Introducing ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh for inguinal and ventral hernia repair

Designed to help advance patient outcomes and ease of use

Color sticky notes represent customer insights.

ETHICON
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Shaping the future of surgery

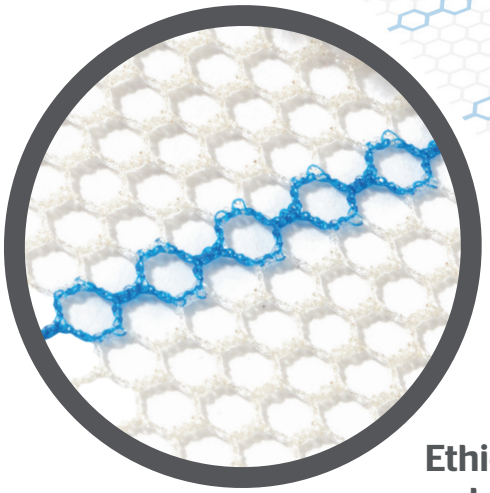
ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh

Inspired by your needs… designed with advanced features to benefit you and your patients

Advanced features of ULTRAPRO *ADVANCED* Mesh

- **Physiologically designed for comfortable healing**
  - Flexible in a way that approximates the natural movement of the abdominal wall, with 2:1 stretch[1-3*†]
  - Unique knitted mesh construction promotes good tissue ingrowth/tissue integration[4‡]

- **Balanced strength for strong and lasting repair**
  - High suture pullout strength[3]
  - High tensile strength[3]
  - Withstands ~2x maximum intraabdominal pressure in healthy adults[3,5,6]
  - No bulge visible in a preclinical study at 28 days and 91 days[4‡]



Ethicon's honeycomb pore design accommodates multiple fixation devices[7]

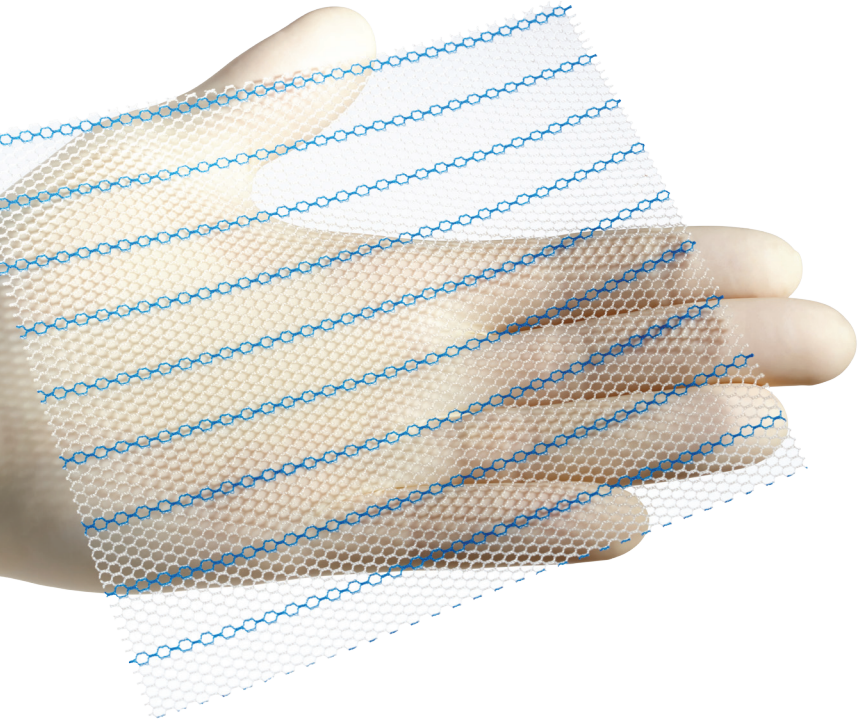
*The abdominal wall stretches 2:1 at the linea alba (longitudinal to transversal).
†Compared with ULTRAPRO® Macroporous Partially Absorbable Mesh, which has 4:1 stretch.
‡Evidence shown in an animal model.
§34% stiffer in transverse direction and 144% stiffer in longitudinal direction.

- **Designed for exceptional intraoperative handling**
  - Increased initial stiffness for easier handling[3§]
  - Springs open for easier deployment in laparoscopic repairs
  - Packaged flat, without folds, for easier positioning
  - Blue stripes facilitate orienting and positioning the mesh[8]
  - Trimmable based on surgeon's discretion, while leaving sufficient overlap to help prevent recurrence[8]

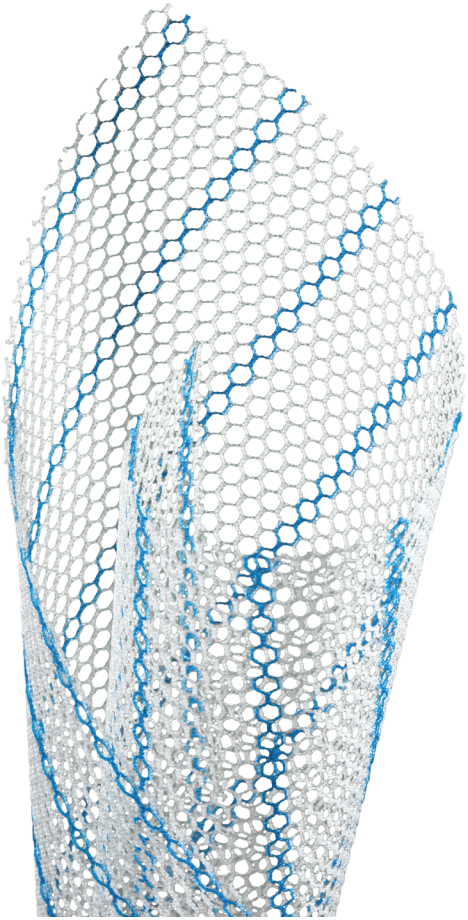
ULTRAPRO *ADVANCED* Mesh is designed to achieve the appropriate balance between flexibility and strength to help optimize patient outcomes and ease of use.[3]

ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh

Designed for exceptional intraoperative handling



- Blue orientation stripes facilitate orientation and placement and provide clear visualization of the underlying anatomy[8]



- Springs open when passed through a trocar in laparoscopic repairs for easier handling and placement

Surgeons rated ULTRAPRO *ADVANCED* Mesh highest in overall handling in open and laparoscopic repairs versus other meshes studied.[9*]

*After performing an open and laparoscopic handling evaluation (n=10). Study compared ULTRAPRO *ADVANCED* Mesh, ULTRAPRO® Macroporous Partially Absorbable Mesh, and Bard® Soft Mesh.
†Compared with ULTRAPRO Mesh, which has 4:1 stretch. The abdominal wall stretches 2:1 at the linea alba
‡"As received" mesh (mesh with absorbable component)
§"Naked" mesh (mesh after absorption)
‖Evidence shown in an animal model.

Balanced strength for strong and lasting repair

ULTRAPRO *ADVANCED* Mesh versus ULTRAPRO Mesh

ULTRAPRO *ADVANCED* Mesh has 2:1 stretch to approximate the natural movement of the abdominal wall and withstands ≈2x maximum intraabdominal pressure in healthy adults.[1-3,5,6†]

Tensile strength

Ratio of transverse to longitudinal is more evenly balanced (ie, 2:1 versus 5:1)[3‡]

Suture pullout strength

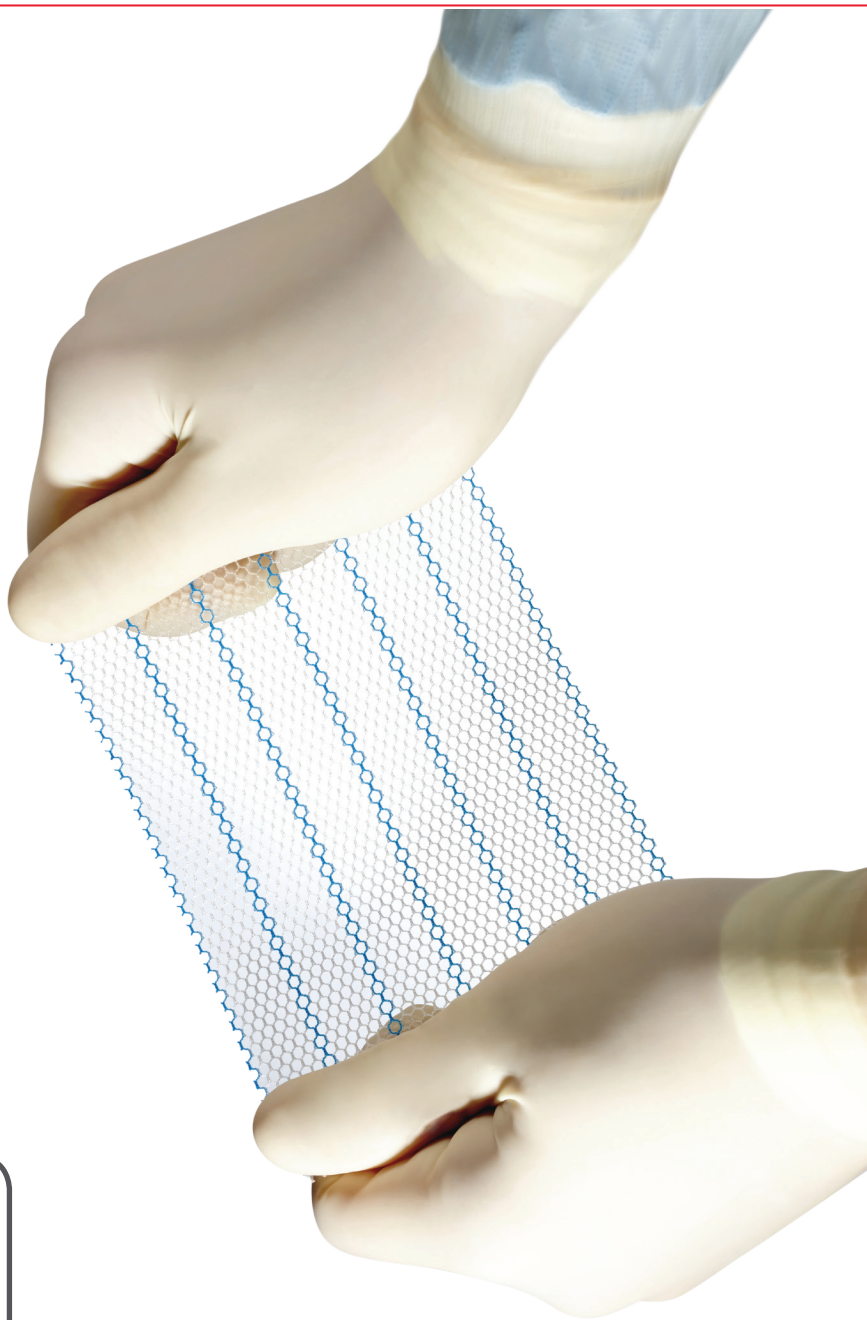
Transverse: **24%** stronger [3‡]
Longitudinal: **9%** stronger [3‡]

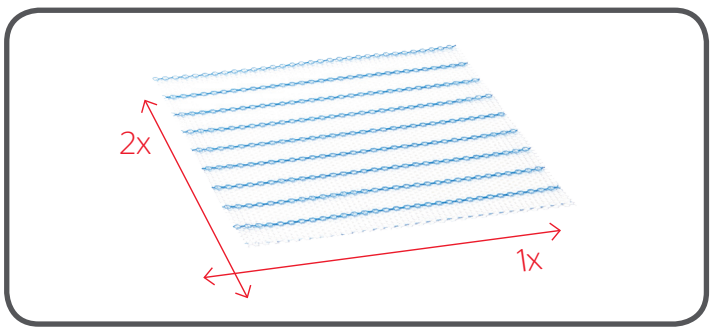
Density

Increased density of **14%**[3§]

ULTRAPRO *ADVANCED* Mesh is designed to reduce the potential for mesh bulging

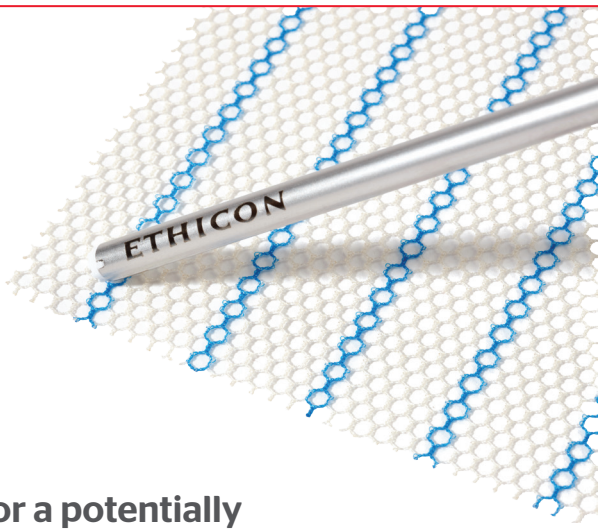
No bulge visible in a preclinical study at 28 days and 91 days[4‖]





ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh

Good tissue ingrowth with low foreign body mass



Demonstrated results from a study of ULTRAPRO *ADVANCED* Mesh* at 28 days and 91 days[4†]

- Good tissue ingrowth/tissue integration
- No evidence of mesh migration/compression, based on absence of wrinkling and folding at necropsy

ULTRAPRO *ADVANCED* Mesh has low foreign body mass for a potentially more comfortable repair

- ULTRAPRO *ADVANCED* Mesh is designed to leave behind low foreign body mass after partial absorption[3]
  - Macroporous design promotes host tissue penetration and fibrin fixation of the mesh to the tissue, helping to eliminate dead space and reduce the risk of seroma formation[10]
- Macroporous thin-filament design helps prevent bridging fibrosis[2]

Low surface area may help reduce bacterial colonization

- Microporous meshes and multifilament meshes may pose a higher risk of infection[11]

ULTRAPRO *ADVANCED* Mesh has a macroporous, thin-filament design that is partially absorbable, for low foreign body mass and comfortable healing.[2,12]

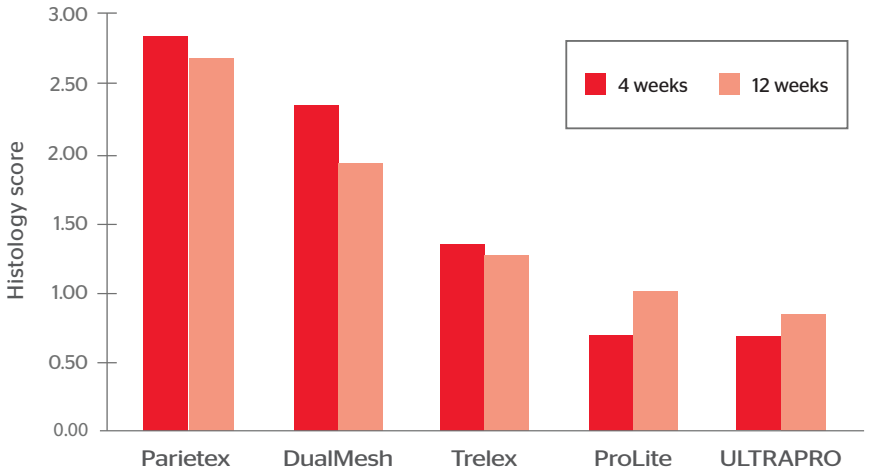
*Approximately equal parts absorbable MONOCRYL® (poliglecaprone-25) monofilament fiber to stiffen the mesh structure and nonabsorbable PROLENE® (polypropylene) monofilament fiber for permanent support.
†Evidence shown in an animal model.

Built on the proven technology of ULTRAPRO® Macroporous Partially Absorbable Mesh[13,14]

In a study of 5 meshes, which included ULTRAPRO Mesh

ULTRAPRO Mesh showed the highest biocompatibility at the implant site versus competitor meshes tested[15‡]

Foreign body response at 4 weeks and 12 weeks[§]



- Medium-density polyester mesh with pore size of 1.8 x 1.5 (Parietex™) induced the most pronounced foreign body reaction and most severe fibrosis
- Low-density polypropylene with poliglecaprone-25 mesh with pore size of 2 to 4 mm (ULTRAPRO Mesh) induced the least foreign body reaction and low fibrosis

‡Parietex™ (polyester), DualMesh™ (ePTFE), Trelex® (polypropylene), ProLite™ (polypropylene), and ULTRAPRO Mesh (polypropylene with poliglecaprone).
§Foreign body response based on quantity of infiltrating foreign body giant cells.

- Low-density macroporous ULTRAPRO Mesh showed the highest biocompatibility at the implant site versus competitor meshes tested, based on foreign body response and fibrosis parameters
- Histology score: 0=none, 1=minimal/mild, 2=moderate, 3=severe

ULTRAPRO® Macroporous Partially Absorbable Mesh

Physiologically designed to get patients back to their prehernia lives

Real-world, ongoing results since 2007

The Ethicon-sponsored International Hernia Mesh Registry (IHMR) is the largest international data registry with a vision to advance hernia repair. The IHMR provides prospective, longitudinal, patient-reported data on ventral, incisional, and inguinal hernia repairs for more than 4000 patients and reflects patient outcomes as seen in clinical practice.[16]

- The IHMR includes Ethicon products and non-Ethicon products
- IHMR data are independently collected and managed by a third party

Proven to reduce patients' pain and improve movement limitation

In 2 studies from the IHMR[13,14*†‡]

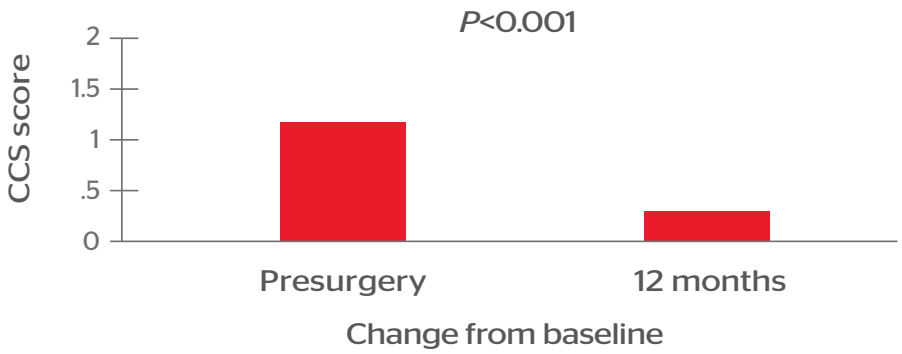
- Patients receiving hernia repair with ULTRAPRO Mesh reported a statistically significant improvement in pain and movement limitation scores at 12 months postsurgery versus presurgery (P<0.001)[13,14*†‡]

*Data from a prospective, longitudinal study of 151 patients receiving open hernia repair with ULTRAPRO® Partially Absorbable Lightweight Mesh from the International Hernia Mesh Registry (IHMR). Hernia types ; 53.0% incisional /ventral, 39.7% inguinal, 4.0% epigastric, 2.6% umbilical and 0.7% femoral. Common techniques utilized; 34.4% Lichtenstein, 29.8% Retro-rectus and 23.8% Preperitoneal. Fixation methods; 90.1% sutures , 6.0% sutures + glue,2.0% glue, 1.3% tackers+ sutures and 0.7% no fixation

†Data from a prospective, longitudinal study of 2792 patients receiving hernia repair with ULTRAPRO® Hernia System from the IHMR. Mostly large size direct or combined groin hernias. 91.76% were primary cases and 8.24% were recurrent cases.

‡Data from a prospective, longitudinal study of 71 patients receiving open hernia repair with ULTRAPRO® Plug from the IHMR. Two additional patient-reported recurrences could not be medically confirmed by a clinician. Hernia types: 90.2% inguinal; 8.7% umbilical; 1.1% femoral, 94.6% were primary repairs. Fixation methods: 97.8% sutures; 1.1 % sutures and glue; 1.1% none

Significant reduction in pain score at 1 year postsurgery versus presurgery[13]*



- The IHMR uses the Carolinas Comfort Scale (CCS), a **validated, hernia-specific** quality-of-life tool for assessing early and long-term symptoms following hernia repair[17]
- The CCS uses a 6-point scale from 0 (no symptoms) to 5 (disabling symptoms)[17]

The increased call for registries worldwide shows a growing focus on the value of utilizing patient outcome measurements in hernia repair.[17-19]

*Data from a prospective, longitudinal study of 470 patients receiving laparoscopic hernia repair with ULTRAPRO flat mesh from the IHMR (96.6% inguinal, 3.4% other).

ULTRAPRO® Macroporous Partially Absorbable Mesh

Low rates of recurrence and complications

Low rate of recurrence demonstrates strong and lasting repair[13,14]

In 2 studies from the IHMR

- Patients demonstrated a rate of recurrence of <1% with ULTRAPRO Mesh[13,14*†]

Recurrence rate of <1% at 1 year postsurgery[13,14]

In the same 2 studies

Low rates of complications, including infections, hematomas, and seromas[13,14]

Most common adverse events	Tollens et al.	Berrevoet et al.
Infection	**NA**	**4.6%**
Hematoma	**1.3%**	**2.7%**
Seroma	**3.6%**	**9.9%**

*Data from a prospective, longitudinal study of 470 patients receiving laparoscopic hernia repair with ULTRAPRO flat mesh from the IHMR (96.6% inguinal, 3.4% other).
†Data from a prospective, longitudinal study of 151 patients receiving open hernia repair with ULTRAPRO flat mesh from the IHMR (39.7% inguinal, 53.0% ventral/incisional, 7.3% other).

ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh is available in a range of sizes

ULTRAPRO *ADVANCED* Mesh Product Specifications

Ordering code	Mesh size	How supplied
UPA3612	6 x 12 cm	Sterile, 3 per box
UPA37615	7.6 x 15 cm	Sterile, 3 per box
UPA31015	10 x 15 cm	Sterile, 3 per box
UPA31515	15 x 15 cm	Sterile, 3 per box
UPA1530	15 x 30 cm	Sterile, 1 per box
UPA3030	30 x 30 cm	Sterile, 1 per box

MPPAM
MacroPorous, Partially Absorbable Mesh Technology

ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh—an advanced solution to meet your inguinal and ventral hernia repair needs

- Physiologically designed for comfortable healing[1-3]
- Balanced strength for strong and lasting repair[3,5,6]
- Designed for exceptional intraoperative handling[3,8,9]
- Patient outcomes based on the proven technology of ULTRAPRO Mesh[13,14]

The IHMR is the world's largest international hernia registry.[16]

ULTRAPRO *ADVANCED* Mesh is designed to achieve the appropriate balance between flexibility and strength to help optimize patient outcomes and ease of use.[3]

For more product information, go to www.ethicon.com.

For complete indications, contraindications, precautions, and adverse reactions, please reference full package insert.

References: 1. Förstemann T, Trzewik J, Holste J, et al. Forces and deformations of the abdominal wall—a mechanical and geometrical approach to the linea alba. *J Biomech.* 2011;44(4):600-606. **2.** Junge K, Klinge U, Prescher A, Giboni P, Niewiera M, Schumpelick V. Elasticity of the anterior abdominal wall and impact for reparation of incisional hernias using mesh implants. *Hernia.* 2001;5(3):113-118. **3.** Data on File. Ethicon, Inc. Vailhe E. Report for 510k testing for ETHICON ULTRAPRO ADVANCED, Version 1 (AST-2014-0415, technical report). **4.** Data on File. Ethicon, Inc. Shnoda P. Final Report, PSE Accession No. 14-0094, Project No. 14795. 28 and 91-day definitive study of ULTRAPRO ADVANCED mesh to evaluate tissue integration and tissue reaction in a single stage hernia swine model. February 26, 2015. **5.** Data on File. Ethicon, Inc. Validation Report, Ultrapro Preproduction. Project PE 02/527. June 25, 2003. **6.** Cobb WS, Burns JM, Kercher KW, Matthews BD, Norton HJ, Heniford BT. Normal intraabdominal pressure in healthy adults. *J Surg Res.* 2005;129(2):231-235. **7.** Data on File. Ethicon, Inc. Chantereau P. Fixation Compatibility Test Reports. Project SAMS1. Project number 100093053. March 25, 2015. **8.** ULTRAPRO ADVANCED Macroporous Partially Absorbable Mesh. Instructions for Use. Ethicon, Inc. **9.** Data on File. Ethicon, Inc. Deichmann T. Surgeon feedback regarding handling and design characteristics of flat mesh prototypes. Program SAMS Phase 1. September 2012. **10.** Amid PK. Classification of biomaterials and their related complications in abdominal wall surgery. *Hernia.* 1997;1(1):15-21. **11.** Klinge U, Junge K, Spellerberg B, Piroth C, Klosterhalfen B, Schumpelick V. Do multifilament alloplastic meshes increase the infection rate? Analysis of the polymeric surface, the bacteria adherence, and the in vivo consequences in a rat model. *J Biomed Mater Res.* 2002;63(6):765-771. **12.** Holste JL. Are meshes with lightweight construction strong enough? *Int Surg.* 2005;90(3 suppl):S10-S12. **13.** Tollens T, Bringman S, Romanowski C, Jones P, McRoy L. Laparoscopic macroporous partially absorbable flat mesh—12 month outcomes from the IHMR. Poster presented at: 15th Annual Hernia Repair; March 13-16, 2013; Orlando, FL. **14.** Berrevoet F, Tollens T, Romanowski C, Jones P, McRoy L. Open macroporous partially absorbable flat mesh—12 month outcomes. Poster presented at: 15th Annual Hernia Repair; March 13-16, 2013; Orlando, FL. **15.** Orenstein SB, Saberski ER, Kreutzer DL, Novitsky YW. Comparative analysis of histopathologic effects of synthetic meshes based on material, weight, and pore size in mice. *J Surg Res.* 2012;176(2):423-429. **16.** International Hernia Mesh Registry (IHMR). NIH Clinical Trials Registry Web site. Available at: http://www.clinicaltrials.gov/ct2/show/NCT00622583/. Accessed July 6, 2015. **17.** Colavita PD, Tsirline VB, Belyansky I, et al. Prospective, long-term comparison of quality of life in laparoscopic versus open ventral hernia repair. *Ann Surg.* 2012;256(5):714-723. **18.** Muysoms F, Campanelli G, Champault GG, et al. EuraHS: the development of an international online platform for registration and outcome measurement of ventral abdominal hernia wall repair. *Hernia.* 2012;16(3):239-250. **19.** Americas Hernia Society Quality Collaborative Web site. Available at: http://www.ahsqc.org/. Accessed July 3, 2015.

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