



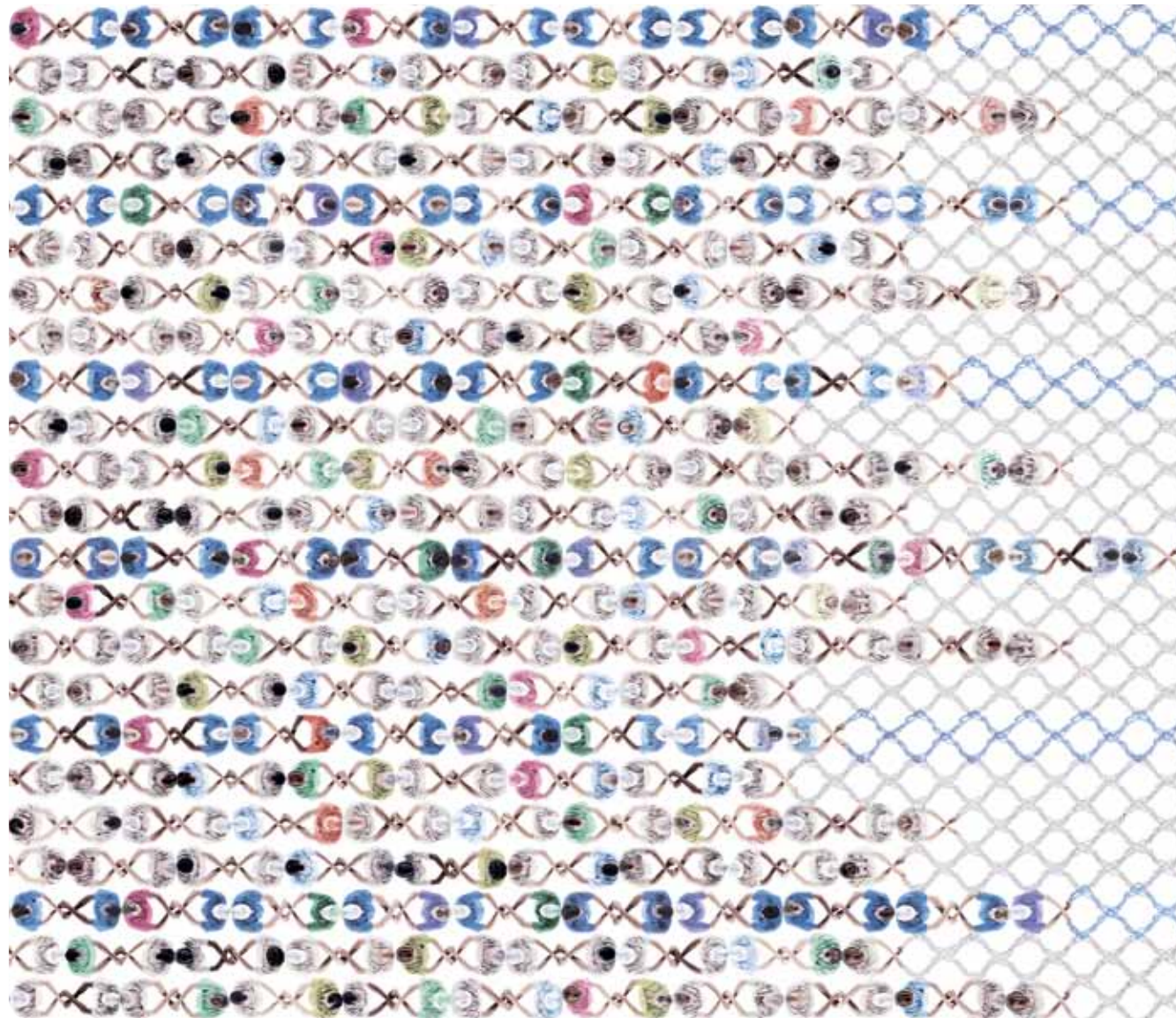
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**HERNIA SOLUTIONS**

Together for life



"When it comes to your work and your patients' lives, ETHICON understands that team work is vital to everyone's success—and we are proud to play our role. That's why our HERNIA SOLUTIONS technologies are designed to improve long-term patient outcomes. It's our long-term commitment to you."

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# HERNIA SOLUTIONS

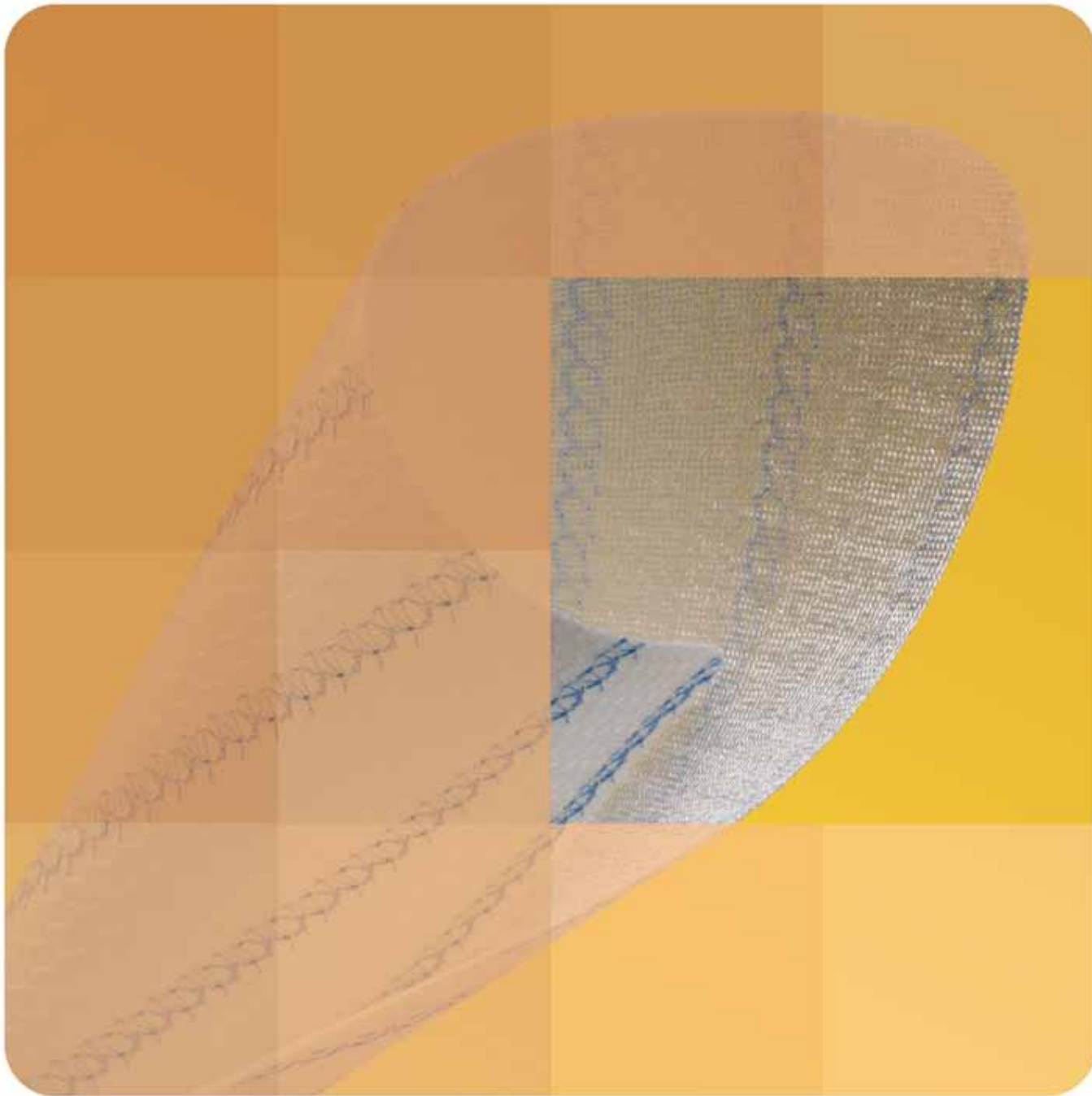
## Application Chart

- Flat Mesh
- Mesh Device
- Tissue Separating Mesh
- Biologics

	VENTRAL	UMBILICAL	INGUINAL
<b>PROCEED™</b> Surgical Mesh	●	●	
<b>PROCEED™</b> Ventral Patch	●	●	
<b>ULTRAPRO*</b> Partially Absorbable Lightweight Mesh	●	●	●
<b>ULTRAPRO*</b> Plug			●
<b>FlexHD®</b> Acellular Hydrated Dermis	●		
<b>ULTRAPRO*</b> Hernia System			●
<b>PROLENE*</b> Polypropylene Hernia System			●
<b>PROLENE*</b> 3-D Patch Polypropylene Mesh	●		●
<b>PROLENE*</b> Polypropylene Mesh	●	●	●
<b>PROLENE*</b> Soft Polypropylene Mesh	●	●	●
<b>VICRYL*</b> (polyglactin 910) Woven Mesh	●	●	●
<b>MERSILENE*</b> Polyester Fiber Mesh	●	●	●







**VENTRAL HERNIA**

**PROCEED™**  
Surgical Mesh

*For intra-abdominal  
hernia repair*

*Heal strongly.*

*Heal naturally.*

*Heal comfortably.*

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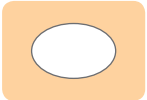

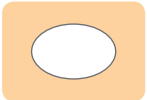


# PROCEED™ Surgical Mesh

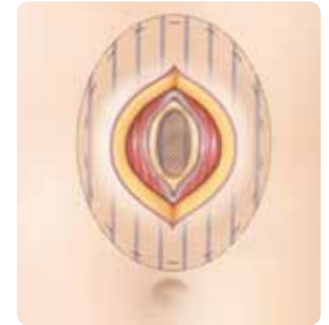
ETHICON's PROCEED™ Surgical Mesh is designed for general surgeons who perform intra-abdominal hernia repairs, and is distinctive for its combination of large pore, monofilament mesh and natural, absorbable tissue-separating technology that together enable patients to heal more naturally, strongly, and comfortably.



Multilayer tissue-separating mesh is ideal for open and laparoscopic ventral hernia repair.

	<b>Product Code</b>	<b>Units per Box</b>	<b>Size</b>
	<b>PCDB1</b>	1 Per Box	2" x 4" (5cm x 10cm)
	<b>PCDR1</b>	1 Per Box	3" x 6" (7.5cm x 15cm)
	<b>PCDN1</b>	1 Per Box	4" x 6" (10cm x 15cm)
	<b>PCDM1</b>	1 Per Box	6" x 6" (15cm x 15cm)
	<b>PCDD1</b>	1 Per Box	4" x 8" (10cm x 20cm)

	<b>Product Code</b>	<b>Units per Box</b>	<b>Size</b>
	<b>PCDG1</b>	1 Per Box	6" x 8" (15cm x 20cm)
	<b>PCDH1</b>	1 Per Box	8" x 10" (20cm x 25cm)
	<b>PCDJ1</b>	1 Per Box	8" x 12" (20cm x 30cm)
	<b>PCDT1</b>	1 Per Box	10" x 13" (26cm x 34cm)
	<b>PCDW1</b>	1 Per Box	10" x 14" (25cm x 35.5cm)
	<b>PCDL1</b>	1 Per Box	12" x 12" (30.5cm x 30.5cm)



For additional ordering and size information for PROCEED™ Surgical Mesh, please visit [www.ecatalog.ethicon.com](http://www.ecatalog.ethicon.com), contact your ETHICON representative, or call 1-877-ETHICON.

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UMBILICAL HERNIA

**PROCEED™**  
Ventral Patch

*For umbilical hernia repair*

*Heal strongly.*

*Heal naturally.*

*Heal comfortably.*

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a *Johnson & Johnson* company

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**HERNIA SOLUTIONS**

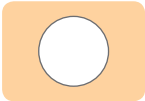
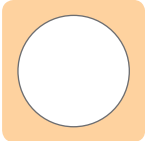
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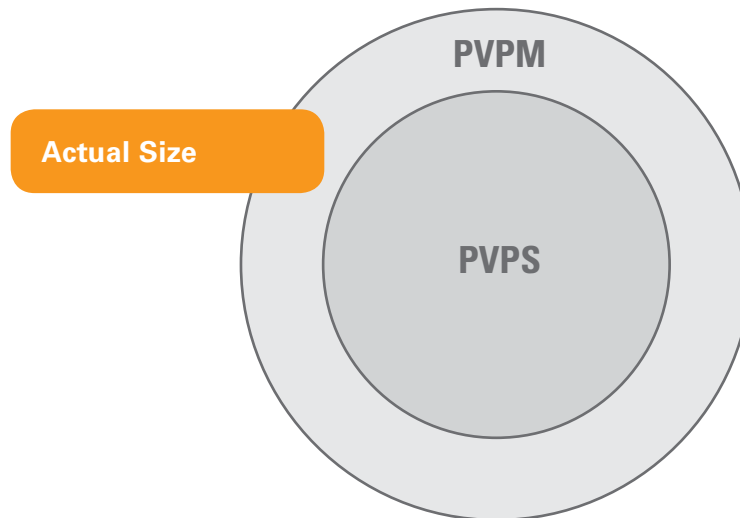
# PVP™ Device

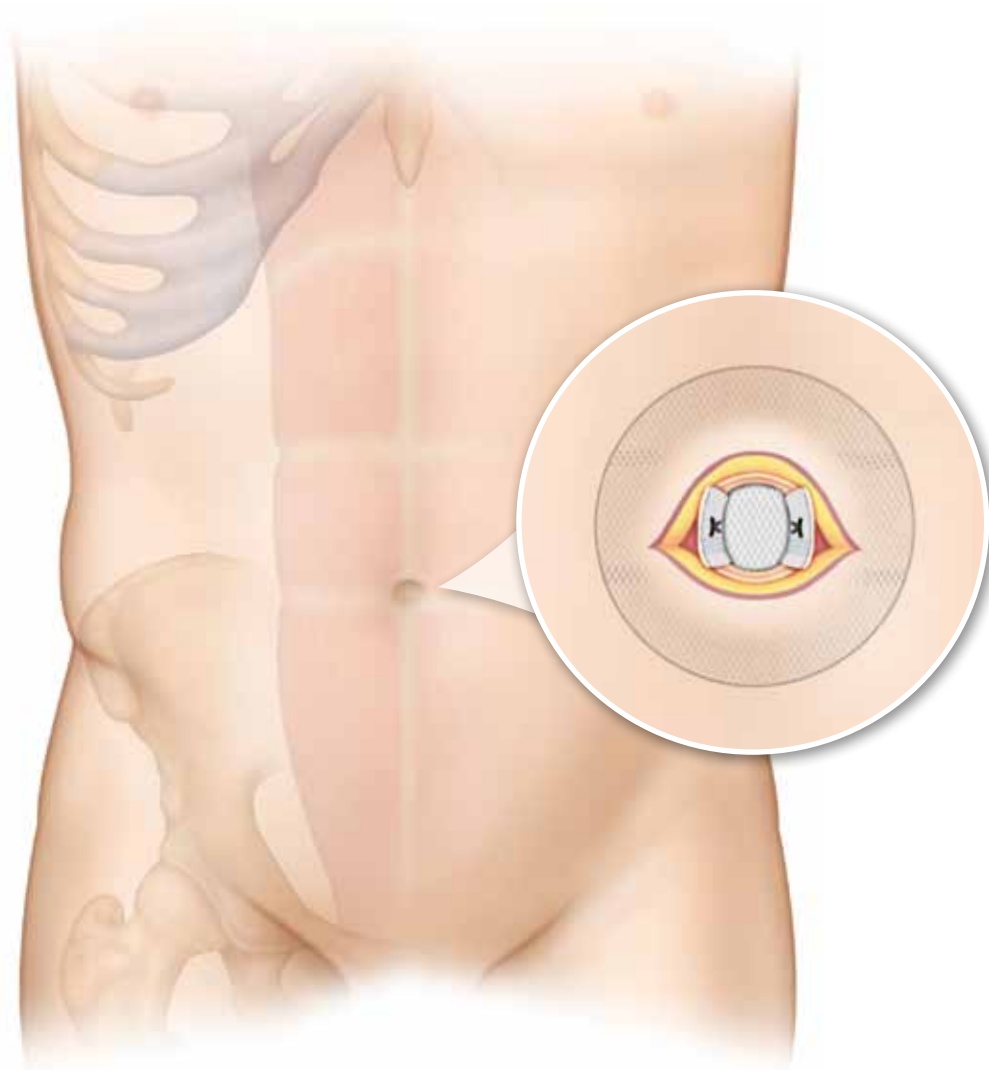
ETHICON's PVP™ Device is the first and only umbilical hernia repair device for general surgeons featuring large pore monofilament mesh with an exclusive absorbable deployment technology, that together enable patients to heal more naturally, strongly, and comfortably.



Unique design contours with the body for secure placement and stable positioning.

	Product Code	Units per Box	Size
	<b>PVPS</b>	2 Per Box	1.7" x 1.7" (4.3cm x 4.3cm)
	<b>PVPM</b>	2 Per Box	2.5" x 2.5" (6.4cm x 6.4cm)





For additional ordering and size information for PVP™ Device, please visit [www.ecatalog.ethicon.com](http://www.ecatalog.ethicon.com), contact your ETHICON representative or call 1-877-ETHICON.

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HERNIA: MULTI-USE

## ULTRAPRO\*

Partially  
Absorbable  
Lightweight  
Mesh

*Versatile. Flexible.  
Live comfortably.*

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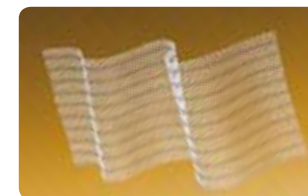
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# ULTRAPRO\* Partially Absorbable Lightweight Mesh

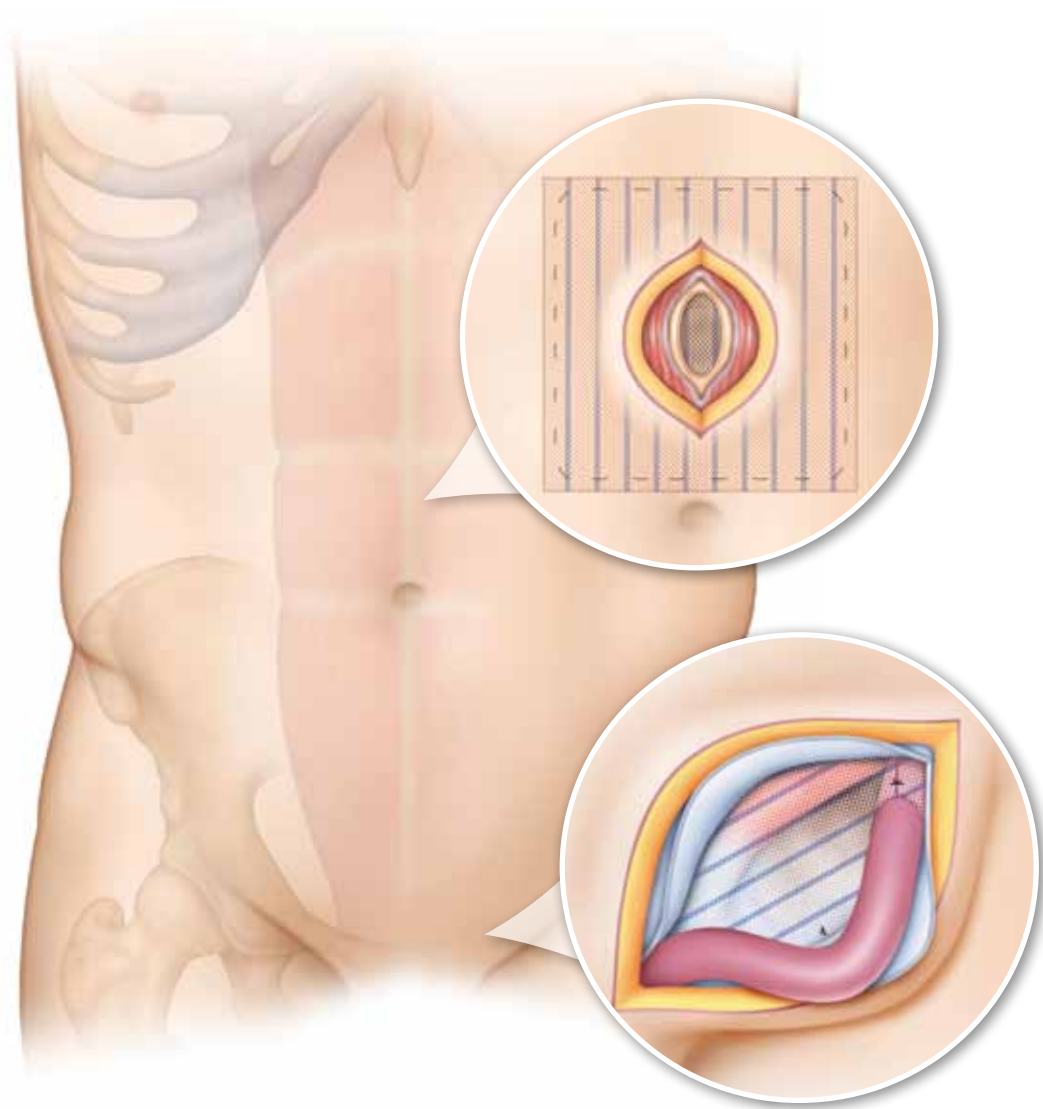
ETHICON's ULTRAPRO Mesh is a unique and superior macroporous partially absorbable mesh, which allows general surgeons the versatility to perform various hernia repairs with a single technology. It offers an appropriate amount of strength with minimal foreign body mass, which allows patients to heal more naturally.



ULTRAPRO Mesh is designed for open and laparoscopic hernia repairs.

	Product Code	Units per Box	Size
	<b>UMM3</b>	3 Per Box	6" x 6" (15cm x 15cm)
	<b>UMR3</b>	3 Per Box	3" x 6" (7.6cm x 15cm)
	<b>UMS3</b>	3 Per Box	2.4" x 4.3" (6cm x 11cm)
	<b>UML1</b>	1 Per Box	12" x 12" (30cm x 30cm)





For additional ordering and size information for ULTRAPRO<sup>®</sup> Mesh, please visit [www.ecatalog.ethicon.com](http://www.ecatalog.ethicon.com), contact your ETHICON representative or call 1-877-ETHICON.

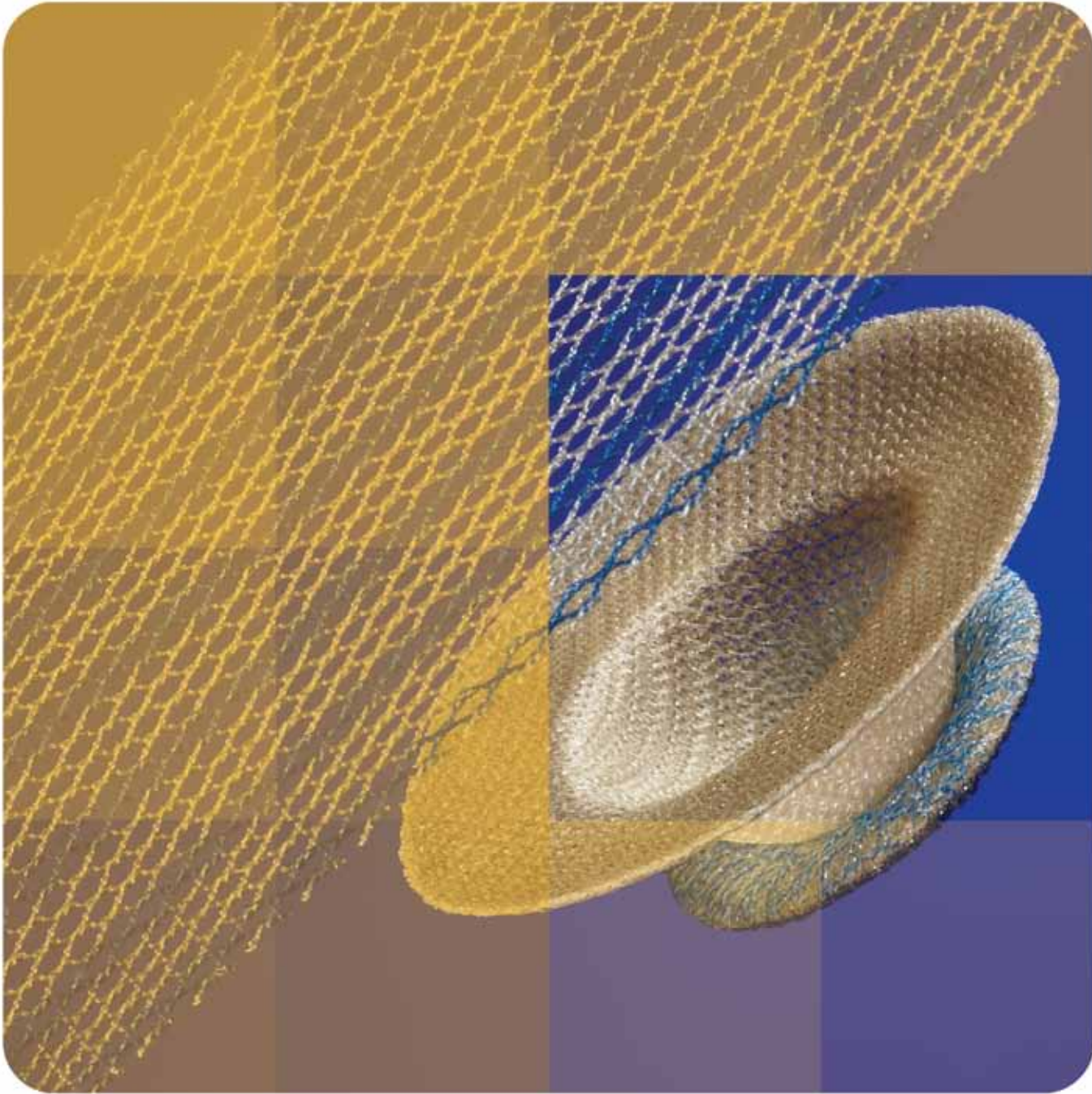
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INGUINAL HERNIA

# ULTRAPRO\*

Plug

*Secure. Familiar.  
Live comfortably.*

**ETHICON**, INC.  
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**HERNIA SOLUTIONS**


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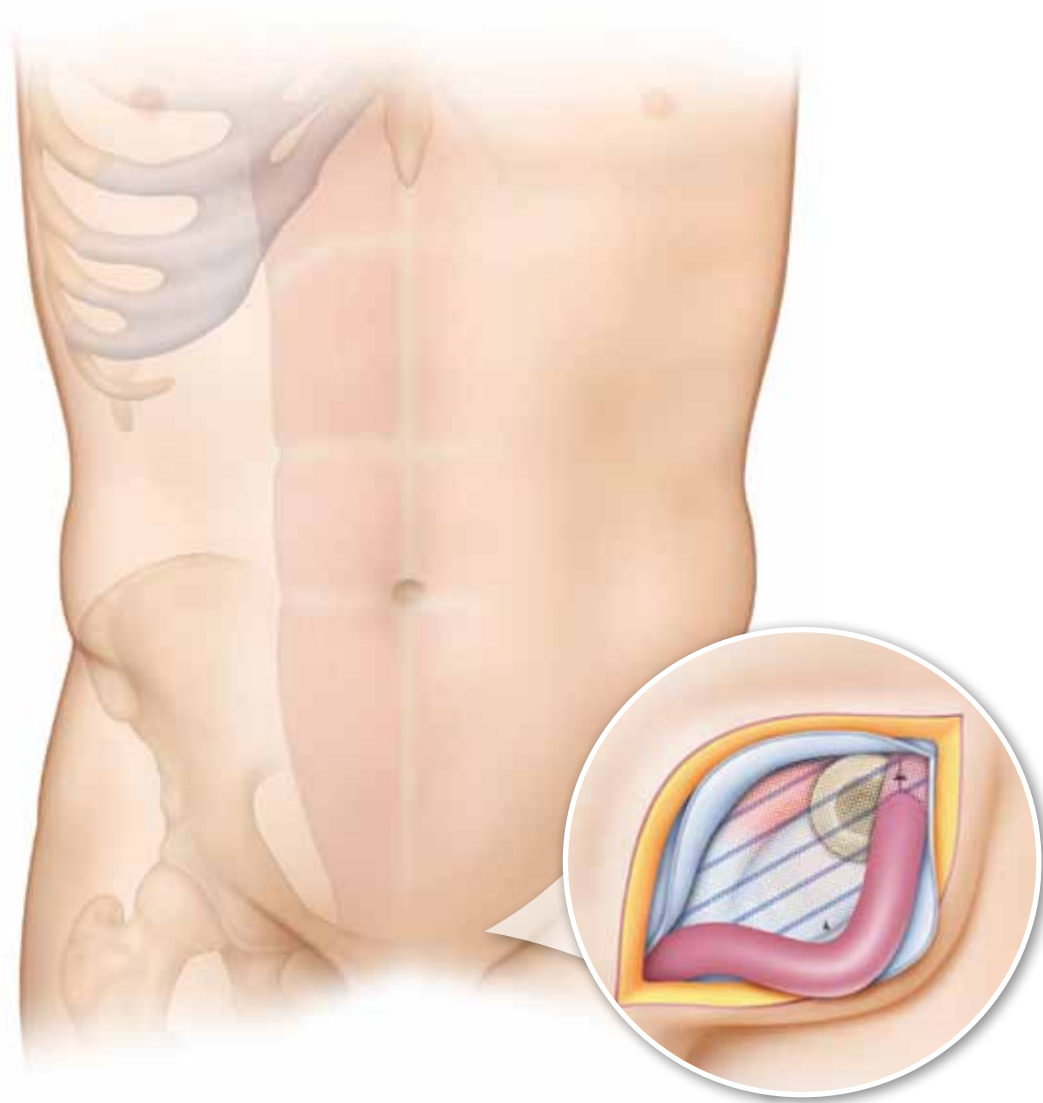
# ULTRAPRO\* Plug

ETHICON's ULTRAPRO Plug is the only partially absorbable plug-and-patch device for inguinal hernia repairs, with an intuitive design that provides security and comfort for patients.



Unique design provides stability in the defect and minimizes the risk of migration.

	Product Code	Units per Box	Size	
 SMALL	<b>UPPS2</b>	2 Per Box	Anchor Rim	3cm 5cm
 SMALL	<b>UPPS6</b>	6 Per Box	Anchor Rim	3cm 5cm
 MEDIUM	<b>UPPM2</b>	2 Per Box	Anchor Rim	4cm 5cm
 MEDIUM	<b>UPPM6</b>	6 Per Box	Anchor Rim	4cm 5cm
 LARGE	<b>UPPL2</b>	2 Per Box	Anchor Rim	5cm 5cm
 LARGE	<b>UPPL6</b>	6 Per Box	Anchor Rim	5cm 5cm



For additional ordering and size information for ULTRAPRO<sup>®</sup> Plug, please visit [www.ecatalog.ethicon.com](http://www.ecatalog.ethicon.com), contact your ETHICON representative or call 1-877-ETHICON.

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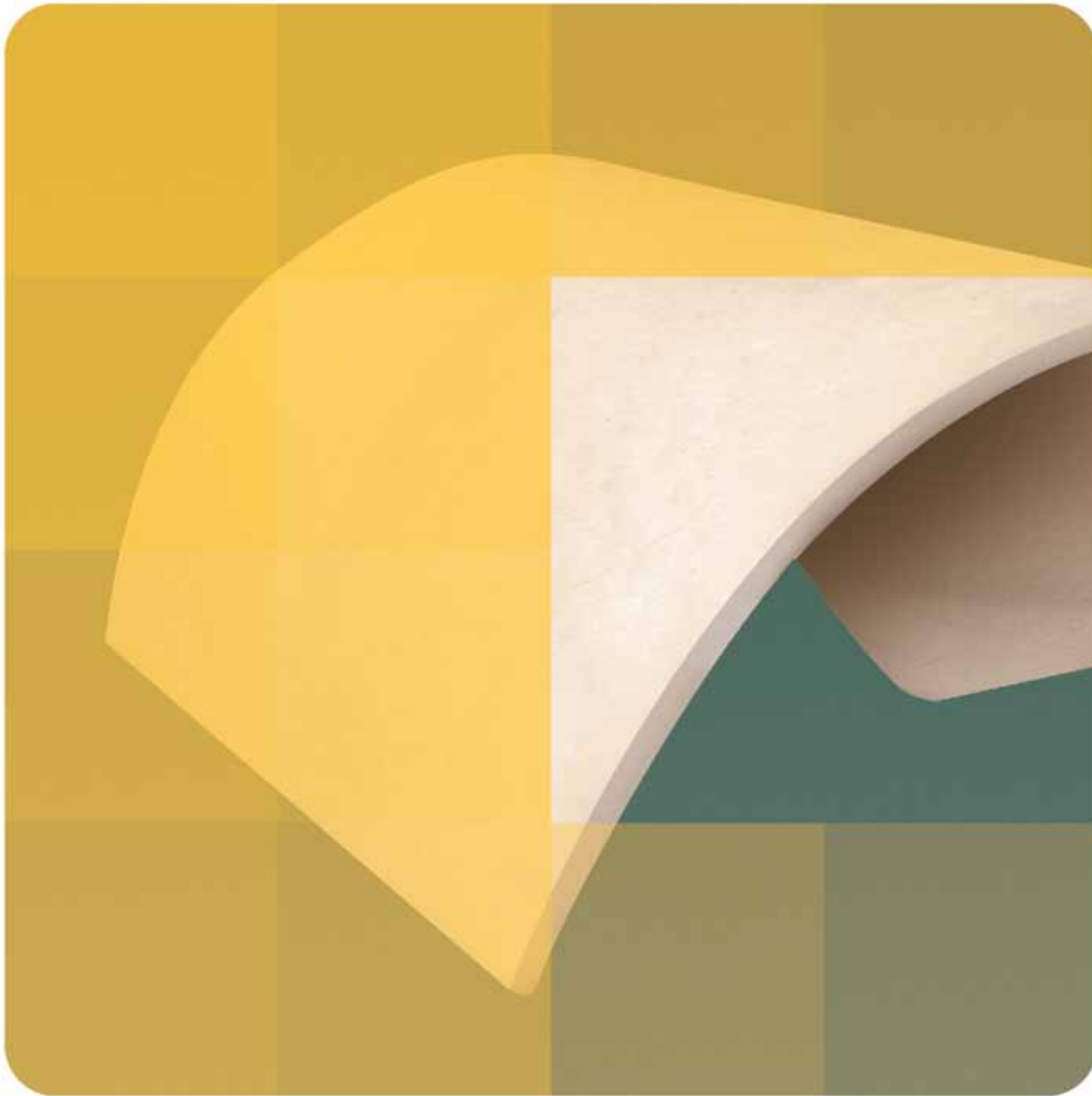
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**VENTRAL HERNIA**

**FlexHD<sup>®</sup>**  
Acellular Hydrated  
Dermis

*Natural tissue.  
Natural healing.*

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**HERNIA SOLUTIONS**

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# FlexHD® Acellular Hydrated Dermis

FlexHD® is an acellular dermal allograft derived from donated human tissue that is processed by the Musculoskeletal Transplant Foundation. FlexHD® tissue is a strong, versatile, ready-to-use dermal matrix.



Prehydrated and no refrigeration necessary.

## Thin

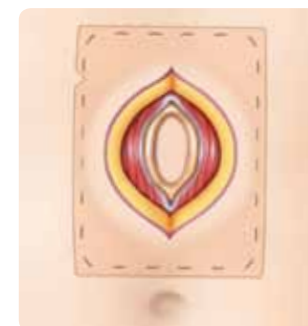
Tissue Code	Description	Thickness	Description	Thickness
	Centimeters		Inches	
470102	1cm x 2cm	0.4mm – 0.8mm	0.4" x 0.8"	0.016" – 0.032"
470204	2cm x 4cm	0.4mm – 0.8mm	0.8" x 1.6"	0.016" – 0.032"
470307	3cm x 7cm	0.4mm – 0.8mm	1.2" x 2.8"	0.016" – 0.032"
470407	4cm x 7cm	0.4mm – 0.8mm	1.6" x 2.8"	0.016" – 0.032"
470412	4cm x 12cm	0.4mm – 0.8mm	1.6" x 4.7"	0.016" – 0.032"

## Thick

Tissue Code	Description	Thickness	Description	Thickness
	Centimeters		Inches	
471102	1cm x 2cm	0.8mm – 1.7mm	0.4" x 0.8"	0.032" – 0.067"
471104	1cm x 4cm	0.8mm – 1.7mm	0.4" x 1.6"	0.032" – 0.067"
471204	2cm x 4cm	0.8mm – 1.7mm	0.8" x 1.6"	0.032" – 0.067"
471207	2cm x 7cm	0.8mm – 1.7mm	0.8" x 2.8"	0.032" – 0.067"
471307	3cm x 7cm	0.8mm – 1.7mm	1.2" x 2.8"	0.032" – 0.067"
471407	4cm x 7cm	0.8mm – 1.7mm	1.6" x 2.8"	0.032" – 0.067"
471608	6cm x 8cm	0.8mm – 1.7mm	2.4" x 3.1"	0.032" – 0.067"
471510	5cm x 10cm	0.8mm – 1.7mm	2" x 3.9"	0.032" – 0.067"
471212	2cm x 12cm	0.8mm – 1.7mm	0.8" x 4.7"	0.032" – 0.067"
471312	3cm x 12cm	0.8mm – 1.7mm	1.2" x 4.7"	0.032" – 0.067"
471412	4cm x 12cm	0.8mm – 1.7mm	1.6" x 4.7"	0.032" – 0.067"
471512	5cm x 12cm	0.8mm – 1.7mm	2" x 4.7"	0.032" – 0.067"
471612	6cm x 12cm	0.8mm – 1.7mm	2.4" x 4.7"	0.032" – 0.067"
471812	8cm x 12cm	0.8mm – 1.7mm	3.1" x 4.7"	0.032" – 0.067"

## Thick

Tissue Code	Description	Thickness	Description	Thickness
		Centimeters		Inches
471122	12cm x 12cm	0.8mm – 1.7mm	4.7" x 4.7"	0.032" – 0.067"
471416	4cm x 16cm	0.8mm – 1.7mm	1.6" x 6.3"	0.032" – 0.067"
471616	6cm x 16cm	0.8mm – 1.7mm	2.4" x 6.3"	0.032" – 0.067"
471816	8cm x 16cm	0.8mm – 1.7mm	3.1" x 6.3"	0.032" – 0.067"
471216	12cm x 16cm	0.8mm – 1.7mm	4.7" x 6.3"	0.032" – 0.067"
471220	12cm x 20cm	0.8mm – 1.7mm	4.7" x 7.9"	0.032" – 0.067"
471620	16cm x 20cm	0.8mm – 1.7mm	6.3" x 7.9"	0.032" – 0.067"
471224	12cm x 24cm	0.8mm – 1.7mm	4.7" x 9.4"	0.032" – 0.067"



## Ultra Thick

Tissue Code	Description	Thickness	Description	Thickness
		Centimeters		Inches
472510	5cm x 10cm	≥1.8mm	2" x 3.9"	≥0.07"
472312	3cm x 12cm	≥1.8mm	1.2" x 4.7"	≥0.07"
472412	4cm x 12cm	≥1.8mm	1.6" x 4.7"	≥0.07"
472512	5cm x 12cm	≥1.8mm	2" x 4.7"	≥0.07"
472612	6cm x 12cm	≥1.8mm	2.4" x 4.7"	≥0.07"
472812	8cm x 12cm	≥1.8mm	3.1" x 4.7"	≥0.07"
472122	12cm x 12cm	≥1.8mm	4.7" x 4.7"	≥0.07"
472416	4cm x 16cm	≥1.8mm	1.6" x 6.3"	≥0.07"
472616	6cm x 16cm	≥1.8mm	2.4" x 6.3"	≥0.07"
472816	8cm x 16cm	≥1.8mm	3.1" x 6.3"	≥0.07"
472216	12cm x 16cm	≥1.8mm	4.7" x 6.3"	≥0.07"
472220	12cm x 20cm	≥1.8mm	4.7" x 7.9"	≥0.07"
472620	16cm x 20cm	≥1.8mm	6.3" x 7.9"	≥0.07"
472224	12cm x 24cm	≥1.8mm	4.7" x 9.4"	≥0.07"

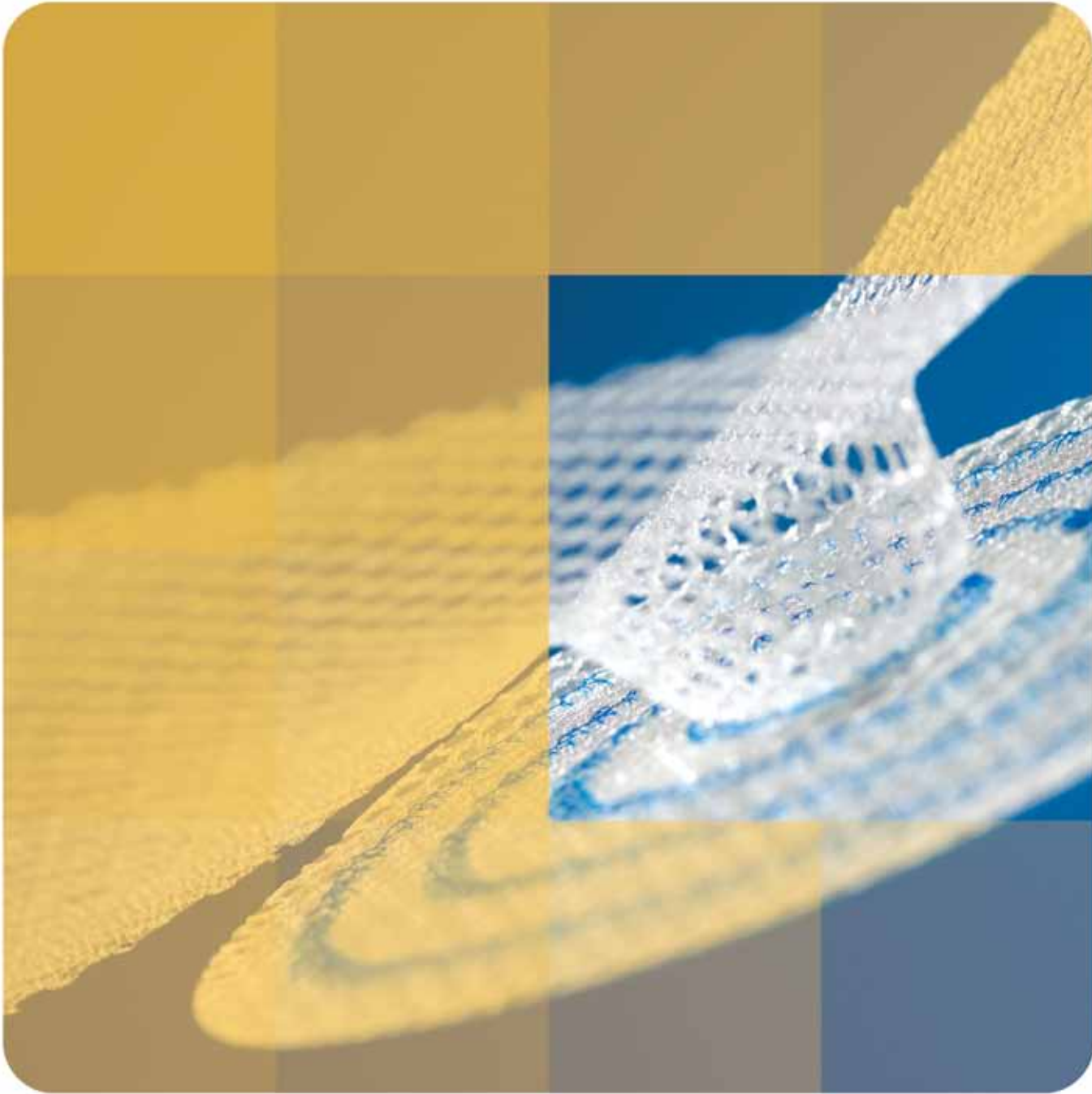
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For additional ordering and size information for FlexHD® Acellular Hydrated Dermis, please visit [www.ecatalog.ethicon.com](http://www.ecatalog.ethicon.com), contact your ETHICON representative or call 1-877-ETHICON.

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INGUINAL HERNIA

# ULTRAPRO\*

Hernia System

*Proven performance.  
Live comfortably.*

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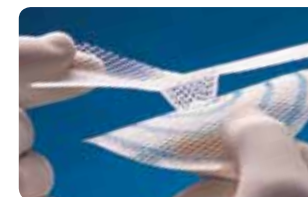
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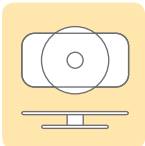
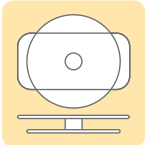
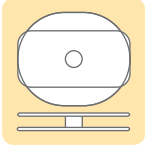
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# ULTRAPRO\* Hernia System

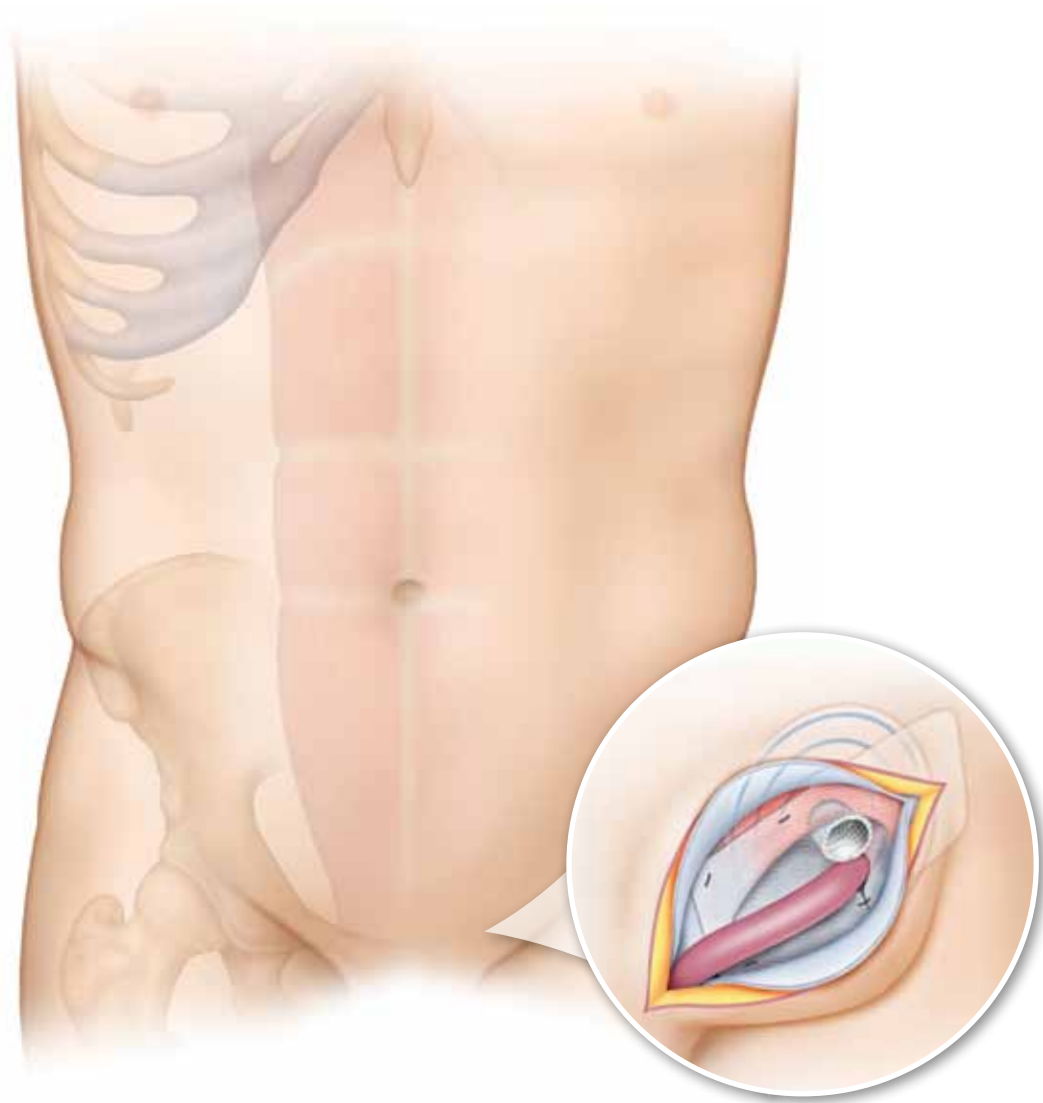
ETHICON's ULTRAPRO Hernia System is a macroporous, partially absorbable mesh device for hernia repairs. The unique design enhances preperitoneal deployment, providing surgeons with confidence that they have performed the most reliable posterior repair.



Provides three points of protection with an onlay patch that covers and protects, a connector that virtually eliminates migration, and the underlay patch that provides posterior support.

	Product Code	Units per Box	Size		
 MEDIUM	<b>UHSM</b>	3 Per Box	Onlay Patch	width	2.4 in (6cm)
				length	4.7 in (12cm)
			Underlay Patch	diameter	3.0 in (7.5cm)
	<b>UHSM6</b>	6 Per Box			
 LARGE	<b>UHSL</b>	3 Per Box	Onlay Patch	width	2.4 in (6cm)
				length	4.7 in (12cm)
			Underlay Patch	diameter	4.0 in (~10cm)
	<b>UHSL6</b>	6 Per Box			
 OVAL	<b>UHSOV</b>	3 Per Box	Onlay Patch	width	2.4 in (6cm)
				length	4.7 in (12cm)
			Underlay Patch	width	4.0 in (~10cm)
				length	4.7 in (12cm)





For additional ordering and size information for ULTRAPRO<sup>®</sup> Hernia System, please visit [www.ecatalog.ethicon.com](http://www.ecatalog.ethicon.com), contact your ETHICON representative or call 1-877-ETHICON.

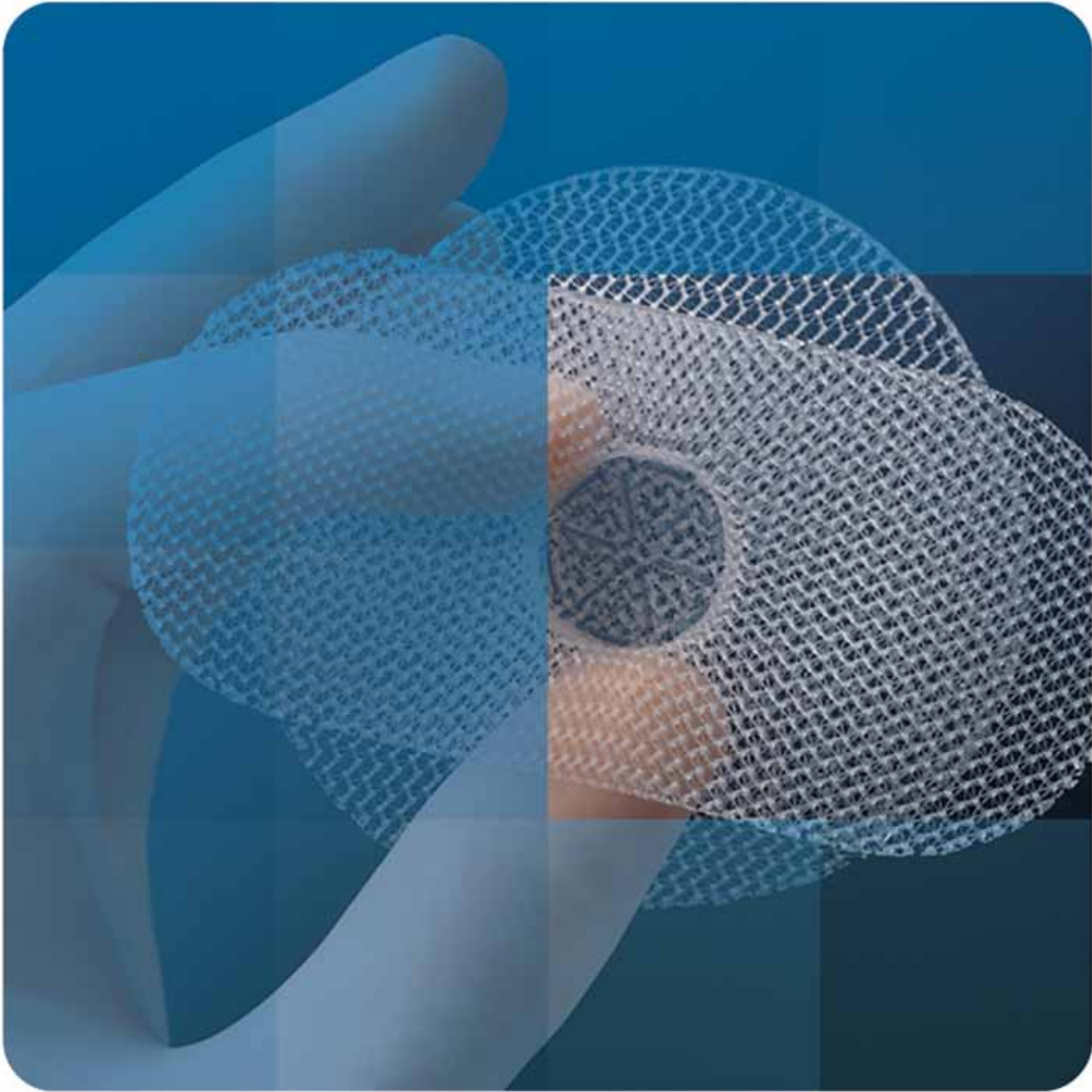
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## INGUINAL HERNIA

# PROLENE\*

Polypropylene  
Hernia System

Features three dimensions of effectiveness for direct and indirect inguinal hernia repair and gives extended support during and following wound healing.

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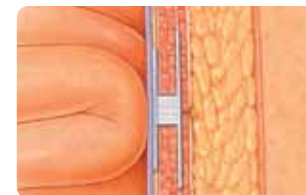
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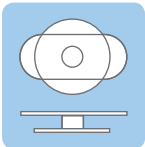
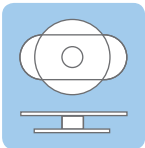
# PROLENE\* Polypropylene Hernia System

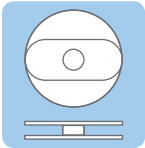
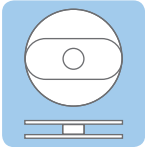
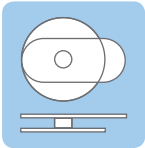

## Three-dimensional advantage over tension-free hernia repair

PROLENE Hernia System is a sterile, preshaped, three-dimensional device made of nonabsorbable mesh. It consists of an underlay patch for posterior repair, a connector that functions like a plug, and an onlay patch that fits over the abdominal wall.



PROLENE Hernia System remains soft and pliable and allows tissue to grow through its interstices, thereby incorporating into adjacent tissue.

	Product Code	Units per Box	Size		
 MEDIUM	<b>PHSM</b>	3 Per Box	Onlay Patch:	width	1 3/4" (4.5cm)
				length	3 15/16" (10cm)
			Connector:	diameter	3/4" (1.9cm)
			height	1/2" (1.3cm)	
			Underlay Patch:	diameter	3" (7cm)
 MEDIUM	<b>PHSM6</b>	6 Per Box	Onlay Patch:	width	1 3/4" (4.5cm)
				length	3 15/16" (10cm)
			Connector:	diameter	3/4" (1.9cm)
			height	1/2" (1.3cm)	
			Underlay Patch:	diameter	3" (7cm)

	Product Code	Units per Box	Size		
 LARGE	PHSL	6 Per Box	Onlay Patch:	width	1 3/4" (4.5cm)
				length	3 15/16" (10cm)
			Connector:	diameter	3/4" (1.9cm)
			height	1/2" (1.3cm)	
			Underlay Patch:	diameter	4" (10cm)
 LARGE	PHSL6	6 Per Box	Onlay Patch:	width	1 3/4" (4.5cm)
				length	3 15/16" (10cm)
			Connector:	diameter	3/4" (1.9cm)
			height	1/2" (1.3cm)	
			Underlay Patch:	diameter	4" (10cm)
 EXTENDED	PHSE	3 Per Box	Onlay Patch:	width	2 5/32" (5.5cm)
				length	4 15/16" (12.8cm)
			Connector:	diameter	3/4" (1.9cm)
			height	1/2" (1.3cm)	
			Underlay Patch:	diameter	4" (10cm)
 EXTENDED	PHSE6	6 Per Box	Onlay Patch:	width	2 5/32" (5.5cm)
				length	4 15/16" (12.8cm)
			Connector:	diameter	3/4" (1.9cm)
			height	1/2" (1.3cm)	
			Underlay Patch:	diameter	4" (10cm)

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For additional ordering and size information for PROLENE® Polypropylene Hernia System, please visit [www.ecatalog.ethicon.com](http://www.ecatalog.ethicon.com), contact your ETHICON representative or call 1-877-ETHICON.

**HERNIA SOLUTIONS**

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MULTI-USE

## ADDITIONAL PRODUCTS

- PROLENE\*  
Polypropylene Mesh
- PROLENE\* Soft  
Polypropylene Mesh
- PROLENE\*  
3-D Patch  
Polypropylene Mesh
- VICRYL\*  
(polyglactin 910)  
Woven Mesh
- MERSILENE\*  
Polyester Fiber Mesh

ETHICON offers a variety of products that can be used in conjunction with any hernia procedure.

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# PROLENE\* Polypropylene Mesh

Polypropylene mesh for the repair of abdominal wall fascial defects







	Product Code	Units per Box	Size
	<b>PMH</b>	6 Per Box	6" x 6" (15cm x 15cm)
	<b>PMI1</b>	6 Per Box	3" x 6" (8cm x 15cm)
	<b>PML</b>	3 Per Box	12" x 12" (30cm x 30cm)
 LARGE PRE-SHAPED KEYHOLE	<b>PMLK</b>	6 Per Box	2.4" x 5.4" (6cm x 13.7cm)
 SMALL PRE-SHAPED KEYHOLE	<b>PMSK</b>	6 Per Box	1.8" x 4.0" (4.6cm x 10cm)
	<b>PMXL</b>	6 Per Box	2" x 12" (5cm x 30cm)
	<b>PMXS</b>	6 Per Box	1" x 4" (2.54cm x 10cm)



Nonabsorbable mesh used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing.

# PROLENE\* Soft Polypropylene Mesh

Polypropylene mesh for the repair of abdominal wall fascial defects

	Product Code	Units per Box	Size
	<b>SPMH</b>	6 Per Box	6" x 6" (15cm x 15cm)
	<b>SPMII</b>	6 Per Box	3" x 6" (7.6cm x 15cm)
	<b>SPMLI</b>	3 Per Box	10" x 10" (25cm x 25cm)
	<b>SPMS</b>	6 Per Box	2" x 4" (5cm x 10cm)
	<b>SPMXS</b>	6 Per Box	1" x 4" (2.54cm x 10cm)
	<b>SPMXXL</b>	3 Per Box	14" x 12" (35.6cm x 30cm)



Nonabsorbable synthetic surgical mesh that is designed for greater comfort and healing in patients.

For additional ordering and size information for PROLENE\* Polypropylene Mesh, please visit [www.ecatalog.ethicon.com](http://www.ecatalog.ethicon.com), contact your ETHICON representative or call 1-877-ETHICON.



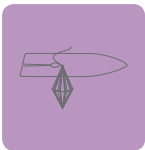
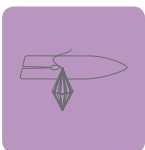
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# PROLENE\* 3D Patch Polypropylene Mesh

One-piece low profile hernia device for the repair of inguinal wall hernias

	Product Code	Units per Box	Size		
 <p>LARGE WITH EXTENDED ONLAY</p>	<b>3DPL</b>	3 Per Box	Onlay Patch	width	2 5/32" (5.5cm)
				length	4 15/16" (12.8cm)
			Underlay Patch	diameter	1 31/32" (5cm)
 <p>MEDIUM WITH EXTENDED ONLAY</p>	<b>3DPM</b>	3 Per Box	Onlay Patch	width	2 5/32" (5.5cm)
				length	4 15/16" (12.8cm)
			Underlay Patch	diameter	1 3/8" (3.5cm)
 <p>LARGE WITH PRESHAPED ONLAY</p>	<b>P3DPL</b>	3 Per Box	Onlay Patch	width	2 5/32" (5.5cm)
				length	4 3/4" (12cm)
			Underlay Patch	diameter	1 31/32" (5cm)
 <p>MEDIUM WITH PRESHAPED ONLAY</p>	<b>P3DPM</b>	3 Per Box	Onlay Patch	width	2 5/32" (5.5cm)
				length	4 3/4" (12cm)
			Underlay Patch	diameter	1 3/8" (3.5cm)



Nonabsorbable mesh device used to repair or bridge abdominal wall hernia defects to provide extended support during and following wound healing.

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For additional ordering and size information for PROLENE\* 3D Patch Polypropylene Mesh, please visit [www.ecatalog.ethicon.com](http://www.ecatalog.ethicon.com), contact your ETHICON representative or call 1-877-ETHICON.

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# VICRYL\* (polyglactin 910) Woven Mesh

Absorbable mesh for temporary wound or organ support

	Product Code	Units per Box	Size
 KNITTED	<b>VKML</b>	3 Per Box	12" x 12" (30cm x 30cm)
 KNITTED	<b>VKMM</b>	3 Per Box	6" x 6" (15cm x 15cm)
 WOVEN	<b>VWML</b>	3 Per Box	12" x 12" (30cm x 30cm)
 WOVEN	<b>VWMM</b>	3 Per Box	6" x 6" (15cm x 15cm)

Vicryl Bag	Product Code		
	<b>VM101K</b>	1 Per Box	6" x 3" (15cm x 8cm)
	<b>VM102K</b>	1 Per Box	6" x 4" (15cm x 10cm)
	<b>VM106K</b>	1 Per Box	10" x 12" (26cm x 30cm)
	<b>VM210K</b>	1 Per Box	17" x 12" (44cm x 30cm)
	<b>VM220K</b>	1 Per Box	20" x 8" (50cm x 20cm)



VICRYL\* Woven Mesh is made of an absorbable material to provide temporary support during the healing process.



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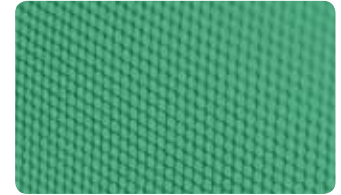
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# MERSILENE\* Polyester Fiber Mesh

Designed for consistent deployment

	Product Code	Units per Box	Size
	<b>RML</b>	3 Per Box	12" x 12" (30cm x 30cm)
	<b>RMS</b>	3 Per Box	2.5" x 4.5" (6cm x 11cm)



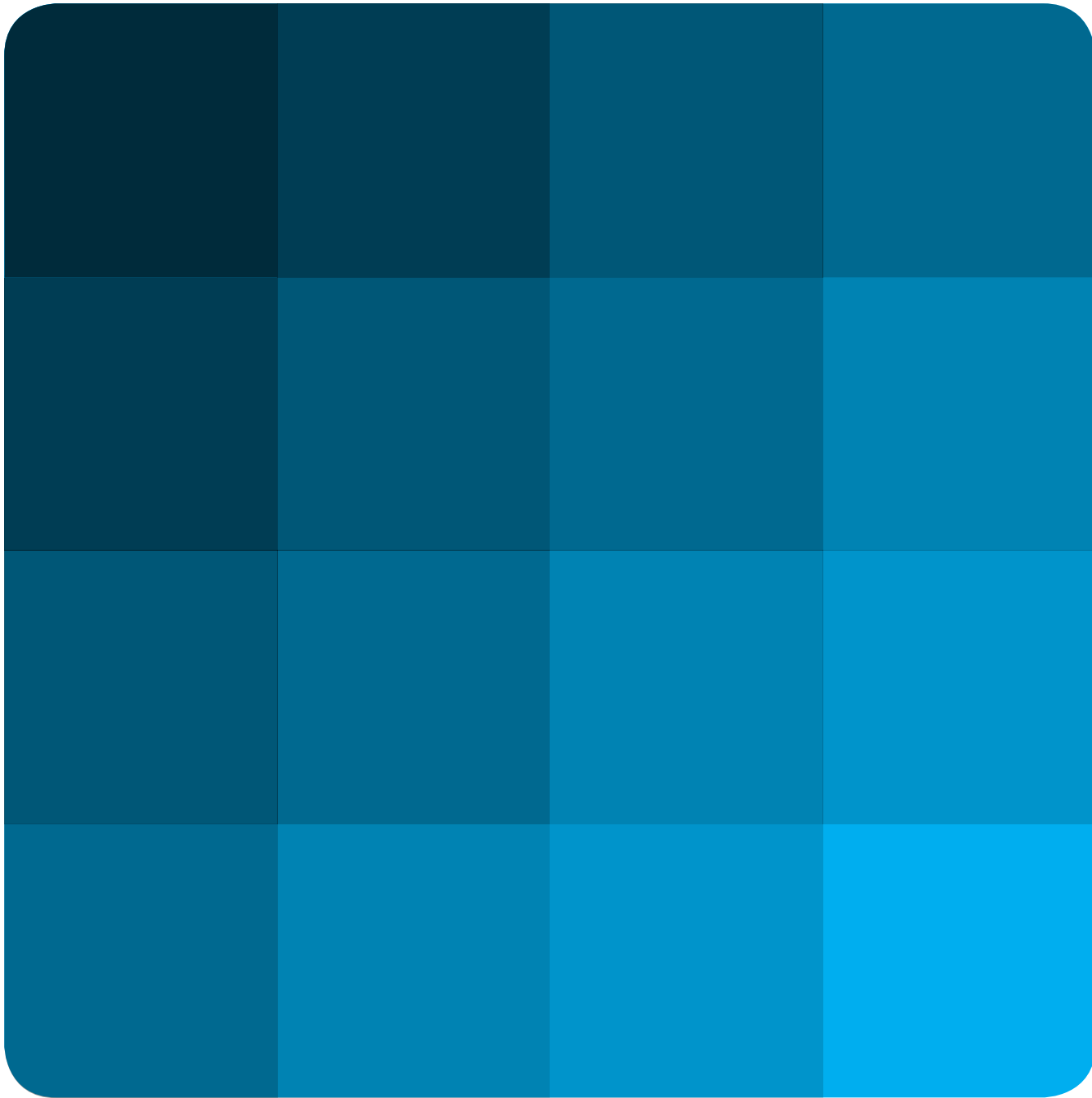
Nonabsorbable mesh used for the repair of hernia and other fascial defects that require a reinforcing or bridging material for extended support during and following healing.

For additional ordering and size information for MERSILENE\* Polyester Fiber Mesh, please visit [www.ecatalog.ethicon.com](http://www.ecatalog.ethicon.com), contact your ETHICON representative or call 1-877-ETHICON.

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# RESOURCES

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## **www.herniasolutions.com**

- An online patient resource for information about hernias and hernia repair.

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## **www.clinicalexpertise.com**

- An online resource for healthcare professionals that provides medical information and a detailed clinical focus on hernia repair.

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## **Hernia Discourse**

- The Hernia Discourse: A hernia repair podcast for surgeons.

ETHICON, INC. is proud to sponsor this educational podcast series, hosted by Dr. Arthur Gilbert, the founding president of the American Hernia Society. Included in this series are interviews in which Dr. Gilbert discusses topics presented at annual Scientific Meetings with some of the leading names in hernia surgery. This podcast series is a must for all surgeons interested in hernia repair.

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# PROCEED\* Surgical Mesh

## DESCRIPTION

PROCEED\* Surgical Mesh is a sterile, thin, flexible laminate mesh designed for the repair of hernias and other fascial deficiencies. The mesh product is comprised of an oxidized regenerated cellulose (ORC) fabric, and PROLENE\* Soft Mesh, a nonabsorbable polypropylene mesh, which is encapsulated by a polydioxanone polymer. The polypropylene mesh side of the product allows for tissue ingrowth while the ORC side provides a bioresorbable layer that physically separates the polypropylene mesh from underlying tissue and organ surfaces during the wound-healing period to minimize tissue attachment to the mesh. The polydioxanone provides a bond to the ORC layer.

The PROLENE Soft Mesh component is constructed of knitted filaments of extruded polypropylene identical in composition to that used in PROLENE\* Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, Inc.). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The PROLENE Soft Mesh affords excellent strength, durability and surgical adaptability, with a porous structure to enable mesh incorporation into surrounding tissues.

The ORC component is an absorbable off-white knitted fabric prepared by the controlled oxidation of regenerated cellulose. The ORC layer is absorbed from the site of implantation within four (4) weeks. Absorption rate depends upon several factors including the amount used and implantation site.

The polydioxanone components made from the polyester, poly (p-dioxanone) polymer that is identical to the polymerized in PDS\* II (polydioxanone) Suture, Synthetic Absorbable Suture, U.S.P. (ETHICON, Inc.). The polydioxanone polymer has been found to be nonantigenic, nonpyrogenic and to elicit only a mild tissue reaction during absorption. The polydioxanone component is absorbed within six (6) months.

## ACTIONS/PERFORMANCE

PROCEED Mesh is a laminate mesh, whose PROLENE Soft Mesh component is knitted with nonabsorbable fibers, used to reinforce or bridge traumatic or surgical wounds to provide extended support during and following wound healing. The ORC is intended to physically separate the mesh from underlying tissue and organ surfaces during the critical wound healing period, thereby reducing the severity and extent of tissue attachment to the mesh.

Animal studies show that implantation of PROCEED Mesh elicits a transient inflammatory reaction that does not interfere with integration of the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired.

The ORC and polydioxanone components are essentially absorbed within six (6) months, whereas the polypropylene material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes. Minimal visceral tissue attachment has been demonstrated in animal studies that show reduction in the extent and severity of adhesions to the mesh.

## INDICATIONS

PROCEED Mesh may be used for the repair of hernias and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

## CONTRAINDICATIONS

None known.

## WARNINGS

When this mesh is used in infants, children, pregnant women, or women planning pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

In animal studies, PROCEED Mesh did not potentiate infections. However, it is recommended that the mesh not be used following planned intraoperative or accidental opening of the gastrointestinal tract. If the mesh is used in a contaminated field, contamination of the mesh may lead to infection that may require removal of the mesh.

PROCEED Mesh is provided by ETHICON, Inc. as a single use, sterile product. Do not resterilize. Do not use if packaging is opened or damaged. Discard opened unused products.

Users should be familiar with surgical procedures and techniques involving nonabsorbable meshes before using PROCEED Mesh.

PROCEED Mesh has an ORC component that should not be used in the presence of uncontrolled and/or active bleeding as fibrinous exudates may increase the chance of adhesion formation.

Foreign body reactions may occur in some patients.

## PRECAUTIONS

The mesh should be shaped using sharp cutting instrumentation and in such a way that sufficient overlap of the fascial defect on all sides is achieved, thereby allowing adequate stabilization of each of the fascial borders. When cutting or shaping, use caution to avoid damaging the mesh. Do not soak or stretch PROCEED Mesh.

The safety and effectiveness of PROCEED Mesh in combination with solutions other than saline (such as peritoneal instillates, and/or medications) have not been studied.

## ADVERSE EVENTS

Potential adverse events are those typically associated with surgically implantable materials including potentiation of procedure-related infection, inflammation, adhesion formation, fistula formation, and extrusion.

## INSTRUCTIONS FOR USE

Correct surface orientation is critical for PROCEED Mesh to function as intended. The polypropylene mesh side (side with the blue stripes) of the product should be placed adjacent to those tissues where tissue ingrowth is desired. The other surface, the ORC side, should be placed adjacent to those tissues where minimal tissue attachment is desired (i.e. visceral surfaces). The orientation is essential.

Uncontrolled and/or active bleeding should be controlled prior to placement of the PROCEED Mesh.

The mesh should be shaped in such a way that sufficient overlap of

the fascial defect on all sides is achieved, thereby allowing adequate stabilization of each of the fascial borders.

To avoid dislodging, crinkling or curling of the edges, a sufficient number of fixation points should be placed along the borders of the PROCEED Mesh. Fixation may be accomplished with devices such as tackers, anchors, staples or nonabsorbable sutures.

It is recommended that points of fixation be placed 6.5mm to 12.5mm (1/4" to 1/2") apart at a distance approximately 6.5mm (1/4") from the edge of the mesh.

Fixation of this product with tissue adhesives has not been evaluated.

## STORAGE

Store at 25°C or less. Brief exposures up to 40°C is acceptable.

## HOW SUPPLIED

PROCEED Mesh is available in single packets as sterile, undyed sheets with blue stripes in a variety of sizes.

## CAUTION

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

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## PROCEED\* Ventral Patch

Partially Absorbable Mesh Device

### DESCRIPTION

PROCEED\* Ventral Patch (PVP) is a sterile, self-expanding, partially absorbable, flexible laminate mesh device designed for the repair of hernias and other fascial deficiencies such as those caused by trocar use. The mesh patch is comprised of multiple layers of absorbable and nonabsorbable materials, laminated together with an absorbable polydioxanone polymer and is available in different sizes. Full details are provided in the catalogue.



See Figure 1

The bottom layer of the patch, facing underlying tissue and organ surfaces is comprised of an oxidized regenerated cellulose (ORC) fabric bonded to PROLENE\* Soft Mesh, a nonabsorbable, macroporous polypropylene mesh. The polypropylene mesh side of the product allows for tissue ingrowth. The ORC side of the patch provides a bioresorbable layer that physically separates the polypropylene mesh from underlying tissue and organ surfaces while minimizing tissue attachment to the polypropylene mesh during the critical wound healing period. The polypropylene mesh layer is encapsulated with layers of PDS\* film.

The parietal side of the patch contains a polydioxanone polymer reinforcement film and positioning ring, which provide memory to the patch. These patch reinforcements offer stability to help the clinician achieve proper placement. VICRYL\* Mesh is placed on top of the polydioxanone polymer reinforcement film to facilitate placement of the mesh. The VICRYL Mesh layer is encapsulated with layers of PDS film. Anchoring straps of the patch are designed to facilitate placement and fixation of the mesh device. An ETHIBOND\* polyester suture is attached to each anchoring strap enabling tension to be placed on the patch prior to fixation. After the patch has been fixated, the sutures should be removed and discarded.

The ORC component is an absorbable off-white knitted fabric prepared by the controlled oxidation of regenerated cellulose. The ORC layer is absorbed from the site of implantation within four (4) weeks. Absorption rate depends upon several factors including the amount used and implantation site.

The PROLENE Soft Mesh components are constructed of knitted filaments of extruded polypropylene, identical in composition to that used in PROLENE\* Polypropylene Suture, Nonabsorbable Surgical Suture, U.S.P. (ETHICON, Inc.). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The PROLENE Soft Mesh affords excellent strength, durability and surgical adaptability, with a porous structure to enable mesh incorporation into surrounding tissues.

The polydioxanone components are made from poly (p-dioxanone) polymer that is identical to the polymer used in PDS\* II Polydioxanone Suture, Synthetic Absorbable Suture, U.S.P. (ETHICON, Inc.). The polydioxanone polymer has been found to be nonantigenic, nonpyrogenic, and to elicit only a mild tissue reaction during absorption. The polydioxanone component is essentially absorbed within six (6) months.

The VICRYL Mesh component is prepared from polyglactin 910, a synthetic absorbable copolymer of glycolide and lactide, derived respectively from glycolic acid and lactic acids. Polyglactin 910 polymer is identical to the polymer used in VICRYL\* Polyglactin 910 Synthetic Absorbable Suture, U.S.P. (ETHICON, Inc.). The polyglactin 910 polymer has been found to be nonantigenic, nonpyrogenic, and to elicit only a mild tissue reaction during absorption. The polyglactin 910 component is essentially absorbed within 56 to 70 days.

### ACTIONS/PERFORMANCE

PROCEED Ventral Patch (PVP) is a laminate mesh device, whose PROLENE Soft Mesh component is knitted with nonabsorbable fibers, used to reinforce or bridge traumatic or surgical wounds to provide extended support during and following wound healing. The ORC is intended to physically separate the mesh from underlying tissue and organ surfaces during the critical wound healing period, thereby reducing the severity and extent of tissue attachment to the mesh.

An animal model shows that implantation of PVP elicits a mild inflammatory reaction that does not interfere with integration of the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired.

The ORC, VICRYL Mesh, and polydioxanone components are essentially absorbed within six (6) months, whereas the polypropylene material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes. Minimal visceral tissue attachment has been demonstrated in an animal model that shows reduction in the extent and severity of adhesions to the mesh.

### INDICATIONS

PROCEED Ventral Patch (PVP) is intended for the repair of hernias or other abdominal fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

PVP is also indicated for the repair of tissue deficiencies caused by trocar use.

### CONTRAINDICATIONS

None known.

### WARNINGS

Do not cut or reshape any portion of the PROCEED Ventral Patch (PVP), aside from the fixation appendages, as this could impact effectiveness.

When this mesh is used in infants, children, pregnant women, or women planning pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

In animal studies, the PROCEED Mesh component (Polypropylene mesh encapsulated in PDS film with ORC) of PROCEED Ventral Patch did not potentiate infections. It is recommended that the mesh not be used following planned intraoperative or accidental opening of the

gastrointestinal tract. If the mesh is used in a contaminated field, contamination of the mesh may lead to infection that may require removal of the mesh.

PROCEED Ventral Patch is provided by ETHICON, Inc. as a single use, sterile product.

Do not resterilize. Do not use if packaging is opened or damaged. Discard opened unused products.

Ensure proper orientation; the ORC side must be oriented towards the viscera of the body.

Users should be familiar with surgical procedures and techniques involving nonabsorbable meshes before using PROCEED Ventral Patch.

PROCEED Ventral Patch has an ORC component, which should not be used in the presence of uncontrolled and/or active bleeding, as fibrinous exudates may increase the chance of adhesion formation.

Foreign body reactions may occur in some patients.

### PRECAUTIONS

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

When fixating mesh, use caution not to penetrate the bottom layer of the mesh to avoid penetrating underlying tissue layers. Do not fixate to the umbilicus.

Selected mesh size should allow for adequate overlap of the fascial defect on all sides.

The safety and effectiveness of PROCEED Ventral Patch in combination with solutions other than saline (such as peritoneal instillates, and/or medications) have not been studied. Do not soak or stretch the PROCEED Ventral Patch.

Care should be taken to avoid intraoperative damage to the device, specifically the ORC (uniformly off-white) side of the patch, e.g. with sharp instruments or thermal devices.

Currently available animal data concerning the amount of implanted absorbable material supports the implantation of up to five medium size devices per 60 kg (132.3lb) body weight during a timeframe of 8 months.

### ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials, including potentiation of procedure-related infection, inflammation, adhesion formation, seroma formation, hematomas, fistula formation, and extrusion.

### INSTRUCTIONS FOR USE

Correct surface orientation is critical for PROCEED Ventral Patch to function as intended. The VICRYL Mesh side (side with straps) should be placed adjacent to those tissues where tissue ingrowth is desired. The ORC side (uniformly off-white) should be placed adjacent to those tissues where minimal tissue attachment is desired (e.g. visceral surfaces).

Uncontrolled and/or active bleeding should be controlled prior to placement of PROCEED Ventral Patch.

Hernia Repair Technique:

Just prior to insertion, dip mesh patch in saline for ease of use and to avoid attachment of tissue during insertion.

Fold the mesh patch into a semi-circle with the ORC side facing outward (straps folded in) for insertion into the defect (See Fig. 2).

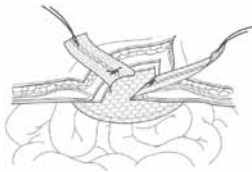


During insertion, secure suture loops with a clamp or fingers. When using a mesh clamp, be certain to avoid kinking the mesh. Be sure to refold as previously described if re-insertion is needed. Once the mesh patch has been inserted into the defect, manipulate the suture loops to facilitate proper positioning of the patch. Pulling up on the suture loops allows the mesh patch to flatten itself against the abdominal wall.

Pull the device with sufficient tension to assure tight seating against the abdominal wall as demonstrated in Figure 3.



It is important to manually ensure that no tissue is trapped between the device and the abdominal wall. Secure the patch to the margins of the defect through the mesh straps to anterior fascia (Figure 4). Excess length of the straps should be cut off and discarded. The incision should then be closed.



It is recommended that non-absorbable sutures be used to fixate the patch. Alternative means of fixation (i.e. tissue adhesives, staples, tackers) have not been evaluated.

#### **STORAGE**

Store at 25°C or less and away from moisture. Avoid prolonged exposures to elevated temperatures.

#### **HOW SUPPLIED**

PROCEED Ventral Patch (PVP) is available in single packages as sterile devices.

\* = Trademark

RMC 8550905

Status 7/08

Made in Germany

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# ULTRAPRO\*

(Poliglecaprone-25 / Polypropylene)

Synthetic Partially Absorbable Mesh

Status: 5/07

RMC: 8554475

## INSTRUCTIONS FOR USE

### DESCRIPTION

ULTRAPRO\* 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 (phthalocyanineblue, Color Index No.: 74160) is identical to the material used for dyed / undyed PROLENE\* suture material. Poliglecaprone-25 fiber consists of a copolymer containing glycolide and  $\epsilon$ -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 structure and size of this remaining mesh are optimally designed for the physiological stresses of the abdominal wall.

### ACTIONS

ULTRAPRO\* Mesh is used for permanent stabilization of the abdominal wall e.g. in hernia repair. The absorbable poliglecaprone part of the mesh helps to keep the polypropylene structure rigid thus making intraoperative manipulation and positioning of the mesh easier. In ULTRAPRO\* Mesh implanted subcutaneously in rats, the poliglecaprone-25 copolymer is essentially absorbed at 84 days after implantation. Due to the wide pore construction of ULTRAPRO\* Mesh, during healing, a strong, three-dimensional collagen fiber network is formed. The residual polypropylene mesh does not hinder this process, thereby avoiding excessive connective tissue deposition and deleterious scar formation. The biomechanical properties of the polypropylene mesh, which are nearly identical to those of the abdominal wall, permit physiologically normal abdominal wall dynamics while guaranteeing optimal stability under major strain.

### INDICATIONS

ULTRAPRO\* Mesh may be used for the repair of hernias or other abdominal fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

### CONTRAINDICATIONS

ULTRAPRO\* Mesh must always be separated from the abdominal cavity by peritoneum.

ULTRAPRO\* Mesh is not suitable for insertion into the inguinal canal as in the case of a plug. ULTRAPRO\* Mesh must not be used following planned intra-operative or accidental opening of the gastrointestinal tract. Use in these cases may result in contamination of the mesh, which may lead to infection that may require removal of the mesh.

### WARNINGS

ULTRAPRO\* Mesh is provided as a sterile product. Do not resterilize. Do not use if packaging is opened or damaged. Discard opened unused products. When ULTRAPRO\* Mesh is used in infants, children, pregnant women, or women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows. As with all foreign substances, ULTRAPRO\* Mesh should not be placed in a contaminated surgical site.

If ULTRAPRO\* Mesh is used in a contaminated wound, subsequent infection is possible which may require removal of the material. Use of ULTRAPRO\* Mesh in a contaminated or infected wound can lead to fistula formation and/or to rejection of the mesh.

Users should be familiar with surgical procedures and techniques involving non-absorbable meshes before using ULTRAPRO\* Mesh.

Foreign body reactions may occur in some patients.

### PRECAUTIONS

For incisional hernias, the mesh should be shaped so that it overlaps the abdominal fascial defect on all sides by about 5 cm (2").

The mesh should be fixed, as non fixated mesh may result in migration of the mesh.

The mesh should be always fixed in accordance with the instructions for use indicated below to minimize risk of mesh migration or recurrence of hernia.

For all types of hernia repair, permanent mesh fixation should be at least 1 cm (3/8") from the edge of the mesh (including at least two complete cross-sections) with 1 cm (3/8") spacing between fixation points. For non permanent fixation, less distance to edge of the mesh or too much distance between fixation points may result in recurrence of hernia.

### ADVERSE REACTIONS

Potential adverse reactions with ULTRAPRO\* Mesh are those typically associated with surgically implantable materials, including inflammation such as seroma formation, adhesion formation, fistula formation, extrusion and potentiation of infection.

### INSTRUCTIONS FOR USE

For open and laparoscopic incisional hernia repair, the preferred positioning of the mesh is extraperitoneal as a sublay (retromuscular) with closure of the anterior fascia over the defect wherever possible.

The mesh should be shaped so that it overlaps the abdominal fascial defect on all sides by about 5 cm (2").

For inguinal hernias, the mesh is implanted according to currently accepted surgical mesh procedures either open or laparoscopically. Adequate preparation and mesh size must be considered to prevent the risk of insufficient covering of the abdominal fascial defect.

The mesh should be placed tension-free and without creases or folds. To avoid dislodging, crinkling or curling of the edges, ULTRAPRO\* Mesh should be fixed in place with a sufficient number of sutures or staples inserted along the borders of the mesh.

It is recommended that non-absorbable sutures should be placed at least 1 cm (3/8") from the edge of the mesh with 1 cm (3/8") spacing between fixation points. Alternatively, suitable nonabsorbable fixation devices (e.g. stapler, tacker, anchor, etc.) may also be used using the same placement requirements described for the sutures. The non absorbable device design must ensure that at least one cross-section of the mesh is included. It must be ensured that no strands are cut with any fixation device. Some surgeons prefer to suture into position an uncut section of mesh that is considerably larger than the defect. When the margin sutures have all been placed, the extra mesh may be trimmed away.

### STORAGE

Store at 25° C or less away from moisture and direct heat. A brief exposure up to 40° C is acceptable.

### HOW SUPPLIED

ULTRAPRO\* Mesh is available in single packets as sterile sheets with blue striping. ULTRAPRO\* Mesh comes in a variety of sizes. Full details are provided in the ETHICON\* Product Catalog.

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Somerville, New Jersey 08876-0151



# ULTRAPRO\* PLUG

## MONOCRYL\*-PROLENE\* Composite

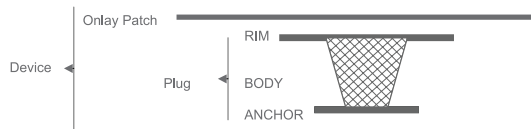
### Partially Absorbable Synthetic Surgical Mesh Device

#### DESCRIPTION

The ULTRAPRO\* PLUG device comprises a sterile, thermo-formed, three-dimensional plug manufactured from Spacer Fabric material (three dimensional warp knitting technology) and a flat preshaped onlay patch. The Spacer Fabric is composed of a non-absorbable mesh, manufactured from polypropylene monofilament fibers and an absorbable mesh, manufactured from poliglecaprone 25 monofilament fibers. Both parts are connected by poliglecaprone 25 monofilament fibers.

The BODY and RIM are manufactured of undyed polypropylene fibers and the ANCHOR consists of dyed (phthalocyanine blue, Color Index No.: 74160) and undyed polypropylene mesh for better differentiation. The ANCHOR is attached to the BODY using undyed polypropylene threads. (fig. 1)

Fig. 1 Illustration of the ULTRAPRO\* PLUG device



The ULTRAPRO preshaped onlay patch is manufactured from approximately equal parts of absorbable poliglecaprone 25 monofilament fibers and non-absorbable dyed (phthalocyanine blue, Color Index No.: 74160) and undyed polypropylene monofilament fibers.

The polymer of the undyed and dyed polypropylene fibers (phthalocyanine blue, Color Index No.: 74160) is identical to the material used for dyed / undyed PROLENE\* suture. Poliglecaprone 25 fiber consists of a copolymer containing glycolide and  $\epsilon$ -caprolactone. This copolymer is identical to the material used for MONOCRYL\* suture.

After absorption of the poliglecaprone 25 components, only the polypropylene mesh remains. The structure and size of this remaining mesh is designed to withstand the physiological forces of the abdominal wall. The device is available in different sizes, which refer to the diameter of the ANCHOR. Full details are provided in the product catalog.

#### INDICATIONS

This product is indicated for open repair of groin hernia defects.

#### APPLICATION

An appropriate plug should be chosen according to the size of the defect. The ANCHOR should not be cut or trimmed.

For indirect inguinal hernia repair, a high dissection of the neck of the hernia sac can be performed to utilize the space for insertion of the plug. The ANCHOR (blue) is inserted through the internal ring, allowing the ANCHOR to expand. Surgical manipulation may be used to facilitate deployment.

For direct inguinal hernia repair, the defect is circumscribed at its base and the contents fully reduced. The PLUG is inserted into the defect, allowing the ANCHOR (blue) to expand. Surgical manipulation may be used to facilitate the deployment.

In femoral hernia repair the sac is reduced and an appropriately sized plug inserted, so that the RIM lies flush with the opening of the femoral canal.

In order to avoid migration of the device the PLUG must be adequately fixed through the middle of the RIM to the fascia (inguinal) or in femoral hernia the tissue that comprises the opening of the femoral canal. If the RIM is cut or trimmed, secure fixation must be ensured.

For inguinal hernia the flat onlay patch is then positioned to cover the posterior wall (floor of the canal) and may be modified as needed to accommodate the cord structures. Adequate preparation must be considered in order to ensure that the mesh sufficiently overlaps the defect on all sides so that the fascial edges are also adequately stabilized. The onlay patch should be positioned tension and fold free with the longer side parallel to the inguinal ligament. For femoral hernia an onlay patch is used only if there is adequate space for it to be placed.

The onlay patch should be adequately fixed to avoid edge rollup and folding and to minimize the risk of hernia recurrence. It is recommended that points of fixation be placed at a distance approximately 1 cm (0.4") from the edge of the mesh. The tails created to accommodate the cord structures must be brought together and fixed. Fixation should be permanent as absorbable fixation methods have not been studied.

#### ACTIONS / PERFORMANCE

The ULTRAPRO\* PLUG is a partially absorbable device used to fill and reinforce abdominal wall hernia defects to provide permanent support during and following wound healing. When implanted subcutaneously in animals, the poliglecaprone 25 copolymer is essentially absorbed 119 days after implantation. The device elicits a transient mild to moderate foreign body reaction.

#### CONTRAINDICATIONS

The device must be separated from the abdominal cavity by peritoneum.

#### WARNINGS

If this product is used in patients with the potential for growth or tissue expansion (such as infants or children or women who may become pregnant), the surgeon should be aware that the device will not stretch significantly as the patient grows.

Users should be familiar with open surgical procedures and techniques involving non-absorbable meshes. Do not use if package is opened or damaged.

#### PRECAUTIONS

In inguinal hernia repair the ULTRAPRO\* PLUG should always be used as a whole, i.e. plug plus onlay patch. The preshaped flat onlay patch itself is not suitable for use as a plug. Use in contaminated or infected wounds can lead to fistula formation and/or rejection of the mesh; subsequent infection may require removal of the device.

In order to minimize the risk of hernia recurrence the following precautions should be observed:

- Care should be taken to avoid intraoperative damaging of the device, e.g. with sharp instruments or thermal devices.
- The PLUG must be adequately fixed through the middle of the RIM to the fascia (inguinal) or in femoral hernia the tissue that comprises the opening of the femoral canal. The onlay patch should sufficiently overlap the defect on all sides so that the fascial edges are also adequately stabilized.
- The onlay patch should be adequately fixed to avoid edge rollup and folding. The points of fixation should be placed at a distance approximately 1 cm (0.4") from the edge of the mesh. Fixation should be permanent.

Currently available animal data concerning the amount of implanted absorbable material supports the implantation of up to two large size devices per 60 kg (132.3 lb) body weight during a timeframe of 4 months.

#### ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials, which include chronic inflammatory foreign body reaction, seroma formation, infection potentiation, adhesion formation, fistula formation and extrusion.

#### STERILITY

The ULTRAPRO\* Plug is sterilized by Ethylene Oxide. Do not resterilize. Do not use if package is opened or damaged. Discard open, unused product.

#### STORAGE

Recommended storage conditions: below 25°C, away from moisture and direct heat. Do not use after expiry date.

#### CAUTION

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



# Flex HD™

## Acellular Dermis Composite

### PROCESSED HUMAN ALLOGRAFT TISSUE

**CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY. ASEPTICALLY PROCESSED. PASSES USP <71> FOR STERILITY. DO NOT STERILIZE.**

**DESCRIPTION**

**THIS TISSUE WAS RECOVERED FROM A DONOR WITH DOCUMENTED PERMISSION FOR RECOVERY AND DONATION. THIS RECOVERY WAS PERFORMED USING ASEPTIC TECHNIQUES. PROCESSING AND PACKAGING WERE PERFORMED UNDER ASEPTIC CONDITIONS. TERMINAL STERILIZATION AGENTS WERE NOT USED IN THE PROCESS.**

Flex HD is human allograft skin minimally processed to remove epidermal and dermal cells and is packaged in an ethanol solution. The process utilized preserves the extracellular matrix of the dermis. The resulting allograft serves as a framework to support cellular repopulation and vascularization at the surgical site.

#### INDICATIONS FOR USE

Flex HD is processed to remove cells while maintaining the integrity of the matrix with the intent to address the issues of the specific and nonspecific inflammatory responses. It is used for the replacement of damaged or inadequate integumental tissue or for the repair, reinforcement or supplemental support of soft tissue defects.

#### CONTRAINDICATIONS

Use of Flex HD in patients exhibiting autoimmune connective tissue disease is not recommended.

#### ADVERSE EFFECTS

Possible adverse effects of using human skin include but are not limited to:

- Low vascularity of the surrounding tissue
- Local or systemic infection
- Dehiscence and/or necrosis due to poor revascularization
- Specific or nonspecific immune response to some component of the graft

*Within the United States: Adverse outcomes attributable to the tissue must be promptly reported to MTF. Outside of the United States: Adverse outcomes attributable to the tissue must be promptly reported to your local representative.*

#### PRECAUTIONS

When applied properly, Flex HD has been shown to support the migration of host cells from wound margins and surrounding tissue. Conditions that could potentially inhibit integration of Flex HD include, but are not limited to:

- Fever
- Uncontrolled diabetes
- Pregnancy
- Low vascularity of the surrounding tissue
- Local or systemic infection
- Mechanical trauma
- Poor nutrition or poor general medical condition
- Dehiscence and/or necrosis due to poor revascularization
- Inability to cooperate with and/or comprehend post-operative instructions

- Infected or nonvascular surgical sites

#### CAUTIONS

No known sensitizing agents are present in this tissue. Trace amounts of ethanol may be present. NOTE: No  $\beta$ -lactam are used during the processing of tissue in Flex HD.

Extensive medical screening procedures have been used in the selection of all tissue donors for MTF (please see Donor Screening and Testing). Transmission of infectious diseases such as HIV or hepatitis, as well as a theoretical risk of the Creutzfeldt-Jakob (CJD) agent, may occur in spite of careful donor selection and serological testing.

#### ALLOGRAFT INFORMATION

Flex HD is composed of an acellular dermal matrix. During tissue processing and packaging, this allograft was tested for sterility in accordance with the procedures in the current United States Pharmacopoeia, USP <71>. **Do not subject allograft to additional sterilization procedures.**

Dispose of excess or unused tissue and all packaging that has been in contact with the tissue in accordance with recognized procedures for discarding regulated medical waste materials.

#### INSTRUCTIONS FOR USE

Flex HD is packaged in a foil pouch that is designed to be passed directly into the sterile field.

1. Peel back the outer Tyvek Package and pass the inner foil pouch to the sterile field.
2. Remove Flex HD from the inner-foil pouch using sterile gloves/forceps.
3. Flex HD may be aseptically trimmed to fit the dimensions of the application site. The tissue can be shaped with scissors or scalpel and rolled or folded to desired thickness. At this point the Flex HD is ready for application in the surgical site.

**Once the foil pouch containing Flex HD has been opened and exposed, the tissue shall be transplanted within 30 minutes otherwise, it can be maintained in a sterile saline bath and must be implanted or discarded within 24 hours provided the allograft is maintained in an aseptic environment.**

#### ORIENTATION

In order to discern the dermal side from the epidermal side, note that the dermal side is shiny and smooth; the epidermal side is dull and textured. To ensure proper orientation of Flex HD, position it so that the indicating notch is in the upper left-hand side of the tissue, facing left. This will assure that the epidermal side is facing up.

Every effort is made to ensure that all hair has been effectively removed from the skin allograft. If any hair is present, remove them before implantation. If they cannot easily be removed, **please contact MTF.**

#### DONOR SCREENING & TESTING

Prior to donation, the donor's medical/social history was screened for medical conditions or disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures approved by the MTF Medical Advisory Board.

Donor blood samples taken at the time of recovery were tested by a CLIA licensed facility for:

- Hepatitis B surface antigen
- HIV-1/2 antibody
- Hepatitis B core antibody
- HTLV-III antibody
- Hepatitis C antibody
- Syphilis

In addition to the testing listed above, HIV Nucleic Acid Amplification Testing (NAT) was performed. Furthermore, donors recovered on or after May 1, 2004 were tested for HCV utilizing the HCV NAT testing method. The results of all serological testing were negative. The allograft tissue has been determined to be suitable for transplantation.

The infectious disease test results, consent, current donor medical history interview, physical assessment, available relevant medical records to include previous medical history, laboratory test results, autopsy and coroner reports, if performed, and information obtained from any source or records which may pertain to donor suitability, have been evaluated by an MTF physician and are sufficient to indicate that donor suitability criteria current at the time of procurement, have been met. This tissue is suitable for transplantation. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published in 21 CFR Part 1270 and Part 1271 Human Tissue Intended for Transplantation, as applicable. All procedures for donor screening, serologic and microbiologic testing meet or exceed current standards established by the American Association of Tissue Banks.

#### PACKAGING & LABELING

Flex HD is aseptically packaged in a hermetically sealed foil pouch. The foil pouch containing Flex HD is inside a sealed Tyvek pouch. The Tyvek pouch is sealed, labeled and then placed inside a labeled box.

This allograft must not be used under any of the following circumstances:

- If the container seal is damaged or not intact or has any physical damage;
- If the container label or identifying bar code is severely damaged, not legible or is missing; or
- If the expiration date shown on the container label has passed.

**Once a container seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.**

#### STORAGE

Flex HD should be stored between 15°C and 37°C. No refrigeration or freezing is required. It is the responsibility of the transplant facility or clinician to maintain the tissue intended for transplantation in the appropriate recommended storage conditions prior to transplant.

#### PATIENT RECORD

Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of tracing tissue post-transplantation to facilitate the investigation of actual or suspected transmission of communicable disease, and the appropriate and timely corrective action. A TissueTrace® Tracking Form and peel-off labels have been included with each package of tissue. Record the patient name, the name and address of the transplant facility, allograft tissue information (using the peel-off labels) and comments regarding the use of the tissue on the TissueTrace Tracking Form. Within the United States: Once completed, the bottom page of the form should be returned to MTF using the self addressed, postage paid mailer. Copies of this information should be retained by the transplant facility for future reference. Outside of the United States: Once completed, the bottom page of the form should be returned to the local allograft representative or provider. Copies of this information should be retained by the hospital for future reference.

#### REFERENCES:

1. Current Standards for Tissue Banking, AATB, McLean, VA.
2. Current Policies and Procedures of MTF, Edison, NJ.
3. Tomford WW, Dopelt SH, Mankin HJ, Friedlander GE, Bone Bank Procedures, Clinical Orthopaedics, 1983.

**CAUTION: Federal (US) law restricts this tissue to sale, distribution and use by or on the order of a physician.**

FlexHD™ is a registered trademark of MTF  
MTF® is a registered trademark of the Musculoskeletal Transplant Foundation

# ULTRAPRO\* Hernia System MONOCRYL\* (poliglecaprone) – PROLENE\* (polypropylene) Composite

## Synthetic Partially Absorbable Surgical Mesh Device

### Description

The ULTRAPRO\* Hernia System (UHS) is a sterile, pre-shaped, three-dimensional device constructed of an undyed onlay patch (1) connected by a mesh cylinder (connector) (2) to an underlay patch (3), which is reinforced by a flat undyed absorbable film of Poliglecaprone-25 (MONOCRYL). The underlay patch is marked with dyed polypropylene fibers to be clearly distinguishable from the onlay patch. The onlay patch, connector and underlay patch are 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 fibers (phthalocyanine blue, Color Index No.: 74160) is identical to the material used for dyed / undyed PROLENE\* suture material. Poliglecaprone-25 fiber consists of a copolymer containing glycolide and ε-caprolactone. This copolymer is also used for MONOCRYL\* suture material. After absorption of the Poliglecaprone-25 components only the polypropylene mesh remains. The structure and size of this remaining mesh are designed for the physiological stresses to which the abdominal wall is subject. The UHS is available in different sizes. Full details are provided in the catalogue.

### Indications

This product is indicated for open repair of abdominal wall hernia defects.

### Application

#### Inguinal hernia repair

For indirect hernia, a high dissection of the neck of the hernia sac can be performed to utilize the preperitoneal space for insertion of the UHS. The underlay patch of the device (marked with blue threads) is folded and inserted through the internal ring, allowing the underlay patch to deploy in the preperitoneal space (beneath the epigastric vessels) and cover the entire myopectineal orifice. Correct expansion of the underlay patch may be supported by surgical manipulation, if necessary, to ensure that it is free of folds.

For direct hernia, the defect is circumscribed at its base, the contents fully reduced, and the preperitoneal space is entered. After adequate dissection, the underlay patch of the device (marked with blue threads) is folded and inserted through the defect allowing the underlay patch to expand and to cover the myopectineal orifice. Correct expansion of the underlay patch may be supported by surgical manipulation, if necessary, to ensure that it is free of folds. For indirect as well as for direct hernia the onlay patch of the device is designed to cover the floor of the canal. It is necessary to modify the onlay patch as needed to accommodate the cord structures. This can be done by creating a slit in the mesh. The longer side of the onlay patch should be positioned parallel to the inguinal ligament. The onlay patch should be positioned without folds, and should be adequately fixed (e.g. sutures, staples) in order to avoid edge rollup and/or folding and to minimize the risk of hernia recurrence. It is recommended that points of fixation be placed at a distance approximately 1 cm (0.4") from the edge of the mesh. The tails created to accommodate the cord structures need to be fixated.

### Ventral/incisional or umbilical hernias

The hernia sac is dissected free down to the abdominal fascia. Dissection then proceeds to create a preperitoneal space. An additional space is created anterior to the rectus sheath. A UHS of appropriate size for the defect is then selected. The hernia sac is reduced and the underlay patch is deployed in the preperitoneal space. The onlay patch is then positioned anterior to the rectus sheath. After tension-free placement of the device without folds, the onlay patch should be adequately fixed (e.g. sutures, staples) in order to avoid edge rollup and/or folding and to minimize the risk of hernia recurrence. It is recommended that points of fixation be placed at a distance approximately 1 cm (0.4") from the edge of the mesh. The patches can be cut to size as required using scissors or a scalpel; do not use thermal devices.

### Actions/Performance

The UHS is a partially absorbable device used to reinforce or bridge abdominal wall hernia defects by providing permanent support of the abdominal wall during and following wound healing. The absorbable poliglecaprone parts of the device help to keep the polypropylene structure rigid, thus making intraoperative manipulation and positioning of the device easier. When implanted subcutaneously in animals, the poliglecaprone-25 copolymer is essentially absorbed at 84 days after implantation. The device elicits a transient minimal to moderate foreign body reaction, which is accompanied by the formation of a three-dimensional collagen fiber network. Due to the wide-mesh construction, excessive connective tissue deposition and deleterious scar formation is avoided.

### Contraindications

The device must always be separated from the abdominal cavity by peritoneum. The device is not suitable for use as a plug.

### Warnings

The UHS is provided by ETHICON as a sterile product. This device is for single use only. Do not resterilize. Discard opened packages and unused product. If this device is used in patients with the potential for growth or tissue expansion (such as infants or children or women who may become pregnant), the surgeon should be aware that this product will not stretch significantly as the patient grows. Users should be familiar with open surgical procedures and techniques involving non-absorbable meshes; the UHS is to be used in open abdominal wall hernia repair only. Use in contaminated or infected wounds can lead to fistula formation and/or rejection of the device; subsequent infection may require removal of the material.

### Precautions

The underlay and onlay patches of the device should sufficiently overlap the defect on all sides so that the fascial edges are also adequately stabilized. Care should be taken to avoid intraoperative damaging of the device, e.g. with sharp instruments, thermal devices. The onlay patch should be adequately fixed (e.g. sutures, staples) in order to avoid edge rollup and/or folding to minimize the risk of hernia recurrence. It is recommended that points of fixation be placed at a distance approximately 1 cm (0.4") from the edge of the mesh.

### Adverse Reactions

Potential adverse reactions are those typically associated with surgically implantable materials, which include (transient) inflammatory foreign body reaction, seroma formation, infection potentiation, adhesion formation, fistula formation and extrusion.

### Sterility

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

### Storage

Recommended storage conditions: below 25°C, away from moisture and direct heat. Do not use after expiry date.

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# PROLENE\*

## Polypropylene Hernia System

### Description

The PROLENE\* Polypropylene Hernia System is a sterile, pre-shaped, three dimensional device constructed of an onlay patch connected by a mesh cylinder to an oblong or circular underlay patch. The material is undyed PROLENE\* Polypropylene Mesh constructed of knitted nonabsorbable polypropylene filaments.

### Actions/Performance

The PROLENE Hernia System is a nonabsorbable mesh used to reinforce or bridge inguinal hernia deficiencies to provide extended support during and following wound healing. Animal studies show that implantation of PROLENE Mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is neither absorbed nor is it subject to degradation or weakening by the action of tissue enzymes.

### Indications

This product is indicated for the repair of abdominal wall hernia defects.

### Warnings

The PROLENE Hernia System is provided by ETHICON, INC. as a sterile product. This device is for single use only. Do not resterilize. Discard opened packages and unused product. When this device is used in infants or children with future growth potential, the surgeon should be aware that this product will not stretch significantly as the patient grows. The PROLENE Hernia System should only be used in contaminated wounds with the understanding that subsequent infection may require removal of the device.

### Precautions

Sutures or clips, if necessary, should be placed such that a minimum of 6.5 mm (1/4") of mesh should extend beyond the suture line.

### Adverse Reactions

Potential adverse reactions are those typically associated with surgically implantable materials which include infection potentiation, inflammation, adhesion formation, fistula formation, and extrusion.

### Instructions for Use

For indirect hernia repair, a high dissection of the neck of the hernia sac to utilize the potential of the preperitoneal space can be performed to insert the PROLENE Hernia System. The oblong/circular or bottom underlay portion of the PROLENE Hernia System is folded and is inserted through the internal ring allowing the mesh to expand to the underlay position. Surgical manipulation may be used to facilitate the expansion of the device to the underlay position. No sutures are necessary in the bottom underlay patch. The top onlay patch, which is designed to cover the posterior wall (floor of the canal), is then modified as needed to accommodate the cord structures. If one end of the oval onlay patch is longer than the other, the PROLENE Hernia System is positioned so that the longer end covers the posterior wall (floor of the canal) and overlaps the pubic tubercle. Sutures or clips may be used to secure the top onlay patch in place. The cord structures then lie on top of the medial portion of the onlay patch. For direct hernia, the defect is circumscribed at its base, the contents fully reduced, and the preperitoneal space is actualized prior to the insertion of the PROLENE Hernia System. The circular, or bottom underlay portion of the PROLENE Hernia System is folded and is inserted through the defect or the internal ring allowing the mesh to expand to the underlay position. The underlay portion should expand under the defect in the floor of the inguinal canal. Surgical manipulation may be used to facilitate the expansion of the device to the underlay position. Sutures or clips may be used to secure the top onlay patch in place.

For repair of ventral/incisional or umbilical hernias the sac is dissected free down to the abdominal fascia. Dissection then proceeds under the anterior abdominal fascia to create a submuscular space that is anterior to the posterior fascia and peritoneum. An additional space is created anterior to the rectus muscle and posterior to the anterior rectus sheath. A PROLENE Hernia System of appropriate size for the defect is then selected. The hernia sac is reduced and the underlay mesh is placed posterior to the rectus muscle and anterior to

the posterior rectus sheath. Adequate overlap with the rectus muscle is assured. The overlap mesh is then positioned anterior to the rectus muscle and posterior to the anterior rectus sheath. Sutures or clips may be used to secure the top onlay and/or the bottom underlay patch in place.

### Sterility

The PROLENE Hernia System is sterilized by Ethylene Oxide. Do not resterilize. Do not use if package is opened or damaged. Discard open, unused product.

# **PROLENE\***

## **POLYPROPYLENE MESH**

### **Nonabsorbable Synthetic Surgical Mesh**

#### **STERILE**

#### **DESCRIPTION**

PROLENE\* polypropylene mesh is constructed of knitted filaments of extruded polypropylene identical in composition to that used in PROLENE\* Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). The mesh is approximately 0.020 inches thick. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use.

PROLENE mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The fiber junctions are not subject to the same work fatigue exhibited by more rigid metallic meshes. This bi-directional elastic property allows adaption to various stresses encountered in the body.

#### **ACTIONS**

PROLENE mesh is a nonabsorbable mesh used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing. Animal studies show that implantation of PROLENE mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed nor is it subject to degradation or weakening by the action of tissue enzymes.

#### **INDICATIONS**

This mesh may be used for the repair of hernia and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

#### **CONTRAINDICATIONS**

When this mesh is used in infants or children with future growth potential, the surgeon should be aware that this product will not stretch significantly as the patient grows.

PROLENE mesh in contaminated wounds should be used with the understanding that subsequent infection may require removal of the material.

#### **WARNINGS**

PROLENE mesh is provided by ETHICON, INC. as a sterile product. Resterilization of the device is NOT recommended. However, testing has demonstrated that reprocessing of unused PROLENE mesh which has been removed from the package will not be adversely affected when exposed not more than one time to conventional steam autoclave conditions of 250° F (121° C) for 20 minutes. Reprocessing under any other condition or by any other means is neither recommended nor endorsed by ETHICON, INC. PROLENE mesh should not be flash autoclaved.

If this product should become stained with blood or soiled, it should not be resterilized for reuse.

When reprocessed as outlined above, it is the responsibility of the end-user to assure sterility of the product via a validated sterilization process as ETHICON, INC. has no control over environmental conditions the product may encounter prior to, during, or after reprocessing.

#### **PRECAUTIONS**

A minimum of 6.5mm (1/4") of mesh should extend beyond the suture line.

#### **ADVERSE REACTIONS**

Potential adverse reactions are those typically associated with surgically implantable materials which include infection potentiation, inflammation, adhesion formation, fistula formation and extrusion.

#### **INSTRUCTIONS FOR USE**

It is recommended that nonabsorbable sutures be placed 6.5mm to 12.5mm (1/4" to 1/2") apart at a distance approximately 6.5mm (1/4") from edge of the mesh. Some surgeons prefer to suture an uncut section of mesh that is considerably larger than the defect into position over the wound. The opposite sides are then sutured to assure proper closure under correct tension. When the margin sutures have all been placed, the extra mesh is trimmed away.

#### **HOW SUPPLIED**

PROLENE mesh is available in single packets as sterile, undyed (clear) sheets in nine sizes. The sizes available are 2.5cm x 10cm (1" x 4"), 4.6cm x 10.2cm (1.8" x 4"), 5.1cm x 30 cm (2" x 12"), 6cm x 11cm (2.5" x 4.5"), 6.1cm x 13.7cm (2.4" x 5.4"), 7.6cm x 12.7cm (3" x 5"), 7.6cm x 15cm (3" x 6") 15cm x 15cm (6" x 6") and 30cm x 30cm (12" x 12"). Each sheet is approximately 0.5mm (0.020") thick.

\*Trademark

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## PROLENE\* 3D Patch mesh

**Description:** The PROLENE\* 3D Patch Polypropylene Mesh is a sterile three-dimensional device. The device is fabricated from PROLENE\* Polypropylene Mesh. It consists of a flat mesh onlay patch secured to a formed expandable diamond-shaped mesh patch component. The expandable patch portion of the device is a hollow diamond-shaped component that is deployed through the use of an integrated looped non-absorbable suture.

**Actions/Performance:** The PROLENE 3D Patch is a nonabsorbable mesh device used to repair or bridge abdominal wall hernia defects to provide extended support during and following wound healing. Animal studies show that implantation of PROLENE Mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is neither absorbed nor is it subject to degradation or weakening by the action of tissue enzymes.

**Indications:** This product is indicated for the repair of inguinal (direct & indirect) and abdominal wall hernia defects.

**Warnings:** The PROLENE 3D Patch is provided by ETHICON, INC. as a sterile product. This device is for single use only. Do not resterilize. Discard opened packages and unused product. When this device is used in infants or children with future growth potential, the surgeon should be aware that this product will not stretch significantly as the patient grows. If the PROLENE 3D Patch is used in contaminated wounds, it should be with the understanding that subsequent infection may require the removal of the device.

**Precautions:** Sutures or staples, if necessary, should be placed such that a minimum of 6.5 mm (1/4") of mesh will extend beyond the suture line.

**Adverse Reactions:** Potential adverse reactions are those typically associated with surgically implantable materials, which include infection potentiation, inflammation, adhesion formation, fistula formation, and extrusion.

**Instructions for Use:** 1. Dissect and invert sac. 2. Insert into defect. 3. Hold the device in place with one hand and grasp the free end of the suture with the other. 4. Pull the suture while holding the knot down between the thumb and forefinger. 5. Cut off excess suture above slipknot. 6. Inspect to be certain that the diamond has flattened out within the defect and is secure under healthy fascia.

**Indirect Inguinal Hernia:** For indirect inguinal hernia repair, deal with the hernia sac as per standard hernia repair techniques. The diamond-shaped portion of the PROLENE 3D Patch is inserted through the internal ring. Once in place, hold the device in position and pull on the free end of the looped suture to deploy the device. Pulling on the suture will expand the diamond-shaped mesh causing it to fill the defect and to partially flatten below the fascia layer. Sutures may be used to fix the device in place within the defect. The onlay patch, designed to cover the posterior wall (floor of the canal), is then modified as needed to accommodate the cord structures. Sutures or staples may be used to secure the onlay patch in place. Check to be certain that the flattened, deployed, diamond-shaped portion is under the transversalis fascia.

**Direct Inguinal Hernia:** For direct inguinal hernia, the defect is circumscribed at the base of the sac and its contents fully reduced. The diamond-shaped portion of the PROLENE 3D Patch is inserted through the defect. Once in place, hold the device in position and pull on the free end of the looped suture to deploy the device. Pulling on the suture will expand the diamond-shaped mesh causing it to fill the defect and to partially flatten below the fascia layer. Sutures may be used to fix the device in place within the defect. The onlay patch, which is designed to cover the posterior wall (floor of the canal), is then modified as needed to accommodate the cord structures. Sutures or staples may be used to secure the onlay patch in place. Check to be certain that the deployed, diamond-shaped portion is under the transversalis fascia.

**Ventral/Incisional/Umbilical Hernia:** For the repair of ventral, incisional and umbilical hernias, the sac is dissected free, down to the abdominal fascia. Once the hernia sac is reduced, the diamond-shaped portion of the device is inserted through the defect. Once in place, hold the device in position and pull on the free end of the looped suture to deploy the device. Pulling on the suture will expand the diamond-shaped mesh causing it to fill the defect and to partially flatten below the fascia

layer. Ensure an adequate area of overlap with healthy fascia. Sutures or staples may be used to fix the device in place within the defect. The overlay mesh is then positioned anterior to the rectus muscle and posterior to the anterior rectus sheath. Sutures or clips may be used to secure the onlay and/or the connector mesh in place. The anterior rectus sheath is then closed over the onlay mesh.

**Sterility:** The PROLENE 3D Patch is sterilized by Ethylene Oxide. Do not resterilize. Do not use if package is opened or damaged. Discard open, unused product.

**Storage:** Recommended storage conditions: below 25°C, 77°F, away from moisture and direct heat. Do not use after expiry date.

**How Supplied:** The PROLENE 3D Patch is available sterile, in several sizes.

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

### ETHICON, INC.

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# VICRYL\* Woven Mesh

## DESCRIPTION

VICRYL\* (polyglactin 910) woven mesh is prepared from a synthetic absorbable copolymer of glycolide and lactide, derived respectively from glycolic and lactic acids. This tightly woven mesh is prepared from uncoated, undyed fiber identical in composition to that used in VICRYL\* (polyglactin 910) synthetic absorbable suture, which has been found to be inert, nonantigenic, nonpyrogenic and to elicit only a mild tissue reaction during absorption.

VICRYL woven mesh is intended for use as a buttress to provide temporary support during the healing process.

## ACTIONS

Two important characteristics describe the in vivo function and behavior of VICRYL woven mesh: reinforced wound strength and the rate of absorption (loss of mass).

The dehiscence force of healing abdominal wounds in rats closed with size 4-0 absorbable sutures was compared with corresponding wounds closed with size 4-0 absorbable sutures and reinforced with VICRYL woven mesh. In this animal model, the strength of the incision, when supported by the mesh, was significantly greater than the sutured incisional wound. Explanted VICRYL woven mesh, which, before implantation had an initial average burst strength of approximately 121 lbs., was found to have approximately 23% of its original burst strength remaining after fourteen days in vivo.

Subcutaneous implantation studies in rats indicate that the absorption of VICRYL mesh material is minimal until about six weeks post implantation and essentially complete between 60 and 90 days.

## INDICATIONS

VICRYL woven mesh may be used wherever temporary wound or organ support is required. The woven mesh structure is less porous than VICRYL knitted mesh. It is indicated in instances in which containment of wound transudate is desirable. VICRYL woven mesh may be cut to the shape or size desired for each specific application.

## CONTRAINDICATIONS

Because VICRYL woven mesh is absorbable, it should not be used where extended wound or organ support is required.

## WARNINGS

DO NOT RESTERILIZE.

The safety and effectiveness of VICRYL woven mesh in neural tissue and in cardiovascular tissue has not been established.

## PRECAUTIONS

None.

## ADVERSE REACTIONS

None known.

## DIRECTIONS FOR USE

It is recommended that absorbable or nonabsorbable sutures be placed 1/4 to 1/2 inch (6 to 12mm) apart at a distance at least 1/4 inch (6mm) from the edge of the mesh. Some surgeons prefer to suture a mesh larger than the defect into position over the defect. The edges are then sutured to assure proper closure under correct tension. When all margin sutures have been placed, the excess mesh is trimmed away, leaving at least 1/4 inch of mesh extending beyond the suture line.

## HOW SUPPLIED

VICRYL woven mesh is available in single packets as a sterile, undyed, fabric mesh in single sheet sizes of approximately 6 x 6 inches and 12 x 12 inches (15 x 15 centimeters and 30 x 30 centimeters).

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# VICRYL\* Mesh Bag

## Polyglactin 910 Absorbable Mesh Device

### DESCRIPTION

VICRYL\* Mesh Bag consists of VICRYL\* (polyglactin 910) Mesh and VICRYL\* (polyglactin 910) Synthetic Absorbable Suture, U.S.P. (ETHICON, INC.). VICRYL Mesh Bag can be adapted to the form and size of a spleen or liver by pulling and tying integrated strands of VICRYL suture [dyed with D&C Violet #2 and undyed]. VICRYL Mesh Bag is also available pre-shaped for use on the kidney.

VICRYL Mesh is made of polyglactin 910, a synthetic absorbable copolymer of glycolide and lactide, derived respectively from glycolic acid and lactic acids. The mesh consists of uncoated, undyed fiber identical in composition to that used in VICRYL suture, which has been found to be inert, nonantigenic, and nonpyrogenic and to elicit only a mild tissue reaction during absorption. VICRYL Mesh Bags are available in different sizes as perirenal, perisplenic, and perihepatic prostheses to envelop these organs.

### ACTIONS

Two important characteristics describe the in vivo function and behavior of VICRYL Mesh Bag: wound healing support and absorbability (loss of mass).

Surgical functionality has been demonstrated in animal studies in which the mesh supported the apposition of traumatically induced wounds of the liver, spleen, and kidney.

Subcutaneous implantation studies in rats indicate that the absorption of VICRYL Mesh material is minimal until about six weeks post-implantation and essentially complete between 60 and 90 days. Used as temporary organ support, the VICRYL Mesh Bag can control bleeding of the organs in traumatic kidney, spleen, and liver lesions, and in elective surgeries of these organs. The best effect is achieved by completely covering the kidney, spleen, or liver. When additional parenchymal sutures are used, the VICRYL Mesh Bag also serves as a buttress for the sutures, protecting the tissue against cutting and especially tearing out of the sutures. The mesh structure allows egress of fluids and the ingrowth of tissue. Use of supporting mesh in cases of traumatic or surgical injury to the organ can facilitate organ salvage.

VICRYL polymer absorption occurs by means of hydrolysis, where the copolymer degrades to glycolic and lactic acids, which are subsequently metabolized and absorbed in the body. Absorption begins as a loss of tensile strength followed by a loss of weight. All original tensile strength of the VICRYL suture is lost between four and five weeks post-implantation. Absorption of VICRYL suture is essentially complete between 56 and 70 days.

### INDICATIONS

VICRYL Mesh Bag may be used whenever temporary wound or solid organ support is required (kidney, liver, spleen).

### CONTRAINDICATIONS

Because VICRYL Mesh Bag is absorbable, it should not be used where extended wound or organ support is required.

### WARNINGS

Care should be taken to avoid compression of the major blood vessels of the organ, especially at the hilus for all prosthesis and also the ureter for the perirenal prosthesis. If VICRYL Mesh Bag is used in a contaminated field, contamination of the mesh may lead to infection that may require removal of mesh.

VICRYL Mesh Bag is provided by ETHICON, INC. as a sterile product. Do not reuse or resterilize. Do not use if packaging is opened or damaged. Discard opened unused products.

Users should be familiar with surgical procedures and techniques involving absorbable meshes before using VICRYL Mesh Bag. Foreign body reactions may occur in some patients.

### PRECAUTIONS

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

When cutting or shaping, use caution to avoid damaging the mesh.

### ADVERSE REACTIONS

Adverse reactions associated with the use of this device include transitory local irritation at the wound site and a transitory inflammatory foreign body response. As with all foreign devices, potential adverse events may also include inflammation and potentiation of procedure-related infection.

### INSTRUCTIONS FOR USE

#### Perirenal Prosthesis:

Step 1. Choose the Small (6 x 3 inch) or large (7 x 4 inch) prosthesis depending on the size of the kidney.

Note: Enclosed measuring tape can be utilized to determine size.

Step 2. Mobilize the kidney to facilitate placement.

Step 3. Place the bag over the kidney. The mesh should completely cover the surface of the kidney, except for the hilar vessels and the ureter.

Step 4. The integrated suture strands will be used to facilitate the adjustment and compression of the organ.

First cinch the UNDYED VICRYL strand around the hilum to contain the organ within the prosthesis. Tie and cut the undyed suture strand. Care must be taken not to compress the hilar vessels and the ureter as the suture is tied.

Step 5. Cinch and tie down the DYED suture strands on both poles of the bag to achieve desired compression.

Step 6. Clamps can be placed at one or both poles of the bag to further aid compression, while the integrated dyed suture strands are adjusted.

Step 7. Additional sutures may be placed at each pole to achieve further compression of the organ. These sutures can be passed through the mesh but not the capsule or the parenchyma.

Step 8. If necessary, a VICRYL suture can be placed in the region of the hilus for additional mesh fixation.

Step 9. After complete fixation of the prosthesis, redundant mesh material should be cut off.

#### Perisplenic Prosthesis:

Step 1. The gastric surface of the spleen must be dissected free (taking down the short gastric vessels will help facilitate this mobilization).

Step 2. Wrap the mesh around the injured organ ensuring that the integrated suture strands (and tabs) are on the exterior, non-splenic side of the mesh.

Step 3. First pull the outer peripheral DYED integrated VICRYL strand to contain the spleen within the prosthesis. This peripheral VICRYL Suture strand is cinched around the hilus and tightened without compressing the hilar vessels.

Step 4. The second UNDYED integrated VICRYL strand is then appropriately tightened and tied down to provide adequate compression of the organ.

Step 5. In case of severe damage and if increased coaptation of the wound is required, the third integrated DYED VICRYL strand can be tightened and tied down on the diaphragmatic side of the spleen.

#### Perihepatic Prosthesis:

Separate mesh bag shapes for the right and left liver lobe must be used.

Step 1. Mobilize the injured liver lobe from its peritoneal attachment including the coronary ligament, triangular ligament and falciform ligament.

#### LEFT LOBE:

Step 2. To place the mesh, orient the longest straight edge of the mesh towards the fissure of the lobes of the liver, perpendicular to the transverse axis.

Step 3. Gently lifting the lobe, place the mesh posteriorly and wrap the mesh anteriorly around the lobe.

Note: Utilizing long curved clamps on the corners of the mesh, while lifting up the lobe may help facilitate the placement of the mesh posteriorly.

Step 4. First secure the mesh to the falciform ligament remnants by a continuous suture starting posteriorly.

Step 5. Initiate compression of the organ by cinching down the UNDYED VICRYL strand starting at the edge of the mesh closest to the fissure.

Step 6. It is recommended to start tightening and tying down the alternating UNDYED and DYED VICRYL strands sequentially from the falciform ligament proceeding to the lateral part of the lobe in order to achieve a complete wrapping of the mesh around the organ and to achieve adequate compression.

The integrated VICRYL strands should be tightened so that sufficient compression can achieve hemostasis.

Step 7. If hemostasis is insufficient, additional sutures (continuous or interrupted) can be passed through the prosthesis but not the capsule or the parenchyma. Mild compression to achieve hemostasis is well tolerated by the liver parenchyma.

Step 8. Postoperatively, patients should be monitored closely for signs of cholestasis and/or liver necrosis as well as circulatory impairment.

#### RIGHT LOBE:

Step 2. To place the mesh, orient the edge of the mesh with the longer side towards the fissure of the lobes of the liver, perpendicular to the transverse axis.

Step 3. Gently lifting the lobe, place the mesh posteriorly and wrap the mesh anteriorly around the lobe.

Note: Utilizing long curved clamps on the corners of the mesh, while lifting up the lobe may help facilitate the placement of the mesh posteriorly.

Step 4. First secure the mesh to the falciform ligament remnants by a continuous suture starting posteriorly.

Step 5. Initiate compression of the organ by cinching down the DYED VICRYL strand starting at the edge of the mesh closest to the fissure.

Step 6. It is recommended to start tightening and tying down the alternating DYED and UNDYED VICRYL strands sequentially from the falciform ligament proceeding to the lateral part of the lobe in order to achieve a complete wrapping of the mesh around the organ and to achieve adequate compression.

The integrated VICRYL strands should be tightened so that sufficient compression can achieve hemostasis and stop bile leakage.

Step 7. If hemostasis is insufficient, additional sutures (continuous or interrupted) can be passed through the prosthesis but not the capsule or the parenchyma. Mild compression to achieve hemostasis is well tolerated by the liver parenchyma.

Step 8. Postoperatively, patients should be monitored closely for signs of cholestasis and/or liver necrosis as well as circulatory impairment.

#### STORAGE

Store at 25° C or less and away from moisture. Avoid prolonged exposures to elevated temperatures.

Do not use after expiration date.

#### HOW SUPPLIED

VICRYL Mesh Bags are available individually packaged in a variety of shapes and sizes for perirenal, perisplenic, and perihepatic prostheses.

Manufactured by ETHICON GmbH

Distributed by (USA):

Somerville, New Jersey 08876-0151

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# MERSILENE\* POLYESTER FIBER MESH

## Nonabsorbable Synthetic Surgical Mesh

### STERILE

#### DESCRIPTION

MERSILENE\* Polyester Fiber Mesh is constructed from polyethylene terephthalate, the same material used to make MERSILENE\* Polyester Fiber Suture, Nonabsorbable Surgical Suture, U.S.P. (ETHICON, INC.) MERSILENE Polyester Fiber Mesh affords excellent strength, durability and surgical adaptability, along with maximal porosity for necessary tissue ingrowth. The mesh is approximately 0.010 inches thick and is a highly flexible and compliant material.

MERSILENE mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The fiber junctions are not subject to the same work fatigue exhibited by more rigid metallic meshes. This bi-directional elastic property allows adaption to various stresses encountered in the body.

#### ACTIONS

MERSILENE mesh is a nonabsorbable mesh used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing. Animal studies show that implantation of MERSILENE mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed nor is it subject to degradation or weakening by the action of tissue enzymes.

#### INDICATIONS

This mesh may be used for the repair of hernia and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

#### CONTRAINDICATIONS

When this mesh is used in infants or children with future growth potential, the surgeon should be aware that this product will not stretch significantly as the patient grows.

MERSILENE polyester fiber mesh in contaminated wounds should be used with the understanding that subsequent infection may require removal of the material.

#### WARNINGS

MERSILENE mesh is provided by ETHICON, INC. as a sterile product. Unused MERSILENE Mesh which has been removed from the package may be resterilized not more than one time by a conventional steam autoclaving process at conditions of 250°F (121°C) for 20 minutes. MERSILENE mesh may also be flash autoclaved not more than one time at conditions of 270°F (132°C) for 10 minutes. Resterilization under any other conditions or by any other means is neither recommended nor endorsed by ETHICON, INC.

If this product should become stained with blood or soiled, it should not be resterilized for reuse.

#### PRECAUTIONS

A minimum of 6.5mm (1/4 inch) of mesh should extend beyond the suture line.

#### ADVERSE REACTIONS

No significant adverse clinical reactions to MERSILENE mesh have been reported. The use of nonabsorbable MERSILENE mesh in a wound that is contaminated or infected could lead to fistula formation and/or extrusion of the mesh.

#### INDICATIONS FOR USE

It is recommended that nonabsorbable sutures be placed 6.5 to 12.5mm (1/4 to 1/2 inch) apart at a distance approximately 6.5mm (1/4 inch) from edge of the mesh. Some surgeons prefer to suture an uncut section of mesh that is considerably larger than the defect into position over the wound. The opposite sides are then sutured to assure proper closure under correct tension. When the margin sutures have all been placed, the extra mesh is trimmed away.

#### HOW SUPPLIED

MERSILENE mesh is available in single packets as sterile, undyed (white) sheets in two sizes. The sizes available are 6 x 11cm (2.5 x 4.5 inches) and 30 x 30cm (12 x 12 inches). Each sheet is 0.25mm (0.010 inch) thick.

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