References:
5. Data on File, Ethicon Inc. Shnoda P. 28 day mesh fixation study of the ETHICON SECURESTRAP® Fixation Device to evaluate mesh migration and tissue response using a swine model. IDE Accession: 09/128; project: 67547
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 meshes and techniques – both Ethicon’s and our competitors’.

Many Ethicon products—including ETHICON SECURESTRAP® Absorbable Strap Fixation Device, ETHICON PHYSIOMESH® Flexible Composite Mesh, 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.
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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, PROCEED Mesh-like products make up the majority of the market with over 24 different types. 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.

To further advance tissue-separating mesh technology, Ethicon introduced ETHICON PHYSIOMESH® Flexible Composite Mesh. Designed to be physiologically compatible with the abdominal wall, it is currently the market-leading tissue-separating mesh.

By bringing these innovative products to market, Ethicon affirms its commitment to developing products that address patient needs, and contribute to superior outcomes.

**Synthetic mesh**

**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 (96% vs. 0%; P<0.001) and fistula formation (66% vs. 0%; P<0.05)
- MERSILENE Mesh accounted for the significant difference among groups in the incidence of fistula (P=0.007) and infection (P=0.04)
- Polyester mesh should no longer be used for incisional hernia repair.


- Meta-analysis of 2,311 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)
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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<0.01) 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

Preclinical evidence supporting value of ULTRAPRO Mesh


- Review of surgical literature, including authors’ in vivo porcine studies of heavy-, mid-, and lightweight meshes
- Light-weight mesh reduces foreign body response, improves mobility, causes less contraction, and improves tissue incorporation. In-vivo study demonstrated significant reduction in stiffness of the abdominal wall. Pore size has important effect on the biocompatibility of the foreign body
- An in-vivo study of heavy- and light-weight mesh demonstrated significant increase of total and mature collagen, thus making a more secure repair. Implantation of a macroporous, lightweight polypropylene mesh results in less restriction of abdominal wall compliance whilst providing adequate strength

Evidence supporting ETHICON PHYSIOMESH® Flexible Composite Mesh


- This study investigated 103 patients receiving hernia repair (incisional/ventral hernia, inguinal, umbilical, trocar and epigastric) with ETHICON PHYSIOMESH Mesh
- Mean change from baseline in CCS pain scores showed improvement at 6 and 12 months (δ+48 [0.87], P=0.001 and δ+62 [1.07], P=0.002)
- Complications included: seroma, ileus, and 1 each of pneumonia, hematoma, deep vein thrombosis, intestinal obstruction, intestinal perforation, and cellulitis. There were no recurrences


- This study investigated 88 patients receiving hernia repair with ETHICON PHYSIOMESH Mesh
- Postoperative pain scores (n=69) were significantly lower vs. preoperative (P<0.001). Median and mean preoperative VAS scores were 4 (range: 0 to 9)/40 ± 3.2. One month postoperative, median mean pain VAS scores were 0 (range: 0 to 9)/14 ± 2.4
- There were 20 minor complications (n = 20/88, 22.7%) and 1 major complication (adhesion, n = 1/88, 1.1%)

<table>
<thead>
<tr>
<th>Complication</th>
<th>n</th>
<th>%</th>
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<tr>
<td>Seroma</td>
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<td>90</td>
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<tr>
<td>Persistent pain</td>
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<tr>
<td>Hematoma</td>
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<td>45</td>
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<tr>
<td>Postoperative infection</td>
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<td>23</td>
</tr>
<tr>
<td>Adhesions/obstruction</td>
<td>1</td>
<td>11</td>
</tr>
</tbody>
</table>

Pre- and Postoperative pain VAS scores*

*Dots represent statistical outliers

Complications in postoperative population (n=88)

Preoperative Postoperative

pain VAS score

0 2 4 6 8 10

0 Preoperative

Postoperative
Evidence supporting ULTRAPRO® Partially Absorbable Lightweight Mesh


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• Lightweight polypropylene mesh was associated with significantly better pain scores, patient comfort, and sexual function as compared with heavy-weight mesh. There was no infection or recurrence with either type of mesh

Preclinical evidence supporting value of ULTRAPRO Mesh


• Review of surgical literature, including authors’ in vivo porcine studies of heavy-, mid-, and light-weight meshes
• Lightweight mesh reduces foreign body response, improves mobility, causes less contraction, and improves tissue incorporation. In vivo study demonstrated significant reduction in stiffness of the abdominal wall. Pore size has important effect on the biocompatibility of the foreign body
• An in vivo study of heavy- and light-weight mesh demonstrated significant increase of total and mature collagen, thus making a more secure repair. Implantation of a macroporous, lightweight polypropylene mesh results in less restriction of abdominal wall compliance whilst providing adequate strength

Evidence supporting ETHICON PHYSIMESH® Flexible Composite Mesh


• This study investigated 103 patients receiving hernia repair (incisional/ventral hernia, inguinal, umbilical, trocar and epigastric) with ETHICON PHYSIMESH Mesh
• Mean change from baseline in CCS pain scores showed improvement at 6 and 12 months (<0.48 (0.17), P=0.001 and <0.62 (1.07), P=0.002)
• Complications included: seroma (11), ileus (3), and 1 each of pneumonia, hematoma, deep vein thrombosis, intestinal obstruction, intestinal perforation, and cellulitis. There were no recurrences


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• There were 20 minor complications (n = 20/88, 22.7%) and 1 major complication (adhesion, n = 1/88, 1.1%)

- Prospective, longitudinal study from IHMR of patients receiving hernia repair
- Inguinal hernia repair (n=29): number of patients experiencing pain decreased significantly from 41% preoperatively, to 25.9% by month 1, 0% at month 6, and 16% at month 12
- Ventral hernia repair (n=71): number of patients experiencing pain decreased significantly, from 59% preoperatively, to 21% at 12 months post-surgery
- At 1 year post surgery, 10.5% of patients reported mesh sensation—less than half the expected rate (25.7%) based on a large-scale study of quality of life outcomes in ventral hernia repair


- This study queried the IHMR to assess QOL in patients who underwent LVR-H (n=770) and OVR-H (n=402)
- At 1 month follow-up, more LVR-H patients experienced pain (P<0001) and movement limitations (P<0001). At 6 and 12 months, there were no differences in QOL with 466 (65.6%) and 478 (67.3%) patients responding, respectively
- LVR-H resulted in a shorter length of stay (LOS) (P<0001) and fewer infections (P<0004)
- Rates of complication and recurrence rates were equal

Preclinical evidence supporting ETHICON PHYSIOMESH® Flexible Composite Mesh

Konerding MA, Chantereau P, Delventhal V, et al. Biomechanical and histological evaluation of abdominal wall compliance with intraperitoneal onlay mesh implants in rabbits: a comparison of six different state-of-the-art meshes. w 2012 Sep;34(7):806-16

- This study evaluated the biomechanical properties of six meshes: ETHICON PHYSIOMESH Mesh, Composix® L/P® (Bard), DualMesh® (Gore Medical), Sepramesh® (Bard), ETHICON PHYSIOMESH Mesh, or Parietex® Composite (Covidien) in a rabbit model 21 weeks post-implantation
- There were no mesh-related complications. ETHICON PHYSIOMESH Mesh demonstrated the highest compliance during plunger testing. ETHICON PHYSIOMESH Mesh had less collagen and less foreign body reaction, contributing to comfort


- This paper presents results from randomized, preclinical studies evaluating the ability of ETHICON PHYSIOMESH Mesh to provide tissue separation and tissue integration
- In a rabbit sidewall model, ETHICON PHYSIOMESH Mesh promoted mesothelial coverage at 3 days postimplantation, and it had excellent tissue separation, tissue integration, reactivity, and absorption properties beginning at 7 days postimplantation. Excellent tissue integration properties were confirmed in a minipig hernia model at 28, 56, and 91 days postimplantation, with no evidence of mesh migration or shrinkage


- This paper presents results from a randomized, preclinical comparator study to evaluate the ability of ETHICON PHYSIOMESH Mesh to provide tissue separation in abdominal hernia repair in a rabbit sidewall model
- Using an adhesion scoring scale, ETHICON PHYSIOMESH Mesh proved to be highly resistant to intraperitoneal adhesion formation, equivalent to PROCEED® Surgical Mesh and Sepramesh® (C.R. Bard Inc.). ETHICON PHYSIOMESH was superior to Composix® L/P® (C.R. Bard Inc.), Parietex® Composite (Covidien), and DualMesh® (Gore Medical)

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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<0001). The rate of recurrence was low (2.8%)


- Randomized clinical trial compared herniorrhaphy (primary suture) with hernioplasty (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=0.00015


- 3-year cumulative rates of recurrence among patients who had suture repair and those who had mesh repair were 43% and 24% (P=0.002). 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

Mean pain score and 95% confidence interval

<table>
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<th>Carolina Comfort Scale – score</th>
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<th>12 months</th>
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</tr>
</tbody>
</table>

Change from baseline * P<0.001 (0.000) - 0.064 (0.277) - 0.000
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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

Precaline 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)

Data on File, Ethicon Inc. Hutchinson R, Chagnon M, Divillio L. Preclinical Abdominal Adhesion Studies With PROCEED Surgical Mesh

- 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
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- 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 (4.6%) 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 greatest 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)
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- 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 SeproMesh™ (Genzyme Corp.) and equivalent to Composix® and DualMesh®, with regard to adhesion scoring. 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<0.001). 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 (4.6%) 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) 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=320) vs. the Lichtenstein onlay mesh technique (n=320).
- 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<0.07). Hematoma/seroma rates were 6.9% for PROLENE Hernia System and 12.6% for Lichtenstein (P=0.05). The recurrence rate for PROLENE Hernia System was 0.6% vs. 2.7% for Lichtenstein (P=0.04).


- 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%).


- Article reviews abdominal wall anatomy considerations in inguinal hernia repair, including nomenclature of the groin and the bony and tissue anatomy of the groin.
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Fixation

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 holding strength with absorbable materials that can be fixed at multiple angles—providing strength without compromising patient comfort.

To date, IHMR results from 77 patients illustrate that nearly all (97.3%) reported minimal to no pain at 6 months post-surgery with ETHICON SECURESTRAP Fixation Device, with a low rate of complications and no hernias (the type of mesh and repair procedure used may have also contributed to these outcomes). Within 18 months of launch, ETHICON SECURESTRAP Fixation Device became the market leader—clear evidence of both surgeon and patient satisfaction with the results.

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


- Prospective, longitudinal study of 56 patients receiving hernia repair with 1 and 6 month data on 44 and 14 patients, respectively
- Hemia 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 hernias were reported.
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- 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 tissue modeled laparoscopic condition: 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 30°, ETHICON SECURESTRAP Fixation Device was statistically superior to AbsorbaTack™. SorbaFix™ testing was terminated early, as the blunt tacks were frequently unable to penetrate the mesh at aggressive angles.

Acute holding strength at various deployment angles

![Acute holding strength graph](image)

Data was generated using a benchtop test with porcine flank, utilizing consistent preload force.

- **ETHICON SECURESTRAP** Fixation Device
- **AbsorbaTack™**
- **SorbaFix™**

* 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.

Data on File, Ethicon Inc. Roy S, Shnoda P, Savidge S, et al. Reduction in Fixation Time and Related Surgical Stress with the use of ETHICON SECURESTRAP™ Open Absorbable Strap Fixation Device in the Deployment of Intra-Peritoneal Onlay Mesh (IPOM) for Open Ventral Hernia Repair

- 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.
- The design works well with the lightweight polypropylene ETHICON PHYSIMESH® Flexible Composite Mesh.

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**Biologic mesh**

Ethicon believes in offering a choice of biologic meshes for abdominal wall repair.

To that end, Ethicon now offers an allograft, FlexHD® STRUCTURAL Acellular Hydrated Dermis+, and a porcine-derived xenograft, XCM BIOLOGIC® Tissue Matrix.

FlexHD Structural is available through an agreement with the Musculoskeletal Transplant Foundation. FlexHD® STRUCTURAL Acellular Hydrated Dermis+ provides strength for healing comparable to leading biologic meshes. It also supports revascularization and cellular infiltration with a minimal inflammatory response.

XCM BIOLOGIC Tissue Matrix is available through an agreement with DSM Biomedical. Intact collagen fibers retain natural strength and provide pliability, while its open pore structure allows for cell ingrowth and revascularization.

+ FlexHD™ Structural is a registered trademark of the Musculoskeletal Transplant Foundation, Edison, New Jersey.

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**Evidence Supporting FlexHD® STRUCTURAL Acellular Hydrated Dermis+**


- Study evaluated uniaxial tensile test data of FlexHD Structural, AlloDerm®, Strattice™ (LifeCell), Firm, Strattice™ Pliable, Permacol™ (Covidien), Surgimpact® (T.E.I. Biosciences), AlloMax™ (Bard), and Biodesign® Surgipex® (Cook).
- There was a significant difference in the ultimate tensile strength among the seven products tested (P<0.05). FlexHD Structural was found to be stronger than AlloDerm®, Strattice™ Firm, Strattice™ Pliable, Permacol™, and AlloMax™ (P<0.05).


- Prospective study evaluated the efficacy of AlloDerm® (n=55) vs. Flex HD Structural (n=40) in complicated ventral hernia with follow-up at 2 weeks, 3 months, 6 months, and 1 year.
- Repair techniques included interposition, overlay, and underlay, as well as components separation.
- 100% of patients in AlloDerm® arm and 11 patients (37%) in the Flex HD Structural arm developed a hernia recurrence. FlexHD Structural appears to have reduced recurrence and laxity rates when compared to AlloDerm®.


- Prospective study evaluated patients with complex ventral incisional hernias who underwent repair utilizing a component separation technique (CST) with either FLEX HD Structural or Strattice™. Patients were assessed at 6 weeks, 3 months, 6 months, and 12 months.
- Wound complications and early hernia recurrence rates were similar for FlexHD® Structural and Strattice™. Wound complications occurred more frequently in patients with higher wound classifications and those with obesity—all wound complications occurred in patients with pre-operative BMI ≥ 30.

Kaufman J. What is the ideal acellular dermal matrix (ADM) for complex AWR? (poster).

- Review of allografts in abdominal wall reconstruction.
- FlexHD Structural is author’s acellular dermal matrix of choice due to strict donor procurement criteria, unique tissue processing and anatomical shape for less waste and ease of placement, and high tensile strength.
Evidence Supporting FlexHD® STRUCTURAL Acellular Hydrated Dermis+  


- Study evaluated uniaxial tensile test data of FlexHD Structural, AlloDerm®, Strattice™ (LifeCell), Fibr, Strattice™ Pliable, Permacol® (Cook), Surgimend® (TEI Biosciences), AlloMax™ (Bard), and Biodesign® SurgeX® (Cook)  
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Roth JS, Plymale M, Zachem A, et al. Results of a prospective trial comparing a hydrated human acellular dermal matrix and a porcine dermal matrix for complex abdominal wall reconstruction: an interim analysis (poster)  

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Evidence supporting XCM BIOLOGIC® Tissue Matrix


- Case study in ventral hernia repair with XCM BIOLOGIC Tissue Matrix
- The patient recovered satisfactorily and returned to work -3 weeks postoperatively

Harth KC, Rosen MJ. Major complications associated with xenograft biologic mesh implantation in abdominal wall reconstruction. Surg Innov. 2009 Dec;16(4):324-9

- Retrospective FDA database review found major complications reported for xenograft biologic meshes. Cross-linked meshes had the most AE reports to FDA (fair balance)


- XCM BIOLOGIC Tissue Matrix had the highest postoperative tensile strength versus native fascia (sheep study)


- Case study of modified sandwich technique combining components separation closure of the midline with a biologic underlay and overlay
- The author found the modified sandwich technique using XCM BIOLOGIC Tissue Matrix to be excellent for primary giant ventral hernias and recurrent ventral hernias

Pre-clinical Evidence Supporting XCM BIOLOGIC Tissue Matrix


- The study compared two porcine dermal, non-crosslinked biologic grafts (XCM BIOLOGIC Tissue Matrix and Stratiss™) in a rat model of infected fields
- XCM BIOLOGIC Tissue Matrix exhibited greater cellular ingrowth and collagen deposition at 10° and 10° inocula vs. Stratiss at 28 days and 60 days
- XCM BIOLOGIC Tissue Matrix demonstrated superior neovascularization compared to Stratiss™ in the 28 day control (P=0.02) and 60 day 10° (P=0.002) groups


- Preclinical study compared retention of cytokines, tensile strength and Young’s modulus in XCM BIOLOGIC Tissue Matrix vs. raw porcine dermis and Stratiss™
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References

5. Data on File, Ethicon Inc. 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.