UNCOMPROMISED CONFIDENCE

Strength Plus Scaffold
OVERVIEW

GORE® SYNECOR Intraperitoneal Biomaterial is a unique combination of a macroporous knit of dense, monofilament PTFE fibers and a bioabsorbable copolymer scaffold comprised of polyglycolic acid (PGA) and trimethylene carbonate (TMC) on the parietal surface, and a PGA / TMC nonporous film on the visceral surface.

GORE® SYNECOR Intraperitoneal Biomaterial combines long-term strength with rapid tissue ingrowth and vascularization providing a single-stage durable repair in complex cases.

- GORE® BIO-A® Web scaffold facilitates cell infiltration and tissue generation
- A macroporous knit of dense, monofilament PTFE fiber, which may reduce the risk of harboring bacteria due to the solid fiber
- Nonporous PGA / TMC film minimizes visceral attachment to the material
APPLICATIONS / PRODUCT USE RECOMMENDATIONS

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

The material is designed specifically for soft tissue reinforcement. Hospital surgical departments — including general surgery, trauma, and plastics — find value in the material and some common applications include:

- Laparoscopic ventral hernia repair
- Open ventral hernia repair
- High-risk ventral hernia repair

VALUE

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

- Less complications and better quality outcomes
- As a single-stage durable repair, can replace many other meshes on the shelf
- Replacing biologics in complex patients reduces cost
OPTIMUM STRENGTH

GORE® SYNECOR Intraperitoneal Biomaterial is soft and conformable, 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 strength requirement for intraperitoneal ventral hernia repair has been suggested in the literature as having an abdominal wall surface tension of 32 N/cm. 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.

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

Ball Burst Strength vs Pore Size

- **GORE® SYNECOR Intraperitoneal Biomaterial**: 578 N, 1.59 mm
- **ETHICON ULTRAPRO® Partially Absorbable Lightweight Mesh**: 396 N, 1.80 mm
- **MEDTRONIC SYMBOTEX Composite Mesh**: 227 N, 1.86 mm
- **MEDTRONIC PARIETEX Optimized Composite Mesh**: 222 N, 0.39 mm
- **BARD® Soft Mesh**: 233 N, 1.03 mm

Potential tensile strength needed for obese patients: EQUIVALENT 47.8 N/CM LINE EQUIVALENT 32 N/CM LINE

Improving Tissue Response

Minimum Pore Size (mm)
RAPID CELL MIGRATION AND VASCULARIZATION

Our bioabsorbable web scaffold supports the rapid development of quality tissue without the risks associated with biologics. The web component of GORE® SYNECOR Intraperitoneal Biomaterial is designed to break down primarily by hydrolysis and provides uniformity and consistency. Within one to two weeks, the patient’s own cells migrate into the GORE® BIO-A® Web scaffold and begin generating vascularized soft tissue. Over approximately six to seven months, the web component is gradually absorbed by the body and replaced 1:1 with patient’s own favorable Type I collagen.

- GORE® BIO-A® Web scaffold facilitates cell infiltration and tissue generation
- Nonporous PGA/TMC film minimizes visceral attachment to the material

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

![Graph showing vessel count per field increasing over days](image)

Material replaced by tissue at 1:1 ratio**

![Bar graph showing percent volume of defect over time](image)

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, there is even more importance in evaluating the presence of blood vessels throughout the device structure in the immediate postoperative time period.

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

![Images showing MicroCT scans with arrows indicating blood vessel penetration](image)


INGROWTH

The combination of the GORE® BIO-A® Web scaffold and the PTFE knit, having a pore size between 1.0 to 3.0 mm, 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, a neoperitoneal layer formed on the surface of the film and that 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.

ENGINEERING TISSUE RESPONSE WITH MATERIAL STRUCTURE:

The effect of pore size

- **MACROPOROUS PTFE Knit**
  - Tissue ingrowth device (macroporous)

- **GORE® BIO-A® Web Scaffold**
  - OPTIMAL PORE SIZE RANGE: Tissue ingrowth and tissue generating / angiogenic device with optimal porosity for cellular infiltration and vascularization

- **Tissue ingrowth barrier device (microporous)**
Mean pore size and tissue response

- Nonporous = capsule
- 5 and 60 μm pores = vascularized tissue surrounding implant
- 700 μm pores = “pseudocapsules” around nodules

Typical tissue forming around the polyvinyl alcohol (PVA) implants. The implant is facing up from the bottom and the surrounding tissue is extending down from the top of each micrograph. Small blood vessels near the implant-tissue interface are indicated by small black arrows. Solid nodules of the PVA are indicated by large black arrowheads (original magnification x100). Note the dense tissue structure and relative avascularity of the (a) PVA-skin capsule. By contrast, the tissue response to the porous (b) PVA-5 and (c) PVA-60 implants is highly vascular, as noted by the abundance of small vessels, and comprises a less dense, more randomly oriented fibrous tissue structure. Note the pseudocapsules that form around each nodule of solid PVA in between the pores within the (d) PVA-700 implant.

SHRINKAGE

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 shrinkage at 30 and 180 days.

ADHESIONS

Typical neoperitonealization is thought to occur within five to eight days and, during this time, the film surface remains intact providing a uniform surface for cellular deposition. The nonporous PGA / TMC film is designed to limit cellular penetration, which serves to minimize visceral adhesion to the material. Animal studies have shown no mid-surface adhesions to the material at both 30 days and 180 days.
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. The PTFE knit is designed with a fiber diameter similar to lightweight polypropylene but with the strength of a heavyweight polypropylene. The PTFE knit is designed from a dense, monofilament fiber, similar to polypropylene fibers. The macroporous knit of dense, monofilament PTFE fiber may reduce the risk of harboring bacteria due to the solid fiber. Thus, the PTFE knit can maintain the surface area desired in lightweight materials but not sacrifice strength as happens with polypropylene knits.

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

Bacterial adherence was examined among various materials, including the PTFE knit of GORE® SYNECOR Intraperitoneal Biomaterial, various polypropylene knits (lightweight to heavyweight) and a polyvinylidene fluoride (PVDF) / polypropylene construct. 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 and whether it attaches within the structure as analyzed in the Z-direction through the material.

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: PTFE, Polypropylene, PVDF
- 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

Overall, bacteria in all constructs were found only on the surface and tended to localize in the knots and overlapping fiber area. It was observed that the PTFE knit had the least bacteria on the surface of all constructs.

*S. Aureus* stains green; Red represents the fiber
Data on file.
PRODUCT CHARACTERISTICS / SIZES

Handling

- No pre-soaking of GORE® SYNECOR Intraperitoneal Biomaterial is needed
- The material is soft and conformable, allowing for easy deployment through the trocar
- Material memory facilitates easy unrolling of the mesh after insertion, for optimal placement
- The material is appropriate for use during robotic procedures

Catalogue Numbers / Sizing

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<th>Catalogue Number</th>
<th>Description</th>
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# PRODUCT REFERENCE CHART

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

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<tr>
<th>Company</th>
<th>Product Name</th>
<th>Biologic Mesh</th>
<th>Biosynthetic Mesh</th>
<th>Permanent Mesh</th>
<th>Composite Mesh*</th>
<th>Hybrid Mesh**</th>
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* Composite Meshes are permanent mesh with an absorbable visceral protection layer.
** Hybrid Meshes have permanent mesh with a bioabsorbable (biologic or biosynthetic) tissue scaffold material.
REFERENCES


