

# ADVANCING THE ART

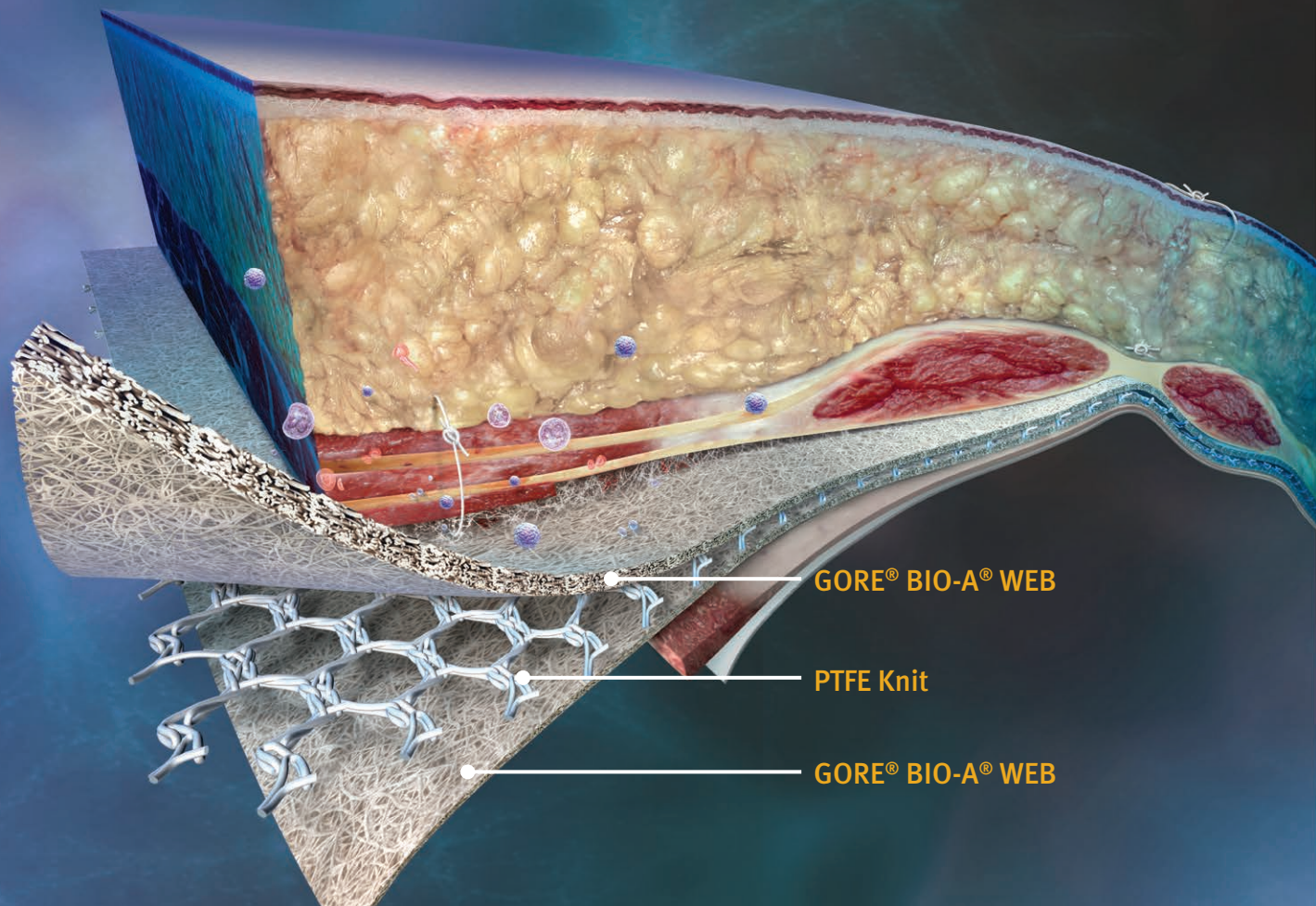
OF SINGLE-STAGE REPAIR

Designed for  
**INGROWTH**  
on  
**BOTH SIDES**



**SYNECOR**  
PREPERITONEAL

BIOMATERIAL



## OVERVIEW

**GORE® SYNECOR Preperitoneal Biomaterial is designed specifically for preperitoneal, retromuscular and onlay placements. It offers an ideal combination of permanent strength within a tissue-building scaffold.**

GORE® SYNECOR Preperitoneal Biomaterial combines strength with rapid tissue ingrowth and vascularization providing a single-stage repair for advanced surgical techniques and procedures in complex soft tissue reconstruction.

- GORE® BIO-A® Web technology – a tissue-building scaffold facilitates rapid cell infiltration and vascularity.
- Dense, monofilament PTFE fiber – may reduce the risk of harboring bacteria due to the solid fiber, provides optimum strength for a durable repair.

# APPLICATIONS / PRODUCT USE RECOMMENDATIONS

The GORE® SYNECOR Preperitoneal Biomaterial device is intended for use in the repair of hernias and abdominal wall soft tissue deficiencies that may require the addition of a nonabsorbable reinforcing or bridging material.

The material is designed specifically for use in open, laparoscopic, and robotic procedures. Hospital surgical departments, including general surgery, trauma, and plastics, find value in the material. Some common applications include:

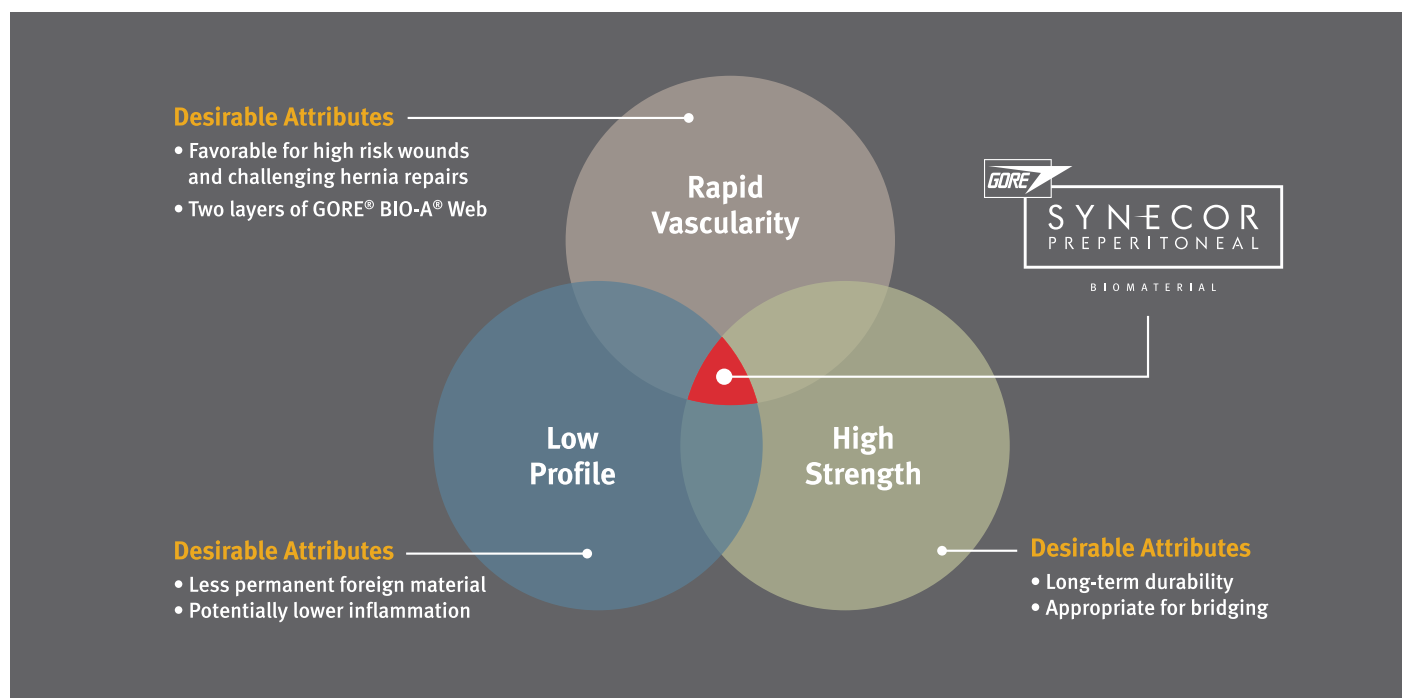
- Transversus abdominis release (TAR) procedure
- Component separation technique
- Preperitoneal ventral hernia repair
- High-risk ventral hernia repair

## VALUE

GORE® SYNECOR Preperitoneal Biomaterial brings value to the market in several ways:

- Compared to biologics, it offers durable strength that may lead to fewer hernia recurrences and better quality outcomes
- By enabling single-stage durable repair for challenging hernia cases, it reduces overall cost
- Can replace many other devices on the shelf

## PRODUCT DIFFERENTIATION

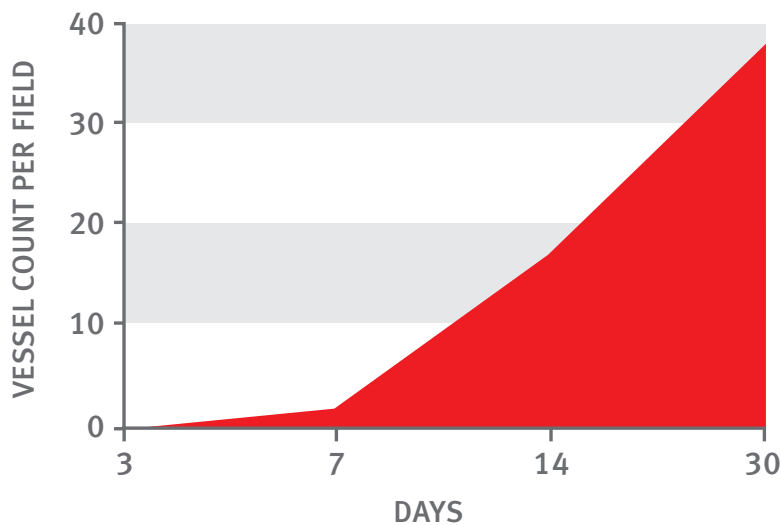


## RAPID VASCULARITY

Vascularity is an important assessment to be made during the acute healing process of implanted mesh materials, especially in complex abdominal wall repairs. In addition, the presence of blood vessels throughout the device structure is important in the immediate post-operative time period.

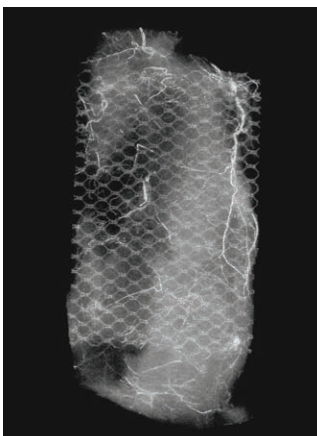
GORE® SYNECOR Preperitoneal Biomaterial is a unique combination of a macroporous PTFE knit embedded between two GORE® BIO-A® Web scaffolds. Within one to two weeks, cells migrate into the GORE® BIO-A® Web scaffold and begin generating vascularized soft tissue. Within approximately six months, the web component is gradually absorbed by the body and replaced 1:1 with the patient's own favorable Type I collagen.

Vascularity within GORE® BIO-A® Web increases over time\*



\*GORE® BIO-A® Tissue Reinforcement; Rabbit abdominal wall implant. Data on file.

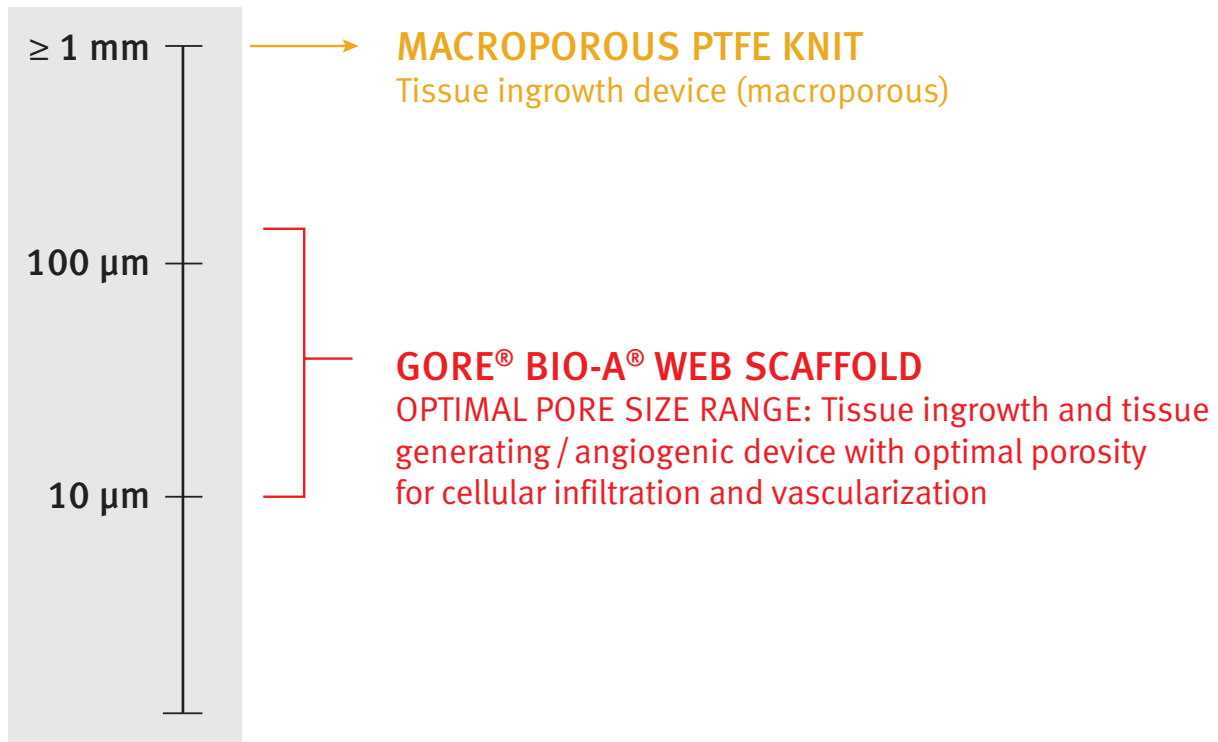
Within one to two weeks, cells migrate into the GORE® BIO-A® Web scaffold and begin generating vascularized soft tissue.



Assessing vascularity via microcomputed tomography (MicroCT), it was shown that as early as seven days post implant, numerous newly formed blood vessels were observed both around and within the GORE® SYNECOR Preperitoneal Biomaterial.



## ENGINEERING TISSUE RESPONSE WITH MATERIAL STRUCTURE: The effect of pore size



## POROSITY

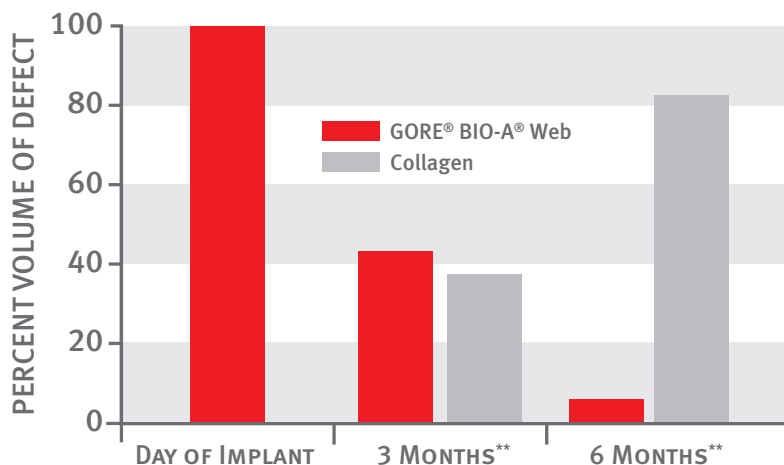
**The extent of ingrowth achieved for any device is influenced by the size of the pores within the scaffold.** While very small pores may inhibit tissue ingrowth, larger pores encourage the ingrowth of new tissue. GORE® BIO-A® Web, which serves as the scaffold in GORE® SYNECOR Preperitoneal Biomaterial provides optimal porosity for rapid cellular infiltration and vascularization.

**The PTFE knit layer of GORE® SYNECOR Preperitoneal is a macroporous knit of large pores** (average size 1.6 mm). The two web layers, on either side of the knit, form interconnected pores that are similar in structure to the collagen fiber network. **This combination results in cellular migration and vascularization**, which can facilitate healing after a hernia repair.

## QUALITY TISSUE FAST

Rapid vascularity supports generating quality tissue fast. Due to optimum porosity, the GORE® BIO-A® Web Technology provides a 3-dimensional matrix of interconnected pores that fills quickly with collagen fibers and generates a 1:1 tissue generation within the thickness of the material.

### Material Replaced by Tissue at 1:1 Ratio\*\*

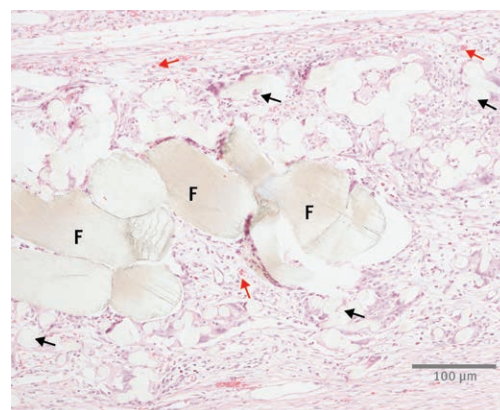


\*\* Cells and blood vessels make up remaining volume. GORE® BIO-A® Hernia Plug. Data on file.

## INGROWTH

The combination of the GORE® BIO-A® Web scaffold and the PTFE knit, allows for rapid cellular ingrowth and appropriate tissue integration without negatively affecting abdominal wall compliance typically associated with heavyweight polypropylene meshes.

Studies demonstrated that at 30 days<sup>1</sup> tissue ingrowth was present throughout the device with various densities around the knit fibers and within the web. The ingrowth was vascularized, organized, and filled the macropores.



*This section shows the GORE® SYNECOR Preperitoneal Biomaterial device (Web: black arrows, Fibers: F) filled completely with collagen, vessels (red arrows) and cells. 10x. H&E. 30 days. Data on file.*

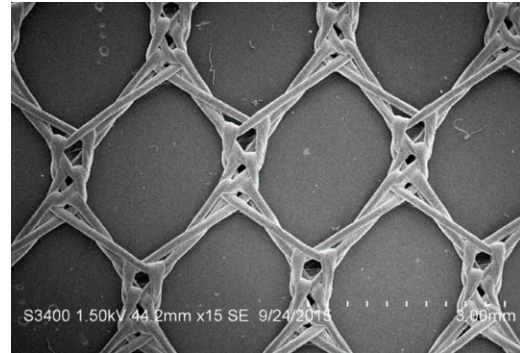
# LOW PROFILE

## Macroporous knit of dense, monofilament fibers

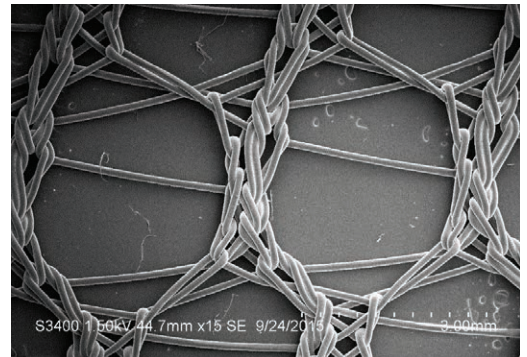
The treatment of ventral hernias with prosthetic devices has reduced recurrence rates but has led to questions concerning infection. Open hernia repair has been associated with infection rates from 3% to 18%; laparoscopic ventral hernia repair has been associated with lower incidence of infection.<sup>2</sup>

The PTFE knit is designed with a fiber diameter similar to lightweight polypropylene but with the strength of a heavyweight polypropylene. Thus, the PTFE knit can maintain the surface area desired in lightweight materials but not sacrifice strength. The macroporous knit of dense, monofilament PTFE fiber, which is similar to polypropylene fibers, may reduce the risk of harboring bacteria due to the solid fiber.

The macroporous knit of dense, monofilament PTFE fiber may reduce the risk of harboring bacteria due to the solid fiber.



*Macroporous knit of dense monofilament PTFE fiber*



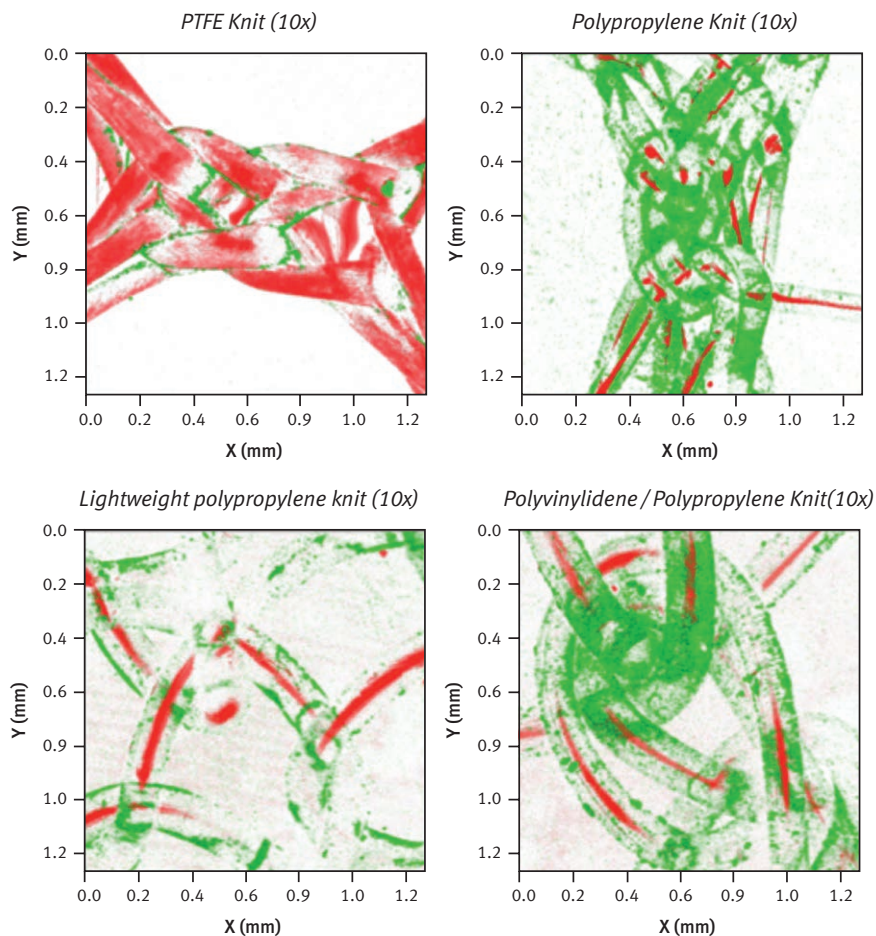
*Polypropylene*

## BACTERIAL ADHERENCE

Bacterial adherence was examined among various materials, including the PTFE knit of GORE® SYNECOR Preperitoneal Biomaterial and other various knits. The materials were incubated in *S. aureus* overnight, rinsed, and subjected to staining and analysis through confocal microscopy which allowed for analysis of where bacteria attaches.

Via confocal fluorescence imaging, the interaction of *S. aureus* to various knitted polymer materials were compared and it was concluded that:

- All bacteria are located only on the surface of the fibers for each type of polymer
- Bacteria localize in the knot or overlapping fiber areas of all the knits
- No bacteria was located within the materials
- PTFE had the least bacteria on the surface



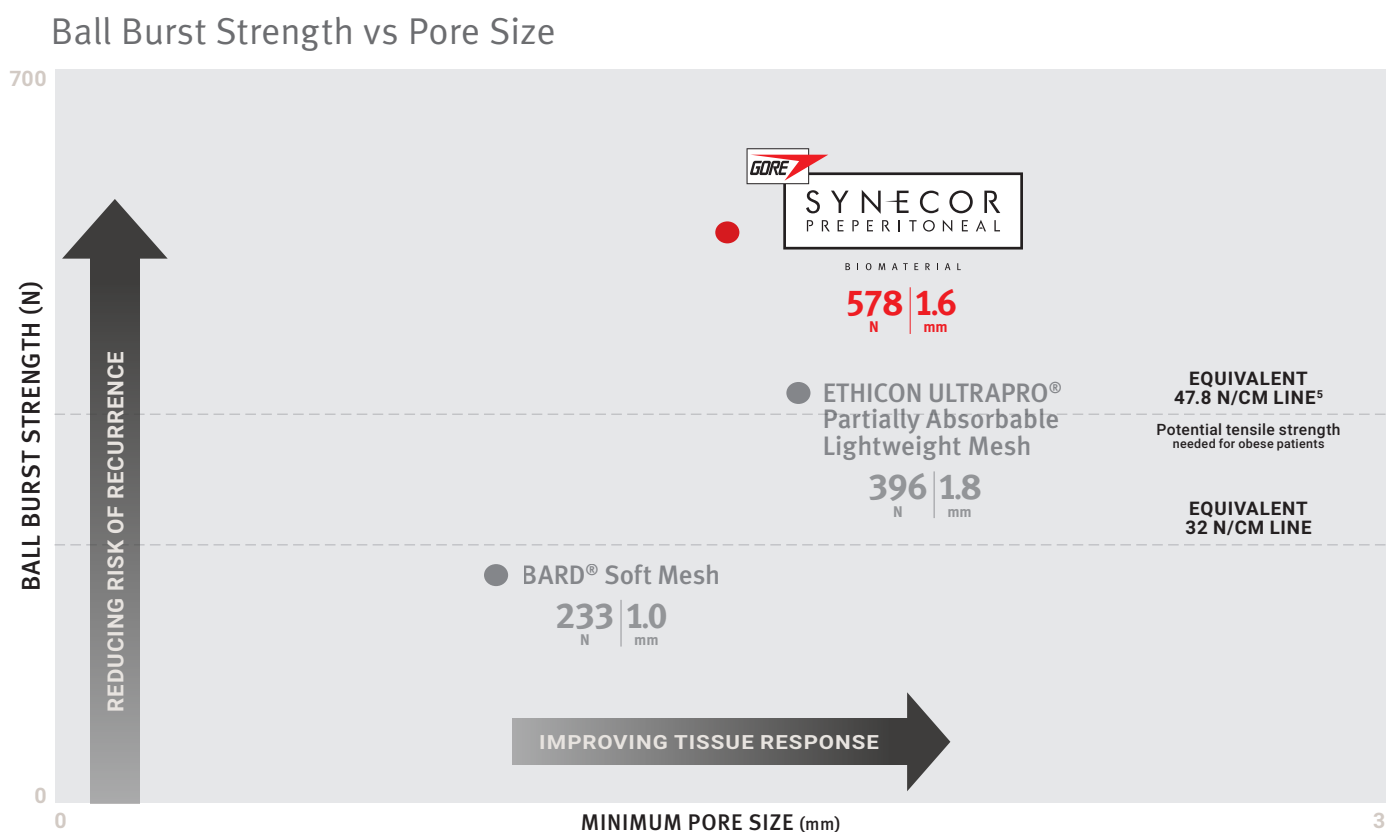
*S. Aureus* stains green; Red represents the fiber  
Data on file.



# HIGH STRENGTH

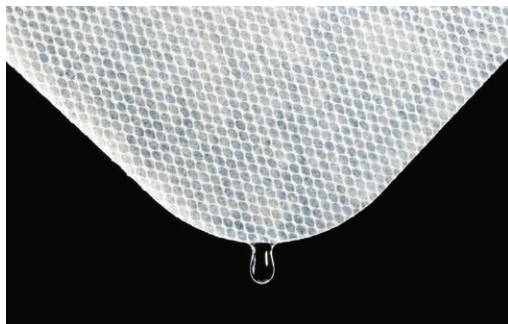
GORE® SYNECOR Preperitoneal Biomaterial is easy to handle, yet strong and compliant. Strength is an obvious concern when performing a structural repair such as bridging a fascial defect in ventral hernia repair. This has become critical as patient body mass indices (BMIs) continue to increase. A permanent biomaterial must be able to serve its intended use over the life of the patient without degradation or loss in strength.

The macroporous, monofilament PTFE knit provides permanent strength when bridging a hernia or soft tissue defect. Testing has shown the PTFE within GORE® SYNECOR Preperitoneal Biomaterial to have a burst strength over 500 N providing strength for large defects or BMIs.<sup>3</sup>



The strength requirement for ventral hernia repair has been suggested in the literature as having an abdominal wall surface tension of 32 N/cm.<sup>4,5,6</sup> However, to be compliant with ASTM D3787, the burst strength or load (N) is typically reported. A calculation is utilized based upon the test method, resulting in a load of 255 N rounded to the nearest 0.5 N per ASTM D3787.

## PRODUCT CHARACTERISTICS / SIZES



### Handling

- Pre-soaking is not required
- Absorbs fluids (i.e. blood); may be dipped in sterile saline to facilitate handling
- Material memory facilitates optimal placement
- The material is appropriate for use during robotic procedures



### Catalog Numbers / Sizing

CATALOG NUMBER	DESCRIPTION
GKVV1015	10 cm x 15 cm oval
GKVR1215	12 cm x 15 cm rectangle
GKVV1520	15 cm x 20 cm oval
GKVR2025	20 cm x 25 cm rectangle
GKVR2030	20 cm x 30 cm rectangle

# PRODUCT REFERENCE CHART

Based on patient selection criteria, clinicians may utilize GORE® SYNECOR Preperitoneal Biomaterial in place of the following products:

COMPANY	PRODUCT NAME	BIOLOGIC MESH	BIOSYNTHETIC MESH	PERMANENT MESH	COMPOSITE MESH*	HYBRID MESH**
ALLERGAN	STRATTICE Reconstructive Tissue Matrix	•				
ATRIUM®	PROLITE Mesh			•		
ATRIUM®	VITAMESH			•		
ATRIUM®	VITAMESH Blue			•		
BARD®	3DMAX Light			•		
BARD®	3DMAX Mesh			•		
BARD®	Soft Mesh			•		
BARD®	Mesh			•		
BARD®	XENMATRIX AB Surgical Graft	•				
BARD®	XENMATRIX Surgical Graft	•				
BARD® DAVOL	PHASIX Mesh		•			
COOK®	BIODESIGN® Advanced Tissue Repair	•				
COOK®	ZENAPRO® Hybrid Hernia Repair Device					•
ETHICON	PROLENE® Soft Polypropylene Mesh			•		
ETHICON	PROLENE® Polypropylene Mesh			•		
ETHICON	ULTRAPRO ADVANCED Macroporous Partially Absorbable Mesh				•	
ETHICON	ULTRAPRO® Partially Absorbable Lightweight Mesh				•	
ETHICON	XCM BIOLOGIC® Tissue Matrix	•				
FEG TEXTILTECHNIK	DYNAMESH® – PP			•		
MEDTRONIC	PARIETEX Lightweight Monofilament Mesh			•		
MEDTRONIC	PARIETEX Flat Sheet Mesh			•		
MEDTRONIC	PERMACOL Surgical Implant	•				
MEDTRONIC	PROGRIP Laparoscopic Self-Fixating Mesh				•	
MEDTRONIC	VERSATEX Monofilament Mesh			•		
NOVUS SCIENTIFIC	TIGR® Matrix Surgical Mesh		•			
RTI SURGICAL®	TUTOMESH® Fenestrated Bovine Pericardium	•				
RTI SURGICAL®	TUTOPATCH® Bovine Pericardium	•				
TELA BIO	OVITEX Reinforced Scaffold					•
TEI BIOSCIENCES	SURGIMEND® Collagen Matrix	•				

\* Composite Meshes are permanent mesh with an absorbable component.

\*\* Hybrid Meshes have permanent mesh with a bioabsorbable (biologic or biosynthetic) tissue scaffold material.

# REFERENCES

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6. Song C, Alijani A, Frank T, Hanna GB, Cuschieri A. Mechanical properties of the human abdominal wall measured in vivo during insufflation for laparoscopic surgery. *Surgical Endoscopy* 2006;20(6):987-990.



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