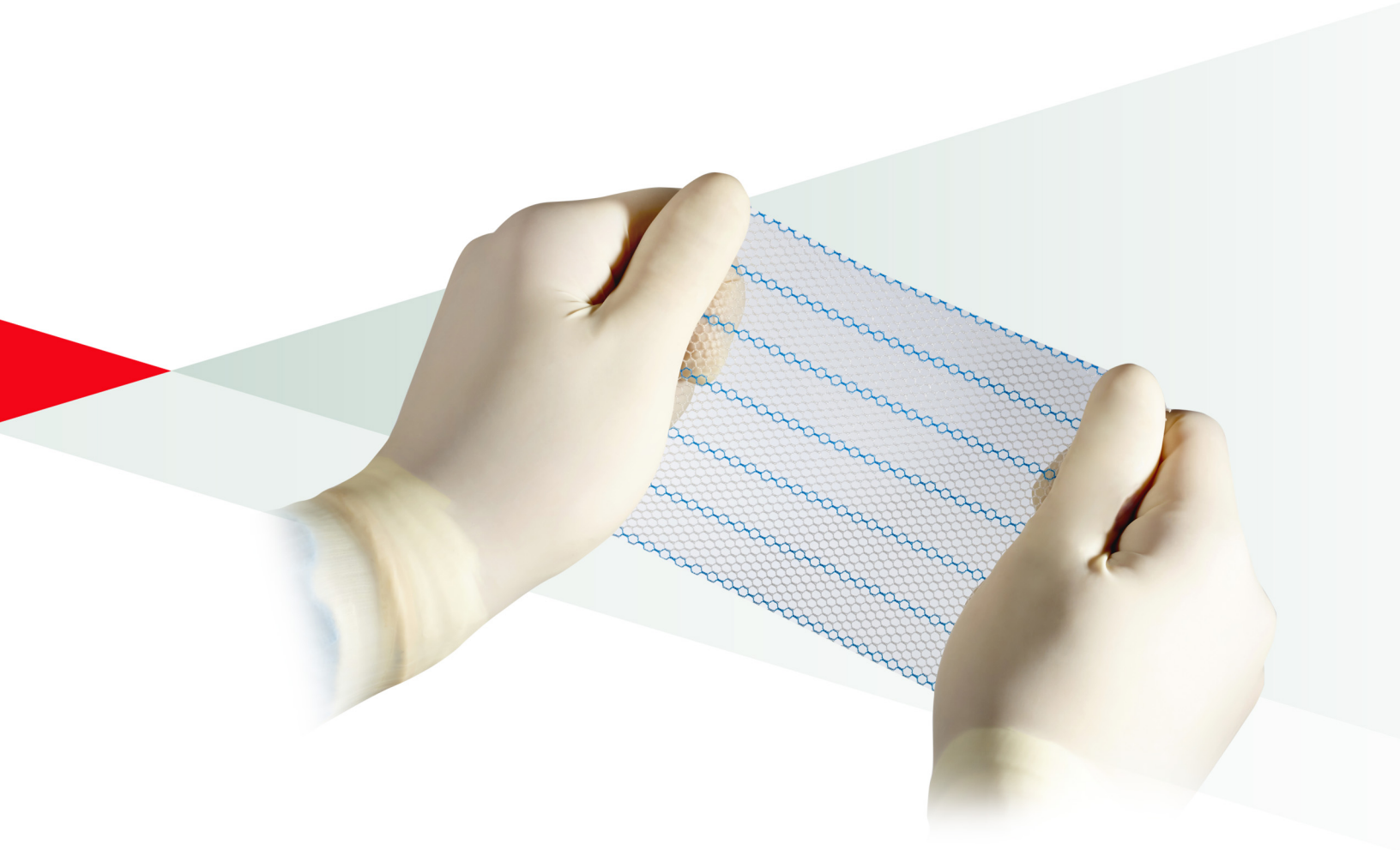
Value Analysis Committee

ULTRAPRO ADVANCED™ Macroporous Partially Absorbable Mesh

Product Information Kit



ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Shaping the future of surgery

Table of Contents

Product Information

Advanced Solution for Inguinal and Ventral Hernia Repairs. 3

Designed for Exceptional Intraoperative Handling 4

Balanced Strength* for Strong and Lasting Repair 5

Built on the Proven Technology of ULTRAPRO®
Macroporous Partially Absorbable Mesh 6

Device Details 10

Sizes and Codes. 11

Ordering Information. 14

Instructions for Use 15

Additional Resources

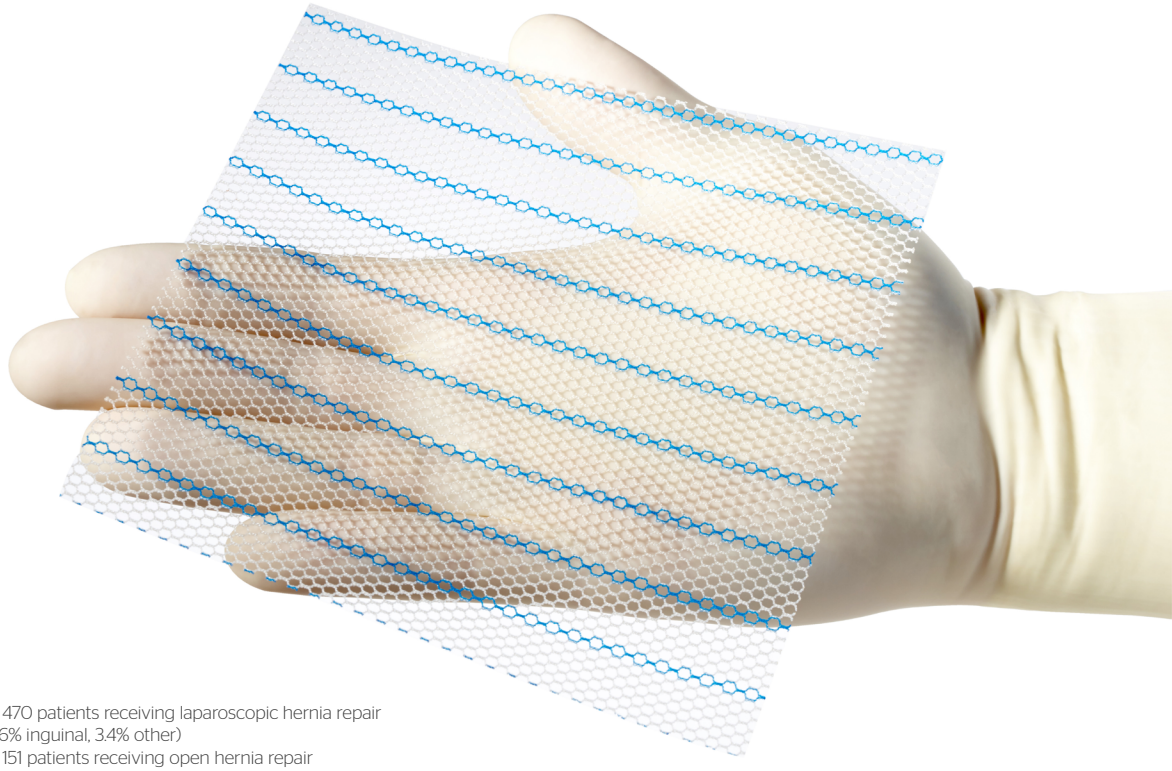
Product Information Brochure 16

*Based on preclinical study

Advanced Solution for Inguinal and Ventral Hernia Repairs

ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh is inspired by your needs... designed with advanced features to benefit you and your patients

- Physiologically designed for comfortable healing
- Balanced strength* for strong repair
- Designed for exceptional intraoperative handling[4§]
- Built on the proven technology of ULTRAPRO® Macroporous Partially Absorbable Mesh[1,2†‡]

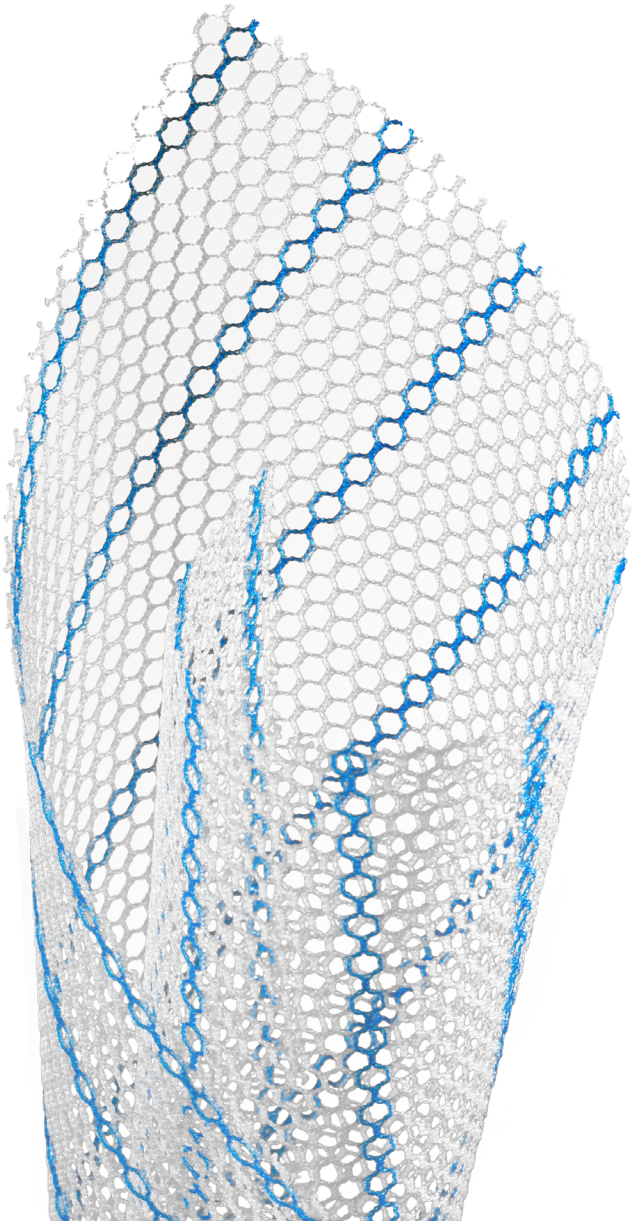


*Based on preclinical study
†Data from a prospective, longitudinal study of 470 patients receiving laparoscopic hernia repair with ULTRAPRO flat mesh from the IHMR (96.6% inguinal, 3.4% other)
‡Data from a prospective, longitudinal study of 151 patients receiving open hernia repair with ULTRAPRO flat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

Designed for Exceptional Intraoperative Handling[4‡]

Surgeons rated ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh highest in overall handling in open and laparoscopic repairs versus BARD™ Soft Mesh and ULTRAPRO® Partially Absorbable Lightweight Mesh[3*]

- Increased initial stiffness for easier handling[4†]
- Blue orientation stripes facilitate orientation and placement[5]
- Mesh is transparent to provide clear visualization of the underlying anatomy[5]
- Springs open when passed through a trocar in laparoscopic repairs for easier handling and placement[17]
- Trimmable based on surgeon's discretion, while leaving sufficient overlap to help prevent recurrence[5]
- Packaged flat without folds, for easier positioning

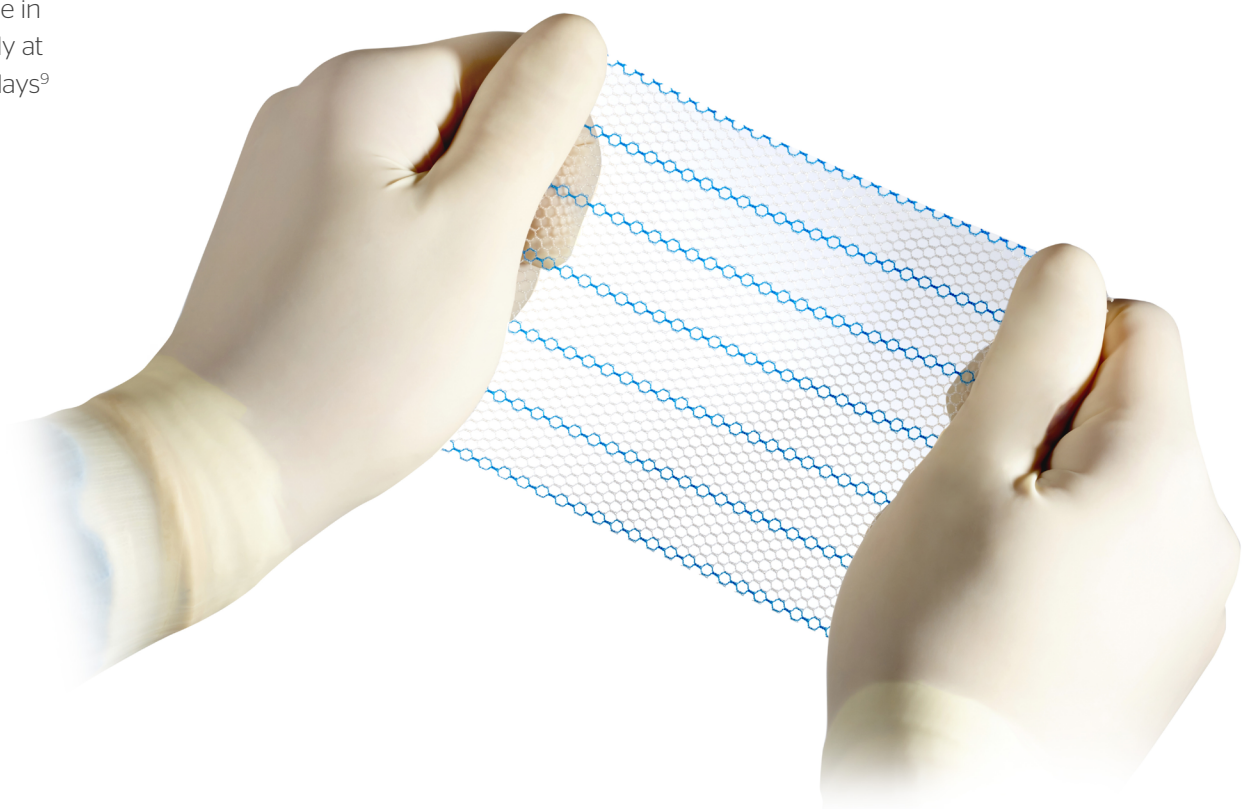


*After performing an open and laparoscopic handling evaluation (n=10) of the onlay and sublay/retro muscular placement techniques in an animal model
†34% stiffer in transverse direction and 144% stiffer in longitudinal direction
‡In porcine model

Balanced Strength for Strong Repair

ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh is designed to achieve the appropriate balance between flexibility and strength to optimize patient outcomes and ease of use[4]

- 2:1 stretch to approximate the natural movement of the abdominal wall[4-7*]
- Withstands ~2x maximum abdominal pressure[4,8]
- High suture pullout strength[4†]
- High tensile strength[4†]
- Increased density of 14%[4‡]
- No bulging visible in a preclinical study at 28 days and 91 days[9]



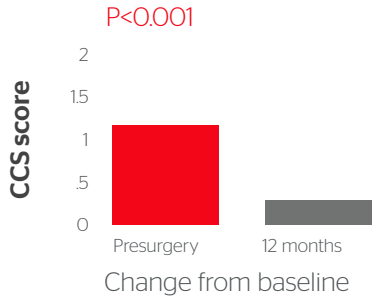
*Compared with ULTRAPRO® Macroporous Partially Absorbable Mesh, which has 4:1 stretch in bench top testing and applying force of 2 N or 10 N. Bench top testing was done to show ULTRAPRO ADVANCED™ Mesh withstands approximately 2x maximum intra-abdominal strength. The abdominal wall stretches 2:1 at the linea alba (longitudinal to transversal).
†"As received" mesh=mesh with the absorbable component
‡"Naked" mesh=mesh after absorption

Built on the Proven Technology of ULTRAPRO® Macroporous Partially Absorbable Mesh

ULTRAPRO Mesh is demonstrated to reduce patients' pain and improve movement limitation[1,2*†]

In two studies from the International Hernia Mesh Registry (IHMR), patients receiving hernia repair with ULTRAPRO Mesh reported a statistically significant improvement in pain and movement limitation scores at 12 months postsurgery versus presurgery[1,2*†]

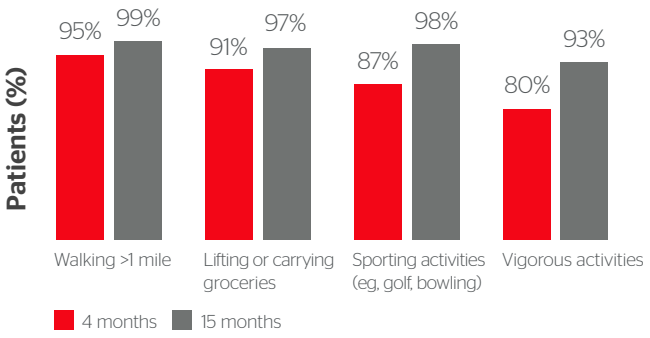
SIGNIFICANT REDUCTION IN PAIN SCORE AT 1 YEAR POSTSURGERY VERSUS PRESURGERY[1*]



- 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[10]
- The CCS uses a 6-point scale from 0 (no symptoms) to 5 (disabling symptoms)[10]

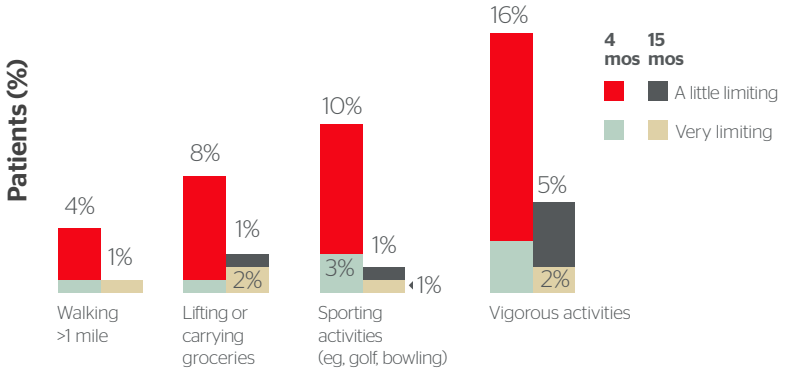
In another clinical study, ULTRAPRO Mesh was shown to offer continuous long-term improvement in return to daily activities[11‡]

NO LIMITATIONS AT 4 MONTHS AND 15 MONTHS



- No limitations resuming daily activities[11‡]
- Nearly 90% at 4 months
  - ≥96% at 15 months

LIMITATIONS AT 4 MONTHS AND 15 MONTHS



- "Very limiting" in resuming vigorous activities[11‡]
- Only up to 4% at 4 months
  - Only up to 2% at 15 months

*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 (53.0% ventral/incisional, 39.7% inguinal, 7.3% other)
‡Prospective study of 90 patients undergoing laparoscopic totally extraperitoneal (TEP) inguinal repair using ULTRAPRO Mesh at a single specialist institution; follow-up at 15 months included 89 patients using ULTRAPRO Mesh

Built on the Proven Technology of ULTRAPRO® Macroporous Partially Absorbable Mesh[1,2]

ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh uses Ethicon Macroporous Partially Absorbable Mesh (MPPAM) technology

- Good tissue ingrowth with low foreign body mass after partial absorption for a potentially more comfortable repair[4,7,12]*
- In two studies from the International Hernia Mesh Registry (IHMR), patients receiving hernia repair with ULTRAPRO Mesh[1,2†‡]
  - Demonstrated low rates of intra- and postoperative complications, such as seromas, (3.6-9.9%)[§] and a recurrence rate <1% at 1 year postsurgery
  - Reported significant improvement in pain and movement limitations from baseline at 1 year postsurgery[1,2†‡]

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 4,000 patients and reflects patient outcomes as seen in clinical practice[13]

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

MPPAM™
MacroPorous, Partially Absorbable Mesh Technology

In the same 2 studies
Low rates of complications, including infections, hematomas, and seromas[1, 2†‡]

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

*Shown in animal model
†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 (53.0% ventral/incisional, 39.7% inguinal, 7.3% other)
§This compares favorably with reported seroma rates of 2.6% to 33%[14]

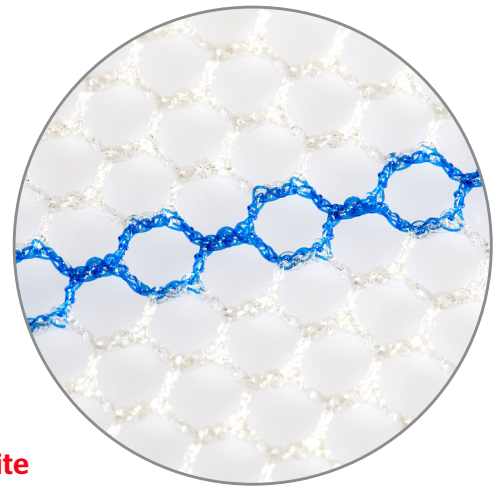
ULTRAPRO® Macroporous Partially Absorbable Mesh

Good Tissue Ingrowth with Low Foreign-Body Mass and Superior Biocompatibility[4,10*,15]

Unique knitted mesh construction promoted good tissue ingrowth and tissue integration[10*]

A study of ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh† at 28 days and 91 days demonstrated good tissue ingrowth and tissue integration[10*]

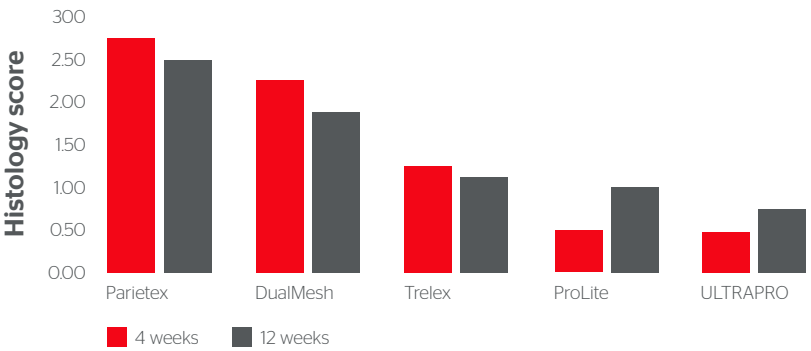
- No evidence of mesh migration or compression, based on absence of wrinkling and folding at necropsy



ULTRAPRO *ADVANCED* Mesh is designed to leave behind low foreign-body mass after partial absorption[4]

ULTRAPRO Mesh showed the highest biocompatibility at the implant site versus competitor meshes tested based on foreign body response and fibrosis parameters[15‡]

FOREIGN BODY RESPONSE AT 4 WEEKS AND 12 WEEKS[§¶ß]



- 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

*Evidence shown in an animal model
†Approximately equal parts absorbable MONOCRYL® (poliglecaprone-25) monofilament fiber to stiffen the mesh structure and nonabsorbable PROLENE® (polypropylene) monofilament fiber for permanent support
‡Parietex™ (polyester), DualMesh™ (ePTFE), Trelex® (polypropylene), ProLite™ (polypropylene), and ULTRAPRO® Mesh (polypropylene with poliglecaprone) in a study of 5 meshes
§Foreign body response based on quantity of infiltrating foreign body giant cells.
¶Under FBR chart at 4 weeks and 12 weeks: Parietex™ (polyester), DualMesh™ (ePTFE), Trelex® (polypropylene), ProLite™ (polypropylene), and ULTRAPRO Mesh (polypropylene with poliglecaprone).
ßEvidence shown in an animal model
The third-party trademarks used herein are trademarks of their respective owners.

ULTRAPRO® Macroporous Partially Absorbable Mesh

Low Rates of Recurrence and Complications

Designed for a strong repair[1,2*†]

In two studies from the International Hernia Mesh Registry (IHMR), patients receiving hernia repair with ULTRAPRO Mesh demonstrated a **rate of recurrence of <1% at 1 year postsurgery[1,2*†]**

Macroporous design promotes host tissue penetration and fibrin fixation of the mesh to the tissue, helping to eliminate dead space and reduce risk of seroma formation[16]

In the same 2 studies

Low rates of complications, including infections, hematomas, and seromas[1,2*†]

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 (53.0% ventral/incisional, 39.7% inguinal, 7.3% other)
‡This compares favorably with reported seroma rates of 2.6% to 33%[14]

Device Details[5]

ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh is provided sterile and is designed for the repair of abdominal fascial deficiencies, such as hernias.

ULTRAPRO *ADVANCED* Mesh is manufactured from approximately equal parts of absorbable poliglecaprone-25 monofilament fiber and non-absorbable polypropylene monofilament fiber.

The polymer of the undyed and dyed polypropylene fiber (phthalocyanine blue) is identical to the material used for dyed/undyed PROLENE™ Suture material. Dyed polypropylene fiber has been added for better intraoperative visibility and orientation purposes.

Poliglecaprone-25 fiber consists of a copolymer containing glycolide and ε-caprolactone; this copolymer is identical to the material used for MONOCRYL™ Suture. After absorption of the poliglecaprone-25 component, only the polypropylene mesh remains. The remaining polypropylene mesh stretches to a greater degree perpendicular to the blue orientation stripes.



Available in a Range of Sizes

ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh Competitive Code Conversions

	Ethicon		BARD		
	ULTRAPRO *ADVANCED* Mesh	**ULTRAPRO® Partially Absorbable Lightweight Mesh**	**3DMax™ Mesh**	**3DMax™ Light Mesh**	**BARD® Soft Mesh**
Inguinal Hernia Repair	UPA3612 Size (cm) 6 x 12	UMS3 Size (cm) 6 x 11	0115310 Size (cm) 8.5 x 13.7	0117310 Size (cm) 7.9 x 13.4	0117008 Size (cm) 5 x 10
	UPA37615 Size (cm) 7.6 x 15	UMR3 Size (cm) 7.6 x 15	0115320 Size (cm) 8.5 x 13.7	0117320 Size (cm) 7.9 x 13.4	0117009 Size (cm) 7.5 x 15
	UPA31015 Size (cm) 10 x 15		0115311 Size (cm) 10.8 x 16	0117311 Size (cm) 10.3 x 15.7	0117010 Size (cm) 10 x 15
			0115321 Size (cm) 10.8 x 16	0117321 Size (cm) 10.3 x 15.7	
			0115312 Size (cm) 12.4 x 17.3	0117312 Size (cm) 12.2 x 17	
Inguinal/ Ventral	UPA31515 Size (cm) 15 x 15		0115322 Size (cm) 12.4 x 17.3	0117322 Size (cm) 12.2 x 17	0117011 Size (cm) 15 x 15
		UMM3 Size (cm) 15 x 15			
	UPA1530 Size (cm) 15 x 30				
Ventral Hernia Repair	UPA3030 Size (cm) 30 x 30	UML1 Size (cm) 30 x30			0117016 Size (cm) 30.5 x 30.5

The third-party trademarks used herein are trademarks of their re:spective owners.

Available in a Range of Sizes

ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh Competitive Code Conversions

	Ethicon		Medtronic				
	ULTRAPRO *ADVANCED* Mesh	**ULTRAPRO® Partially Absorbable Lightweight Mesh**	**ProGrip™ Laparoscopic Self-Fixating Mesh**	**Parietex ProGrip™ Self-Fixating Mesh**	**Parietex™ Flat Sheet Mesh**	**Parietex™ Hydrophilic Anatomical Mesh**	**Parietex™ Lightweight Monofilament Mesh**
Inguinal Hernia Repair	UPA3612 Size (cm) 6 x 12	UMS3 Size (cm) 6 x 11	LPG1510AR Size (cm) 10 x 15	TEM1208GL Size (cm) 8 x 12		TECT1510ADP2L Size (cm) 10 x 15	TCM1106 Size (cm) 6 x 11
	UPA37615 Size (cm) 7.6 x 15	UMR3 Size (cm) 7.6 x 15	LPG1510AL Size (cm) 10 x 15	TEM1208GR Size (cm) 8 x 12		TECT1612AL Size (cm) 12 x 16	TCM1106X3 Size (cm) 6 x 11
	UPA31015 Size (cm) 10 x 15		LPG1510 Size (cm) 10 x 15	TEM1409GL Size (cm) 9 x 14		TECT1510ADP2R Size (cm) 10 x 15	TCM1510 Size (cm) 10 x 15
			LPG1510X2 Size (cm) 10 x 15	TEM1409GR Size (cm) 9 x 14		TECT1510AL Size (cm) 10 x 15	TCM1510X3 Size (cm) 10 x 15
			LPG1510AK2 Size (cm) 10 x 15	TEM1509G Size (cm) 9 x 15		TECT1510AR Size (cm) 10 x 15	TCM1515 Size (cm) 15 x 15
	UPA31515 Size (cm) 15 x 15					TECT1510ADPL Size (cm) 10 x 15	TCM1515X3 Size (cm) 15 x 15
Inguinal/ Ventral		UMM3 Size (cm) 15 x 15				TECT1510ADPR Size (cm) 10 x 15	
						TECT1612AR Size (cm) 12 x 16	
	UPA1530 Size (cm) 15 x 30			TEM2015G Size (cm) 15X20	TEC2020 Size (cm) 20 x 20		
					TET2020 Size (cm) 20 x 20		
Ventral Hernia Repair	UPA3030 Size (cm) 30 x 30	UML1 Size (cm) 30 x30		TEM3015G Size (cm) 15X30	TEC3030 Size (cm) 30 x 30		
					TET3030 Size (cm) 30 x 30		

The third-party trademarks used herein are trademarks of their respective owners.

Available in a Range of Sizes

ULTRAPRO *ADVANCED*™ Macroporous Partially Absorbable Mesh Competitive Code Conversions

	Ethicon		Pierson Surgical
	ULTRAPRO *ADVANCED* Mesh	**ULTRAPRO® Partially Absorbable Lightweight Mesh**	**ProLite ULTRA™ Mesh**
Inguinal Hernia Repair	UPA3612 Size (cm) 6 x 12	UMS3 Size (cm) 6 x 11	30710 Size (cm) 2.5 x 10
	UPA37615 Size (cm) 7.6 x 15	UMR3 Size (cm) 7.6 x 15	30711 Size (cm) 5 x 10
	UPA31015 Size (cm) 10 x 15		30713 Size (cm) 7.5 x 7.5
			30714 Size (cm) 7.5 x 15
			30715 Size (cm) 10 x 15
	UPA31515 Size (cm) 15 x 15		30716 Size (cm) 10 x 18
Inguinal/ Ventral		UMM3 Size (cm) 15 x 15	30717 Size (cm) 15 x 15
	UPA1530 Size (cm) 15 x 30		30718 Size (cm) 20 x 25
			30719 Size (cm) 25 x 25
Ventral Hernia Repair	UPA3030 Size (cm) 30 x 30	UML1 Size (cm) 30 x30	30720 Size (cm) 25 x 35
			30721 Size (cm) 30 x 30

The third-party trademarks used herein are trademarks of their respective owners.

Ordering Information

Product can be ordered direct through Johnson & Johnson Health Care Systems, Inc. (JJHS) and through distributor channels

Electronic ordering options

Note: Placing orders electronically avoids minimum order fees for hospitals

Order 360™: order360.jnjgateway.com
For questions about your order, visit the website or call 1-866-565-4283

Global Healthcare Exchange: ghx.com
For questions about your order, visit the website or call 1-800-YOUR-GHX

Electronic Data Interchange
Call JJHCS EDI Help Line: 1-800-262-2888

Nonelectronic/Manual ordering options

Call JJHCS at 1-800-255-2500 (option 1) between 8:30 a.m. and 8:00 p.m. eastern time, or fax your order to 1-832-562-2212 or 1-800-997-1122. For more information or product support, call 1-877-ETHICON (384-4266)

Customer support

For product use assistance, clinical guidelines, service and repair, emergency assistance, copy of 510(k) clearance letter or complaints, please contact our Customer Support Center at customersupport@eesus.jnj.com or by calling 1-877-ETHICON (384-4266). Our support center is staffed 24 hours a day, 7 days a week by qualified nurses to answer your product-related questions

For complete product details,
see Instructions for Use.

For more information,
contact your local Ethicon representative
or call 1-877-ETHICON (384-4266)



Instructions for Use

Instructions for Use

ENGLISH

ULTRAPRO ADVANCED™ Mesh

Please read all information carefully.

Failure to properly follow instructions may result in improper functioning of the device and could lead to injury.

CAUTION

Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

ULTRAPRO ADVANCED™ Mesh is intended for use only by physicians who are trained in the surgical procedures and techniques required for the repairs of abdominal fascial defects, such as hernias, and the implantation of synthetic meshes.

The physician is advised to consult the medical literature regarding techniques, complications, and hazards associated with the intended procedures.

DESCRIPTION

ULTRAPRO ADVANCED™ Mesh is provided sterile and is designed for the repair of abdominal fascial deficiencies, such as hernias.

ULTRAPRO ADVANCED™ Mesh is manufactured from approximately equal parts of absorbable poliglecaprone-25 monofilament fiber and non-absorbable polypropylene monofilament fiber.

The polymer of the undyed and dyed polypropylene fiber (phthalocyanine blue) is identical to the material used for dyed/undyed PROLENE™ Suture material.

Dyed polypropylene fiber has been added for better intraoperative visibility and orientation purposes.

Poliglecaprone-25 fiber consists of a copolymer containing glycolide and ε-caprolactone; this copolymer is identical to the material used for MONOCRYL™ Suture. After absorption of the poliglecaprone-25 component, only the polypropylene mesh remains. The remaining polypropylene mesh stretches to a greater degree perpendicular to the blue orientation stripes.

INDICATIONS

ULTRAPRO ADVANCED™ Mesh may be used for the repair of abdominal fascial deficiencies, such as hernias, that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

CONTRAINDICATIONS

ULTRAPRO ADVANCED™ Mesh must not be placed intraperitoneally.

APPLICATION/INSTRUCTIONS FOR USE

ULTRAPRO ADVANCED™ Mesh must always be placed extraperitoneally. ULTRAPRO ADVANCED™ Mesh can be trimmed according to the surgeon's discretion while providing the necessary overlap to reduce the likelihood of recurrence. The effects of the use of thermal cutting devices to cut the mesh have not been tested.

Ventral/Incisional and Inguinal Hernia Repair

Ensure that the ULTRAPRO ADVANCED™ Mesh, when used in ventral / incisional repair, is large enough to extend at least 3 to 5 cm beyond the margins of the hernia defect according to the surgeon's discretion to provide adequate overlap onto healthy tissue to reduce the likelihood of recurrence.

When used in inguinal hernia repair, the mesh should be large enough that sufficient overlap of the fascial defect on all sides is achieved.

The blue stripes on the mesh can be used for orientation and alignment purposes. After absorption of the poliglecaprone-25 component, the remaining polypropylene mesh stretches to a greater degree perpendicular to the blue orientation stripes.

Place the mesh flat and tension-free in contact with the tissue. The method of securing the implant (e.g., non-absorbable/absorbable sutures, tackers) to provide for adequate mesh fixation and to reduce the likelihood of recurrence should be determined by the surgeon's judgment based on the individual patient's needs and the nature of the reconstruction.

Preclinical data and reported experience suggest having the fixation points at least 1cm from the edge of the mesh. Fixation points should be sufficiently spaced so as not to create a mechanical weakness point on the reconstruction, and to reduce the likelihood of organ entrapment, and/or recurrence.

ACTIONS/PERFORMANCE

ULTRAPRO ADVANCED™ Mesh is a composite mesh, with a polypropylene mesh component that is knitted with non-absorbable fibers, which may be used for the repair of abdominal fascial deficiencies, such as hernias, that require the addition of a reinforcing or bridging material to obtain the desired surgical results.

Animal studies show that implantation of ULTRAPRO ADVANCED™ Mesh elicits a mild inflammatory reaction that does not interfere with integration of the mesh into adjacent tissue. In an animal study, the mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The absorbable component is essentially absorbed within 91 days, whereas the polypropylene material is not absorbed.

In an animal study, the ULTRAPRO ADVANCED™ Mesh did not potentiate infections.

WARNINGS

ULTRAPRO ADVANCED™ Mesh is provided as a sterile product. Do not use if packaging is opened or damaged. Discard opened unused products.

Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.

When ULTRAPRO ADVANCED™ Mesh is used in patients with a potential for growth, e.g. infants, children, pregnant women, or in women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

If the ULTRAPRO ADVANCED™ Mesh is used in a contaminated field, contamination of the mesh may lead to infection that may require removal of the mesh.

To prevent recurrence when repairing hernias, the mesh should be large enough to overlap on all sides of the defect.

For ventral hernia repair fixation points should be appropriately placed as described in the application section as not to create a mechanical weakness point on the reconstruction, and to reduce the likelihood of organ entrapment, and/or recurrence.

PRECAUTIONS

Users should be familiar with surgical procedures and techniques involving non-absorbable or partially absorbable mesh based implants before using ULTRAPRO ADVANCED™ Mesh.

Spacing and distribution between fixation points and technique should be determined by the surgeon's judgment to provide adequate mesh fixation, to reduce the risk of mesh migration and to optimize mesh-to-tissue contact to foster tissue ingrowth.

ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials, including infection, inflammation, seroma formation, acute or chronic pain, foreign body sensation, hematoma, nerve damage, soft tissue injury, adhesion formation, fistula formation, extrusion/erosion, excessive contraction or shrinkage of the tissue surrounding the mesh, mesh failure/hernia recurrence.

STORAGE

No special storage conditions required. Do not use after expiry date.

HOW SUPPLIED

ULTRAPRO ADVANCED™ Mesh is available in single, sterile packets in a variety of sizes.

STERILITY

The device is sterilized by Ethylene Oxide. Do not resterilize. Do not use if package is opened or damaged prior to intended use. Discard open, unused product.

TRACEABILITY

A traceability label that identifies the type, size, expiration date and lot number of the device is attached to every package. This label should be affixed to the patient's permanent medical record to clearly identify the device that was implanted.

SYMBOLS USED ON LABELLING

Caution		Manufacturer	
Use by		LOT	Batch number
Do not reuse		REF	Catalogue number
Do not resterilize		STERILE EO	Sterilized using ethylene oxide
Do not use if package is damaged		CE 0086	CE-mark and Identification number of Notified Body. The product meets the essential requirements of Medical Device Directive 93/42/EEC.
Rx only	Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.		

Johnson & Johnson INTERNATIONAL
c/o European Logistics Centre
Leonardo Da Vincilaan, 15
BE-1831 Diegem
Belgium
1-877-ETHICON
+1-513-337-6928

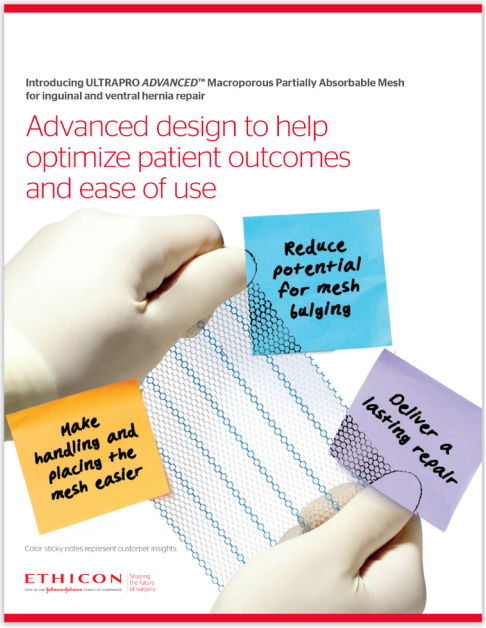
CE 0086

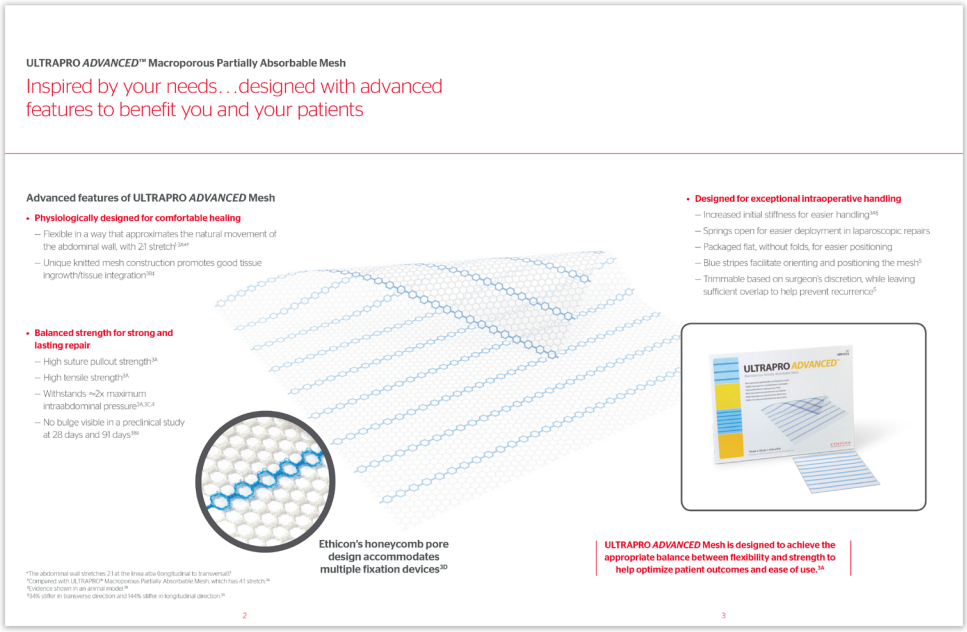
Made in Germany
02/2015
© Ethicon, Inc. 2015

8555605
LAB100258348v1

Additional Resources

PRODUCT INFORMATION BROCHURE





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

References: 1. 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. **2.** 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. **3.** Handling and design characteristics of flat mesh prototypes study report. 2013 Ethicon, Inc. **4.** Vailhe E. Report for 510k testing for ETHICON ULTRAPRO *ADVANCED*, Version 1 (AST-2014-0415, technical report). Ethicon, Inc. **5.** ULTRAPRO *ADVANCED* Macroporous Partially Absorbable Mesh. Instructions for Use. Ethicon, Inc. 2019. **6.** 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. **7.** 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. **8.** 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. **9.** Shnoda P. Final Report, PSE Accession No. 14-0094, Project No. 14795. February 26, 2015. Ethicon, Inc. **10.** 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. **11.** Khan LR, Liong S, de Beaux AC, Kumar S, Nixon SJ. Lightweight mesh improves functional outcome in laparoscopic totally extra-peritoneal inguinal hernia repair. *Hernia*. 2010;14(1):39-45. **12.** Klinge U, Klosterhalfen B, Birkenhauer V, Junge K, Conze J, Schumpelick V. Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model. *J Surg Research*. 2002;103:208-214. **13.** Clinical Trials website. http://clinicaltrials.gov/ct2/show/NCT00622583. Accessed June 13, 2013. **14.** Bradley III JF, Walters AL, Williams KB, et al. Preliminary results of surgical and quality of life outcomes of Physiomesh in an international, prospective study. *Surg Technol Int*. 2012 Dec; 22:113-9. **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.** Amid PK. Classification of biomaterials and their related complications in abdominal wall surgery. *Hernia*. 1997;1(1):15-21. **17.** Deichman T, Ethicon ,Inc. Handling and design characteristics of flat mesh prototypes study report. 2013.

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES
Shaping the future of surgery

ULTRAPRO *ADVANCED*™

©2021 Ethicon US LLC. All rights reserved. 041108-210625