



GORE® BIO-A®
Tissue Reinforcement

BETTER AWR OUTCOMES.
REINFORCED BY DATA.



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® BIO-A® Tissue Reinforcement helps deliver the quality outcomes patients need.

- Helps to improve surgical outcomes for complex patients and providers.¹⁻²
- Repairs with the GORE® BIO-A® Tissue Reinforcement may result in low rates of hernia recurrence/occurrence and low rates of long-term mesh related complications.¹

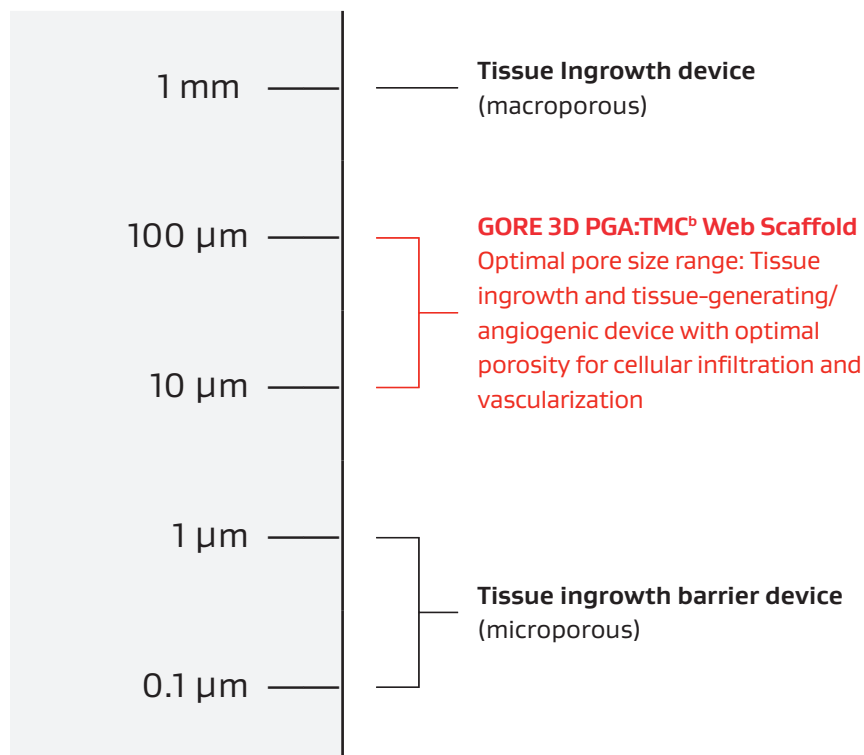
May improve the economics of patient care

- Potential cost-effective alternative to alternate treatment options with mesh in ventral hernia repairs as well as suture alone repairs in hernia prophylaxis.^{a,3}

^a Data on File (cost analysis performed for BTR prophylactic project).

Engineering tissue response with material structure

The effect of pore size^{4,5}



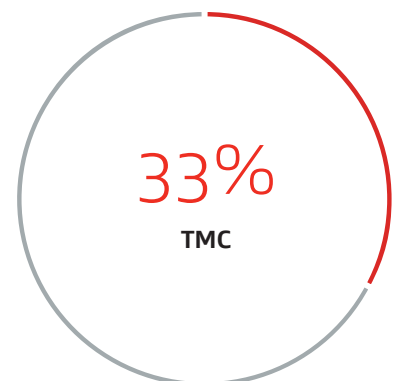
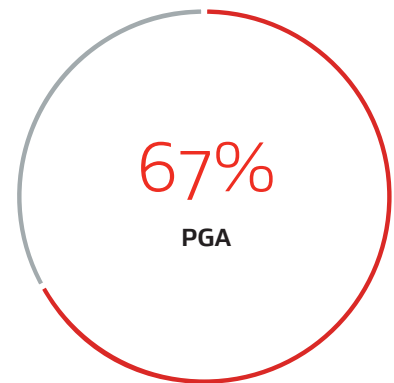
^b Poly (glycolide:trimethylene carbonate) copolymer (PGA:TMC).

GORE® BIO-A®

Tissue Reinforcement

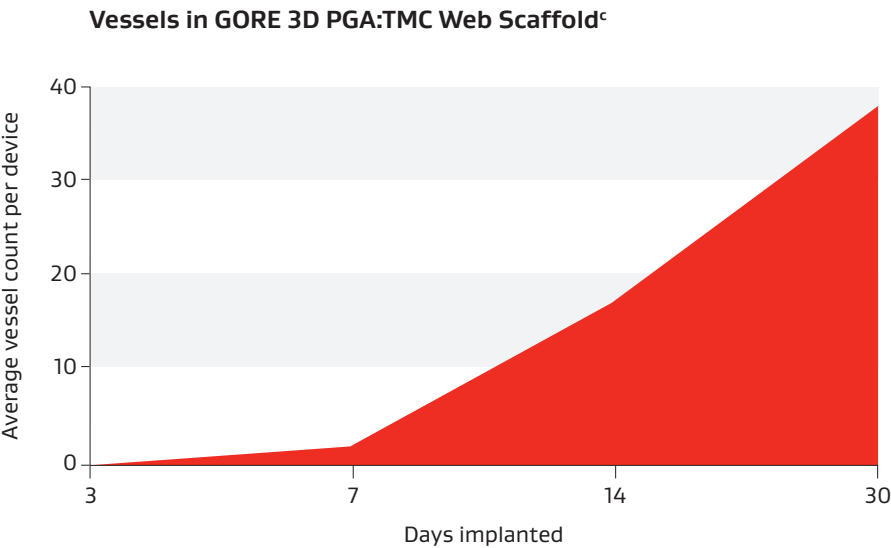
The 3D bioabsorbable tissue-building scaffold that avoids the risk of mesh-related complications after the targeted absorption period of 6 to 7 months.⁶

- Unique 3D scaffold constructed of 67% PGA:33% TMC.
- Highly interconnected, optimal⁴ pore structure elicits tissue response.
- Targeted bioabsorption period supports the critical healing process over 6 to 7 months.
- Material is consistently absorbed by hydrolysis.



GORE 3D PGA:TMC Web Scaffold

Tissue-building scaffold by design



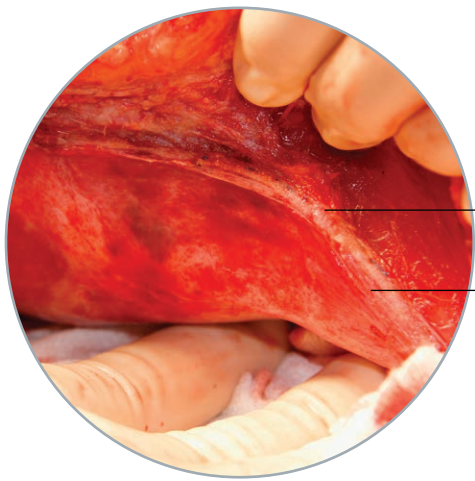
Vascularization begins quickly – **within 1 to 2 weeks**

^c Data on file, W. L. Gore & Associates, Inc; Flagstaff, AZ.

GORE 3D PGA:TMC Web Scaffold – Bioabsorbable web technology designed to facilitate tissue generation

Second look case observation after 4 months

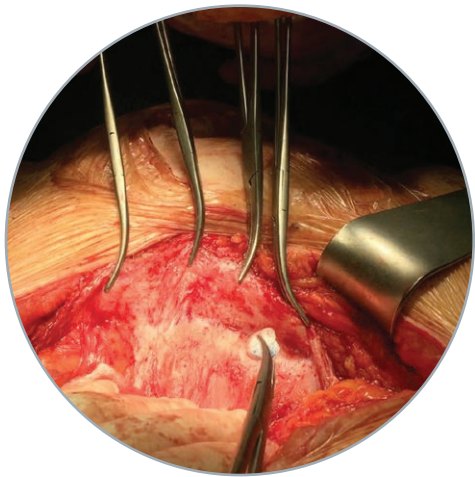
Reoperation following EHS Grade III Classification for parastomal hernia repair at four months for acute intestinal obstruction due to a hard adhesion to the pelvis:



Permanent synthetic mesh

GORE® BIO-A® Tissue Reinforcement

Robust layer of organized collagen
formed and fully replaced the device.



No intra-abdominal adhesions.
Permanent synthetic mesh is not
visible through the peritoneum.

Versatile for numerous applications

Abdominal wall reconstruction

Suture line reinforcement following midline closure.⁷

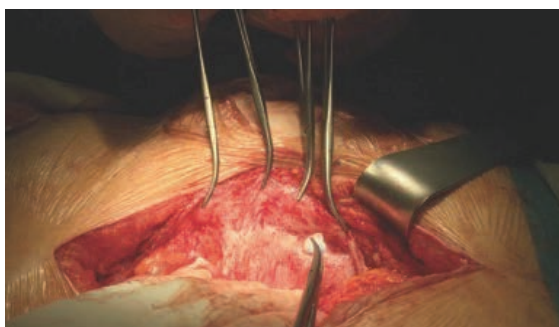
Image courtesy of Garth R. Jacobsen, MD and James J. Chao, MD.
Used with permission.



Complex ventral/ incisional hernia

Robust layer of organized collagen formed and fully replaced the device; no permanent material left in the body.^d

Image courtesy of M.A. Garcia-Urena, MD.
Used with permission.



Hernia prophylaxis

End-colostomy with mesh reinforced closure.⁸

Image courtesy of Francesco Pizza, MD.
Used with permission.



Paraesophageal/ hiatal hernia repair

Onlay following primary closure of crura.^{9,10}

Image courtesy of Timothy B. Ehrlich, MD, FACS.
Used with permission.



^d Data on file, W. L. Gore & Associates, Inc; Flagstaff, AZ.

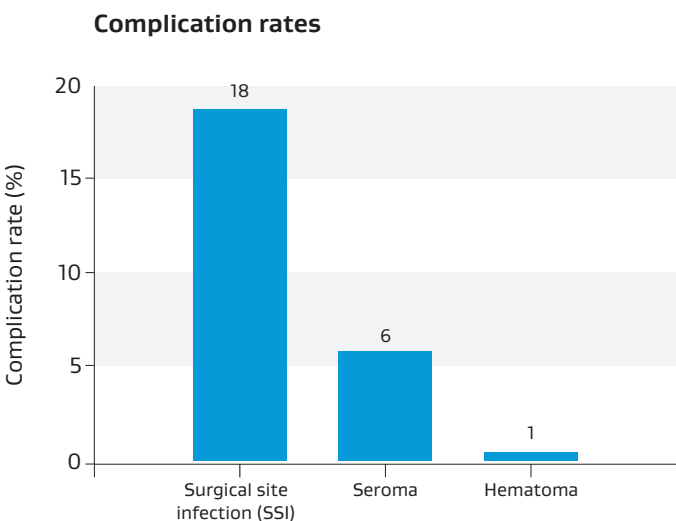
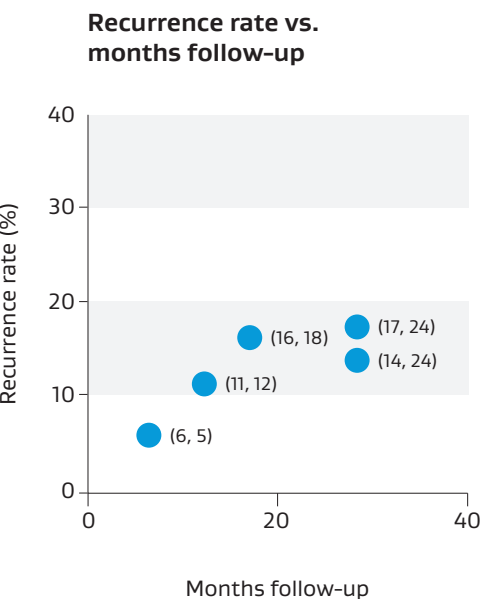
Complex ventral hernia repair

Indication Statement

The GORE® BIO-A® Tissue Reinforcement is intended for use in the reinforcement of soft tissue, including hiatal and ventral hernia repair and hernia prophylaxis as suture-line reinforcement.

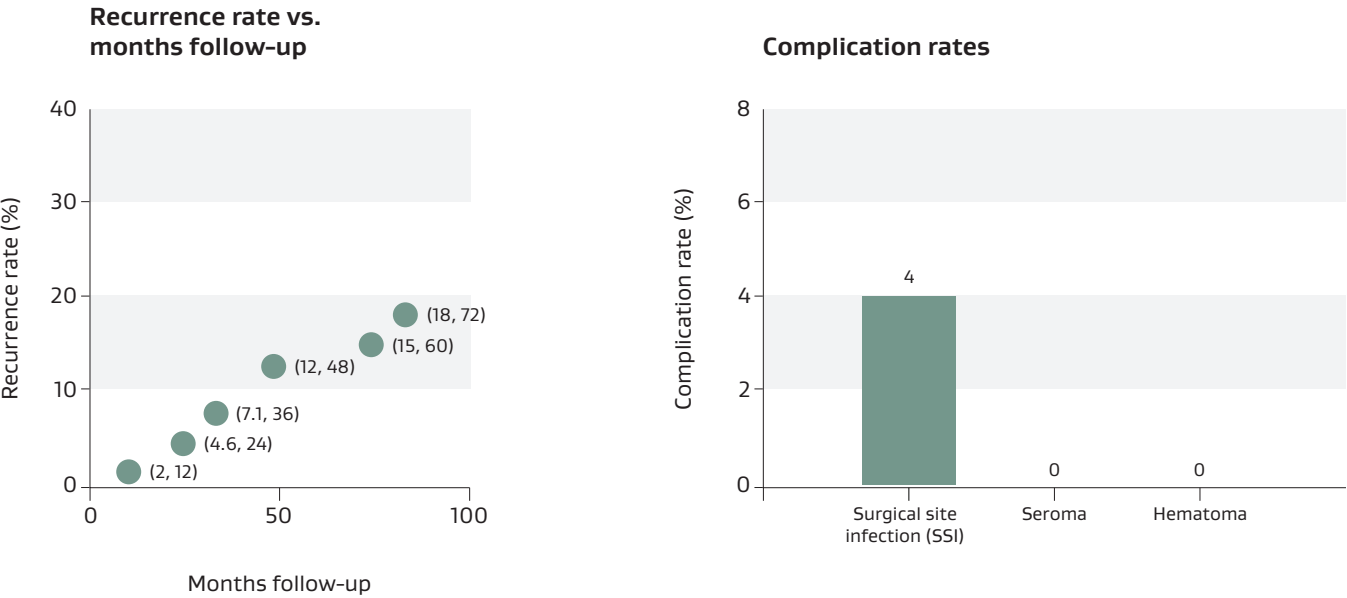
Selected published results: Rosen 2017¹¹

Study type	Number of patients	Demographics
Prospective, multicenter	104	BMI kg/m ² : 28 Recurrent hernia: 45% Active smokers: 19% Diabetes: 18% Mean defect size: 137 cm² CDC class II: 23% CDC class III: 77%



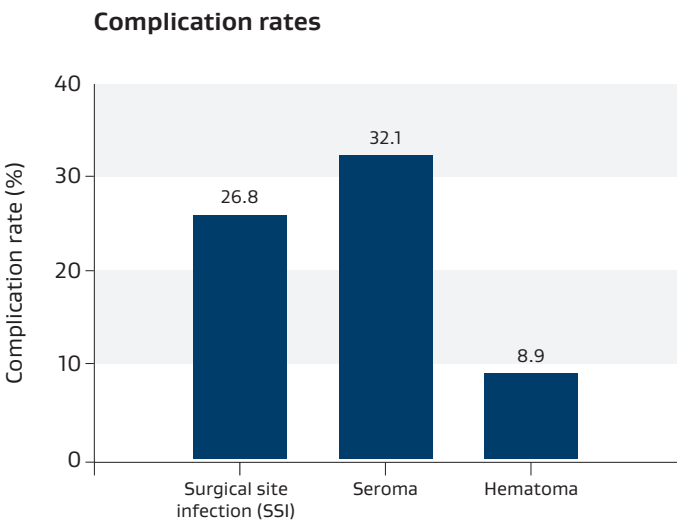
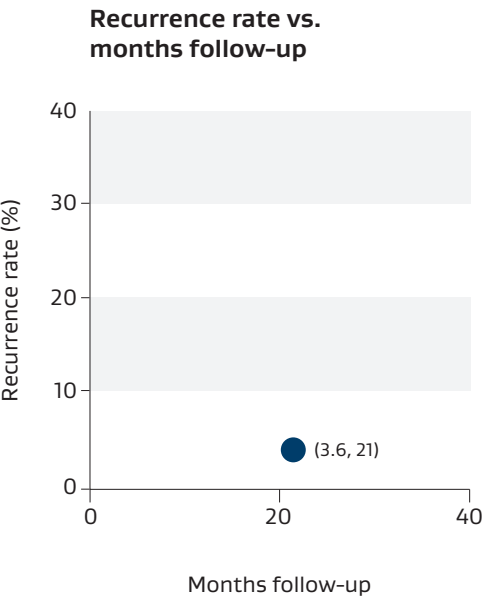
Selected published results: Yu 2022¹²

Study type	Number of patients	Demographics
Retrospective review of prospectively maintained data	49	BMI kg/m ² : 34.4
		Recurrent hernia: 44%
		Active smokers: 12%
		Diabetes mellitus: 6%
		Mean defect size: 163 cm ²



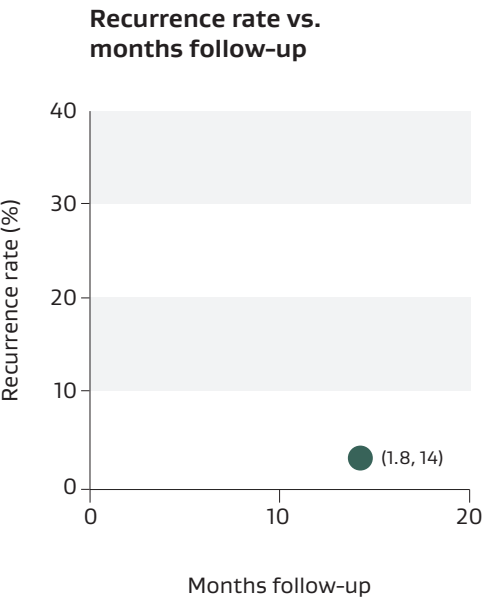
Selected published results: Finch 2021¹³

Study type	Number of patients	Demographics
Retrospective single center review	56	BMI kg/m ² : 29
		Recurrent hernia: 25%
		Active smokers: 23%
		Diabetes mellitus: 25%
		Mean Defect size: 83 cm ²
		CDC class I: 14.3%
		CDC class II: 21.4%
		CDC class III: 1.8%



Selected published results: Keogh 2019¹⁴

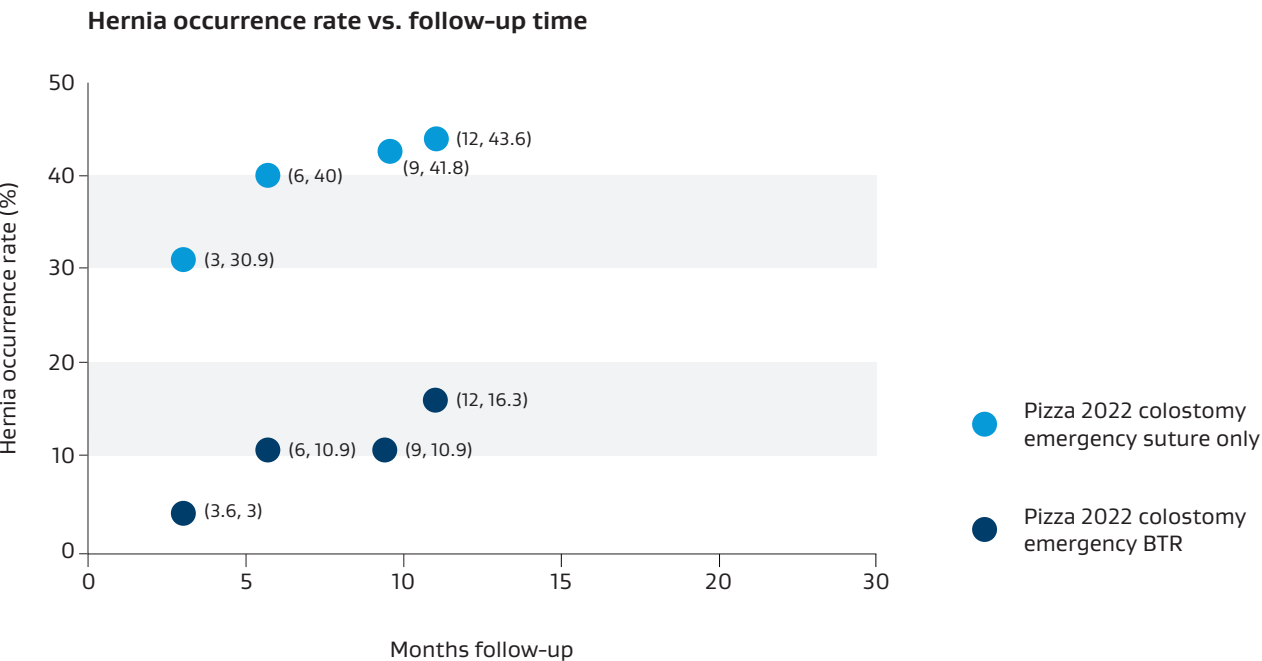
Study type	Number of patients	Demographics
Retrospective review of prospectively maintained data	55 GORE® BIO-A® Tissue Reinforcement	BMI kg/m ² : 33.8 Recurrent hernia: 56% Active smokers: 12% Diabetes mellitus: 6% Mean defect size: NR CDC class clean: 69%/95% CDC class contaminated: 31%/5%
	60 COVIDIEN® PARIETEX® PROGRIP® Self-Fixating Mesh	



Hernia prophylaxis

Selected published results: Pizza 2022⁸

Study type	Number of patients	Demographics	GORE® BIO-A® Tissue Reinforcement	Suture only
Double-blind randomized control trial – Parastomal hernia prevention	55	BMI kg/m ²	28.6	28.1
	GORE® BIO-A® Tissue Reinforcement	ASA I-II (%):	70.9	65.4
	55	ASA III-IV (%):	29.1	34.6
	Suture only	Diabetes mellitus (%):	23.1	27.3
		Oncologic disease (%):	45.4	41.8



NO

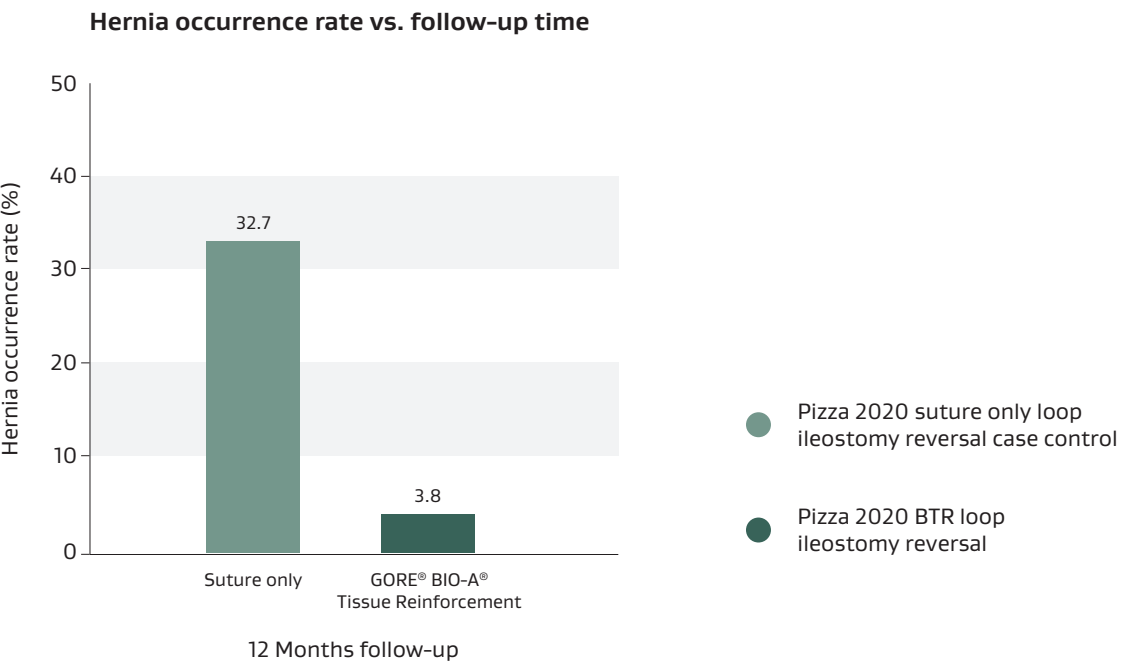
statistically significant difference
in complication rates

NO

mesh removals

Selected published results: Pizza 2020¹⁵

Study type	Number of patients	Demographics	GORE® BIO-A®	
			Tissue Reinforcement	Suture only
Case control – prospective consecutive patients – Loop ileostomy reversal – Incisional hernia prevention	26	BMI kg/m ²	24	23
	GORE® BIO-A®	ASA I-II (%):	85	85
	Tissue Reinforcement	ASA III-IV (%):	15	15
	58	Diabetes mellitus (%):	19	20
	Suture only	Oncologic disease (%):	15	15



NO

statistically significant difference in complication rates

NO

mesh removals

GORE® BIO-A® Tissue Reinforcement: A potential cost-effective solution for reducing hernia occurrence

£2427

estimated savings
per patient

when using GORE® BIO-A® Tissue
Reinforcement to reduce the risk
of ostomy site hernias.^{e,3}

£14.6 million

total estimated savings

when using GORE® BIO-A® Tissue
Reinforcement prophylactically
as suture line reinforcement
for **6,000 patients treated** for
colostomy procedures in the U.K.^{e,3}

^e Data on File (cost analysis performed for BTR prophylactic project).

Hiatal hernia repair

Selected published results

[Diab et al, performed a systematic literature review for GORE® BIO-A® Tissue Reinforcement use in hiatal hernia repair.](#) Results were presented at 2022 American Foregut Society Meeting.¹⁶

[See the results](#)

Overall data summary



Outcomes from **17 studies** and **1,576 patients**:

- Postoperative dysphagia: **15%**
- Persistent dysphagia: **4%**
- Mesh related complications: **0%**
- Symptomatic objective hernia recurrence: **3%**
- Revisional repair: **2%**

Subgroup data summary



Outcomes from **11 studies**
that included mean follow-up duration of **33.4**:

- Postoperative dysphagia: **14%**
- Persistent dysphagia: **3%**
- Mesh related complications: **0%**
- Symptomatic objective hernia recurrence: **4%**
- Revisional repair: **2%**

Gore products referenced within, if any, are used within their approved / cleared indications (FDA or CE Mark). Gore does not have knowledge of the indications and approval / clearance status of non-Gore products or surgical techniques. Gore makes no representations as to the diagnoses, surgical techniques, medical conditions or other factors that may be described in this article. The reader is advised to contact respective manufacturer(s) for current and accurate information.

No Gore materials are derived from human or animal tissue

These biomaterials eliminate the risk of disease transmission by tissue-derived products, residual cellular debris or conflict with religious beliefs/cultural practices.²



Visit: Gore's commitment to sustainability

<https://gmd.cm/VBS-Sustainability>

Imaging

The GORE® BIO-A® Tissue Reinforcement is MR Safe.^f

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

Performance plus value

Ease of use for surgeon and hospital:

- No soaking, refrigeration, or tracking required
- Trimmable
- Three-year shelf life
- Available in large sizes up to 20 cm x 30 cm
- Good value per square cm



Product configuration and sizing chart

Catalogue number	Size
HH0710E	7 cm x 10 cm ⁹
FS0808E	8 cm x 8 cm
FS0915E	9 cm x 15 cm
FS1030E	10 cm x 30 cm
FS2020E	20 cm x 20 cm
FS2030E	20 cm x 30 cm



⁹ Configured for hiatal hernia repair.

References

1. W. L. Gore & Associates, Inc. Clinical Evaluation Report for GORE® BIO-A® Tissue Reinforcement. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2024. [Clinical Evaluation Report – CER]. MD114935. Rev 15.
2. Jenkins ED, Yip M, Melman L, Frisella MM, Matthews BD Informed consent: cultural and religious issues associated with of allogeneic and xenogeneic mesh products. *Journal of the American College of Surgeons* 2010;210(4):402-410.
3. Pizza F, D'Antonio D, Lucido FS, et al. Is absorbable mesh useful in preventing parastomal hernia after emergency surgery? The PARTHENOPE study. *Hernia*. 2022;26(2):507-516.
4. Sharkawy AA, Klitzman B, Truskey GA, Reichert WM. Engineering the tissue which encapsulates subcutaneous implants. II. Plasma-tissue exchange properties. *Journal of Biomedical Materials Research* 1998;40(4):586-597
5. Rosengren A, Bjursten LM. Pore size in implanted polypropylene filters is critical for tissue organization. *Journal of Biomedical Materials Research. Part A* 2003;67(3):918-926.
6. Katz AR, Mukherjee DP, Kaganov AL, Gordon S. A new synthetic monofilament absorbable suture made from polytrimethylene carbonate. *Surgery Gynecology and Obstetrics* 1985;161(3):213-222.
7. Jacobsen GR, Chao JJ. *Clinical use of GORE® BIO-A® Tissue Reinforcement in ventral hernia repair using the components separation technique*. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2018. [Case series]. AX0286-EN1.
8. Pizza F, D'Antonio D, Lucido FS, et al. Is absorbable mesh useful in preventing parastomal hernia after emergency surgery? The PARTHENOPE study. *Hernia* 2022;26(2):507-516.
9. Ehrlich TB. *GORE® BIO-A® Tissue Reinforcement in Hiatal Hernia Repair*. Flagstaff, AZ. W. L. Gore & Associates, Inc; 2008. [Case report]. AM2969-EN1.
10. Zehetner J, Demeester SR, Ayazi S, et al. Laparoscopic versus open repair of paraesophageal hernia: the second decade. *Journal of the American College of Surgeons* 2011;212(5):813-820.
11. Rosen M, Bauer JJ, Harmatz M, et al. Multicenter, prospective, longitudinal study of the recurrence, surgical site infection, and quality of life after contaminated ventral hernia repair using biosynthetic absorbable mesh: the COBRA Study. *Annals of Surgery* 2017;265(1):205-211.
12. Yu JF, Goldblatt HE, Alter-Troilo K, Hetzel E, Goldblatt MI. Long-term outcome of absorbable synthetic mesh in clean ventral hernia repairs. *Surgical Endoscopy* 2022;36(7):5144-5148.
13. Finch D, Mahmood S, Varghese J. Abdominal wall reconstruction using biosynthetic absorbable mesh in high-risk complex ventral hernia. *Swiss Medical Weekly* 2021;151:w20449.
14. Keogh K, Slater K. Comparison of biosynthetic versus synthetic mesh in clean and contaminated ventral hernia repairs. *ANZ Journal of Surgery* 2020;90(4):542-546.
15. Pizza F, D'Antonio D, Arcopinto M, Dell'Isola C, Marvaso A. Safety and efficacy of prophylactic resorbable biosynthetic mesh in loop-ileostomy reversal: a case-control study. *Updates in Surgery* 2020;72(1):103-108.
16. Diab ARF, Sujika JA, Saad AR, DuCoin CG, Docimo S. Bio-A mesh use in hiatal hernia repair. A systematic literature review. Presented at the 2022 American Foregut Society Annual Meeting; September 15-18, 2022; Orlando, FL. *Foregut* 2022;2(3):331. Abstract ID: 47.

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

 Consult Instructions
for Use
eifu.goremedical.com

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. Rx Only

Products listed may not be available in all markets.

© 2025 W. L. Gore & Associates, Inc. All rights reserved. All trademarks referenced are trademarks of either a member of the Gore group of affiliated companies or their respective owners. "Together, improving life" mark and design are trademarks of a Gore company.
25SS6008-EN01 DECEMBER 2025

W. L. Gore & Associates, Inc.
goremedical.com

Asia Pacific +65 6733 2882 Australia/New Zealand 1800 680 424 Europe 00800 6334 4673
United States Flagstaff, AZ 86004 800 437 8181 928 779 2771

