



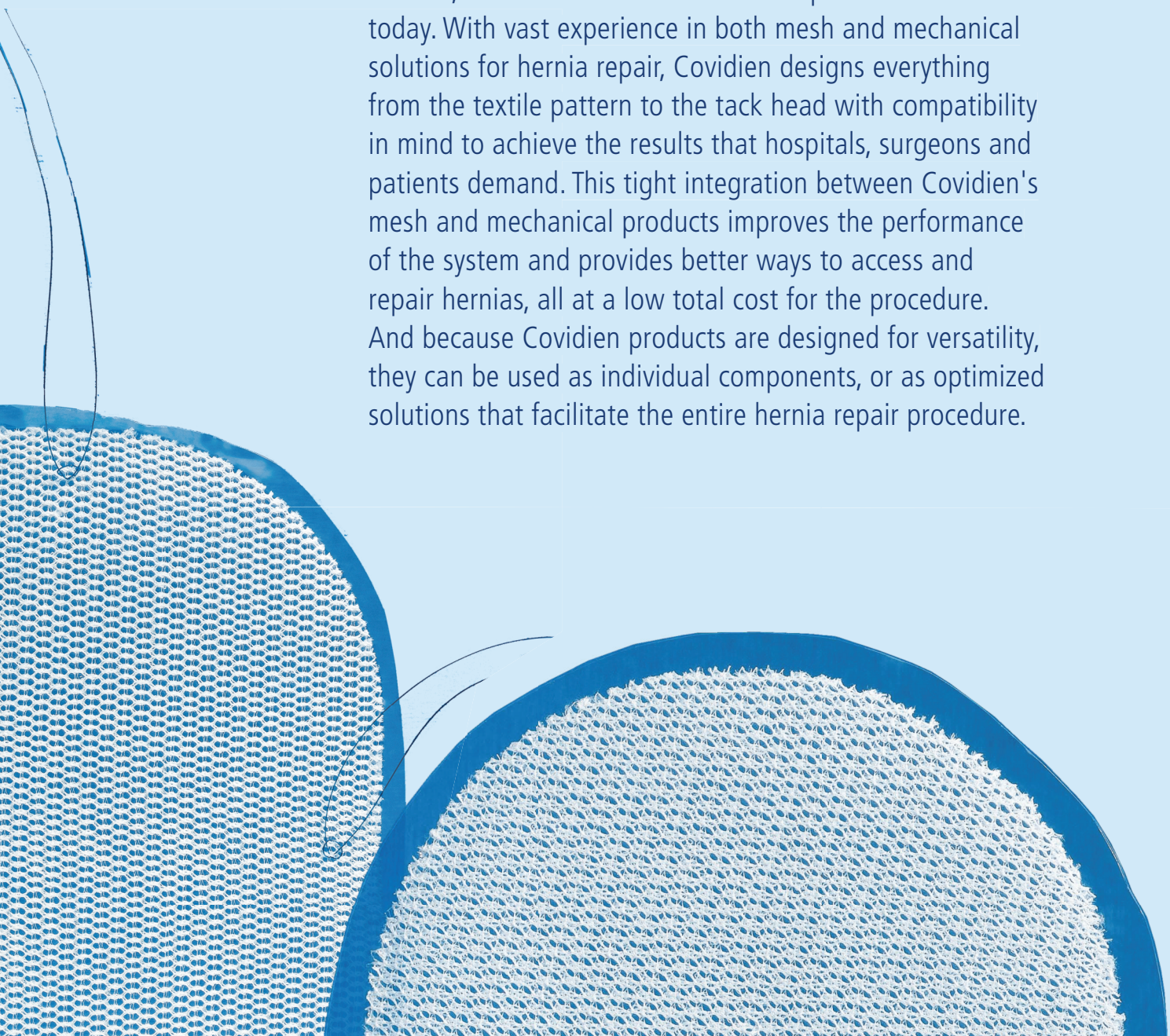
Ventral Hernia Repair System

**[EXCEPTIONAL
COMBINATION]**

Parietex™ Optimized Composite (PCOx) Mesh
and AbsorbaTack™ Fixation Device

Covidien Hernia Repair Solutions

Through innovative biomedical engineering, Covidien delivers the most complete hernia repair solution by combining its synthetic mesh, collagen implants, absorbable fixation, permanent fixation, dissection balloons and entire surgical device portfolio to deliver some of the most studied, innovative and reliable hernia products available today. With vast experience in both mesh and mechanical solutions for hernia repair, Covidien designs everything from the textile pattern to the tack head with compatibility in mind to achieve the results that hospitals, surgeons and patients demand. This tight integration between Covidien's mesh and mechanical products improves the performance of the system and provides better ways to access and repair hernias, all at a low total cost for the procedure. And because Covidien products are designed for versatility, they can be used as individual components, or as optimized solutions that facilitate the entire hernia repair procedure.



The team you trust for outcomes that matter

The Covidien Ventral Hernia Repair System combines the proven performance of Parietex™ composite (PCO) mesh and AbsorbaTack™ fixation device with the latest technological advancements to deliver an exceptional combination in ventral hernia repair. Parietex™ optimized composite (PCOx) mesh and AbsorbaTack™ 30 fixation device deliver:

✓ Optimized Protection

**Minimizes visceral attachments^{†,3,6}
with stronger, more damage-
resistant barrier¹¹**

Nesudaro sqaugu

✓ Optimized Handling

**Easy to use with improved
visibility and pre-placed sutures**

✓ Optimized Integration

**Encourages rapid abdominal wall
integration^{†,2,3} with large pore
x-stitch textile design**

✓ Optimized Fixation

**Clinically proven absorbable
fixation¹³ with 50% more tacks
per device than the original
Absorbatack™**

Mesh & Fixation: Engineered to Work Together

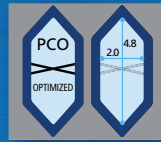
As the leader in hernia fixation, Covidien designs all our hernia products with compatibility in mind, for example:

- Parietex™ optimized composite mesh delivers improved visibility without compromising fixation strength with AbsorbaTack™ device due to innovative x-stitch design

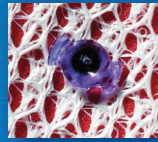
- Parietex™ optimized barrier is 3X more resistant to manipulation with the tip of the AbsorbaTack™ device due to the optimized collagen film¹¹

[†] Based on a preclinical animal study

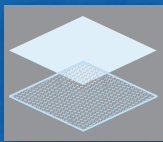
PARIETEX™ OPTIMIZED COMPOSITE(PCOx) MESH



**LARGE
MACROPORE**



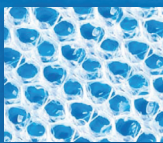
**STRONG
FIXATION**



**TWO SIDED
MESH**

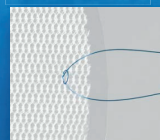


**RESISTANT
BARRIER**



**MINIMIZES
VISCERAL
ATTACHMENTS[†]**

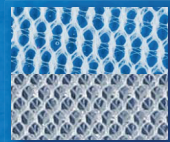
**PREPLACED
SUTURES**



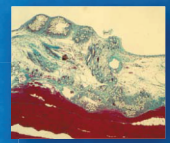
**EASY
TO USE**



**3D
SCAFFOLD**



**IMPROVED
VISIBILITY**



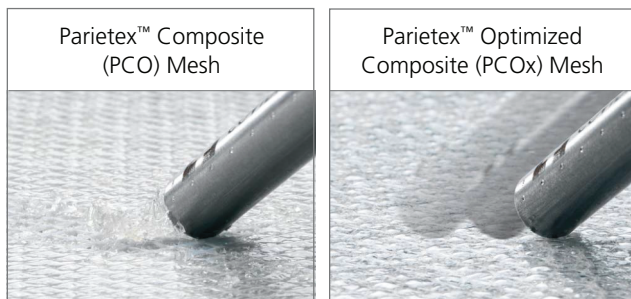
**RAPID
INGROWTH[†]**

[†] Based on a preclinical animal study

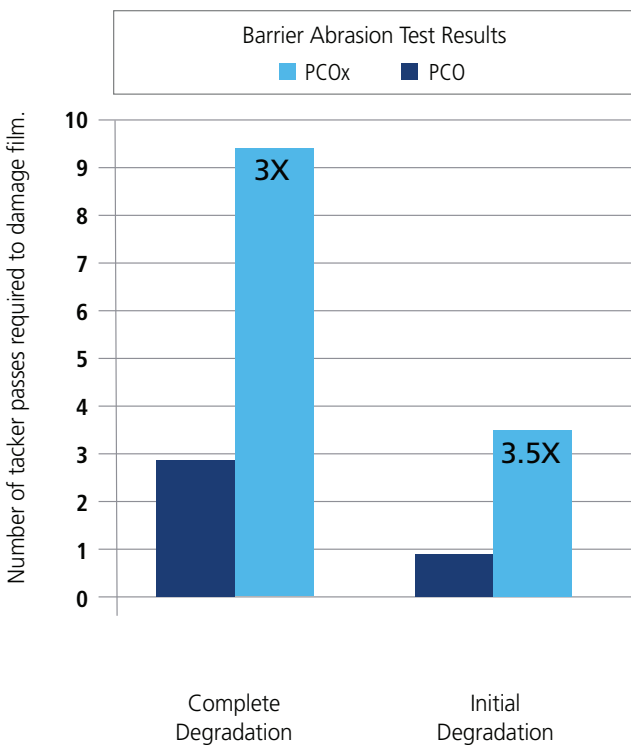
OPTIMIZED COLLAGEN BARRIER

Parietex™ optimized composite mesh is a two-sided mesh with an absorbable collagen barrier on the visceral side. This barrier is similar to the original PCO in that it minimizes visceral attachments to the mesh.¹² Through optimized processing of the collagen, the PCOx barrier is 3X more resistant to damage than original PCO. This increased resistance is designed to minimize the damage caused during insertion and handling to help maintain an intact barrier necessary to prevent attachments.

Galintis kontaktuoti su vidaus organais ir būti tvirtinamas ant pasieninės pilvaplėvės.



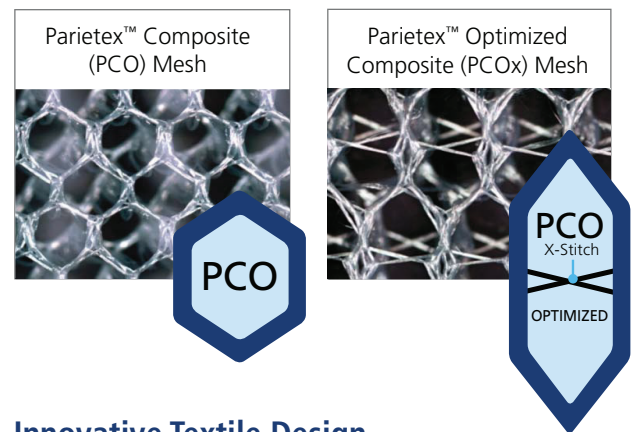
Resistance due to optimized barrier.



Parietex™ optimized composite mesh is 3X more resistant to damage¹¹

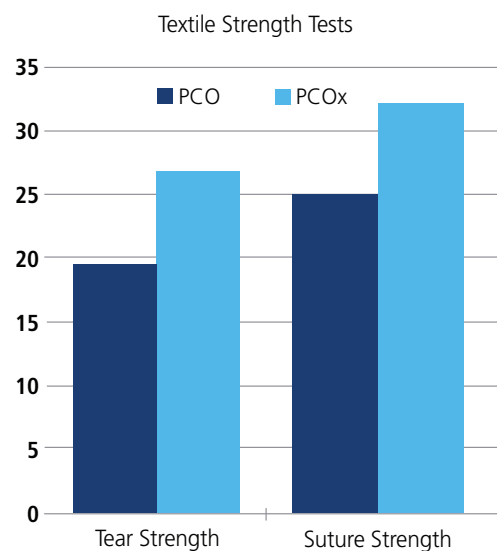
INNOVATIVE X-STITCH DESIGN

Parietex™ optimized composite mesh is a two-sided mesh with a hydrophilic three-dimensional polyester textile on the parietal side. The textile construction is similar to original PCO and encourages rapid abdominal wall integration.¹² In addition, PCOx features an innovative x-stitch textile design which delivers improved visibility through the mesh and an increased tear and suture strength.¹⁵



Innovative Textile Design

- 3D multifilament polyester knit
- Larger macro pore for improved visibility
- 28% higher suture strength¹⁵
- 39% higher tear strength¹⁵

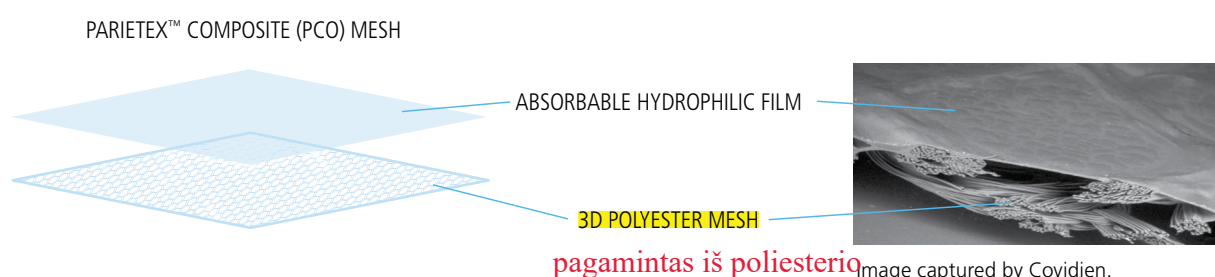


X-stitch textile results in improved visibility and increased strength¹⁵

PROVEN PARIETEX™ PERFORMANCE

Parietex™ optimized composite (PCOx) mesh is based on the proven performance of original PCO. Introduced in 1999, original PCO was the first mesh to offer a resorbable collagen barrier on one side to limit visceral attachments, and a three-dimensional polyester knit structure on the other to promote differentiated tissue ingrowth.

This balance of material properties produces superior cellular proliferation when compared to polypropylene mesh in vitro¹ and provides rapid fibrous ingrowth^{2,3} and minimal shrinkage.^{2,4}



Pre-Clinical and Clinical Evidence of Proven Performance for PCO

Parietex™ composite (PCO) mesh has been highly studied in human trials, has demonstrated positive patient outcomes and has compared favorably with other meshes in over 45 clinical and pre-clinical papers.

Proven Protection

- Proven effective, with more than 12 years of documented success
- Safe based on a mean clinical follow-up of four years in a prospective, multicenter human trial^{5, 18}
- Lower incidences of visceral attachments in comparative and animal studies^{3,6}

Ease of Use

- Larger sizes can be rolled up and inserted through a standard trocar
- Polyester mesh is easy to place and manipulate

Proven Integration

- Stronger incorporation into the abdominal wall in prospective and comparative animal studies^{2,3}
- Incites excellent fibrous ingrowth and a neoperitoneum versus the inflammatory encapsulation of other meshes⁷
- Superior cellular proliferation when compared to polypropylene mesh in vitro¹

Parietex™ composite (PCO) mesh is backed by more than 45 clinical and pre-clinical studies and 12 years of clinical experience

Parietex™ Composite Mesh

An optimized balance of properties backed by the largest portfolio of clinical and pre-clinical studies.

	Visceral Attachments	Integration	Shrinkage	Degradation	Pain	Infection	Elasticity	Low Recurrence
Balique 2005	X				X	X		
Chelala 2006	X		X		X	X		
Burger 2006	X	X	X					
Jacob 2007	X	X	X					
Duffy 2004	X	X						
McGinty 2005	X	X	X					
Clavé 2008				X				
Bracco 2005				X				
Ramshaw 2007				X				
Junge 2001			X				X	
Gonzales 2004	X							
Schreinemacher 2009	X							
Schug-Pass 2008	X		X					
Junge 2008	X							
Rosen 2009						X		
Chelala 2010	X							
Moreno 2009						X		X
Arnaud 2003	X							
Zinther 2010	X							
Aube' 2004	X							

Recurrence

Balique et al. (Hernia 2005)
Four year results of multicenter prospective study: 80 patients
2.5% recurrence.⁵

Moreno et al. (Surg Endosc 2009) Long-term results of laparoscopic repair of incisional hernias: PCO 4 year results 200 patients 6.2% recurrence rate⁸

Visceral Attachments

Chelala et al. (Hernia 2010)
Eighty-five redo surgeries after 733 lap ventral/incisional hernias: Scored patients' adhesions after receiving PCO upon second look and nearly 90% of patients develop none or mild adhesions.⁹

Integration

Gonzalez et al. (World J Surg 2005) Relationship between Tissue Ingrowth and Mesh Contraction: Polyester contracted between 5-24% while Polypropylene contracted 15%-65%¹⁰

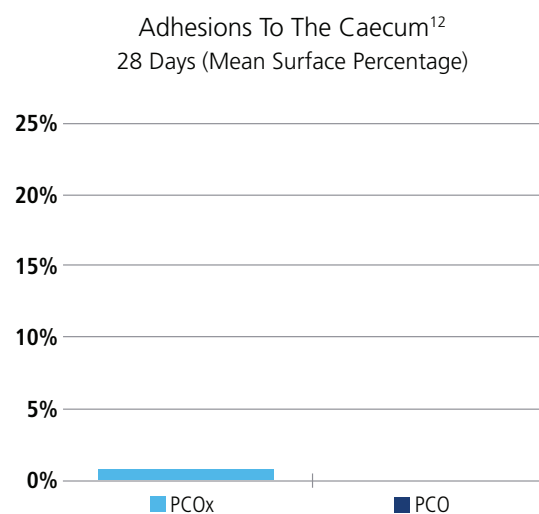
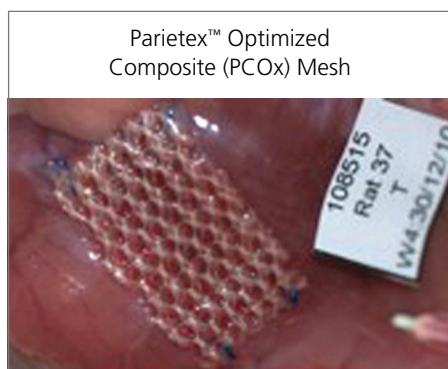
Post op Complications

Rosen et al. (Amer Jour Surg 2009) Polyester-based mesh for ventral hernia repair: is it safe?
109 patients, 14 mo follow up
0% recurrence 1% infection rate (lap) 2.8% (open)⁴

OPTIMIZED PROTECTION

Parietex™ optimized composite (PCOx) mesh offers a resorbable collagen barrier that is similar to that of original PCO. Pre-clinical animal tests showed very low attachment formation and equivalence to original PCO.¹² In addition, the optimized collagen barrier is 3 times more resistant to damage during insertion and handling than the original barrier.¹¹

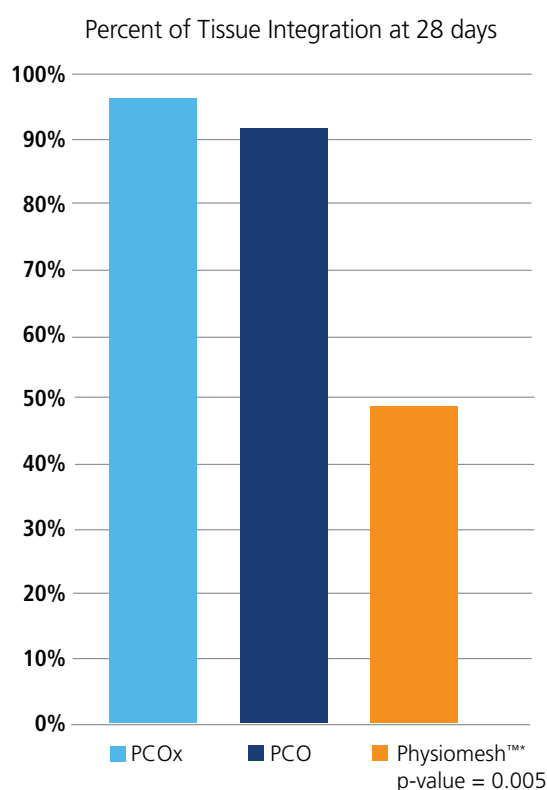
Pre-Clinical Study



These results are indicative, not statistically significant.

Equivalent visceral attachment prevention compared to original Parietex™ composite (PCO) mesh¹²

Parietex™ optimized composite (PCOx) mesh offers a proprietary three-dimensional polyester scaffold with larger macro-pore structure[†] due to the innovative X-stitch textile design. Pre-clinical animal tests showed rapid abdominal wall integration that is equivalent to original PCO and superior to Physiomeshtm*¹² In addition, the X-stitch textile delivers improved visibility and increased tear and suture strength.¹⁵



PCO & PCOx have superior abdominal wall integration compared to Physiomeshtm* in an animal study¹²

PCOx has equivalent abdominal wall integration to original PCO in an animal study¹²

[†]Larger macro pore excluding X-stitch has dimensions of 4.8mm x 2.0mm. Porosity including X-stitch has dimensions of 2.4 x 2.0mm which is equivalent to PCO.

OPTIMIZED HANDLING

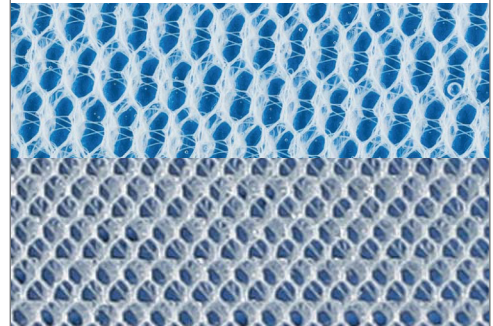
Parietex™ optimized composite (PCOx) mesh is easy to insert and position with improved visibility through the mesh, a more damage resistant barrier and preplaced sutures that eliminate the time associated with traditional suture placements.

The AbsorbaTack™ fixation device eliminates the risk of inadvertent needle sticks with no sharp piloting needle.

Easy to Use



Improved visibility with PCOx



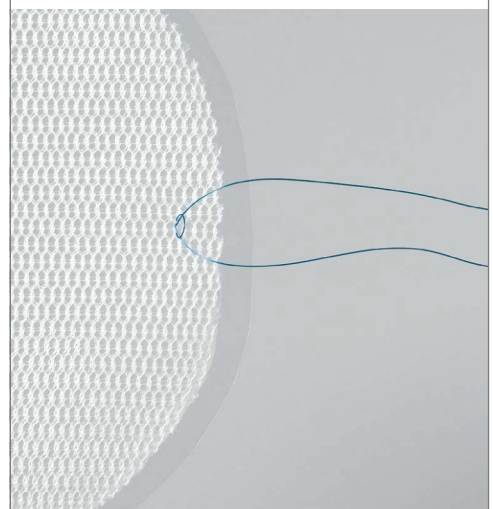
No Sharp Piloting Needle Required



AbsorbaTack™ fixation device.

Other absorbable fixation device.

Only composite mesh with pre-placed sutures



As a leader in hernia repair, Covidien offers both permanent and absorbable fixation solutions. In ventral hernia repair, PCOx and AbsorbaTack™ fixation device represent an exceptional combination now with 50% more tacks than the original AbsorbaTack™ device.

More Tacks, More Value

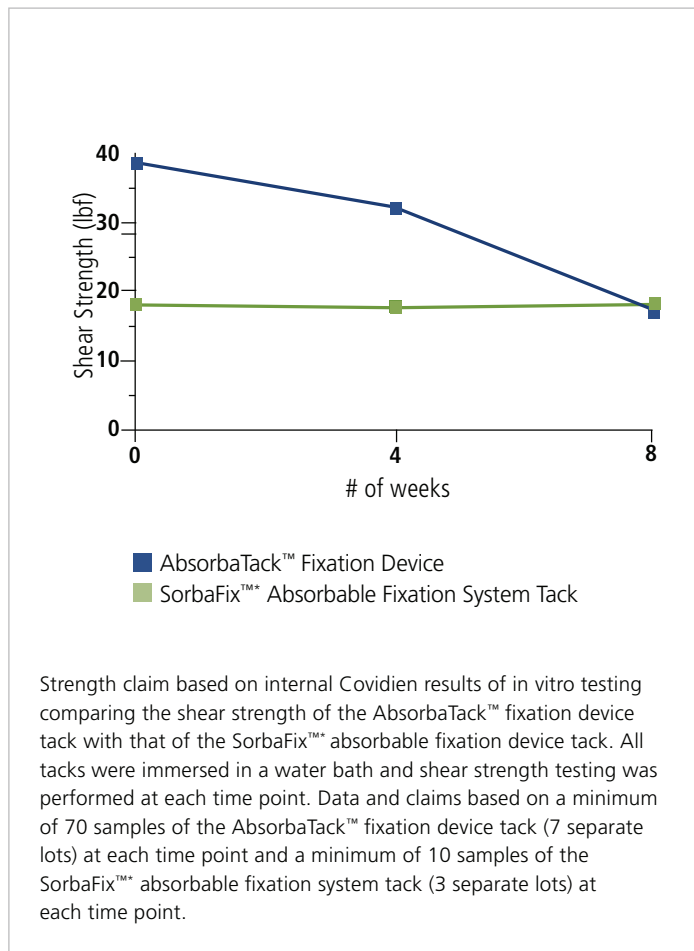
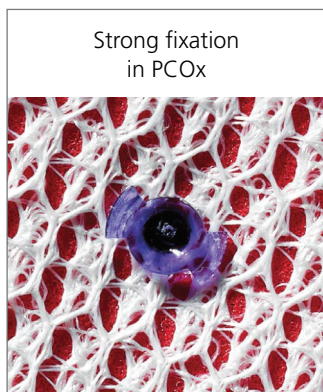
- 50% more tacks than original AbsorbaTack™
- 20% more tacks than Securestrap™*

Patient Comfort

- No foreign material left in patient
- Potentially fewer visceral attachments than permanent fixation¹⁴

Strong Fixation

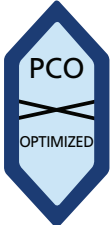
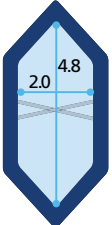
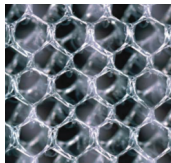

- Strength comparable to the "gold standard" ProTack™ fixation device¹⁴
- Twice as strong in shear as the SorbaFix™* absorbable fixation system tack out of the package¹⁷



Parietex™ optimized composite (PCOx) mesh is designed for use with Covidien fixation including AbsorbaTack™ and ProTack™ devices

TECHNICAL DETAILS

Textile Characteristics

	Parietex™ Optimized Composite Mesh	Parietex™ Composite Mesh
Pore Size (mm) (height x width)	2.4 x 2.0 Porų dydis	2.4 x 2.0
Macropore* (mm) (height x width)	4.8 x 2.0	
Pore shape	  	 
Thickness (mm)	1.7	1.9
Surface density (g/m ²)	78 svoris	79
Burst strength (kPa)	367 ± 20	358 ± 18
Burst distension (mm)	8 ± 0	8 ± 0

*Larger macro pore excluding X-stitch has dimensions of 4.8mm x 2.0mm. Porosity including X-stitch has dimensions of 2.4 x 2.0mm which is equivalent to PCO. See textile characteristics for more details.

Preplaced Sutures

Code	# Sutures
PCO9FX	2
PCO12FX	2
PCO15FX	2
PCO1510FX	2
PCO20FX	4
PCO2015FX	4
PCO2520FX	4
PCO3020FX	4
PCO3728FX	4



Suture: Pre-placed nonabsorbable, monofilament, nylon sutures (Dermalon™) USP size 2-0 with 14N knot strength specification.

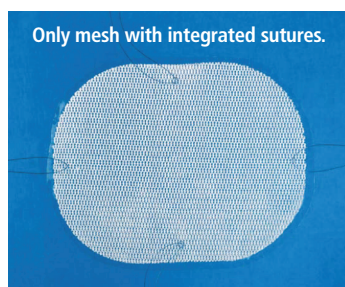
Comparison to Original Parietex™ Composite Mesh

PCOx Improvements Relative to Original PCO			
3x more resistant barrier	+	28% higher suture strength ¹⁵	+
Improved Visibility	+	39% higher tear strength ¹⁵	+

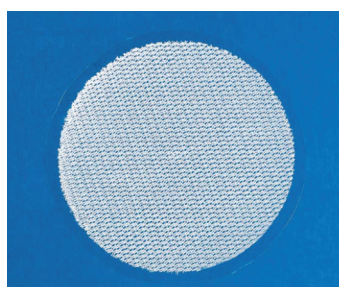
Similarities Between PCOx & PCO	
Textile	Collagen
Equivalent abdominal wall integration in an animal study ¹²	Porcine collagen film
Same multifilament polyester base	Same thickness
Similar three-dimensional construction	Equivalent attachment prevention in an animal study ¹²
Equivalent porosity and density	Same impregnated bond with mesh
	Same absorption profile

Range and Codes

PCO  Parietex™ Composite	## = Circle #### = Rect/Oval	F = With Sutures OS = Open Skirt	X  Optimized
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With Sutures



Without Sutures



Open Skirt for Open Ventral

PCOx with Fixation Sutures

PCO9FX	9cm Round with Sutures
PCO12FX	12cm Round with Sutures
PCO15FX	15cm Round with Sutures
PCO20FX	20cm Round with Sutures
PCO1510FX	15cm x 10cm with Sutures
PCO2015FX	20cm x 15cm with Sutures
PCO2520FX	25cm x 20cm with Sutures
PCO3020FX	30cm x 20cm with Sutures
PCO3728FX	37cm x 28cm with Sutures

PCOx Skirted Mesh for Open Ventral

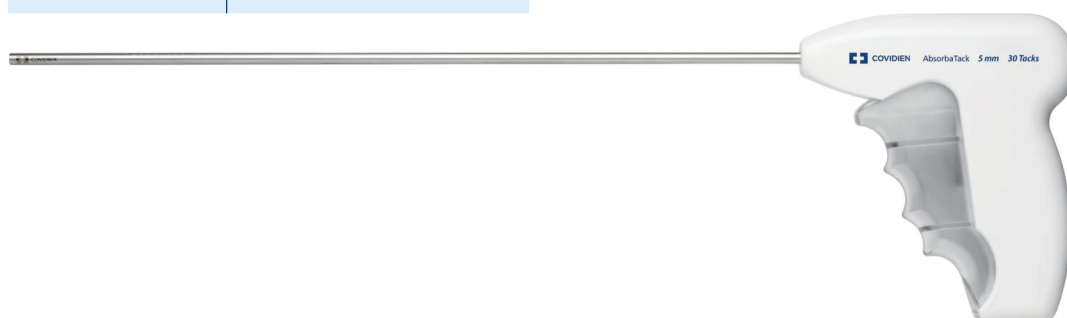
PCO8OSX	Skirted 8cm Round
PCO1510OSX	Skirted 15cm x 10cm
PCO2015OSX	Skirted 20cm x 15cm
PCO2520OSX	Skirted 25cm x 20cm
PCO3020OSX	Skirted 30cm x 20cm

PCOx without Fixation Sutures

PCO9X	9cm Round
PCO12X	12cm Round
PCO15X	15cm Round
PCO20X	20cm Round
PCO1510X	15cm x 10cm
PCO2015X	20cm x 15cm
PCO2520X	25cm x 20cm
PCO3020X	30cm x 20cm
PCO3728X	37cm x 28cm

AbsorbaTack Fixation Device

ABSTACK15	Device w/15 Tacks
ABSTACK30	Device w/30 Tacks



References

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17. Strength claim based on results of in vitro testing comparing the shear strength of the AbsorbaTack™ fixation device tack with that of the SorbaFix™* absorbable fixation device tack. All tacks were immersed in a water bath and shear strength testing was performed at each time point. Data and claims based on a minimum of 70 samples of the AbsorbaTack™ fixation device tack (7 separate lots) at each time point and a minimum of 10 samples of the SorbaFix™* absorbable fixation system tack (3 separate lots) at each time point.
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For more information or to set up a product demonstration, contact your local Covidien Surgical Device Representative or call Customer Service at 1-800-722-8772.

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