Gore’s bioabsorbable web technology clinical history

More than 20 years of experience

Staple line reinforcement

1. GORE® SEAMGUARD® Staple Line Reinforcement

2. GORE® BIO-A® Tissue Reinforcement

3. GORE® ENFORM Intraperitoneal/Preperitoneal Biomaterial

4. GORE® SYNECOR Preperitoneal Biomaterial

Soft tissue reinforcement and hernia repair

1. GORE® SYNECOR Intraperitoneal Biomaterial

2. GORE® SYNECOR Preperitoneal Biomaterial

3. GORE® ENFORM Intraperitoneal/Preperitoneal Biomaterial

4. GORE® ENFORM Intraperitoneal/Preperitoneal Biomaterial
BARIATRICS — STAPLE LINE REINFORCEMENT

GORE® SEAMGUARD® Bioabsorbable ........................................ 1
Staple Line Reinforcement Material
Configured for Endoscopic Surgical Staplers

GORE® SEAMGUARD® Bioabsorbable ........................................ 2
Staple Line Reinforcement Material
Configured for Circular Surgical Staplers

HERNIA REPAIR AND ABDOMINAL WALL RECONSTRUCTION (AWR)

GORE® ENFORM Intraperitoneal Biomaterial .......................... 3–4
GORE® ENFORM Preperitoneal Biomaterial .......................... 3–4
GORE® BIO-A® Tissue Reinforcement ................................. 5–6
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HERNIA, OTHER SOFT TISSUE RECONSTRUCTION

GORE-TEX® Soft Tissue Patch ............................................. 9
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SUTURE

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FOCUS PRODUCT

BARIATRICS — STAPLE LINE REINFORCEMENT

GORE® SEAMGUARD®
Bioabsorbable Staple Line Reinforcement Material

Configured for Endoscopic Surgical Staplers or Configured for Intuitive Surgical® Robotic Endoscopic Surgical Stapler

A synthetic buttressing material engineered to reduce perioperative leaks and bleeding in staple line formation

FOCUS APPLICATIONS

• Bariatric surgery such as sleeve gastrectomy, Roux-en-Y gastric bypass, mini gastric bypass, duodeno-ileal bypass, biliopancreatic bypass

PRODUCT CONSTRUCT

• Bioabsorbable Polyglycolic Acid: Trimethylene Carbonate (PGA:TMC) implant material is held into the form of sleeves using non-absorbable polyester braided suture, which is ultimately removed and discarded.
• Each part consists of one cartridge device and one anvil device loaded on TYVEK® Inserts to facilitate placement onto the jaws of surgical staplers.

SIZES

Configurations specific to staple height and stapler brand /design for 45 and 60 mm stapler lengths. GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement Configured For Intuitive Surgical® Robotic Endoscopic Surgical Staplers is only available in 60 mm configuration.

Available for select Covidien, Ethicon and Intuitive staplers

Average thickness of anvil plus cartridge is 0.4 mm, with a maximum of 0.5 mm

1 or 12 parts per box

INDICATIONS FOR USE – GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement can be used for reinforcement of staple lines during lung resection, bronchial, bariatric, colon, colorectal, gastric, mesentery, pancreas and small bowel procedures.

CONTRAINDICATIONS – Not for the patch reconstruction of cardiovascular defects such as cardiac, great vessel and peripheral vascular arteries or veins. Refer to Instructions for Use at goremedical.com for a complete description of all warnings, precautions and contraindications.

SOLUTION FOR

• Bariatric surgeons
• General surgeons
• Thoracic surgeons

PRODUCT REPLACEMENT†

• BAXTER PERI-STRIPS DRY® with VERITAS® Collagen Matrix Staple Line Reinforcement
• MEDTRONIC ENDO GIA Reinforced Reload with TRI-STAPLE Technology

† Based on patient selection criteria, clinicians may utilize GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement in place of the listed products.

BAXTER, PERI-STRIPS DRY and VERITAS are trademarks of Baxter Healthcare Corporation. INTUITIVE is a trademark of Intuitive Surgical, Inc. Covidien and Ethicon are trademarks of Johnson & Johnson. MEDTRONIC, ENDO GIA and TRI-STAPLE are trademarks of Medtronic, Inc. TYVEK is a trademark of E.I. du Pont de Nemours and Company or its affiliates.

* See full product IFUs on goremedical.com as differences exist between GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material Configured for Endoscopic Surgical Staplers and GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material Configured for Intuitive Surgical® Robotic Endoscopic Surgical Staplers.
GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material

Configured for Circular Surgical Staplers

A synthetic buttressing material engineered to reduce perioperative leaks and bleeding in staple line formation.

FOCUS APPLICATIONS
• Roux-en-Y gastric bypass
• Intestine resection
• Colon resection

SOLUTION FOR
• General surgeons
• Colorectal surgeons
• Bariatric surgeons

PRODUCT REPLACEMENT†
• BAXTER PERI-STRIPS DRY® Staple Line Reinforcement

PRODUCT CONSTRUCT
• Preformed porous bioabsorbable discs with detachable adhesive-backed tabs.
• Anvil and cartridge components identical.
• Implant is a porous fibrous structure composed solely of a synthetic bioabsorbable PGA:TMC web scaffold.
• Devices sized ≤ 25 mm are provided with a disposable introducer sleeve as an optional accessory.

SIZES
Configurations specific to stapler diameter and brand /design
Available for select Covidien and Ethicon staplers
0.25 mm thick

INDICATIONS FOR USE – GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement is indicated for use in surgical procedures in which a soft tissue anastomosis with staple line reinforcement is needed. GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement can be used for reinforcement of staple lines during bariatric, colon, colorectal, gastric and small bowel procedures.

CONTRAINDICATIONS – Not for the reconstruction of cardiovascular defects such as cardiac, great vessel and peripheral vascular arteries or veins. Refer to Instructions for Use at goremedical.com for a complete description of all warnings, precautions and contraindications.

‡ Based on patient selection criteria, clinicians may utilize GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement in place of the listed products.

BAXTER and PERI-STRIPS DRY are trademarks of Baxter Healthcare Corporation.

20 years of clinical history
GOER® ENFORM Biomaterial

Soft, conformable, tailorable, tissue reinforcement device designed to achieve abdominal wall repair by contributing to highly vascularized quality tissue and improved wound healing via an acellular matrix that augments tissue infiltration, integration, and regeneration.

FOCUS APPLICATIONS
- Abdominal wall reconstruction
- Hernia repair
- Muscle flap (e.g., TRAM, DIEP) procedures

PRODUCT REPLACEMENT*
(see Value Analysis Committee (VAC) Kit)
- ALLERGAN STRATTICE Reconstructive Tissue Matrix
- BD® PHASIX Mesh and BD® PHASIX ST Mesh
- ETHICON FLEXHD® Acellular Hydrated Dermis
- ACCELL MATRISTEM® Surgical Matrix
- ALLERGAN ALLODERM Regenerative Tissue Matrix

PRODUCT CONSTRUCT
- A fully absorbable device comprised of our unique 3D PGA:TMC bioabsorbable technology.
- Ingrowth surface(s): textured porous fibrous bioabsorbable PGA:TMC web scaffold.
- Intraperitoneal configurations only — visceral surface: smooth, non-textured, perforated bioabsorbable PGA:TMC film. The smooth film side serves to minimize tissue attachment to the device.
- Both preperitoneal and intraperitoneal configurations have a material thickness of ~2.2 mm.

TROCAR COMPATIBILITY EVALUATION

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</table>

* Based on patient selection criteria, clinicians may utilize GOER® ENFORM Biomaterial in place of the listed products.
† More product replacement information is available in the VAC kit. Please ask your local Gore technical sales associate for more information.
‡ Nominal
HERNIA REPAIR AND AWR

GORE® ENFORM
Intraperitoneal Biomaterial

GORE® ENFORM
Preperitoneal Biomaterial

CONFIGURATIONS
Configurations include solutions for both intraperitoneal and preperitoneal placement.

<table>
<thead>
<tr>
<th>GORE® ENFORM Preperitoneal Biomaterial</th>
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INDICATIONS FOR USE—The GORE® ENFORM Preperitoneal / Intraperitoneal Biomaterial is indicated for use in the reinforcement of soft tissue. This includes use in patients requiring soft tissue reinforcement in plastic and reconstructive surgery. Examples of applications where the GORE® ENFORM Preperitoneal Biomaterial may be used include hernia repair as suture-line reinforcement, muscle flap reinforcement and general tissue reconstructions.

CONTRAINDICATIONS—The GORE® ENFORM Preperitoneal / Intraperitoneal Biomaterial is contraindicated for use in reconstruction of cardiovascular defects. Because GORE® ENFORM Intraperitoneal Biomaterial is absorbable, it is contraindicated for use in patients requiring permanent support from the device. Refer to Instructions for Use at goremedical.com for a complete description of all warnings, precautions and contraindications.

Features our unique 3D PGA:TMC bioabsorbable technology

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**FOCUS PRODUCT**

**PRODUCT CONSTRUCT**

- Comprised of synthetic bioabsorbable PGA:TMC
- Textured porous fibrous web surface on both surfaces
- Nominal 1.7 mm thick (HH0710 device is 1 mm thick)

**SIZES**

<table>
<thead>
<tr>
<th>Catalogue number</th>
<th>Size (cm x cm)</th>
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**INDICATIONS FOR USE** – The GORE® BIO-A® Tissue Reinforcement is intended for use in the reinforcement of soft tissue. An example of an application where the GORE® BIO-A® Tissue Reinforcement may be used is hernia repair as suture line reinforcement.

**CONTRAINDICATIONS** – Not for reconstruction of cardiovascular defects. Refer to Instructions for Use at goremedical.com for a complete description of all warnings, precautions and contraindications.

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*Based on patient selection criteria, clinicians may utilize GORE® BIO-A® Tissue Reinforcement in place of the listed products.

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**SOLUTION FOR**

- General surgeons
- Bariatric surgeons

**PRODUCT REPLACEMENT**

- **BD® PHASIX ST Mesh**
- **COOK® BIODESIGN® Advanced Tissue Repair**
- **NOVUS SCIENTIFIC TIGR® Resorbable Matrix**
- **ETHICON VICRYL® Woven Mesh**

---

**HERNIA REPAIR AND AWR**

**FOCUS APPLICATIONS**

Paraesophageal / hiatal hernia repair

10 years of positive clinical results
 Gore® Bio-A® Tissue Reinforcement

Large sizes

Better outcomes. Reinforced by data.
Features our unique 3D PGA:TMC bioabsorbable technology. This is a tissue-building scaffold with a targeted absorption period of six to seven months. Avoid risks for long-term mesh related complications with permanent polypropylene / polyester mesh or long term resorbable mesh (BD® PHASIX Mesh and BD® PHASIX ST Mesh).

Focus Applications
- Abdominal wall reconstruction (including high risk patients)
- Ventral / Incisional hernia repair

Solution for
- General surgeons

Product Replacement† (see VAC Kit)
- BD® PHASIX Mesh
- BD® PHASIX ST Mesh
- NOVUS SCIENTIFIC TIGR® Resorbable Matrix
- ETHICON VICRYL® Woven Mesh

Product Construct
- Comprised of synthetic bioabsorbable PGA:TMC
- Textured porous fibrous web surface on both surfaces
- Nominal 1.7 mm thick

Sizes

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<th>Catalogue number</th>
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Indications for Use – The Gore® Bio-A® Tissue Reinforcement is intended for use in the reinforcement of soft tissue. An example of an application where the Gore® Bio-A® Tissue Reinforcement may be used is hernia repair as suture line reinforcement.

Contraindications – Not for reconstruction of cardiovascular defects. Refer to Instructions for Use at goremedical.com for a complete description of all warnings, precautions and contraindications.

Complex and high-risk repairs
Ventral hernia
Hiatal hernia
Demonstrated economic value

- MORE than 150 publications
- LOW recurrence rates in hiatal hernias
- LOW recurrence rates in complex ventral hernias
- OVER 1,700 patients in the clinical literature
- NO long-term mesh-related complications

† Based on patient selection criteria, clinicians may utilize Gore® Bio-A® Tissue Reinforcement in place of the listed products. BD, PHASIX and PHASIX ST are trademarks of Becton, Dickinson and Company. ETHICON and VICRYL are trademarks of Ethicon, Inc. NOVUS SCIENTIFIC and TIGR are trademarks of Novus Scientific.
**FOCUS PRODUCT**

**GORE® SYNECOR Intraperitoneal Biomaterial**


**FOCUS APPLICATIONS**

Intraperitoneal mesh placement, when there is a need for permanent strength, during:

- Laparoscopic and open ventral hernia repair including robotic procedures
- High-risk ventral hernia repair
- For bridging, where there is a need for permanent strength

**PRODUCT CONSTRUCT**

- 3-layer composite hybrid biomaterial
- **Visceral surface:** nonporous bioabsorbable PGA:TMC film
- **Inner layer:** macroporous knit of dense, monofilament Polytetrafluoroethylene (PTFE) fibers
- **Ingrowth surface:** bioabsorbable PGA:TMC porous fibrous structure
- Nominal thickness between 0.5–0.8 mm

**SOLUTION FOR**

- General surgeons
- Plastic surgeons
- Trauma surgeons

**PRODUCT REPLACEMENT** *(see VAC Kit)*

- **BD® VENTRALIGHT ST Mesh**
- **MEDTRONIC Symbotex Composite Mesh**
- **MEDTRONIC Parietene DS Composite Mesh**
- **MEDTRONIC Progrrip Laparoscopic Self-Fixating Mesh**
- **ETHICON PROCEED® Surgical Mesh**
- **TELA BIO Ovitex Reinforced Scaffold**

**SIZES**

<table>
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<th>Catalogue number</th>
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<th>Size (cm x cm)</th>
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**TROCAR COMPATIBILITY**

GKFV2030 is designed to fit through a 12 mm trocar incision. Similar minimum trocar sizes to GORE® SYNECOR Preperitoneal Biomaterial could be recommended.

**INDICATIONS FOR USE** – The 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 non-absorbable reinforcing or bridging material.

**CONTRAINDICATIONS** – Not for reconstruction of cardiovascular defects. Refer to Instructions for Use at goremedical.com for a complete description of all warnings, precautions and contraindications.

* Based on patient selection criteria, clinicians may utilize GORE® SYNECOR Intraperitoneal Biomaterial in place of the listed products.

† Oval

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**GOlf® SYNECor Preperitoneal Biomaterial**

**High strength. Rapid vascularity.**
Unique hybrid (tri-layer) solution with ingrowth on both sides.

**FOCUS APPLICATIONS**
Preperitoneal, retromuscular, or onlay placement during open, laparoscopic or robotic procedures such as:
- Transversus abdominis release (TAR) procedure
- Component separation technique
- Preperitoneal ventral hernia repair
- High-risk ventral hernia repair when there is need for permanent strength (cannot get fascia closed and need to bridge a hernia defect)

**SOLUTION FOR**
- General surgeons
- Plastic surgeons
- Trauma surgeons

**PRODUCT REPLACEMENT** (See VAC Kit)
- ETHICON PROLENE® Soft Polypropylene Mesh
- ETHICON ULTRAPRO ADVANCED Macroporous Partially Absorbable Mesh
- BD® Soft Mesh
- MEDTRONIC VERSATEX Monofilament Mesh
- MEDTRONIC PARIETENE DS Composite Mesh

**PRODUCT CONSTRUCT**
- 3-layer composite hybrid biomaterial
- **Inner layer**: macroporous knit of dense, monofilament PTFE fibers
- **Ingrowth surfaces (outer layers)**: bioabsorbable PGA:TMC porous fibrous structure
- **Nominal thickness between 0.5–0.8 mm**

**SIZES**

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<th>Catalogue number</th>
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**TROCAR COMPATIBILITY**

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**INDICATIONS FOR USE** — The GORE® SYNECOR Preperitoneal Biomaterial is intended for use in the repair of hernias and abdominal wall soft tissue deficiencies that may require the addition of a non-absorbable reinforcing or bridging material.

**CONTRAINDICATIONS** — Not for reconstruction of cardiovascular defects. Refer to instructions for Use at goremedical.com for a complete description of all warnings, precautions and contraindications.

‡ Based on patient selection criteria, clinicians may utilize GORE® SYNECOR Preperitoneal Biomaterial in place of the listed products.

SB Oval

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FOCUS PRODUCT

9

HERNIA, OTHER SOFT TISSUE RECONSTRUCTION

GORE-TEX® Soft Tissue Patch

Expanded PTFE (ePTFE) reinforcement designed for permanent strength and host tissue incorporation for long-term performance in demanding soft tissue repairs.

FOCUS APPLICATIONS

• Chest wall reconstruction
• Diaphragmatic hernia
• Ventral hernia
• Gastrochisis
• Omphalocoele

SOLUTION FOR

• General surgeons
• Thoracic surgeons
• Pediatric surgeons

PRODUCT REPLACEMENT*

• BD® Mesh (formerly Marlex Mesh)
• BD® RECONIX® ePTFE Reconstruction Patch

PRODUCT CONSTRUCT

• Made completely of ePTFE
• Both ingrowth surfaces are identical
• Available in 1 mm and 2 mm nominal thicknesses

SIZES

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INDICATIONS FOR USE – Reconstruction of hernias and soft tissue deficiencies. 1 mm and 2 mm thicknesses are available. For full thickness or segmental wall defects, use of the GORE-TEX® Soft Tissue Patch 2 mm should be considered.

CONTRAINDICATIONS – Not for reconstruction of: Cardiovascular defects; Orthopedic defects, as the primary load bearing support for segmental replacement of tendons or ligaments; Passive biological membranes such as dura mater, pericardium, or peritoneum. Use of this product in applications other than those indicated has the potential for serious complications, such as aneurysm formation or undesired healing to surrounding tissues. Refer to Instructions for Use at goremedical.com for a complete description of all warnings, precautions and contraindications.

* Based on patient selection criteria, clinicians may utilize GORE-TEX® Soft Tissue Patch in place of the listed products.
† Oval
BD and RECONIX are trademarks of Becton, Dickinson and Company.
FOCUS PRODUCT

GORE® DUALMESH® Biomaterial

First dual-surface material that encourages host tissue ingrowth while minimizing tissue attachment.

FOCUS APPLICATIONS
• Diaphragmatic hernia
• Ventral / incisional hernia
• Chest wall reconstruction
• Open abdomen (temporary bridging)

SOLUTION FOR
• General surgeons
• Trauma surgeons
• Thoracic surgeons

PRODUCT REPLACEMENT
• BD® DULEX Mesh
• BD® COMPOSIX E/X Mesh
• BD® VENTRALEX® Hernia Patch
• MEDTRONIC PARIETEX Composite Parastomal Mesh

PRODUCT CONSTRUCT
• Made completely of PTFE biomaterial
• One textured GORE CORDUROY Surface to encourage host tissue incorporation
• One smooth surface to minimize tissue attachment
• Available in 1 mm and 2 mm nominal thicknesses

SIZES

<table>
<thead>
<tr>
<th>Catalogue number</th>
<th>Size (cm x cm)</th>
<th>Catalogue number</th>
<th>Size (cm x cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 mm thick</td>
<td></td>
<td></td>
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<tr>
<td>1DLMC02</td>
<td>8 x 12</td>
<td>1DLMC06</td>
<td>18 x 24</td>
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<tr>
<td>1DLMC03</td>
<td>10 x 15†</td>
<td>1DLMC07</td>
<td>20 x 30</td>
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<tr>
<td>1DLMC04</td>
<td>15 x 19†</td>
<td>1DLMC08</td>
<td>26 x 34†</td>
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<td>1DLMC05</td>
<td>7.5 x 10</td>
<td>1DLMC09</td>
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<td>2 mm thick</td>
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<tr>
<td>1DLMC200</td>
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<tr>
<td>1DLMC201</td>
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</tr>
<tr>
<td>1DLMC202</td>
<td>18 x 24</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Oval

INDICATIONS FOR USE – Reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects.

CONTRAINDICATIONS – Use of this product in applications other than those indicated has the potential for serious complications, such as aneurysm formation or undesired healing to surrounding tissues. Refer to Instructions for Use at goremedical.com for a complete description of all warnings, precautions and contraindications.

† Based on patient selection criteria, clinicians may utilize GORE® DUALMESH® Biomaterial in place of the listed products.
‡ Oval

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GORE-TEX® Suture

A microporous, monofilament suture of flexible biomaterial for excellent handling, reduced hole-leakage and minimal irritation in soft tissue approximation.

FOCUS APPLICATIONS
- Intraperitoneal mesh placement during:
  - Laparoscopic ventral hernia repair
  - Open ventral hernia repair
  - High-risk ventral hernia repair
  - When there is a need for permanent strength
  - For Robotic Procedures

PRODUCT CONSTRUCT
- Nonabsorbable, monofilament PTFE suture with porous microstructure, approximately 50% air by volume
- Strong and ductile 300 Series stainless steel alloy needles
- Needles approximate thread diameter, allowing suture to fill needle hole, reducing bleeding and time to hemostasis

SIZES
Suture lengths: 18 / 24 / 30 / 36 / 42 / 48 inches
Taper and piercing points, various needle shapes
Some parts available in a double-armed configuration and / or with 1:1 needle to thread ratio

INDICATIONS FOR USE – The GORE-TEX® Suture is indicated for use in all types of soft tissue approximation, including use in cardiovascular surgery. It is recommended for use where reduced suture line bleeding during cardiovascular anastomotic procedures is desired.

CONTRAINDICATIONS – This device is contraindicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue. Refer to Instructions for Use at goremedical.com for a complete description of all warnings, precautions and contraindications.

** Based on patient selection criteria, clinicians may utilize GORE-TEX® Suture in place of the listed products. ETHICON and PROLENE are trademarks of Ethicon, Inc.

for Robotic Procedures
The success of more than 30 million clinical implants is evidence of the quality of Gore Medical Products. Our innovative, ePTFE-based products have demonstrated superior biocompatibility and inertness in a wide range of applications, including: cardiothoracic, vascular and endovascular surgery, neurosurgery, hernia repair, and thoracic reconstruction.

Our products composed of a unique 3D PGA:TMC bioabsorbable technology degrade via a combination of hydrolytic and enzymatic pathways. The copolymer has been found to be both biocompatible and non-immunogenic. In vivo studies with this copolymer indicate the bioabsorption process should be complete by six to seven months.\(^1\)

All general surgical products included in this guide are manufactured in the United States at a Gore facility in Elkonton, MD.

None of the products listed above require refrigeration, pre-wetting or soaking. Products are completely synthetic and do not contain any human or animal derivatives. Hernia and soft tissue repair products can be trimmed with sharp surgical scissors.

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00800 6334 4673 (Europe)
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928 779 2771 (United States)
goremedical.com


Consult 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. Products listed may not be available in all markets.

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