GORE® SYNECOR
Preperitoneal 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

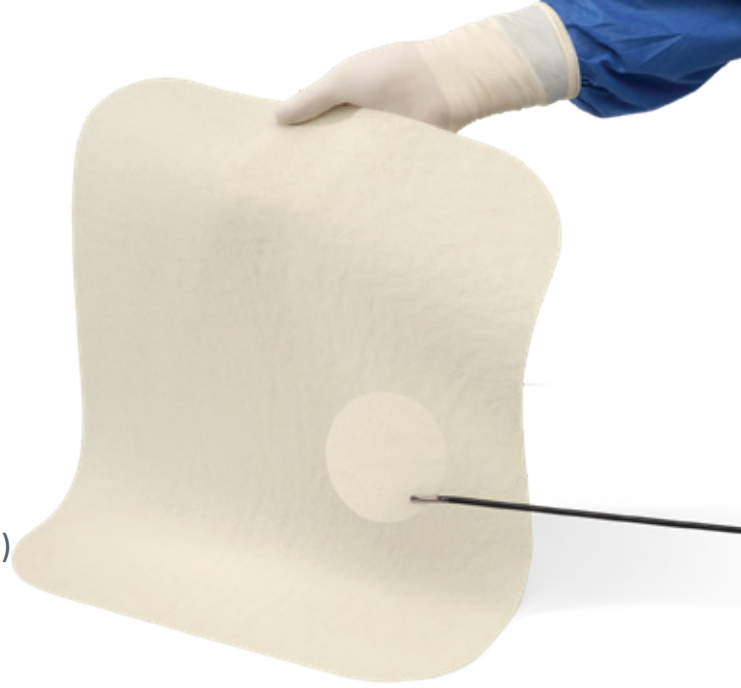
GORE® SYNECOR Preperitoneal Biomaterial helps deliver the quality outcomes patients need.

- Helps to improve surgical outcomes for patients and providers.[1-5]
- Repairs with the GORE® SYNECOR Preperitoneal Biomaterial may result in low rates of procedural interventions for surgical site occurrences (SSOPI).[1]

May improve the economics of patient care.

- Potentially lower total cost of treatment* versus lightweight and midweight meshes, which have clinical literature showing failures due to inadequate strength in ventral hernia repairs[4,6-8]

* cost of treatment includes hospitalization, chronic pain and reoperation.



Designed for ease of use during minimally invasive (laparoscopic and robotic) and open surgical procedures[9*]

- Material is flexible and conformable
- Material has 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

As requested by clinicians, GORE® SYNECOR Preperitoneal Biomaterial is available in large sizes up to 40 x 50 cm for preperitoneal repair of complex hernias.[9]

* refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications and safety information.

Introducing the latest innovations to hernia repair

GORE® SYNECOR Preperitoneal Biomaterial is a tri-layer hybrid solution designed for durable repair in complex hernia patients (Ventral Hernia Working Group (VHWG) Grade 2) to facilitate healing.[1,9,10]

GORE 3D PGA:TMC* Web Scaffold

Designed to promote healing by facilitating rapid vascularization and tissue ingrowth.[11,12]

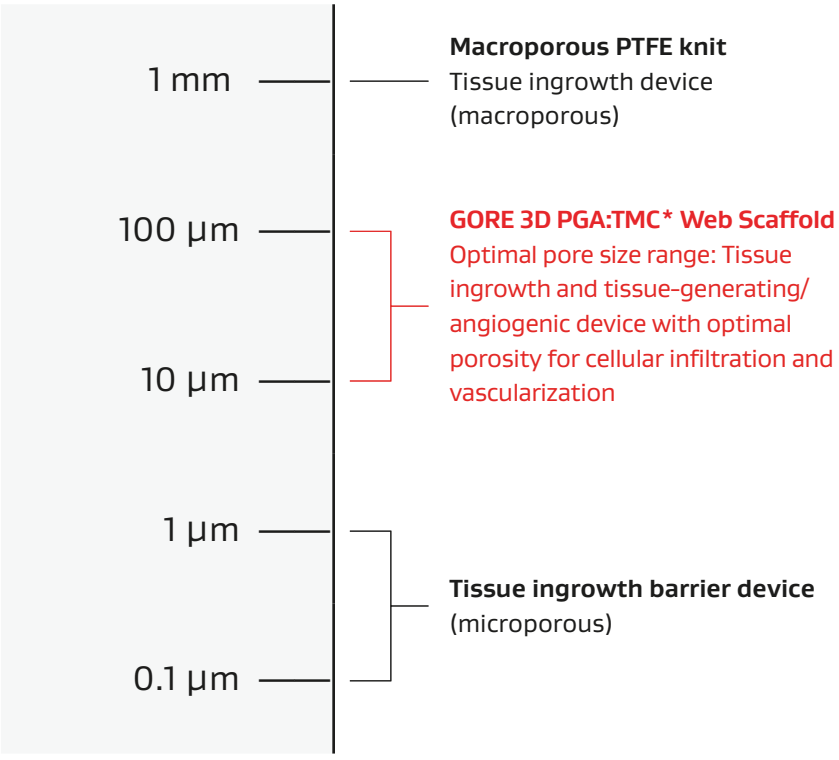
PTFE

Latest generation PTFE fiber is designed for permanent strength.[9] Strong and compliant: The PTFE knit is designed with a fiber diameter similar to lightweight mesh, but with the strength of heavyweight mesh.[9,13,14]

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

Facilitates the natural healing process with tri-layer biomaterial technology

The effect of pore size[15,16]



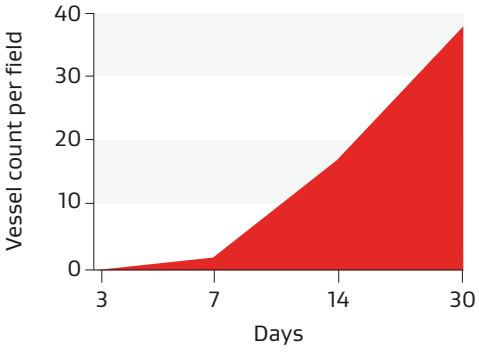
As pioneers of the first mid-term bioabsorbable mesh with a targeted absorption period of six to seven months,[17] we are persistent in the pursuit of perfecting material solutions, so surgeons have more options when assessing the risk for complications and supporting complex cases.[9]

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

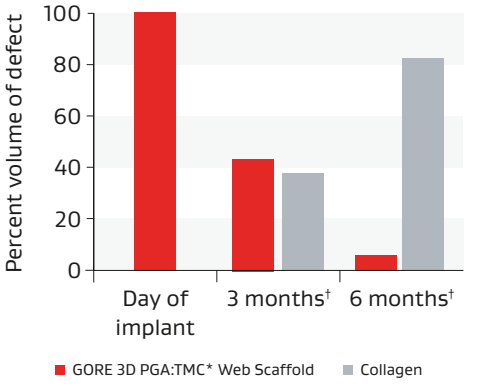
* Poly (glycolide:trimethylene carbonate) copolymer (PGA:TMC).

Rapid vascularization and tissue ingrowth

Vascularity within GORE 3D PGA:TMC Web Scaffold increases over time[18]



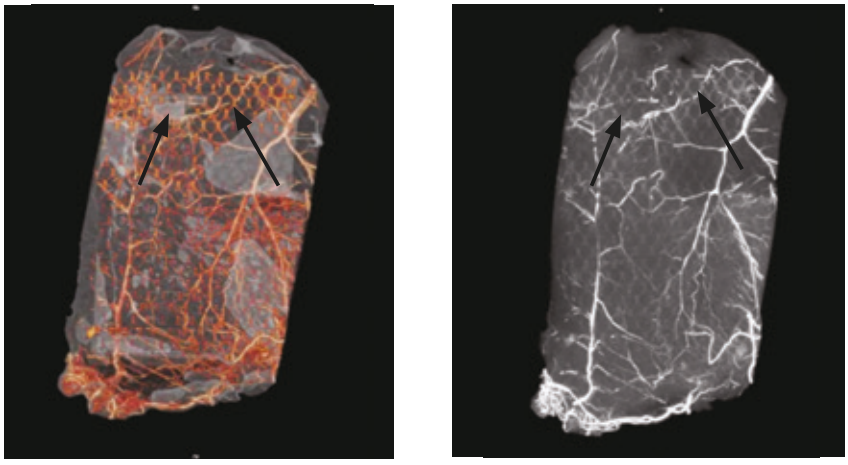
Material replaced by patient's own tissue[20]



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

The GORE 3D PGA:TMC Web Scaffold of GORE® SYNECOR Preperitoneal Biomaterial promotes cellular infiltration and rapid vascularization to aid in overall treatability and mitigate the need for device removal if infection were to occur.[1,11,12]

- Enhances tissue response: Designed to promote rapid cell integration and vascularization.[11,12]
- Designed to break down primarily through hydrolysis and achieve tissue uniformity and consistency.[17,19]
- GORE 3D PGA:TMC Web Scaffold vascularizes as early as 7 days, integrates within 1 month and is replaced by native tissue within 6-7 months.[11,12,17]
- At 30 days, tissue ingrowth is evident throughout the GORE 3D PGA:TMC Web Scaffold with various densities around the knit fibers and within the scaffold.[12]
- GORE 3D PGA:TMC Web Scaffold is absorbed by 180 days, leaving organized fibrous tissue.[17]
- Minimal fibrous tissue encapsulation of the PTFE knit.[17]
- Tissue ingrowth is vascularized, organized, and fills the macropores.[12,17]



Arrows indicate area where blood vessels are penetrating through the PTFE knit at 7 days post-implantation.[11]

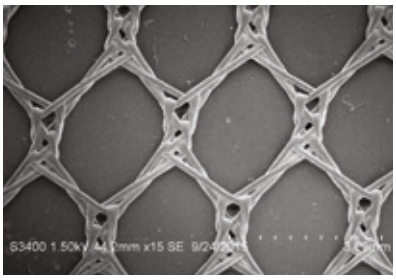
* Poly (glycolide:trimethylene carbonate) copolymer (PGA:TMC).

Latest generation PTFE fiber is designed for permanent strength[9]

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.[21]

The dense monofilament PTFE fiber in GORE® SYNECOR Preperitoneal Biomaterial may reduce the risk of bacterial adherence, which may result in low rates of surgical site infections (SSI).[1,22]

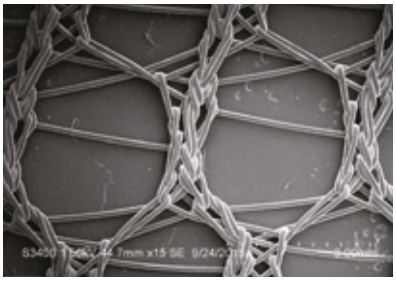


GORE® SYNECOR Biomaterial: Macroporous knit of dense monofilament PTFE fiber

Optimal porosity

The PTFE knit of GORE® SYNECOR Preperitoneal 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[23] and reduce scar plate formation.[24]

The large pore size of the PTFE knit mesh promotes tissue integration with minimal chronic inflammation.[1,17]



Polypropylene knit

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

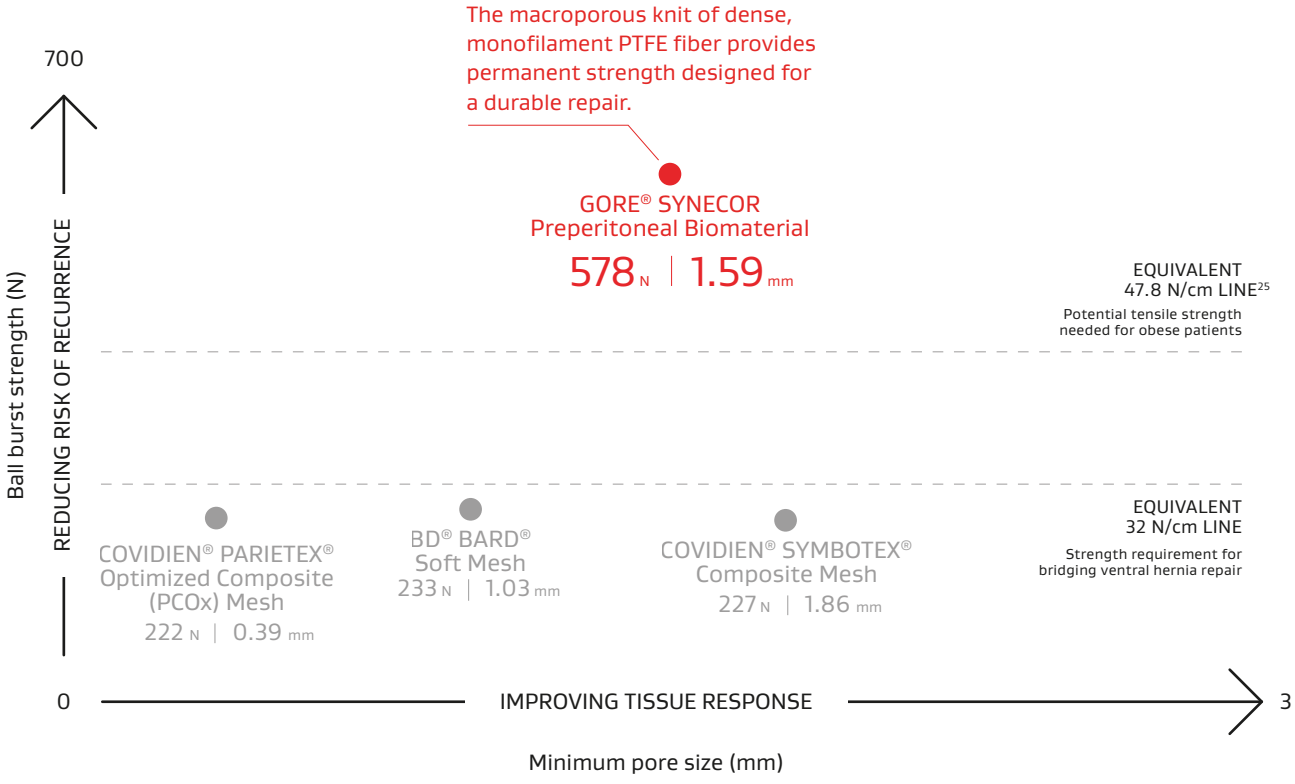
Provides strength for large defects and higher BMIs

Strong and compliant

PTFE knit is designed with a fiber diameter similar to lightweight mesh, but with the strength of heavyweight mesh.[9,13,14]

Permanent strength

Burst strength is > 500 N (578 N load is equivalent to a tensile strength of 72 N/cm). This provides strength for large defects and higher BMIs at almost two times the strength requirement for bridging ventral hernia repairs.[13,14,25,26]



Durable strength of the material helps to support robust healing

- May lower the risk of recurrence versus lightweight and midweight meshes, which may offer inadequate strength in complex patients (Ventral Hernia Working Group (VHWG) Grade 2).[6-8,13,14]

PTFE fiber

May reduce the risk of bacterial adherence, which may result in low rates of surgical site infections (SSI)[1,22]

Bacterial adherence was examined among various materials, including the PTFE knit of GORE® SYNECOR Preperitoneal 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.

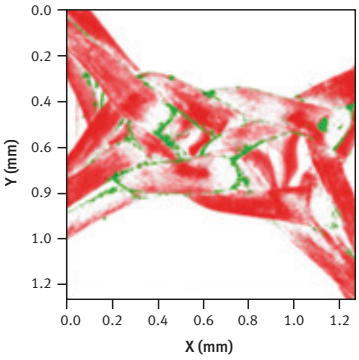
Overall, bacteria localize to the knots and fiber surfaces of all test articles examined in this study.

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.

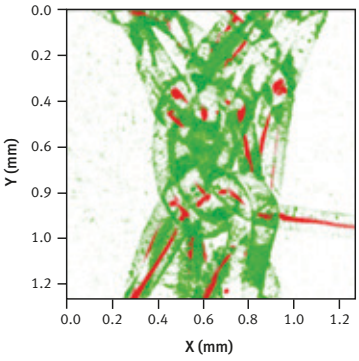
PTFE knit had the least bacterial adherence on the surface when compared with other competitive polypropylene knits.[22]

Gore's latest-generation PTFE macroporous knit.

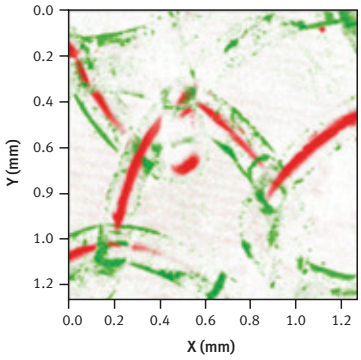
PTFE knit (10×)



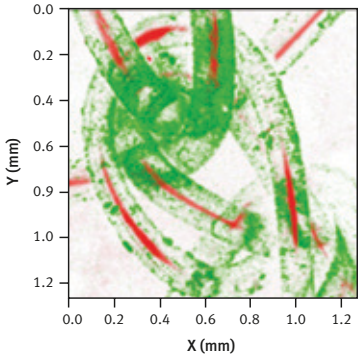
Polypropylene knit (10×)



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

GORE® SYNECOR Preperitoneal Biomaterial has minimal device contraction or shrinkage through 6 months (0% change in area) as demonstrated in an animal study.[17] An increase in device area (15.7%) was observed at 1 month in a separate animal study.[12]

Due to the normal healing process in which the wound contracts, all biomaterials, including polypropylene, polyester and PTFE, will expand or contract to some degree after implantation on account of the myofibroblast activity rather than the mesh itself "shrinking" or contracting.[27,28]

The PTFE knit is designed to expand or contract as needed during the healing process.[9,12,17]

As requested by clinicians, GORE® SYNECOR Preperitoneal Biomaterial is available in large sizes up to 40 x 50 cm for preperitoneal repair of complex hernias.[9]

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.[29]

Sustainability

Visit: Gore's commitment to sustainability

https://gmd.cm/VBS-Sustainability

Imaging

The GORE® SYNECOR Preperitoneal Biomaterial should be visible in CT and MRI images. Given the differences in density between PTFE and the rest of the body, PTFE will be identified by high-resolution imaging techniques, such as CT and MRI, both immediately following implant and after ingrowth. Other than being visible, the material will neither be damaged nor interfere with the imaging.*

*For the most current and complete MR safety information on any product, always refer to the *Instructions for Use* at eifu.goremedical.com.

Clinical outcomes for ventral hernia repair[1]

Literature summary

Five key retrospective review studies demonstrated quality outcomes for GORE® SYNECOR Preperitoneal Biomaterial in ventral hernia repair.[3,5,30-32]

DATA SUMMARY

Long-term follow-up:

30 days to 2.1 years

- Patients: 298
- Robotic, laparoscopic and open approach
- Retromuscular repairs including totally extraperitoneal (TEP) and transversus abdominis muscle release (TAR) (including bridging)
- Preperitoneal placement

QUALITY OUTCOMES

- Hernia recurrence: 0–4.5%
- Seroma: 4.5–15%
- SSI: 0–10%
- SSOPI: 0–10%
- Complete mesh removals: ZERO
- Mesh fractures: ZERO

PATIENT CHARACTERISTICS

- High (BMI): > 30kg/m^2
- Diabetes mellitus
- Smokers
- Immunosuppressed
- History of wound infections
- Recurrent hernias

Prospective study — SYN 20-01[33]

Assessment of GORE® SYNECOR Biomaterial in focused patient populations and long-term application (SYN 20-01).

Sponsor: W. L. Gore & Associates, Inc.

Brief summary: The SYN 20-01 study is a non-interventional, prospective, multicenter, multicohort, international, post-market clinical investigation looking into the assessment of GORE® SYNECOR Biomaterial in focused patient populations and in long-term application.

Patients with ventral/incisional hernia amenable to hernia mesh repair will be enrolled into two cohorts (U.S. and EU cohort) and followed-up over the period of 60 months.

Conditions: Hernia, ventral, hernia incisional, hernia incisional ventral

Enrollment: started February 2023, 320 (anticipated)

Number of groups/cohorts: Two

https://clinicaltrials.gov/ct2/show/NCT05094089?term=synecor&cond=Hernia&draw=2&rank=1

Innovative materials for specialized solutions

Competitor reference chart for ventral hernia repair

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

Manufacturer	Product name	Permanent mesh	Reinforced biologic mesh
C.R. Bard, Inc.	BD® Bard® Mesh	●	
C.R. Bard, Inc.	BD® Bard® Soft Mesh	●	
FEG Textiltechnik mbH	FEG DYNAMESH®-CICAT Implant	●	
Johnson & Johnson	ETHICON PROLENE® Polypropylene Mesh	●	
Johnson & Johnson	ETHICON PROLENE® Soft Polypropylene Mesh	●	
Johnson & Johnson	ETHICON ULTRAPRO ADVANCED® Macroporous Partially Absorbable Mesh	●	
Medtronic, Inc.	COVIDIEN® VERSATEX® Monofilament Mesh	●	
Medtronic, Inc.	COVIDIEN® PROGRIP® Self-Gripping Polyester Mesh	●	
Medtronic, Inc.	COVIDIEN® PARIETENE® Macroporous Mesh	●	
TELA BIO, Inc.	TELA BIO® OVITEX® Reinforced Tissue Matrix		●

The above is a guide for extraperitoneal mesh use in ventral/incisional hernia repair. Not all available products are included.

Sizing

For treating the smallest to largest hernias, devices range in size from a 9 cm circle to a 40 x 50 cm rectangle.

Catalogue number	Shape	Size
GKWC09E	Circle	9 cm diameter
GKWV1015E	Oval	10 cm x 15 cm
GKWR1215E	Rectangle	12 cm x 15 cm
GKWV1520E	Oval	15 cm x 20 cm
GKWR2025E	Rectangle	20 cm x 25 cm
GKWR2030E	Rectangle	20 cm x 30 cm
GKWR3030E	Rectangle	30 cm x 30 cm
GKWR3040E	Rectangle	30 cm x 40 cm
GKWR3535E	Rectangle	35 cm x 35 cm
GKWR4040E	Rectangle	40 cm x 40 cm
GKWR4050E	Rectangle	40 cm x 50 cm

Clinical outcomes for Inguinal Hernia Repair[1]

Long-term results for preperitoneal biomaterial repair of inguinal hernias in a real-world, retrospective, multicenter study.
Aim: To analyze device safety and clinical outcomes of inguinal 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:

- 43 months median
- 34 months mean
- 60 months maximum follow-up

- (Patient follow-up including in-person visit, physical exam, reported adverse event, explant, death, and questionnaire response)
- Patients: 68
- Robotic, laparoscopic and open approach
- Preperitoneal placement
- Bridging repairs: 48.5%

QUALITY OUTCOMES

- Hernia recurrence:
  - 3.08% (clinically confirmed hernia recurrence through 12 months)
  - 6.2% (all-cause hernia recurrence through 57 months)

- Seroma: 0%
- SSI: 0%
- SSOPI: 0%
- Complete mesh removals: ZERO

PATIENT CHARACTERISTICS

- BMI (kg/m^2): 27 mean
- Diabetes mellitus: 13.2%

- Smokers: 27.9%
- VHWG Grade 2: 50%

Inguinal Hernia Repair[1]

- The large pore size of the PTFE knit mesh promotes tissue integration with minimal chronic inflammation, and along with the conformable low-profile design may result in low rates of patient reports of chronic pain at inguinal hernia repair sites.[1,17]
- No device removals were reported when the GORE® SYNECOR Preperitoneal Biomaterial device was used for inguinal hernia repair, which may improve the economics of patient care.[1]
- Designed for ease of use during minimally invasive (laparoscopic and robotic) and open surgical procedures.[9]
  - Material is flexible and conformable, allowing for easier placement in inguinal anatomy.[34,35]
  - Material memory for easy unrolling, handling and optimal placement in inguinal anatomy.[34,35]
- Appropriately sized devices for inguinal hernia repair to give patients the benefits of a tri-layer hybrid biomaterial with rapid vascularity (wound healing) and permanent strength without having to trim a larger device.[9,11,13]

Competitor reference chart for inguinal hernia repair

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

Manufacturer	Product name	Permanent mesh	Reinforced biologic mesh
B. Braun Surgical	BRAUN OPTILENE® Mesh	●	
C.R. Bard, Inc.	BD® 3DMAX® Mesh	●	
C.R. Bard, Inc.	BD® Bard® Mesh	●	
FEG Textiltechnik mbH	FEG DYNAMESH®-ENDOLAP 3D Implant	●	
FEG Textiltechnik mbH	FEG DYNAMESH®-LICHTENSTEIN Implant	●	
Johnson & Johnson	ETHICON PROLENE® Polypropylene Mesh	●	
Johnson & Johnson	ETHICON ULTRAPRO ADVANCED® Macroporous Partially Absorbable Mesh	●	
Medtronic, Inc.	COVIDIEN® DEXTILE® Anatomical Mesh	●	
Medtronic, Inc.	COVIDIEN® PARIETENE® Macroporous Mesh	●	
Medtronic, Inc.	COVIDIEN® PARIETEX® PROGRIP® Self-Fixating Mesh	●	
Medtronic, Inc.	COVIDIEN® PROGRIP® Laparoscopic Self-Fixating Mesh	●	
TELA BIO, Inc.	TELA BIO® OVITEX® IHR Reinforced Tissue Matrix		●

The above is a guide for extraperitoneal mesh use in inguinal hernia repair. Not all available products are included.

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BD and BARD are trademarks of C.R. Bard, Inc.

COVIDIEN is a trademark of Covidien LP.

FEG and DYNAMESH are trademarks of FEG Textiltechnik mbH.

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TELA BIO and OVITEX are trademarks of TELA Bio, Inc.

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

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