LEADING THE FUTURE OF FIXATION

ProGrip™
Laparoscopic Self-Fixating Mesh
Clinical and Technical Performance
Product Benefits

ProGrip™ laparoscopic self-fixating mesh:

- Increases the security of the laparoscopic inguinal hernia repair.1,2,4,7
- Eliminates the pain associated with traditional tack fixation.4,5
- Is easy to use.10
- Potentially lowers the cost of the laparoscopic inguinal procedure by combining the functionality of mesh and fixation into one device and reducing the pain management costs.5,11

Self-Fixating

- More than 5,000 microgrips1 eliminate the need for traditional tack fixation or glue.5,1,2
- Superior fixation strength compared with Bard 3DMax™ light textile with SorbaFix™ tacks or fibrin sealant.7,3
- Equivalent recurrence rate compared with laparoscopic repair with fixation.5,1,4,5,6
- Tack-free fixation over the entire anatomy, including below the inguinal ligament where tacks cannot be placed.7,5

Less Pain

- Eliminates the pain associated with traditional tack fixation.7,4
- Low post-operative pain and fast recovery in laparoscopic inguinal hernia repair.4,5,6,8
- 40% of the mesh weight resorbs reducing foreign material presence in patient over time.11
- Resorbable, atraumatic microgrips preserve cord.10,7

Easy to Use

- Doesn’t stick to itself, making it easy to handle and unfold laparoscopically.10
- Easy to orient with green medial marking

Potential Cost Savings

- Combines the functionality of mesh and fixation into one device
- Less post-operative pain may result in lower cost of pain-management therapy.2,11
*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).*

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

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**Immediate Fixation**

ProGrip™ laparoscopic self-fixating mesh versus Bard 3DMax™ light mesh with Baxter Tisseel™ fibrin sealant versus Bard 3DMax™ light mesh with SorbaFix™ tacks

- 6 x 6 cm mesh implanted in a porcine model (eight 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**

- ProGrip™ laparoscopic self-fixating mesh versus Bard 3DMax™ light mesh with Baxter Tisseel™ fibrin sealant versus Bard 3DMax™ light mesh with SorbaFix™ tacks
- 5 x 10 cm mesh implanted in a porcine model
- Samples explanted at four and eight weeks
- Peel-strength test to measure fixation strength
ProGrip self-gripping mesh has been used extensively in open inguinal hernia repair and has also been successfully tested in laparoscopic procedures.

ProGrip™ self-gripping mesh used in laparoscopic inguinal hernia repair has demonstrated fewer complications and recurrences than traditional meshes with tack fixation.

### ProGrip™ Self-Gripping Mesh in LIHR

<p>| | |</p>
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Trials/Patients</strong></td>
<td>3/130</td>
</tr>
<tr>
<td><strong>Follow-up (months)</strong></td>
<td>6.2 – 24 (mean: 20.8)</td>
</tr>
<tr>
<td><strong>Wound Infection (%)</strong></td>
<td>0</td>
</tr>
<tr>
<td><strong>Seroma (%)</strong></td>
<td>3.9 (0 – 6.7)</td>
</tr>
<tr>
<td><strong>Hematoma (%)</strong></td>
<td>2.1 (0 – 3.3)</td>
</tr>
<tr>
<td><strong>Chronic Pain Rate (%)</strong></td>
<td>0</td>
</tr>
<tr>
<td><strong>Testicular Problem (%)</strong></td>
<td>0</td>
</tr>
<tr>
<td><strong>Urinary Retention (%)</strong></td>
<td>2.3 (0 – 16.7)</td>
</tr>
<tr>
<td><strong>Recurrence (%)</strong></td>
<td>1.3</td>
</tr>
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</table>

LIHR — Laparoscopic inguinal hernia repair

“ProGrip™ laparoscopic self-fixating mesh and ProGrip™ self-gripping mesh have equivalent gripping and mechanical properties.”
Low Postoperative Pain and Fast Recovery in Laparoscopic Inguinal Hernia Repair\textsuperscript{Ω,4,5}

**Totally ExtraPeritoneal (TEP) Procedure\textsuperscript{4}**
- 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

**TransAbdominal PrePeritoneal (TAPP) Procedure\textsuperscript{5}**
- Retropective/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

**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 after 2.1 days; to work after 4.5 days

**Final Results**
- Safe and effective with 1.78% recurrence rate
- Low pain rates: 98.8% of patients had no/low to mild pain

CCS — Carolinas Comfort Scale
**ProGrip™ self-gripping mesh has been used and studied extensively and has demonstrated low patient-pain rates in open inguinal hernia repair.**

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

<table>
<thead>
<tr>
<th>Author</th>
<th>Pain Chapter I</th>
<th>ProGrip™ Mesh</th>
<th>Flat Mesh</th>
<th>p-Value</th>
<th>Measurement Scale∞</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kingsnorth</td>
<td></td>
<td>-10% at discharge -13% at 7 days</td>
<td>+ 39% at discharge + 21% at 7 days</td>
<td>0.007</td>
<td>0 – 15 cm VAS∞ (%) Reduction</td>
</tr>
<tr>
<td>Chastan</td>
<td></td>
<td>1.3 at discharge</td>
<td>NA (Obs.)</td>
<td>-</td>
<td>0 – 10 cm VAS∞</td>
</tr>
<tr>
<td>Kapischke</td>
<td></td>
<td>1.79 at 1 day 3.23 at 1 day</td>
<td></td>
<td>0.031</td>
<td>0 – 10 cm VAS∞</td>
</tr>
<tr>
<td>Garcia Ureña</td>
<td></td>
<td>2.5 ± 1.8 at 7 days</td>
<td>NA (Obs.)</td>
<td>&lt; 0.001</td>
<td>0 – 10 cm VAS∞</td>
</tr>
<tr>
<td>Anadol</td>
<td></td>
<td>2.73 ± 1.72 at 12 hrs 1.23 ± 1.25 at 24 hrs 1.1 ± .92 at 7 days</td>
<td>4.4 ± 1.65 at 12 hrs 1.9 ± 1.09 at 24 hrs 1.8 ± 1.42 at 7 days</td>
<td>0.843</td>
<td>0 – 10 cm VAS∞</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.4 ± 1.65 at 12 hrs 1.9 ± 1.09 at 24 hrs 1.8 ± 1.42 at 7 days</td>
<td>NA (Obs.)</td>
<td>0.545</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.131</td>
<td></td>
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</tbody>
</table>

### Chronic Pain (beyond 3 months)

<table>
<thead>
<tr>
<th>Author</th>
<th>Pain Chapter I</th>
<th>ProGrip™ Mesh</th>
<th>Other Mesh</th>
<th>p-Value</th>
<th>Measurement Scale∞</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chastan</td>
<td></td>
<td>0 at 1 year 0 at 2 year</td>
<td>NA (Obs.)</td>
<td>-</td>
<td>0 – 10 cm VAS∞</td>
</tr>
<tr>
<td>Kapischke</td>
<td></td>
<td>0.38</td>
<td>1.26</td>
<td>0.07</td>
<td>0 – 10 cm VAS∞</td>
</tr>
<tr>
<td>Quyn</td>
<td></td>
<td>7.9% at 6 months 6.3% at 1 year</td>
<td>21% at 6 months 16.8% at 1 year</td>
<td>&lt; 0.05</td>
<td>SF36 questionnaire</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt; 0.05</td>
<td>% of patients reporting pain</td>
</tr>
<tr>
<td>Pedano</td>
<td></td>
<td>4% at 17 months</td>
<td>NA (Obs.)</td>
<td>-</td>
<td>Collection methodology not specified</td>
</tr>
<tr>
<td>Garcia Ureña</td>
<td></td>
<td>0.4 ± 0.9 at 6 months</td>
<td>NA (Obs.)</td>
<td>&lt; 0.001</td>
<td>0 – 10 cm VAS∞</td>
</tr>
</tbody>
</table>

The physical and mechanical properties of ProGrip™ self-gripping polypropylene mesh are at least equivalent to those of ProGrip™ self-gripping polyester mesh.∞

∞ The pain scores are expressed in variation compared to the baseline, i.e. the pain just before surgery.
Easy to Handle and Unfold Laparoscopically†,10

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†,10
- Provides equivalent tissue engagement compared with ProGrip™ self-gripping mesh†,1

**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

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**Force Required to Unroll the Mesh†**

<table>
<thead>
<tr>
<th></th>
<th>Average Force</th>
<th>Maximum Force</th>
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</thead>
<tbody>
<tr>
<td>ProGrip™ Self-Gripping Mesh</td>
<td>4 N</td>
<td>12 N</td>
</tr>
<tr>
<td>ProGrip™ Laparoscopic Self-Fixating Mesh without Collagen Film</td>
<td>2 N</td>
<td>8 N</td>
</tr>
<tr>
<td>ProGrip™ Laparoscopic Self-Fixating Mesh with Collagen Film</td>
<td>1 N</td>
<td>6 N</td>
</tr>
</tbody>
</table>
HERNIA CARE

Our comprehensive product portfolio can enhance your hernia repair procedures.

References

1. Based on internal test report #0902CR123. June 2012.
2. ProGrip™ laparoscopic self-fixating mesh Instructions for Use.
3. Based on internal test report #0902CR114. In vivo pre-clinical pig study at 4 and 8 weeks; comparing ProGrip™ laparoscopic self-fixating mesh fixation strength to Bard™ soft mesh with SorbaFix™ fixation system and Baster Tissue™ fibrin sealant. October 2011. Bard™ soft mesh and Bard 3DMax™ light mesh have the same textile base.
4. Lava 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.
23. ProGrip™ laparoscopic self-fixating mesh and ProGrip™ self-gripping mesh have equivalent gripping and mechanical properties.
24. The pain scores are expressed in variation compared to the baseline, i.e., the pain just before surgery.
25. Measured in millimeter scale.
26. Based on pre-clinical animal and/or benchtop studies.
27. If the mesh is cut to size, additional fixation should be used based on surgeon’s discretion.