantable)                                      | Included in procedure payment     | NA         | NA                     |

| Ambulatory Surgical Center |   |   |                                   |
|----------------------------|---|---|-----------------------------------|
| Code Type                  | Code  | Procedure Description                                   | National Average Medicare Payment |
| CPT                        | 49650   | Laparoscopy, surgical; repair initial inguinal hernia   | \$1,934                           |
| CPT                        | 49651   | Laparoscopy, surgical; repair recurrent inguinal hernia | \$1,934                           |
| <b>HCPCS</b>               | <b>HCPCS Product Codes associated with the Procedures</b> |   |                                   |
| HCPCS                      | C1781   | Mesh (implantable)                                      | Included in procedure payment     |

Outpatient and ASC rates thru 1/1/13. 2013 rates for OP and ASC will not be finalized until November.

# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### COMPETITIVE PRODUCTS OVERVIEW

ProGrip™ laparoscopic self-fixating mesh is a truly unique product that crosses the categories of synthetic mesh and fixation. The microgrip<sup>2</sup> technology provides immediate, effective<sup>4</sup> and long-term<sup>3</sup> fixation avoiding the use of traditional tissue-disrupting tacks or glue. ProGrip™ mesh is designed to provide a unique combination of surgical efficiency and patient benefits.

|  | Covidien ProGrip™ Laparoscopic Self-Fixating Mesh | Bard™ Mesh with SorbaFix™ Fixation | Ethicon UltraPro™ Mesh with SecureStrap™ Fixation |
|--|---|------------------------------------|---|
| Self-Fixating Option   | Yes   | No                                 | No  |
| Mesh Pore Size <sup>34</sup>                                   | 1.8 x 1.8   | 1.0 x 0.8                          | 2.3 x 3.4   |
| Partially Absorbable Mesh                                      | Yes   | No                                 | Yes   |
| Mesh Weight (g/m <sup>2</sup> ) <sup>34</sup>                  | 82  | 100                                | 59  |
| Mesh Weight After Resorption (g/m <sup>2</sup> ) <sup>34</sup> | 49  | N/A                                | 34  |
| Anatomical Shaped Mesh   | Yes   | Yes                                | No  |
| Type of Fixation   | Microgrips <sup>2</sup>                           | Tacks                              | Straps  |
| Fixation Material  | PLA   | Molded Polymer <sup>35</sup>       | PLG Blend <sup>16</sup>                           |
| Points of Fixation   | ~5,000  | ~6                                 | ~6  |
| Fixation Below Inguinal Ligament                               | Yes   | No <sup>35</sup>                   | No <sup>16</sup>                                  |
| Critical Anatomical Structures Preservation                    | Yes <sup>2</sup>                                  | No <sup>35</sup>                   | No <sup>16</sup>                                  |
| Number of Devices/Codes/Boxes Required                         | 1   | 2                                  | 2   |

ProGrip™ laparoscopic self-fixating mesh is the only combination device providing fixation over the entire inguinal anatomy including places where traditional fixations can not be placed.

PLA - Polylactic Acid  
PLG - Polydioxanone and L(-)-lactide/glycolide

# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### COMPETITIVE CROSS-REFERENCE

|                | Covidien <sup>24</sup>                   | Bard <sup>36</sup>                                       | Ethicon <sup>37</sup>            | Covidien Traditional <sup>38</sup>  | Baxter <sup>39</sup>  |
|----------------|--|--|----------------------------------|---|---|
| Mesh Brand     | ProGrip™ Laparoscopic Self-Fixating Mesh | 3DMAX™ Mesh, 3DMAX™ Light Mesh, Flat Sheet Mesh          | ULTRAPRO™ Mesh<br>VYPRO™ II Mesh | Parietex™ Mesh  | —   |
| Mesh Codes     | LPG1510AR                                | 115320<br>115321<br>115322<br>117320<br>117321<br>117322 |                                  | TECT1309AR<br>TECT1510ADP2R<br>TECT1510ADPR<br>TECT1510AR<br>TECT1612AR           |   |
|                | LPG1510AL                                | 115310<br>115311<br>115312<br>117310<br>117311<br>117312 |                                  | TECT1309AL<br>TECT1510ADP2L<br>TECT1510ADPL<br>TECT1510AL<br>TECT1612AL           |   |
|                | LPG1510                                  | 112680<br>112720   | UMS3<br>UMR3                     | TEC1309<br>TEC1510<br>TEC1515<br>TECR1510<br>TECR1515<br>TEC1410P5<br>TECR1410DP2 |   |
|                | LPG1510X2                                |  |                                  |   |   |
|                | LPG1510AK2                               |  |                                  |   |   |
| Fixation Brand |  | SorbaFix™ Fixation System<br>PermaFix™ Fixation System   | SecureStrap™ Fixation Device     | AbsorbaTack™ Fixation Device<br>ProTack™ Fixation Device                          | Duplospray™ System<br>Tisseel™ Fibrin Sealant   |
| Fixation Codes | (Fixation not Needed)                    | 113115<br>113116<br>113120<br>113119                     | STRAP25                          | ABSTACK15<br>ABSTACK30<br>174006  | 0600029 (off label in US)<br>0600030 (off label in US)<br>1501261 (off label in US)<br>1501262 (off label in US)<br>1501263 (off label in US) |

# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### MATERIALS MANAGEMENT INFORMATION

#### Packaging Overview



**Box Dimensions (LxWxH):**  
310 mm x 285 mm x 23 mm



#### Product Order Codes

| Ordering Information |   |                       |
|----------------------|---|-----------------------|
| Code                 | Product Description                     | Product Configuration |
| LPG1510              | 10x15<br>1 Unit per Box                 |                       |
| LPG1510X2            | 10x15<br>2 Units per Box                |                       |
| LPG1510AR            | Right Anatomical<br>1 Unit per Box      |                       |
| LPG1510AL            | Left Anatomical<br>1 Unit per Box       |                       |
| LPG1510AK2           | Bilateral Anatomical<br>2 Units per Box |                       |

#### Ordering Information

**Covidien Products Website:** [www.covidien.com/hernia](http://www.covidien.com/hernia)

**Customer Service:** (800) 722-8772

# ProGrip™ Laparoscopic Self-Fixating Mesh

## The Future of Fixation

### REFERENCES

- <sup>1</sup>Covidien Internal Test Report 0902CR123. Data on File (June 2012).
- <sup>2</sup>Kolbe, T, Hollinsky, C, Walter, I, Joachim, A, Rüllicke, T. Influence of a new self-gripping hernia mesh on male fertility in a rat model. *Surgical Endoscopy* 2010; 24: 455-461.
- <sup>3</sup>Covidien Internal Test Report 0902CR114. Data on File (October 2011). Bard™ soft mesh and Bard™ 3DMax light mesh have the same textile base.
- <sup>4</sup>Covidien Internal Test Report 0902CR141 (STI107). Data on File (November 2012).
- <sup>5</sup>Kingsnorth, A et al. Randomized controlled multicenter international clinical trial of self-gripping Parietex™ ProGrip™ polyester mesh vs lightweight polypropylene mesh in open inguinal hernia repair: interim results at 3 months. *Hernia* 2012; 16: 287-294.
- <sup>6</sup>Kapischke, M et al. Self-fixating mesh for the Lichtenstein procedure – a prestudy. *Langenbeck's Archives of Surgery* 2010; 395: 317-322.
- <sup>7</sup>Quyn, AJ et al. Chronic pain after open inguinal hernia surgery: suture fixation vs self-adhesive mesh repair. *Langenbeck's Archives of Surgery* 2012 May 2 [Epub ahead of print].
- <sup>8</sup>Laxa, B, Jacob, B. An ongoing prospective study evaluating self-gripping mesh (Parietex ProGrip™) without additional fixation during laparoscopic total extraperitoneal (TEP) inguinal hernia repair: initial analysis. IHS 2012 P1620. Covidien sponsored study.
- <sup>9</sup>Birk, D. Self-gripping mesh in laparoscopic inguinal hernia repair. Technique and clinical outcome of 96 operations. IHS 2012 P-1654. Covidien sponsored study.
- <sup>10</sup>Edwards, C. Self-fixating mesh is safe and feasible for laparoscopic inguinal hernia repair. *Surgical Endoscopy and Other Interventional Techniques. Conference: 2011 Scientific Session of the Society of American Gastrointestinal and Endoscopic Surgeons, SAGES San Antonio, TX United States (30.03.2011 – 02.04.2011).* 25: S324.
- <sup>11</sup>Taylor, C et al. Laparoscopic inguinal hernia repair without mesh fixation, early results of a large randomised clinical trial. *Surgical Endoscopy* 2008 Mar; 22(3): 757-62.
- <sup>12</sup>Simons, MP et al. European Hernia Society guidelines on the treatment of inguinal hernia in adults. *Hernia* 2009; 13: 343-403.
- <sup>13</sup>Bittner, R, Arregui, ME et al. Guidelines for laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal hernia [International Endohernia Society (IEHS)]. *Surgical Endoscopy* 2011; 25: 2773-2843.
- <sup>14</sup>Koch, C, Greenlee, S. Randomized Prospective Study of Totally Extraperitoneal Inguinal Hernia Repair: Fixation Versus No Fixation of Mesh. *JLS* 2006; 10: 457-460.
- <sup>15</sup>Estimate derived from the use of information under licence from the following IMS Health information service: Hospital Supply Index for the period Sep '06 – Jun '12. IMS expressly reserves all rights, including rights of copying, distribution and republication. Based on typical prices of anatomical mesh and absorbable fixation in the US.
- <sup>16</sup>Ethicon SecureStrap™ fixation system Instructions For Use.
- <sup>17</sup>ProGrip™ laparoscopic self-fixating mesh Instructions For Use.
- <sup>18</sup>Piccini, G, Lissidini, G et al. No tacks, no glue, no frustration during TAPP groin hernia repair with ProGrip™ and V-Loc™ 180. IHS 2012 FP-1740.
- <sup>19</sup>Covidien Internal Test Report TEX033-a. Data on File (October 2012).
- <sup>20</sup>Covidien Internal Test Report 0902CR122. Data on File (June 2012).



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# ProGrip™ Laparoscopic Self-Fixating Mesh

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### REFERENCES

- <sup>21</sup>Jacob, B, Morseon, M. Post-Inguinal Hernia Repair Pain Management Costs: Survey of physicians regarding costs of pain management strategies. IHS 2012
- <sup>22</sup>Covidien Internal Test Report 98640. Data on File (February 2012).
- <sup>23</sup>Covidien Internal Test Report 0902CR132a. Data on File (July 2012).
- <sup>24</sup>Covidien Internal Test Report 0902CR138a. Data on File (October 2012).
- <sup>25</sup>Chastan, P. Tension-free open hernia repair using an innovative self-gripping semi-resorbable mesh. *Hernia* 2009; 13: 137-142.
- <sup>26</sup>Pedano, N et al. Open tension-free hernioplasty using a novel lightweight self-gripping mesh: medium-term experience from two institutions. *Langenbeck's Archives of Surgery* 2012 Feb; 397(2): 291-5
- <sup>27</sup>Garcia Urena, M, Hidalgo, M et al. Multicentric observational study of pain after the use of a self-gripping lightweight mesh. *Hernia* 2011; 15: 511-515.
- <sup>28</sup>Nienhuijs, S, Kingsnorth, A et al. Benefit of self-gripping Parietex ProGrip™ mesh in open inguinal hernia repair: less pain with nerve preservation. IHS 2012 FP-1673.
- <sup>29</sup>Pierides, G, Scheinin, G et al. Randomized comparison of self-fixating and sutured mesh in open inguinal hernia repair. *British Journal of Surgery* 2012; 99: 630-6.
- <sup>30</sup>Anadol, Z, Akin, M et al. A prospective comparative study of the efficacy of conventional Lichtenstein vs self-adhesive mesh repair for inguinal hernia. *Surgery Today* 2011; 41: 1498-1503.
- <sup>31</sup>Covidien Internal Test Report TEX015-a. Data on File (April 2012).
- <sup>32</sup>Lantis, JC II, Schwaitzberg, SD. Tack entrapment of the ilioinguinal nerve during laparoscopic hernia repair. *J Laparoendosc Adv Surg Tech A*. 1999; 9(3): 285-289.
- <sup>33</sup>Broin, EO, Horner, C, Mealy, K et al. Meralgia paraesthetica following laparoscopic inguinal hernia repair. *Surgical Endoscopy* 1995; 9(1): 76-78.
- <sup>34</sup>Deeken, CR et al. Physicomechanical evaluation of polypropylene, polyester and polytetrafluoroethylene meshes for inguinal hernia repair. *Journal of American College of Surgeons* 2011; 212: 68-79.
- <sup>35</sup>Bard SorbaFix™ absorbable fixation system Instructions For Use.
- <sup>36</sup>Bard website – <http://www.davol.com/products/order-products/#oi21>.
- <sup>37</sup>Ethicon website – <http://www.ecatalog.ethicon.com/hernia-repair>.
- <sup>38</sup>Covidien website – <http://www.covidien.com/imageServer.aspx/doc186183.pdf?contentID=16537&contenttype=application/pdf>.
- <sup>39</sup>Baxter Tisseel™ product list (downloaded from <http://www.ecomm.baxter.com/ecatalog/browseCatalog.do?lid=10001&hid=10001&cid=10016&key=7866aa9f80117a841ae5af83ee164b2>).
- \*If the mesh is cut to size, additional fixation should be used based on surgeon's discretion.
- ΣMeasured in millimeter scale.
- ΩProGrip™ laparoscopic self-fixating mesh and ProGrip™ self-gripping mesh have equivalent gripping and mechanical properties.<sup>†,1</sup>
- †Based on pre-clinical animal and/or benchtop studies.

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