At Covidien, Hernia Care means

LEADING THE FUTURE OF FIXATION

Innovation that matters

ProGrip™ Laparoscopic Self-Fixating Mesh
Clinical and Technical Performance

| HERNIA CARE | MESH • FIXATION • BIOLOGICS • DISSECTION
ProGrip™ Laparoscopic Self-Fixating Mesh

The Future of Fixation

PRODUCT BENEFITS

ProGrip™ laparoscopic self-fixating mesh:

- **Increases the security** of the laparoscopic inguinal hernia repair\(^1\),\(^3\),\(^7\)
- **Eliminates the pain** associated with traditional tack fixation\(^4\),\(^5\)
- **Is easy to use**\(^1\),\(^10\)
- 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\(^6\),\(^11\)

### Self-Fixating

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

### Less Pain

- Eliminates the pain associated with traditional tack fixation\(^4\),\(^5\)
- 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\(^9\)
- Resorbable, atraumatic microgrips\(^2\) preserve cord\(^7\),\(^1\)

### Easy to Use

- Doesn’t stick to itself making it easy to handle and unfold laparoscopically\(^1\),\(^10\)
- 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\(^4\),\(^11\)
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**SUPERIOR FIXATION STRENGTH COMPARED TO BARD 3DMAX™ LIGHT MESH**

**Immediate Fixation**
- 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.

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

**Long-term Fixation Strength**
- 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**

**In-Vivo Fixation Comparison**

**Mesh Displacement**

<table>
<thead>
<tr>
<th>Pressure (mmHg)</th>
<th>ProGrip™ Laparoscopic Self-Fixating Mesh</th>
<th>Bard 3DMAX™ Light Mesh + Baxter Tisseel™ Fibrin Sealant</th>
<th>Bard 3DMAX™ Light Mesh + SorbaFix™ Tacks</th>
</tr>
</thead>
<tbody>
<tr>
<td>225 mmHg</td>
<td>15 ± 2</td>
<td>20 ± 3</td>
<td>22 ± 4</td>
</tr>
<tr>
<td>450 mmHg</td>
<td>20 ± 3</td>
<td>25 ± 4</td>
<td>28 ± 5</td>
</tr>
</tbody>
</table>

**Normalized Work (mJoules/cm)**

- **4 weeks**: ProGrip™ Laparoscopic Self-Fixating Mesh
- **8 weeks**: ProGrip™ Laparoscopic Self-Fixating Mesh

**At 4 and 8 weeks, ProGrip™ laparoscopic self-fixating mesh has statistically superior fixation strength than Bard 3DMAX™ light mesh with tacks and glue.**
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LOW COMPLICATION AND RECURRENCE RATES IN LAPAROSCOPIC INGUINAL HERNIA REPAIR

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 less complications and recurrences than traditional meshes with tack fixation.

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

LIHR — Laparoscopic Inguinal Hernia Repair
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LOW POSTOPERATIVE PAIN AND FAST RECOVERY IN LAPAROSCOPIC INGUINAL HERNIA REPAIR\(\Omega,4,5\)

Totally ExtraPeritoneal (TEP) Procedure\(^4\)
- 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\(^5\)
- 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

First Postoperative Visit
CCS Pain Scores/QoL

<table>
<thead>
<tr>
<th>Pain Score</th>
<th>Pain at Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 10 20 30 40 50 60 70 80 90 100</td>
<td>Pain at Follow-Up</td>
</tr>
<tr>
<td>No/Low Pain</td>
<td>95.2%</td>
</tr>
<tr>
<td>Mild Pain</td>
<td>3.6%</td>
</tr>
<tr>
<td>Severe Pain</td>
<td>1.2%</td>
</tr>
</tbody>
</table>

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

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
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LOW POSTOPERATIVE PAIN THROUGH PROGRIP™ TECHNOLOGY\textsuperscript{0,13,15,16}

ProGrip™ self-gripping mesh has been used and studied extensively and has demonstrated low patient pain rates in Open Inguinal Hernia Repair. \textsuperscript{0,13,15,16}

<table>
<thead>
<tr>
<th>Author</th>
<th>Pain Chapter I</th>
<th>Pain Measure (VAS)</th>
<th>Measurement Scale</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kingsnorth\textsuperscript{13}</td>
<td>*</td>
<td>-10% at discharge -13% at 7 days</td>
<td>0 – 15 cm VAS\textsuperscript{™}</td>
<td>0.007</td>
</tr>
<tr>
<td>Chastan\textsuperscript{14}</td>
<td>*</td>
<td>1.3 at discharge</td>
<td>0 – 10 cm VAS\textsuperscript{™}</td>
<td>-</td>
</tr>
<tr>
<td>Kapischke\textsuperscript{15}</td>
<td>1.79 at 1 day</td>
<td>0 – 10 cm VAS\textsuperscript{™}</td>
<td>0.031</td>
<td></td>
</tr>
<tr>
<td>Garcia Ureña\textsuperscript{18}</td>
<td>2.5 ± 1.8 at 7 days</td>
<td>NA (Obs.)</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Anadol\textsuperscript{21}</td>
<td>2.73 ± 1.72 at 12 hrs 1.23 ± 1.25 at 24 hrs 1.1 ± .92 at 7 days</td>
<td>0 – 10 cm VAS\textsuperscript{™}</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Early Postoperative Pain (1 to 7 days)

<table>
<thead>
<tr>
<th>Author</th>
<th>Pain Chapter I</th>
<th>Pain Measure (VAS)</th>
<th>Measurement Scale</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chastan\textsuperscript{14}</td>
<td>0 at 1 year 0 at 2 years</td>
<td>NA (Obs.)</td>
<td>0 – 10 cm VAS\textsuperscript{™}</td>
<td>-</td>
</tr>
<tr>
<td>Kapischke\textsuperscript{15}</td>
<td>0.38</td>
<td>1.26</td>
<td>0 – 10 cm VAS\textsuperscript{™}</td>
<td>0.07</td>
</tr>
<tr>
<td>Quyn\textsuperscript{16}</td>
<td>7.9% at 6 months 6.3% at 1 year</td>
<td>21% at 6 months 18.8% at 1 year</td>
<td>SF36 questionnaire % of patients reporting pain</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Pedano\textsuperscript{17}</td>
<td>4% at 17 months</td>
<td>NA (Obs.)</td>
<td>Collection methodology not specified</td>
<td>-</td>
</tr>
<tr>
<td>Garcia Ureña\textsuperscript{18}</td>
<td>0.4 ± 0.9 at 6 months</td>
<td>NA (Obs.)</td>
<td>0 – 10 cm VAS\textsuperscript{™}</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Chronic Pain (beyond 3 months)

The physical and mechanical properties of ProGrip™ self-gripping polypropylene mesh are at least equivalent to those of ProGrip™ self-gripping polyester mesh.\textsuperscript{1,22}
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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

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 to ProGrip™ self-gripping mesh†,11
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REFERENCES

1 Covidien Internal Test Report 0902CR123 (June 2012).
2 ProGrip™ laparoscopic self-fixating mesh Instructions For Use.
3 Covidien 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 Baxter Tisseel™ fibrin sealant (October 2011). Bard™ soft mesh and Bard 3DMax™ light mesh have the same textile base.
4 Laxa, B and 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 P-1620.
5 Birk, D. Self-gripping mesh in laparoscopic inguinal hernia repair. Technique and clinical outcome of 96 operations. IHS 2012 P-1654.
9 Covidien Internal Test Report TEX033-a (October 2012).
10 Covidien Internal Test Report 0902CR122 (June 2012).
12 Covidien Internal Test Report 0902CR141 (STI107) - Biomechanical analyses of self-fixation property of different meshes following retroperitoneal implantation in pigs (24 hours) (November 2012).
22 Covidien Internal Test Report TEX015-a (April 2012).
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, ie. the pain just before surgery.
25 Measured in millimeter scale
26 Based on preclinical animal and/or benchtop studies
27 If the mesh is cut to size, additional fixation should be used based on surgeon’s discretion

IMPORTANT - Please refer to the package insert for complete instructions, contraindications, warnings and precautions.
This information is intended only for residents of the European Union.

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