For more than 80 years, Ethicon has been a trusted partner, leading the industry in providing outcomes-based solutions for our customers. An example of this commitment is our sponsorship of the largest hernia registry in the world, the International Hernia Mesh Registry (IHMR).

Ethicon began sponsoring the IHMR in 2007 through a grant program to ensure we could play a significant role in providing large-scale evidence of the safety and Quality-of-Life outcomes for hernia-related products and procedures. This repository includes postoperative hernia data on all synthetic meshes and techniques – both Ethicon’s and our competitors’.

Many Ethicon products—including ETHICON SECURESTRAP® Absorbable Strap Fixation Device, ULTRAPRO® Partially Absorbable Lightweight Mesh, and PROCEED® Surgical Mesh—are tracked and measured in IHMR for continuous assessment of outcomes data. This illustrates our dedication to advancing hernia repair and commitment to evidence generation.
Ethicon developed PROCEED® Surgical Mesh—the first macroporous mesh with an absorbable tissue-separating barrier. Today, because macroporous, thin filament mesh has been shown to reduce postoperative chronic pain and sensation of foreign body in some patients, PROCEED Mesh-like products make up the majority of the market with over 24 different types.¹

Likewise, Ethicon developed the PROLENE® Polypropylene Hernia System—the first preperitoneal mesh device of its kind for open inguinal hernia repair. To date, studies illustrate this device (and its successor ULTRAPRO® Hernia System) have one of the lowest recurrence rates of any inguinal repair.²

By bringing these innovative products to market, Ethicon affirms its commitment to developing products that address patient needs, and contribute to excellent outcomes.
Macroporous, thin-filament polypropylene mesh

• Retrospective study compared incidence rates of major long-term hernia complications according to type of prosthetic material used (monofilamented polypropylene, double-filamented mesh, expanded polytetrafluoroethylene patch, and multifilamented polyester mesh
• MERSILENE™ Polyester Fiber Mesh had a significantly higher rate of infections (16% vs. 0%-2%; P<.001) and fistula formation (16% vs. 0%-6%; P<.05)
• MERSILENE Mesh accounted for the significant difference among groups in the incidence of fistula (P=.007) and infection (P=.04)
• Polyester mesh should no longer be used for incisional hernia repair

• Meta-analysis of 2,231 hernias from 11 randomized controlled trials
• Lightweight mesh (partially absorbable or nonabsorbable), led to less postoperative chronic pain (P<0.05) and less sensation of a foreign body (P=0.05) vs. heavyweight mesh
• There was no significant difference in recurrence, seroma, hematoma, wound infection, urine retention, and testicular atrophy

• Meta-analysis to determine the effect of lightweight mesh on pain and recurrence after Lichtenstein hernioplasty
• Lightweight mesh did not increase recurrence rate or reduce incidence of severe pain
• There was a significant reduction in postoperative foreign body feeling and overall pain

• This study presents QOL results from a randomized clinical trial of patients undergoing Lichtenstein inguinal hernia repair (n=122) using densely woven polypropylene mesh (Surgipro™ Mesh, Covidien; 100-110 g/m2) or a lightweight composite multifilament mesh (Vypro® Mesh, Ethicon; polypropylene 27-30 g/m2)
• At 6 months, lightweight mesh was associated with significantly fewer patients who felt pain during exercise, (P=0.042) and significantly less foreign body sensation, (17.2 vs. 43.8% with conventional mesh; P=0.003)
Evidence supporting ULTRAPRO® Partially Absorbable Lightweight Mesh

- Review of heavyweight small pore mesh vs. lightweight large pore mesh
- Lightweight, large porous mesh was found to be superior with regards to reduced number of long-term complications and increased comfort and QOL after hernia repair

- Prospective, longitudinal IHMR study of 470 patients receiving laparoscopic hernia repair with ULTRAPRO Mesh
- Compared with baseline, there were significant improvements in movement limitation (P<0.001) and pain scores (P<0.001) by month 6, through 12 months post-surgery
- The use of macroporous, lightweight polypropylene mesh may minimize restriction of abdominal wall compliance while providing adequate strength. These meshes are constructed of materials that closely correspond to physiologic weight

- This paper presents results from a double-blind randomized controlled trial comparing heavy- and lightweight polypropylene-based meshes in totally extraperitoneal (TEP) inguinal herniorrhaphy. Twenty-five bilateral TEPs implanting 25 heavy and 25 lightweight polypropylene meshes, one of each type in each patient, were performed
- Lightweight polypropylene mesh was associated with significantly better pain scores, patient comfort, and sexual function as compared with heavyweight mesh. There was no infection or recurrence with either type of mesh
Evidence supporting PROCEED® Ventral Patch


- This prospective, longitudinal study from IHMR presents 12-month outcomes for 177 patients receiving hernia repair with PROCEED Ventral Patch
- There was significant improvement in CCS pain and movement scores from baseline to 12 months (-0.59 (0.89 SD); -0.45 (0.86 SD), P<0.001). The rate of recurrence was low (2.8%)


- Randomized clinical trial compared herniorrhaphy (primary suture) with hemioplasty (polypropylene mesh or plug) in 200 patients with a primary umbilical hernia, with a mean follow-up of 64 months
- Hernia recurrence rate was higher after suture repair (11%) than after mesh repair (1%; P=0.0015)


- 3-year cumulative rates of recurrence among patients who had suture repair and those who had mesh repair were 43% and 24% (P=0.02). Size of hernia didn't affect rate of recurrence
Evidence supporting PROCEED® Surgical Mesh

Bringman S, Tollens T, Murdoch J, et al. Laparoscopic hernia repair surgery using a tissue-separating flat mesh (TSM)—12 month patient reported outcomes from the international hernia mesh registry (IHMR) (poster)

- Prospective, longitudinal IHMR study of laparoscopic hernia repair (n=157) using PROCEED Mesh
- Patients experienced low rates of recurrence (1.3%) and reported significant improvement in movement ability and decreased pain, with a mean pain score (<2) considered clinically asymptomatic, at 12 months post-surgery

PATIENT-REPORTED SYMPTOMATIC PAIN AT BASELINE AND 12 MONTHS POSTOPERATIVELY

![Graph showing patient-reported symptomatic pain at baseline and 12 months postoperatively]

MEAN PAIN SCORE AND 95% CONFIDENCE INTERVAL

![Graph showing mean pain score and 95% confidence interval]

Change from baseline: ^-0.66 (1.16SD) P<0.001; ^-0.64 (1.27) P<0.001
Berrevoet F, Murdoch J, Jones P, et al. Open hernia repair surgery using a tissue-separating flat mesh (TSM)—12 month patient reported outcomes from the International Hernia Mesh Registry (IHMR)

- Prospective, longitudinal study of patients in the IHMR receiving open hernia repair (n=82) using PROCEED® Surgical Mesh
- Patients experienced low rates of recurrence (3.7%) and reported significant improvement in movement ability and decreased pain, with a mean pain score (<2) considered clinically asymptomatic, at 12 months post-surgery vs. baseline


- This analysis reports the first clinical data evaluating the use of PROCEED Mesh in laparoscopic ventral hernia repair (n=114). Endpoints included: conversion rate to open procedure, pain, mesh infection, and recurrences. Mean follow-up was 27 months
- There were no conversions to open repair and no mortality. Complications included 12 seromas/ hematomas, chronic discomfort in 2 patients, and urinary retention in 1 patient. There were 4 recurrences (3.5%). There were no mesh infections


- This study evaluated feasibility and outcomes after laparoscopic ventral hernia repair using PROCEED Mesh (n=49)
- One patient developed an uncomplicated wound infection. No patients developed mesh infections or postoperative seroma requiring surgical intervention. No recurrences were seen during the follow-up period of 17 months


- This paper presents results of a prospective analysis of 50 patients undergoing open (n=20) or laparoscopic (n=30) repair of incisional hernia with PROCEED Mesh
- One case required reintervention. There were no intra-abdominal complications associated with the use of the mesh, and no patient deaths
Preclinical evidence supporting PROCEED® Surgical Mesh


- This study compared adhesion formation, tissue ingrowth, and textile characteristics of 4 different meshes in 20 rabbits: DualMesh®, Composix® (C.R. Bard Inc.) Marlex® (C.R. Bard Inc.) and PROCEED Mesh
- Meshes were explanted after 1 year. DualMesh® had significantly fewer adhesions (0%) than Composix® (40%) and Marlex® (80%) (P<0.001). The mean area of adhesions for PROCEED Mesh (10%) and Composix® (14%) was less than that for Marlex® (40%) (P=0.02). Shrinkage was greatest for DualMesh® (32%) (P=0.001). There were no differences in mesh incorporation between the groups. Mesh compliance in the DualMesh® group was superior to other meshes (P<0.0001). PROCEED Mesh induced the smallest change in the compliance of the tissue adjacent to the mesh (P=0.0001)

Hutchinson R, Chagnon M, Divilio L. Preclinical Abdominal Adhesion Studies With PROCEED Surgical Mesh. Ethicon, Inc.

- This paper presents results from randomized, controlled studies on PROCEED Mesh to evaluate its ability to provide tissue separation during healing. Animals were implanted with either PROCEED Mesh, Composix® or polypropylene mesh
- PROCEED Mesh was shown to be superior to polypropylene mesh and Sepramesh™ (Genzyme Corp.), and equivalent to Composix® and DualMesh®, with regard to adhesion scores. PROCEED Mesh has an additional advantage in that it did not inhibit reperitonealization


- This study evaluated host reaction to intraperitoneal placement of prosthetics and the functional outcomes in an animal model. Fifteen pieces of each mesh were implanted in 30 rabbits. The mesh types included DualMesh® (Gore Medical), Composix® (C.R. Bard Inc.), PROCEED Mesh, and Marlex® (C.R. Bard Inc.). Adhesion formation was evaluated at 1, 4, 8, and 16 weeks using 2-mm mini-laparoscopy
- DualMesh® had significantly fewer adhesions than PROCEED Mesh, Composix®, or Marlex® at 1, 4, 8, and 16 weeks (P<0.0001). Marlex® had significantly more adhesions than other meshes at each time point (P<0.0001). There were no statistically significant differences in adhesions between PROCEED Mesh and Composix® meshes. After mesh explantation, the mean area of adhesions for PROCEED Mesh (46%) was less than for Marlex® (21.7%; P=0.001)


- This study evaluated host response to intraperitoneal placement of DualMesh® (Gore Medical), Composix® (C.R. Bard Inc.), PROCEED Mesh, and Marlex® (C.R. Bard Inc.) in rabbits. Specimens were evaluated for scar plate formation, inflammatory response, and tissue ingrowth
- Ten samples of each mesh were evaluated. There was no difference in tissue incorporation. Mean scar plate formation was greater in the heavyweight polypropylene meshes than for DualMesh® (P=0.04). With PROCEED Mesh, the reduction in scar plate formation compared with that for Composix and Marlex® approached statistical significance (P=0.07)
Evidence supporting PROLENE® Polypropylene Hernia System/ULTRAPRO® Hernia System


- Prospective analysis of 890 UHS devices in 712 patients. 668 UHS implants in 526 patients were assessed at 1 week, 1 month follow-up
- There were no recurrences. Complications included infection (n=3), hematoma (n=5), and DVT (n=1)


- This study evaluated postoperative pain, return to normal activity, operating time and quality of life in 206 patients undergoing hernia repair with PROLENE Hernia System vs. Lichtenstein patch
- Compared with patients undergoing the Lichtenstein procedure, patients undergoing repair with PROLENE Hernia System had reduced surgery time (by 4 minutes [10% (34.1 vs. 38.3 min)]), similar or better postoperative recovery, lower immediate post-op pain, 50% fewer cases of groin pain at one year, faster return to work (14 days with PROLENE Hernia System vs. 19 days with Lichtenstein), and no recurrences (vs. 2 recurrences in the Lichtenstein group)
- An additional patch in the pre-peritoneal space may provide additional safeguards against recurrence


- This retrospective study evaluated recurrence and complication rates in patients undergoing inguinal hernia mesh repair using PROLENE Hernia System (n=321) vs. the Lichtenstein onlay mesh technique (n=302)
- Over 17-month follow-up, PROLENE Hernia System demonstrated improved outcomes vs. Lichtenstein onlay mesh. The complication rate was 17% in the PROLENE Hernia System group vs. 23% in the Lichtenstein group (P=.07). Hematoma/seroma rates were 6.9% for PROLENE Hernia System and 12.6% for Lichtenstein (P=.015). The recurrence rate for PROLENE Hernia System was 0.6% vs. 2.7% for Lichtenstein (P=.04)

- This study compared the results achieved by general surgeons using hernia repair using a bilayer connected mesh device (BCMD) vs. the results achieved by specialists using other techniques
- General surgeons achieved comparable results to specialists


- Multicenter study evaluated pain and recurrence in 2,792 patients who underwent hernia surgery with ULTRAPRO Hernia System, with follow up at 4, 12 and 52 weeks using patient questionnaire and Carolina Comfort Scale™ (CSS)
- 98.6% of patients reported satisfaction with the repair as reflected by CSS score. At 52 weeks the recurrence rate was 10 (0.35%)

**Fagan SP, Awad SS.** Abdominal wall anatomy: the key to a successful inguinal hernia repair. *Am J Surg.* 2004 Dec;188(6A Suppl):3S-8S

- Article reviews abdominal wall anatomy considerations in inguinal hernia repair, including nomenclature of the groin and the bony and tissue anatomy of the groin
Ethicon entered the absorbable fixation market in 2011 with the ETHICON SECURESTRAP® Absorbable Strap Fixation Device. Featuring a unique, 2-point fixation strap, the ETHICON SECURESTRAP Fixation Device combines superior acute holding strength at various deployment angles with absorbable materials—providing strength without potentially compromising patient discomfort.3,6 To date, IHMR results from 77 patients illustrate that nearly all (87.5%) reported minimal to no pain at 6 months post-surgery with ETHICON SECURESTRAP Fixation Device, with a low rate of complications and no hematomas (the type of mesh and repair procedure used may have also contributed to these outcomes).7 Within 18 months of launch, ETHICON SECURESTRAP Fixation Device became the market leader—clearly suggesting both surgeon and patient satisfaction.8 To address surgical challenges in open ventral hernia repair, Ethicon offers ETHICON SECURESTRAP® Open Absorbable Strap Fixation Device. ETHICON SECURESTRAP Open Absorbable Strap Fixation Device is the next generation of a proven, trusted device, now optimized for open repairs—rounding out a complete, evidence-based portfolio of mechanical fixation devices.
Evidence supporting ETHICON SECURESTRAP® Absorbable Strap Fixation Device and ETHICON SECURESTRAP® Open Absorbable Strap Fixation Device

**Doerhoff C, Chudy M, Gauld J, et al.** Preliminary Outcomes using an absorbable fixation device for mesh fixation. AHS 2013 SECURESTRAP (poster)

- Prospective, longitudinal study of 56 patients receiving hernia repair with 1 and 6 month data on 44 and 14 patients, respectively
- Hernia types included 33 incisional/ventral; 13 umbilical; 5 trocar; 3 epigastric and 2 inguinal. 44 were primary repairs. 54 patients underwent laparoscopic repair; 39 intra-peritoneal and 14 preperitoneal. Fixation methods used: tackers only (n=29); tackers and sutures (n=26); tackers, sutures and fibrin sealant (n=1)
- All patients with 6 month data (n=12) were considered asymptomatic in terms of pain and movement limitations. 5 seromas were reported. No hematomas were reported.

- Study assessed acute holding strength at various deployment angles (90°, 60°, 45°, 30°) for ETHICON SECURESTRAP® Absorbable Strap Fixation Device vs. AbsorbaTack™ (Covidien) and SorbaFix™ (Bard) with the application of light device preload and no counter pressure.
- A fixture modeled laparoscopic conditions using fresh porcine flanks tensioned to replicate abdominal cavity insufflation. Three constructs were evaluated by fixing flat mesh to the peritoneum at various implantation angles.
- ETHICON SECURESTRAP Fixation Device and AbsorbaTack™ were found to be comparable for acute holding strength at 90°. However, as the firing angle became more aggressive, the acute holding strength decreased more quickly for AbsorbaTack™. At 45° and 30°, ETHICON SECURESTRAP Fixation Device was statistically superior to AbsorbaTack™. In SorbaFix™ testing, blunt tacks were frequently unable to penetrate the mesh at aggressive angles (45° and 30°).

**ACUTE HOLDING STRENGTH AT VARIOUS DEPLOYMENT ANGLES**

<table>
<thead>
<tr>
<th>Angle</th>
<th>ETHICON SECURESTRAP Fixation Device n=200</th>
<th>AbsorbaTack™ n=100</th>
<th>SorbaFix™ n=100</th>
</tr>
</thead>
<tbody>
<tr>
<td>90°</td>
<td><strong>2.00</strong></td>
<td>1.50</td>
<td>1.00</td>
</tr>
<tr>
<td>60°</td>
<td><strong>1.50</strong></td>
<td>1.00</td>
<td>0.50</td>
</tr>
<tr>
<td>45°</td>
<td><strong>1.00</strong></td>
<td>0.50</td>
<td>0.50</td>
</tr>
<tr>
<td>30°</td>
<td><strong>0.50</strong></td>
<td>0.50</td>
<td>0.50</td>
</tr>
</tbody>
</table>

Data was generated using a benchtop test with porcine flank, utilizing consistent pre-load force.

*AbsorbaTack™ (tapered spiral) instructions for use require that the distal tip of the device be at a right angle to the targeted tissue to facilitate appropriate insertion of the tack.
† SorbaFix™ (wide thread spiral) instructions for use state that the fasteners should be placed entirely into the tissue and the head of the fastener should be firm against the mesh or tissue in order to achieve the best fixation performance.

- This study compared fixation time using ETHICON SECURESTRAP® Open Absorbable Strap Fixation Device vs. suture fixation of IPOM mesh in ventral/ incisional hernia repair. It also assessed surgeon-reported levels of task load experienced during the two fixation approaches.
- 38 IPOM fixation procedures were performed with equal numbers using suture and ETHICON SECURESTRAP® Open Absorbable Strap Fixation Device in live swine models. Each surgeon performed two suture (using their standard technique) and two ETHICON SECURESTRAP Open Absorbable Strap Fixation Device procedures. Procedure duration was recorded. Surgical workload was measured using the validated Surgery Task Load Index (SURG-TLX) questionnaire.
- Using ETHICON SECURESTRAP Open Absorbable Strap Fixation Device significantly reduced time for fixation and related surgical task load vs. suture fixation. ETHICON SECURESTRAP Open Absorbable Strap Fixation Device reduced mean fixation time by 89% vs. suture [mean reduction: 34.9 minutes (SD: 17.9 minutes); P<0.0001]. A 55% reduction in overall workload was observed with SECURESTRAP™ Open Fixation Device compared to suture fixation [mean reduction: 22.17 (SD: 15.12); P=0.0003].


- In this report of 40 consecutive laparoscopic incisional hernia repairs, ETHICON SECURESTRAP Fixation Device tacks were found to be safe, easy to use, and did not increase the risk of mesh dislocation compared with non-absorbable tacks.
For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

References
4. Shnoda P. 28 day mesh fixation study of the ETHICON SECURESTRAP™ Fixation Device to evaluate mesh migration and tissue response using a swine model. PSE Accession: 09-0132, project: 67547. Ethicon, Inc.
7. Early outcomes using an absorbable fixation device for mesh fixation (IHMR data analysis). Ethicon, Inc.