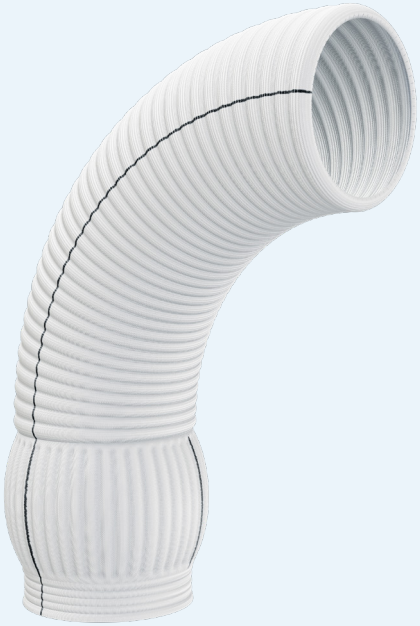
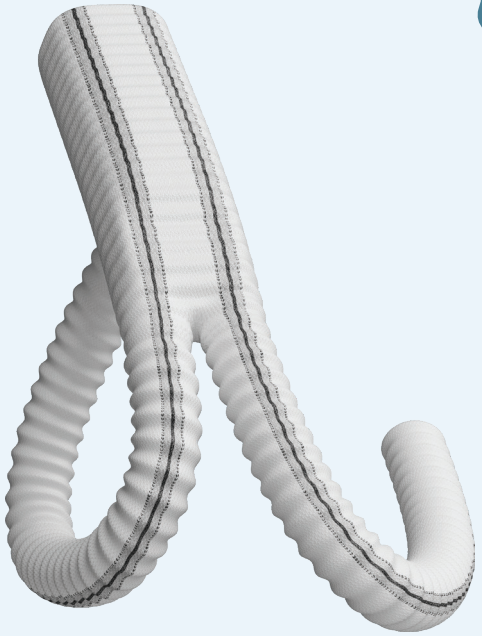


Gelweave™

Woven Aortic Surgical Graft



Gelsoft™ Plus

Knitted Aortic Surgical Graft

Decades of Trust, Sealed with Innovation.

Confidence. Reliability. Control.

For more information, visit
terumoaortic.com

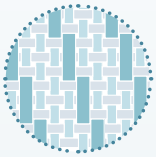
TERUMO AORTIC

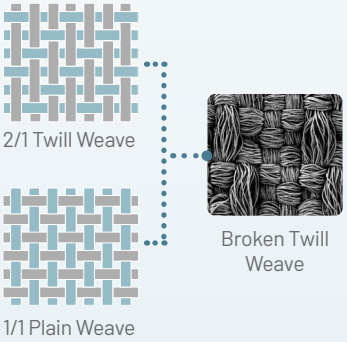
Confidence

For over 40 years, Terumo Aortic's manufacturing facility in Scotland has provided high quality aortic grafts to the world's aortic surgery community. The company offers two umbrella brands in the open surgical graft classification; Gelweave™ and Gelsoft™ Plus. Both are made with proprietary medical textiles technology and hand-finished with specialist artisan skill.

Gelweave™

Woven Aortic Surgical Graft



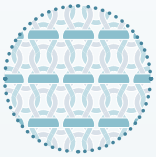


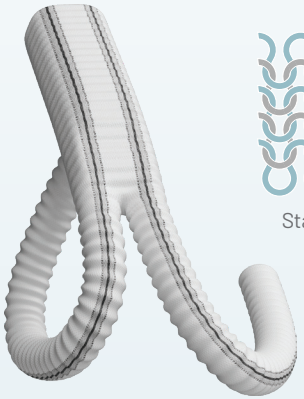
Wall Thickness (crimped)*	Suture Retention*	Burst Strength*	Dilatation Rate*
0.35mm	18.31N (1,867g)	362N	2.36%

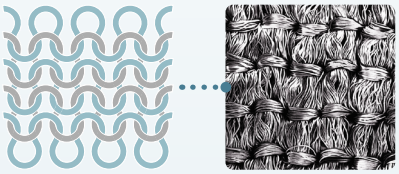
Broken Twillweave polyester features in Thoracic Vascular grafts where enhanced burst strength and minimal dilatation rates cater for local cyclical intra-aortic pressure and graft shape maintenance.**

Gelsoft™ Plus

Knitted Aortic Surgical Graft







Wall Thickness (crimped)*	Suture Retention*	Burst Strength*	Dilatation Rate*
0.62mm	23.71N (2,417g)	297N	5.75%

Köper Knitted polyester features in Abdominal Vascular grafts where burst strength matches typical local aortic pressure and dilatation rates** are improved compared to other knitted grafts[1,2] to resist the development of a graft aneurysm causing pressure on surrounding tissues and possibly leading to catastrophic graft rupture.[3]

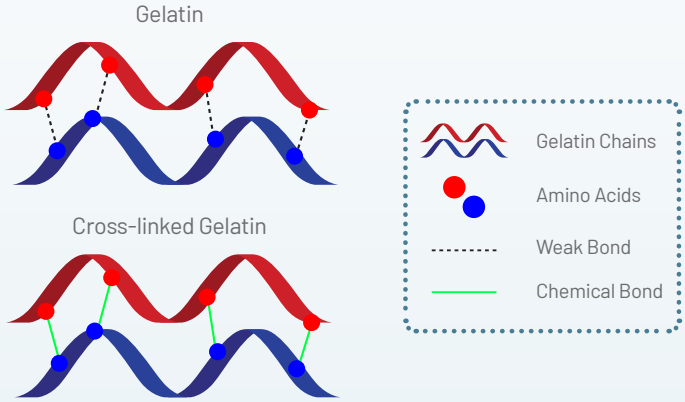
Terumo Aortic's open surgical portfolio meets established internal quality control criteria and maintains compliance with MDR standards, including conformity to ISO 7198:2016**

* Internal Terumo Aortic bench-top testing results, per ISO 7198:2016 International Standards.
** Data on file at Terumo Aortic.

Reliability & Control

Terumo Aortic uses chemically cross-linked gelatin as a sealant to optimise biodegradation [4], minimise the potential of graft derived infection [5] and improve sealant strength and stability. [6] The increased permeability resistance minimises bleeding through the graft wall optimising peri-operative visibility and handling. [4]

- Cross-linked Gelatin minimises graft porosity, improving peri-operative practicality [4]
- Total resorption ~ 14 Days compared with 2-6 months for collagen [7,8]
- Faster healing/cell ingrowth compared to collagen [4,8]
- Antibiotic bonding possible, offering further infection prevention [8,†]



Recent peer reviewed evidence has shown that compared with gelatin sealed grafts, "**collagen-coated grafts were associated with increased biofilm formation and bacterial adherence** in vitro and with **higher rates of perioperative vascular graft infections** in vivo."[9]

Every surgical graft is tested for permeability prior to packaging and shipping.

99% Freedom from graft leakage [10]

98% Freedom from suture hole leakage [11]

*"Very early on I switched to using the Gelweave™ grafts. In part because of the **Gelatin impregnation with the sealing of the interstices**... and I put antibiotic solution with it: we would **soak them in Rifampin† which was the best in the studies**."*

*"I liked the way the graft **handled**, the way it **sutured**, the way it **molded to the anatomy** etc and just with that experience I moved over to it years ago and **I've used it extensively** ever since."*

Joseph S Coselli M.D, FACS | Through the Lens of Innovation: Episode 2

Watch the full video **here:**

† Not cleared by the FDA for use in the USA - Procedural guidance is based on physician preference and opinion derived from their observations and experience.

1. Goëau-Brissonnière O.A. *et al*, (2000). 'Can knitting structure affect dilation of polyester bifurcated prostheses? A randomized study with the use of helical computed tomography scanning.' *Journal of Vascular Surgery*, 31 (1), pp157-158.

2. Walker D. *et al*, (1995). 'Novel structure for a polyester vascular prosthesis with improved mechanical properties.' *Society for Biomaterials*.

3. Schroeder T. *et al*. (2009) 'Dilatation of Aortic Grafts Over Time: What to Expect and When to be Concerned.' *Seminars in Vascular Surgery*. June; 22(2): pp119-124

4. Drury J. *et al*. (1987). 'Experimental and Clinical Experience with a Gelatin Impregnated Dacron Prosthesis.' *Annals of Vascular Surgery*, 1(5), pp542-547.

5. Hayes *et al.* (1999). 'In situ replacement of infected aortic grafts with Rifampicin-bonded prostheses: the Leicester experience (1992 to 1998).' *Journal of Vascular Surgery*, 30, pp92-98.

6. Vohra, R. *et al.* (1987) 'Sealed versus unsealed knitted Dacron prostheses: a comparison of the acute phase protein response.' *Annals of Vascular Surgery*, 5 (1): pp548-551.

7. Barber G. *et al.* (1990). 'Immunologic response to collagen-impregnated vascular grafts: A randomized prospective study.' *Journal of Vascular Surgery*, 12(6): pp741-746.

8. Helfer E. *et al.* (2022). 'Vascular grafts collagen coating resorption and healing process inhumans.' *JVS-Vascular Science*, 3: pp193-204.

9. Schweizer T.A. *et al.* (2020). 'Polyester Vascular Graft Material and Risk for Intracavitary Thoracic Vascular Graft Infection.' *Emerging Infectious Diseases*, 26 (10): pp2248-2452.

10. Based on internal Terumo Aortic data from PANTHER Study; Intraoperative Graft Leakage – (Percentages reported out of 649 Gelweave responses, 405 Gelweave Valsalva responses, 397 Gelsoft Plus responses). Physicians reported no graft leakage in 99% of both Gelweave and Gelsoft Plus cases. Data based on completed surveys at time of publishing. PANTHER Study - Device Assessment Data Export 10APR2024.

11. Based on internal Terumo Aortic data from PANTHER Study; Intraoperative Suture Hole Bleeding– (Percentages reported out of 650 Gelweave responses, 405 Gelweave Valsalva responses, 397 Gelsoft Plus responses). Physicians reported no suture hole leakage in 98% of both Gelweave and Gelsoft Plus cases. Data based on completed surveys at time of publishing. PANTHER Study - Device Assessment Data Export 10APR2024.

NB. All references listed relating to Terumo Aortic grafts feature earlier generations of cross-linked gelatin. (Internal Terumo Aortic data from the PANTHER study on devices feature non-SYGMa gelatin. Data from PANTHER on devices with SYGMa gelatin will be included when available).

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Product availability subject to local regulatory approval. For distributor information, visit terumoaortic.com/contact

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