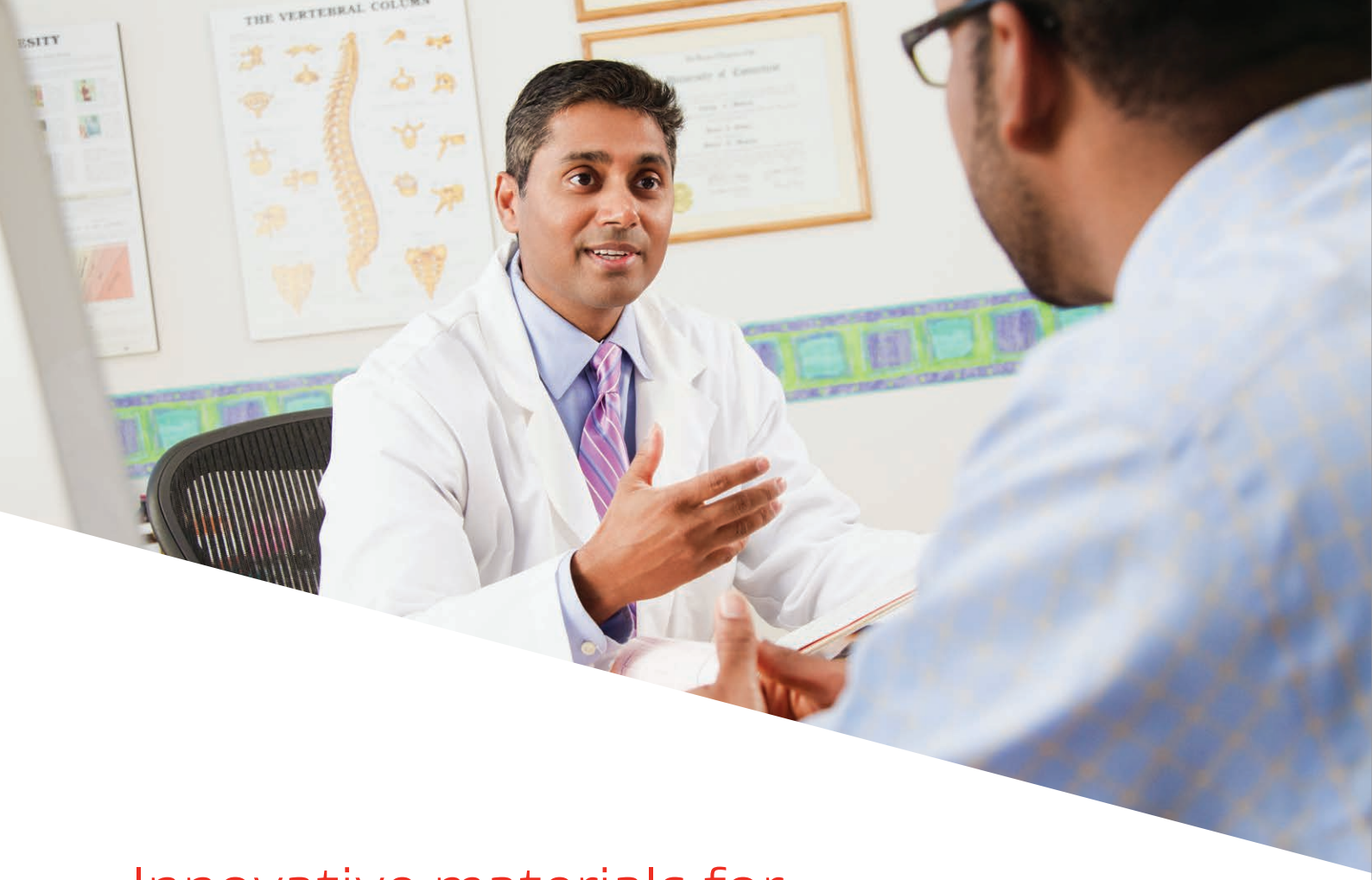
GORE® SYNECOR
Intraperitoneal Biomaterial

MATERIAL INNOVATION FOR PERMANENT STRENGTH

Together, improving life



Innovative materials for specialized solutions

Gore makes a relentless commitment to improving lives through deliberate product innovation

- We have a comprehensive portfolio of biomaterials intended to meet the needs of abdominal wall reconstruction and hernia repair.
- Each biomaterial is specifically designed with the patient and surgeon in mind.
- Our biomaterials have a history of bringing sustainable clinical results to patients.

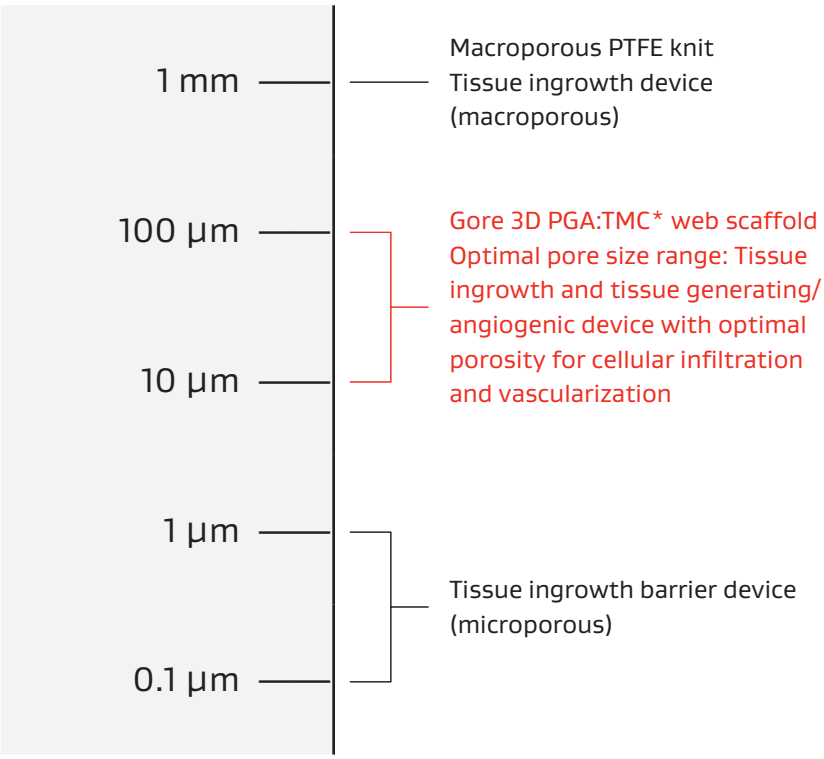
Consistent quality supports the confidence of providers, surgeons and patients

GORE® SYNECOR Intraperitoneal Biomaterial helps deliver the quality outcomes patients need

- Improves the economics of patient care.
- Potentially lower total cost of repair versus lightweight and mid-weight meshes, which have clinical literature case studies demonstrating failure due to inadequate strength in similar indications.[1-3]

Facilitates the natural healing process with tri-layer biomaterial technology

The effect of pore size[4,5]



As pioneers of the first mid-term bioabsorbable mesh with a targeted absorption period of six to seven months, (data on file 2015; W. L. Gore & Associates Inc; Flagstaff, AZ.), we are persistent in the pursuit of perfecting material solutions, so surgeons have more options when assessing the risk for complications and supporting complex cases.

Built upon tri-layer technology, GORE® SYNECOR Intraperitoneal Biomaterial is designed to give surgeons a strong repair with minimal permanent material.

* Poly(glycolide:trimethylene carbonate) copolymer (PGA:TMC)

Bringing the latest innovations to hernia repair and abdominal wall reconstruction

GORE® SYNECOR Intraperitoneal Biomaterial is a tri-layer hybrid solution designed for durable repair in complex patients (VHWG 2) to facilitate healing[6]

Gore 3D PGA:TMC web scaffold

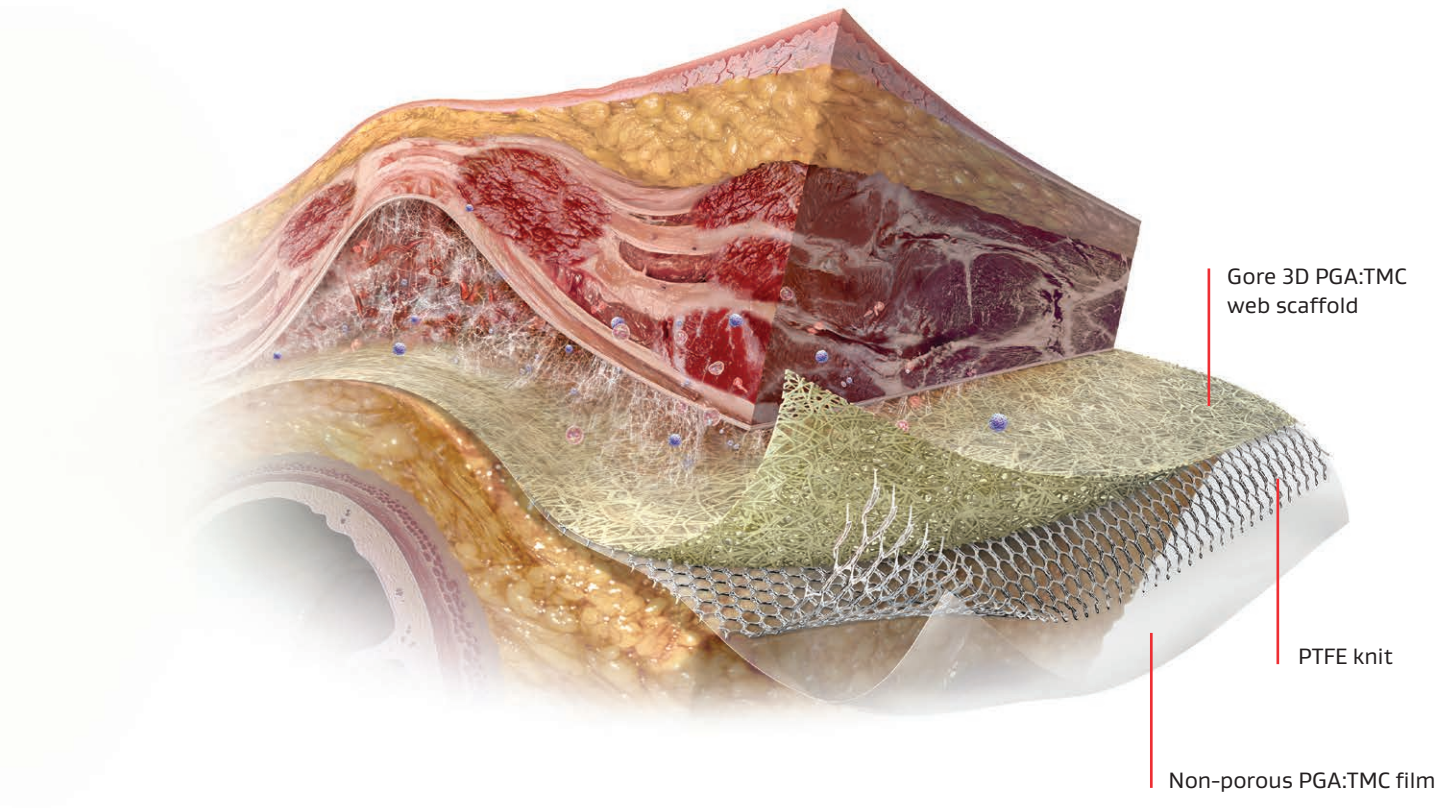
Provides rapid vascularization and tissue ingrowth designed to facilitate healing (data on file 2015; W. L. Gore & Associates Inc; Flagstaff, AZ.).

PTFE

Latest generation PTFE fiber is designed for permanent strength. Strong and compliant: The PTFE knit is designed with a fiber diameter similar to lightweight mesh but with the strength of heavyweight mesh.

Non-porous PGA:TMC film

Provides intra-abdominal protection, minimizing risk of adhesion formation[7] (data on file 2015; W. L. Gore & Associates Inc; Flagstaff, AZ.).



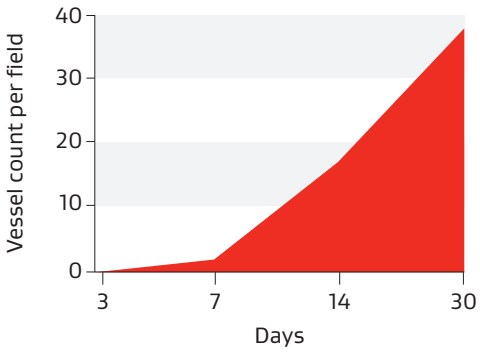
Designed for ease of use during minimally invasive (laparoscopic, robotic) and open surgical procedures

- Material is flexible and conformable
- Material memory for easy unrolling, handling and optimal placement
- Absorbs fluids (i.e., blood)
- No pre-soaking needed, but may be dipped in sterile saline to facilitate handling

GORE® SYNECOR Intarperitoneal Biomaterial is available in sizes ranging from 12 cm circle to 20 cm x 30 cm rectangle.

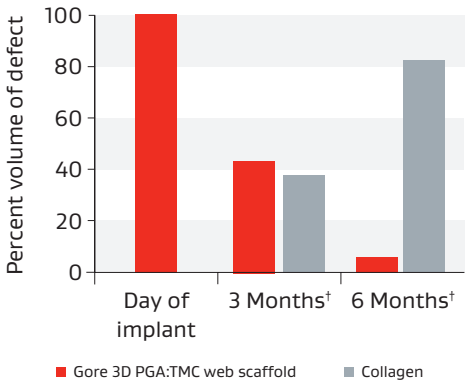
Rapid vascularization and tissue ingrowth[8]

Vascularity within Gore 3D PGA:TMC web increases over time*



* Data on file 2008; W. L. Gore & Associates, Inc; Flagstaff, AZ.

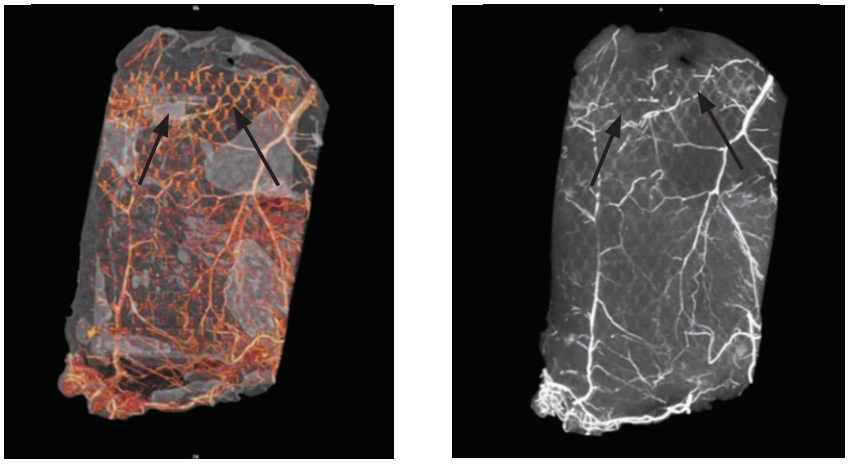
Material replaced by patient's own tissue[9]



† Cells and blood vessels make up remaining volume. GORE® BIO-A® Hernia Plug.

Parietal layer: Gore 3D PGA:TMC web scaffold provides rapid vascularization and tissue ingrowth designed to facilitate healing (data on file 2015; W. L. Gore & Associates Inc; Flagstaff, AZ.)

- Enhances tissue response: Designed to promote rapid cell migration and vascularization (data on file 2015; W. L. Gore & Associates Inc; Flagstaff, AZ.).
- Designed to break down primarily by hydrolysis and provide tissue uniformity and consistency.
- Within 7 days: Tissue shows vascularity.[8]
- At 30 days: Tissue ingrowth (data on file 2015; W. L. Gore & Associates Inc; Flagstaff, AZ.).
- Tissue ingrowth is present throughout the Gore 3D PGA:TMC web scaffold with various densities around the knit fibers and within the scaffold.
- Ingrowth is vascularized, organized and filled the macropores.
- At 180 days: Tissue generation (data on file 2015; W. L. Gore & Associates Inc; Flagstaff, AZ.).
- Gore 3D PGA:TMC web scaffold is absorbed, leaving organized fibrous tissue ingrowth.
- Minimal tissue encapsulation of the PTFE knit.



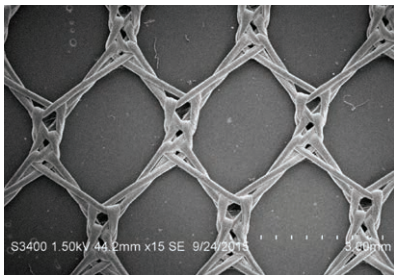
Arrows indicate area where blood vessels are penetrating through the PTFE knit at seven days post-implantation.[8]

Latest generation PTFE fiber is designed for permanent strength

Mid-layer: Macroporous knit of dense, monofilament PTFE 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 percent to 18 percent.[10] Laparoscopic ventral hernia repair has been associated with lower incidence of infection.[10]

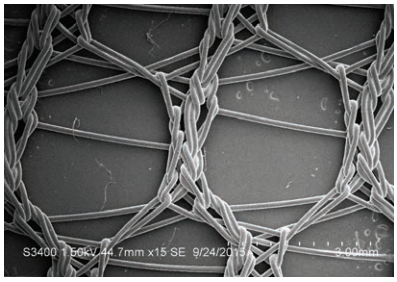
The macroporous knit of dense, monofilament PTFE fibers may reduce the risk of bacterial adherence[11] and along with increased vascularity[5] may aid in the overall treatability of the device to minimize the need for removal if postoperative infection were to occur (data on file 2020; W. L. Gore & Associates, Inc; Flagstaff, AZ.).



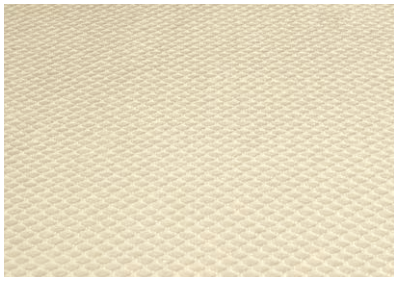
GORE® SYNECOR Biomaterial: Macroporous knit of dense monofilament PTFE fiber

Optimal porosity

The PTFE knit of GORE® SYNECOR Intraperitoneal Biomaterial has a large pore size (1–3 mm). As demonstrated in animal models, large pore sizes have been shown to improve mechanical strength of tissue ingrowth[12] and reduce scar plate formation.[13]



Polypropylene knit



Unique tri-layer hybrid device: GORE® SYNECOR Intraperitoneal Biomaterial

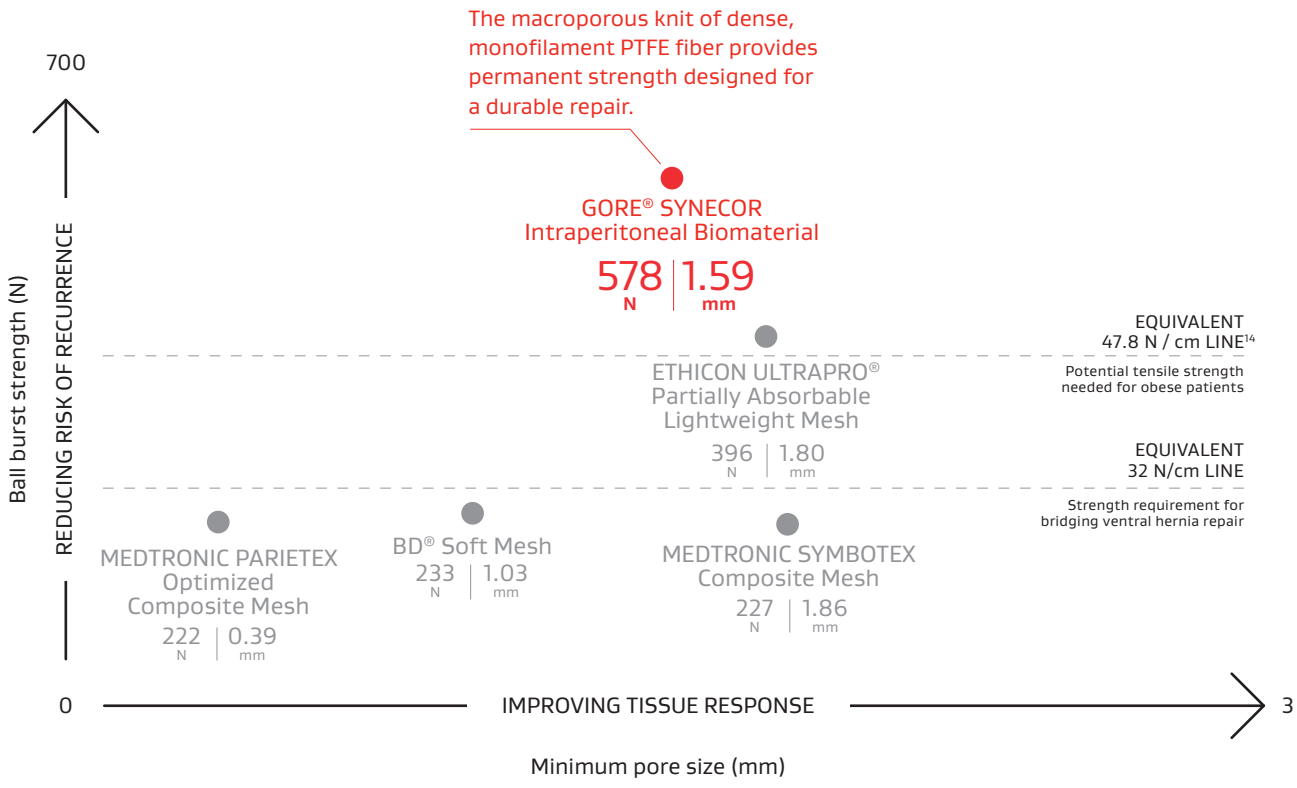
Provides strength for large defects and higher BMIs

Strong and compliant

PTFE knit is designed with a fiber diameter similar to lightweight mesh but with the strength of heavyweight mesh.

Permanent strength

Burst strength is > 500 N. This provides strength for large defects and higher BMIs at almost two times the strength requirement for bridging ventral hernia repairs (data on file 2016; W.L. Gore & Associates, Inc; Flagstaff, AZ.).[14,15]



Durable strength of the material helps to support robust healing

- May lower risk of recurrence versus lightweight and mid-weight meshes, which may have inadequate strength in complex patients (VHWG 2).[1-3]

PTFE fibers may reduce the risk of bacterial adherence[11]

Bacterial adherence was examined among various materials, including, the PTFE knit of GORE® SYNECOR Intraperitoneal Biomaterial, various polypropylene knits and a polyvinylidene fluoride/polypropylene construct.

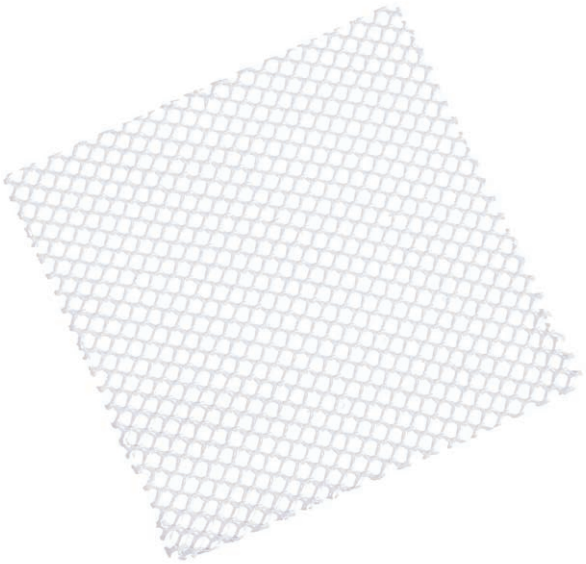
The materials were incubated in Staphylococcus aureus overnight, rinsed and subjected to staining and analysis through confocal microscopy.

This allowed for analysis of where bacteria attached.

Overall, bacteria localize to the knots and fiber surfaces of all test articles examined in this study.

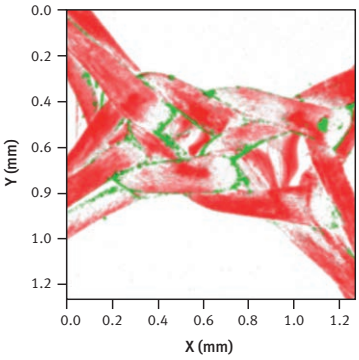
Confocal images suggest that no bacteria are located within the PTFE knit fibers and overall fewer bacteria are located on PTFE knit fibers than other materials.

PTFE knit had the least bacterial adherence on the surface when compared with other competitive polypropylene knits.[11]

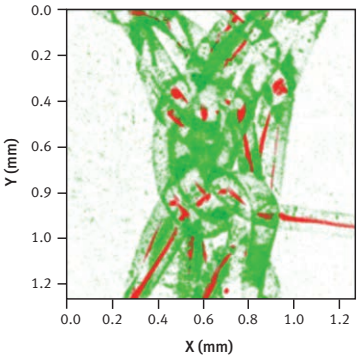


Gore latest-generation PTFE macroporous knit.

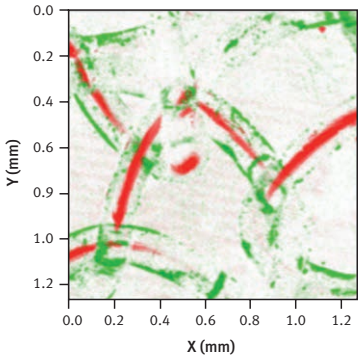
PTFE knit (10×)



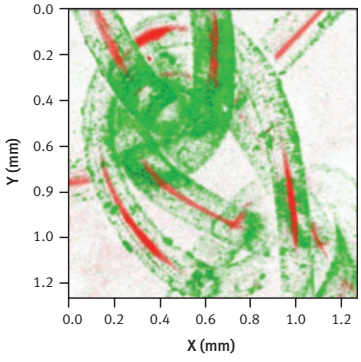
Polypropylene knit (10×)



Lightweight polypropylene knit (10×)



Polyvinylidene/Polypropylene knit (10×)



Staphylococcus aureus stains green; red represents the fiber materials as reflected light.

Designed to provide predictable performance

Minimal contraction

All biomaterials, including polypropylene, polyester and PTFE, will contract to some degree after implantation due to the activity of myofibroblasts during wound healing. Animal studies show GORE® SYNECOR Intraperitoneal Biomaterial has minimal contraction at 30 and 180 days (data on file 2015; W. L. Gore & Associates, Inc; Flagstaff, AZ.).

Protection from abdominal adhesion formation may lower the risk of postoperative complications and reoperation.

Visceral Layer: Non-porous PGA:TMC film provides intra-abdominal protection, minimizing risk of adhesion formation[7] (data on file 2015; W. L. Gore & Associates, Inc; Flagstaff, AZ.).

- PGA:TMC film: A non-porous film, minimizes visceral attachment to the material.
- Designed to limit cellular penetration.
- Film provides a uniform surface while the neoperitoneum is forming.
- PGA:TMC film absorbs in six to seven months (data on file 2015; W. L. Gore & Associates, Inc; Flagstaff, AZ.).
- Animal studies have shown no mid-substance adhesions to the material at both 30 and 180 days (data on file 2015; W. L. Gore & Associates, Inc; Flagstaff, AZ.).

No Gore biomaterials are human, animal or tissue-derived

These biomaterials eliminate the risk of disease transmission by tissue-derived products, residual cellular debris or conflict with religious beliefs/cultural practices.[16]

Innovative Materials for Specialized Solutions

Competitor reference chart

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

Company	Product name	Biosynthetic mesh	Permanent mesh	Composite mesh*
BD®	COMPOSIX E/X Mesh		●	
BD®	COMPOSIX L/P Mesh		●	
BD®	DULEX Mesh		●	
BD®	SEPRAMESH IP Composite			●
BD®	VENTRALIGHT ST Mesh			●
BD®	VENTRIO Hernia Patch		●	
BD®	VENTRIO ST Hernia Patch			●
BD®	PHASIX ST Mesh	●		
FEG TEXTILTECHNIK	DYNAMESH®-IPOM		●	
MEDTRONIC	PARIETEX Optimized Composite (PCOx) Mesh			●
MEDTRONIC	SYMBOTEX Composite Mesh			●

* Composite meshes are permanent mesh with an absorbable visceral protection layer.

Sizing

Catalogue number	Description
GKFC12E	12 cm diameter circle
GKFV1015E	10 cm × 15 cm oval
GKFV1520E	15 cm × 20 cm oval
GKFR2025E	20 cm × 25 cm rectangle
GKFR2030E	20 cm × 30 cm rectangle

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Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.

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