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 offers confidence to providers, surgeons and patients

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

- Repair with the GORE® SYNECOR Intraperitoneal Biomaterial may result in low rates of procedural interventions for surgical site occurrences (SSOPI).[1,2]

May improve the economics of patient care.

- Potentially lower total cost of treatment* versus lightweight and mid-weight meshes, which have clinical literature case studies demonstrating failure due to inadequate strength in ventral and incisional hernia repairs.[3-5]

* which includes reduced risk of hospitalization, chronic pain and reoperation.

Designed for ease of use during minimally invasive (laparoscopic, robotic) and open surgical procedures[6]

- 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 Intraperitoneal Biomaterial is available in sizes ranging from 12 cm circle to 20 cm x 30 cm rectangle.

Bringing the latest innovations to hernia repair

GORE® SYNECOR Intraperitoneal Biomaterial is a tri-layer hybrid solution designed for durable repair in complex patients (VHWG 2) to facilitate healing.[1,7]

GORE 3D PGA:TMC* Web Scaffold

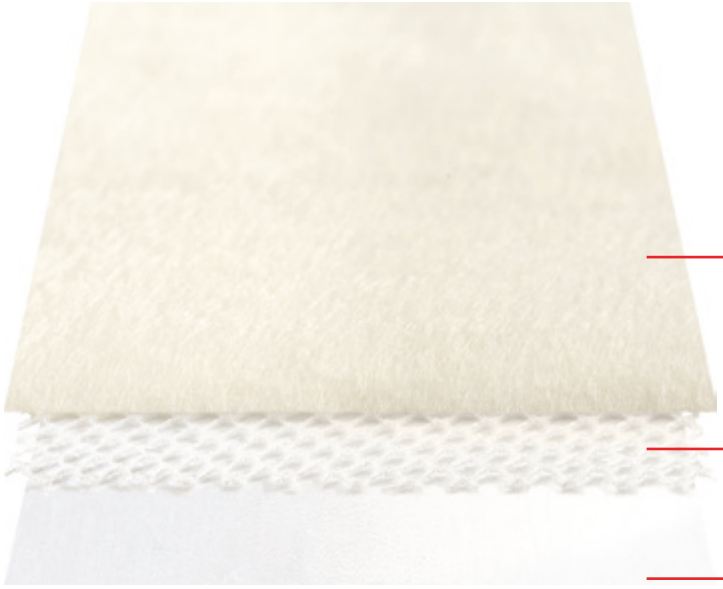
Provides rapid vascularization[8] and tissue ingrowth[9] designed to facilitate healing.

PTFE

Latest generation PTFE fiber is designed for permanent strength.[6] Strong and compliant: The PTFE knit is designed with a fiber diameter similar to lightweight mesh, but with the strength of heavyweight mesh.[6,10,11]

Non-porous PGA:TMC film

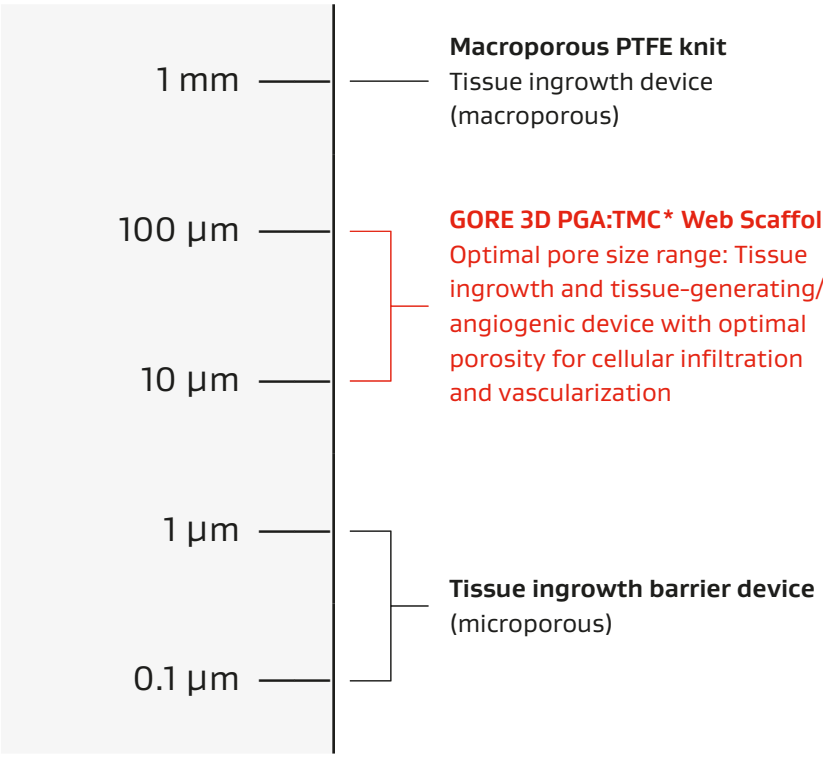
Provides intra-abdominal protection, minimizing risk of visceral attachment.[1,9,12,13]



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

Facilitates the natural healing process with tri-layer biomaterial technology

The effect of pore size[14,15]



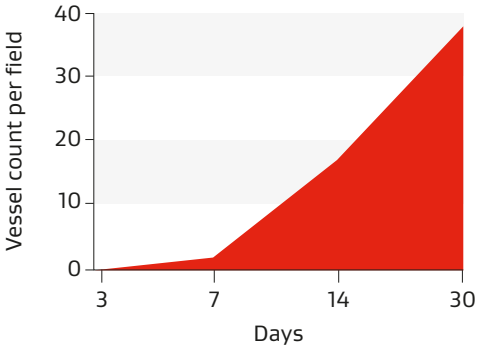
As pioneers of the first mid-term bioabsorbable mesh with a targeted absorption period of six to seven months,[13] we are persistent in the pursuit of perfecting material solutions, so surgeons have more options when assessing the risk for complications and supporting complex cases.

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

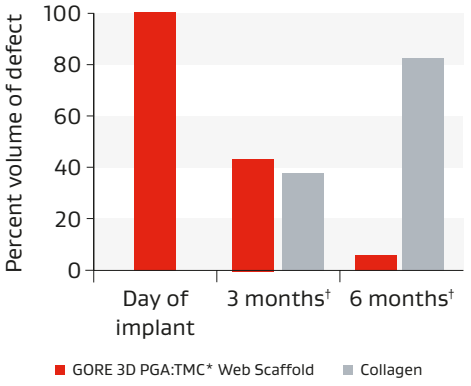
* Poly (glycolide:trimethylene carbonate) copolymer (PGA:TMC).

Rapid vascularization and tissue ingrowth

Vascularity within GORE 3D PGA:TMC Web Scaffold increases over time[16]



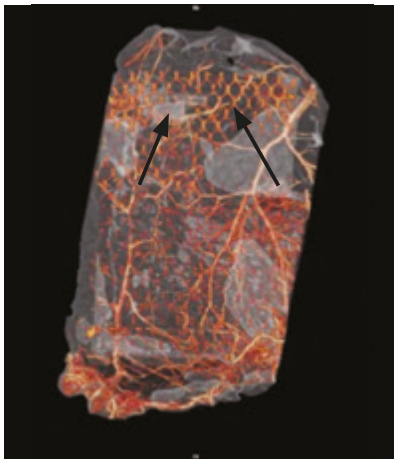
Material replaced by patient's own tissue[17]

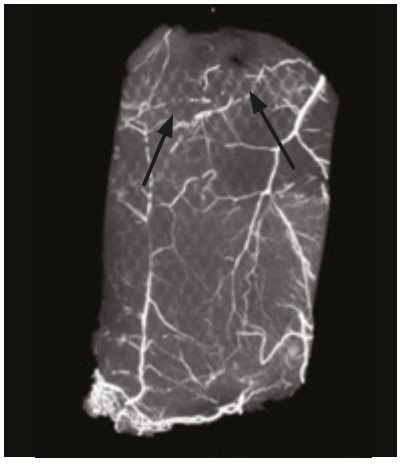


† Cells and blood vessels make up remaining volume. GORE® BIO-A® Hernia Plug.

Parietal layer: GORE 3D PGA:TMC* Web Scaffold fosters cellular infiltration and rapid vascularization which may aid in the overall treatability of the device to mitigate the need for removal if postoperative infection were to occur.[1,2,8,9]

- Enhances tissue response: Designed to promote rapid cell integration and vascularization.[8,9]
- Designed to break down primarily by hydrolysis and provide tissue uniformity and consistency.
- Within seven days: Tissue shows vascularity.[8]
- At 30 days: Tissue ingrowth.[9]
  - Tissue ingrowth is present throughout the GORE 3D PGA:TMC* Web Scaffold with various densities around the knit fibers and within the scaffold.[9]
  - Ingrowth is vascularized, organized and fills the macropores.[9]
- At 180 days: Tissue generation.[13]
  - GORE 3D PGA:TMC Web Scaffold is absorbed, leaving organized fibrous tissue ingrowth.[13]
  - Minimal fibrous tissue encapsulation of the PTFE knit.[13]





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

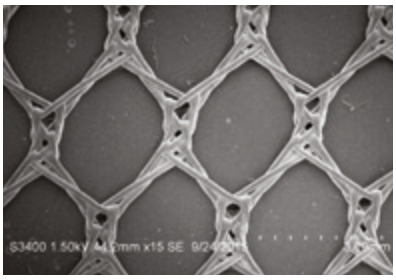
* Poly (glycolide:trimethylene carbonate) copolymer (PGA:TMC).

Latest generation PTFE fiber is designed for permanent strength[6]

Mid-layer: Macroporous knit of dense, monofilament PTFE fiber

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.[18] Laparoscopic ventral hernia repair has been associated with a lower incidence of infection.[18]

The dense monofilament PTFE fiber in GORE® SYNECOR Intraperitoneal Biomaterial may reduce the risk of bacterial adherence, which may result in low rates of surgical site infections (SSI).[1,2,19]

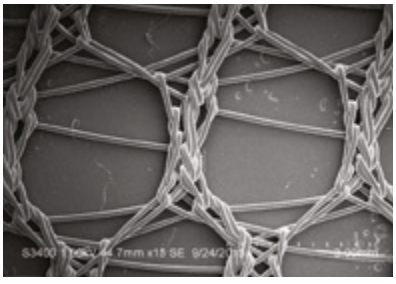


GORE® SYNECOR Biomaterial: Macroporous knit of dense monofilament PTFE fiber

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 the mechanical strength of tissue ingrowth[20] and reduce scar plate formation.[21]

The large pore size of the PTFE knit mesh promotes tissue integrity with minimal chronic inflammation, and along with the conformable low-profile design may result in low rates of patient reports of chronic pain at the repair site.[1,2]



Polypropylene knit

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

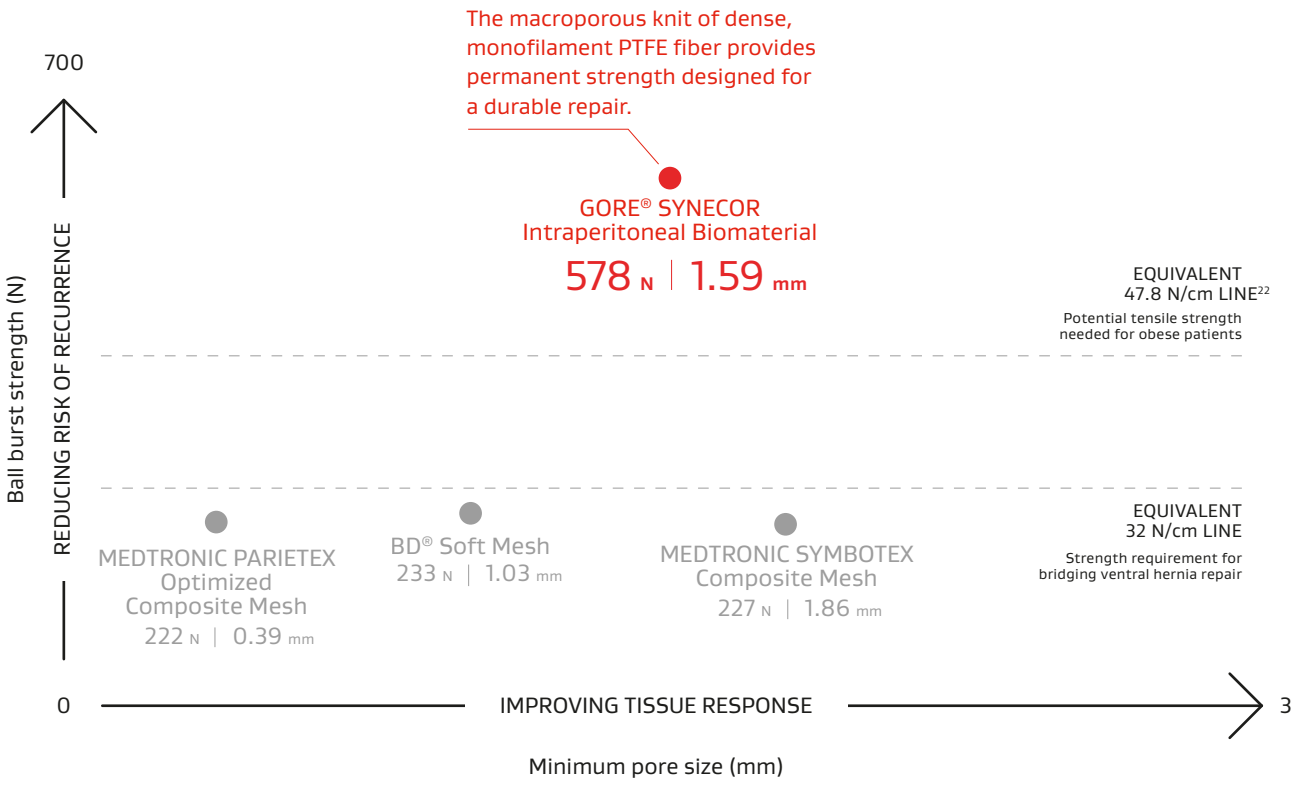
Provides strength for large defects and higher BMIs

Strong and compliant

PTFE knit is designed with a fiber diameter similar to lightweight mesh, but with the strength of heavyweight mesh.[6,10,11]

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.[11,22,23]



Durable strength of the material helps to support robust healing

- May lower risk of recurrence versus lightweight and midweight meshes, which may have inadequate strength in complex patients (VHWG 2).[3-5,10,11]

PTFE fiber

may reduce the risk of bacterial adherence, which may result in low rates of surgical site infections (SSI)[1,2,19]

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.

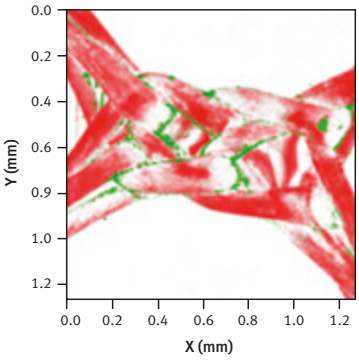
Overall, bacteria localize to the knots and fiber surfaces of all test articles examined in this study.

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.

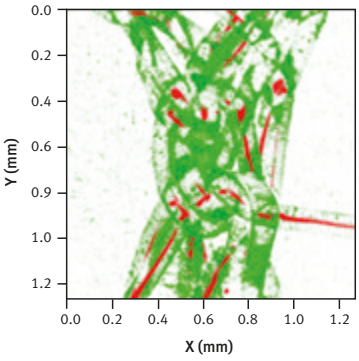
PTFE knit had the least bacterial adherence on the surface when compared with other competitive polypropylene knits.[19]

Gore's latest-generation PTFE macroporous knit.

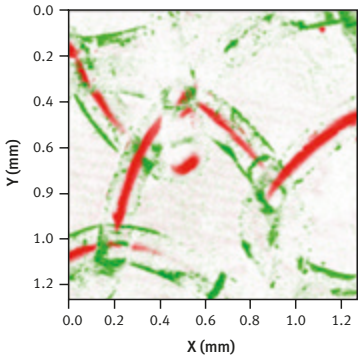
PTFE knit (10×)



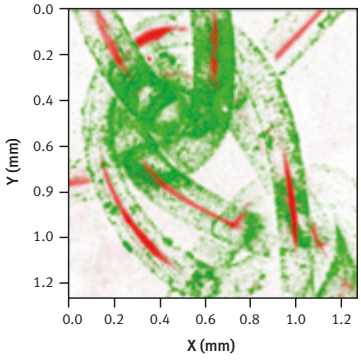
Polypropylene knit (10×)



Lightweight polypropylene knit (10×)



Polyvinylidene/Polypropylene knit (10×)



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

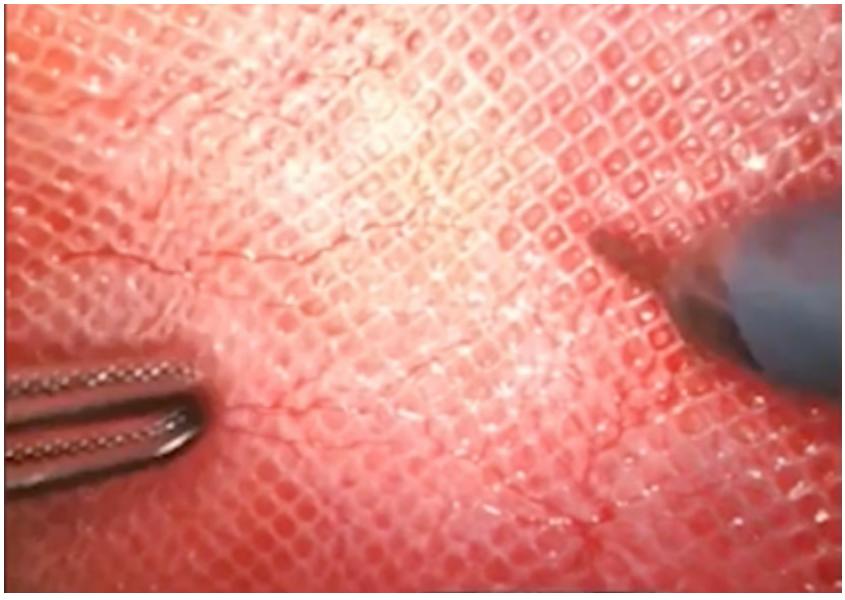
Designed to provide predictable performance

Minimal contraction

Animal studies show GORE® SYNECOR Intraperitoneal Biomaterial has minimal contraction at 30 and 180 days.[9,13]

Due to the normal healing process of the wound contracting, all biomaterials, including polypropylene, polyester, and PTFE experience some degree of contraction after implantation.[24] This is due to the natural wound healing activity associated with myofibroblasts and not the mesh itself "shrinking" or contracting.[25]

Device	Days-in-life	% change in area
GORE® SYNECOR Intraperitoneal Biomaterial	31	-5.1%
	180	-6.6%



GORE® SYNECOR Intraperitoneal Biomaterial: 18-months post-implantation view showing robust collagen formation and vascularization.

Image courtesy of R. Opreanu, M.D.

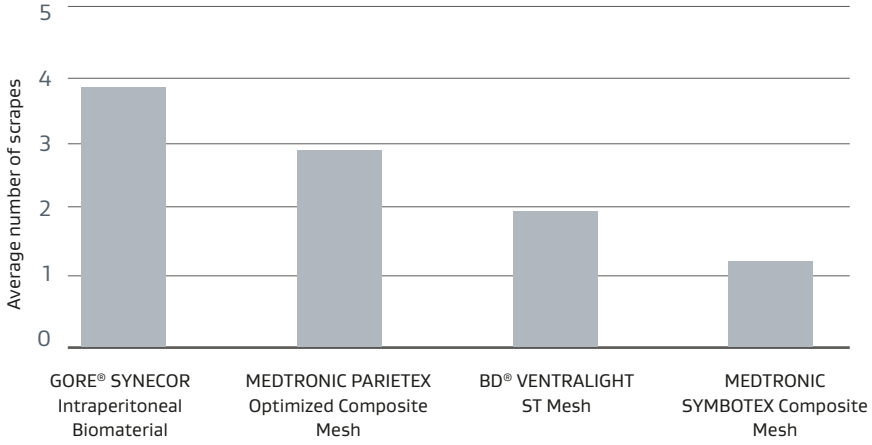
Minimizing risk of visceral attachment

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 visceral attachment.[1,9,12,13]

- 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.[9,13]
- Animal studies have shown no mid-substance adhesions to the material at both 30 and 180 days.[9,13]
- No complications due to adhesions observed clinically at 12 months.[1]

Tacker scrapes to complete damage of film[26]



The non-porous film is designed to be durable and support ease of use of the device during typical surgical manipulation.* The durable film withstands scraping by tackers.†

Postoperative observation of GORE® SYNECOR Intraperitoneal Biomaterial: 9 ½ weeks post implantation


Formation of neoperitoneum visible on surface of device

Image courtesy of C. R. Doerhoff, M.D.

* Such as trimming, insertion through a trocar, positioning, handling with graspers and contact with tackers.

† As tested under wet conditions using a handheld tacker device in a benchtop model.

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.[27]

Sustainability

Visit: Gore's commitment to sustainability

https://gmd.cm/VBS-Sustainability

Imaging

The GORE® SYNECOR Intraperitoneal Biomaterial should be visible in CT and MRI images. Because of the density differences between PTFE and the rest of the body, high resolution imaging techniques, such as CT and MRI, will reveal PTFE, both immediately following implant and after ingrowth. The material will not be damaged nor interfere with the MRI other than by being visible.

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

Linn et al. Study overview[1]

Clinical outcomes

Long-term results for intraperitoneal biomaterial repair of ventral hernias in a real-world, retrospective, multicenter study.[1]

Aim

To analyze device safety and clincial outcomes of ventral hernia repair with a hybrid biomaterial.

Materials and methods

Retrospective, multicenter, case review analyzed device/procedure endpoints and patient-reported outcomes in patients treated for hernia repair ≥ 1 year from study enrollment.

DATA SUMMARY

Long-term follow-up:

33 months median
Range: 14–53 months

- Patients: 459
- Intraperitoneal placement: 75.6%
- 57.3% of all repairs were bridged
- Laparoscopic or robotic approach: 95.4%

QUALITY OUTCOMES

- Hernia recurrence:
  - 0.9% clinically confirmed hernia recurrence (4/459 patients, median 33 months)
- Mesh removal:
  - 0.2% (not due to infection)
- Reoperation rate:
  - 2.4% (30 days)
- Surgical site infection (SSI): 2.2% (12 months)
- Surgical site occurrence requiring procedural intervention (SSOPI): 2.6% (24 months)
- Complications*: 0% (12 months)

PATIENT CHARACTERISTICS

- Mean body mass index (BMI): > 33kg/m^2
  - Obese: 63%
- Tobacco users:
  - Current users: 19%
  - Former users: 32%
- Diabetes mellitus: 20%
- Ventral hernia working group (VHWG) classification
  - Grade 1: 23%
  - Grade 2: 77%

Linn JG, Mallico EJ, Doerhoff CR, Grantham DW, Washington RG Jr. Evaluation of long-term performance of an intraperitoneal biomaterial in the treatment of ventral hernias. *Surgical Endoscopy* 2023;37:3455-3462. https://link.springer.com/article/10.1007/s00464-022-09803-9

* due to adhesions, seroma, fistula, bowel perforation or pain

Innovative materials for specialized solutions

Competitor reference chart

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

Manufacturer	Product name	Composite mesh	Absorbable mesh	Permanent mesh	Reinforced biologic mesh
Becton, Dickinson and Company	BD® VENTRALIGHT ST Mesh	●			
Becton, Dickinson and Company	BD® PHASIX ST Mesh		●		
FEG Textiltechnik mbH	FEG TEXTILTECHNIK DYNAMESH®-IPOM			●	
Medtronic, Inc.	MEDTRONIC PARIETENE DS Composite Mesh	●			
Medtronic, Inc.	MEDTRONIC PARIETEX Optimized Composite (PCOx) Mesh	●			
Medtronic, Inc.	MEDTRONIC SYMBOTEX Composite Mesh	●			
TELA Bio, Inc.	TELA BIO® OVIETEX® LPR Reinforced Tissue Matrix				●

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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This product brochure is intended for surgeons and health care providers only.

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Products listed may not be available in all markets.

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