



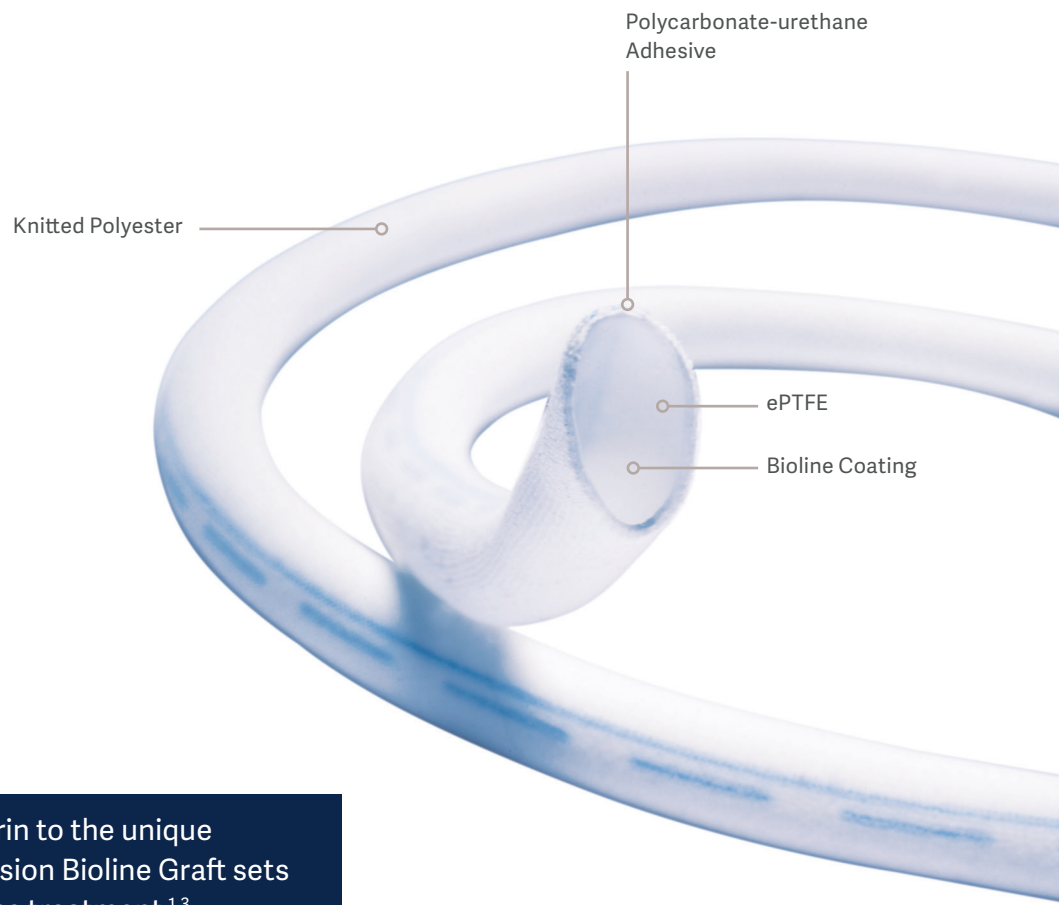
Fusion Bioline Vascular Graft

Heparin Coated Vascular Graft

Combining ePTFE, PET and Heparin

The inner layer is comprised of ePTFE.¹ The Bioline heparin coating is bonded to this inner layer with albumin, the main blood protein found in human blood.¹ The outer layer is a knit polyester textile.¹ These two layers are fused together with a proprietary polycarbonate-urethane.¹

- Smooth luminal surface of PTFE²
- Tissue ingrowth properties of PET¹
- Reduced time to hemostasis¹
- Reduced hemostatic agent usage³
- Enhanced thromboresistance of heparin³



By adding the benefits of heparin to the unique dual-layer construction, the Fusion Bioline Graft sets a standard for peripheral bypass treatment.^{1,3}

Enhancing Graft Performance^{3,4,5}

Fusion Bioline Vascular Grafts:

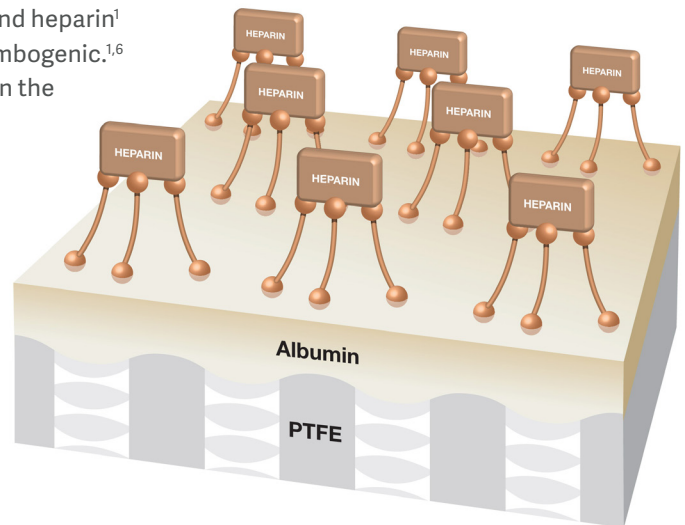
Delivering benefits during and after surgery

- Minimal suture hole bleeding for improved hemostasis³
- Axial compliance designed to help reduce tension on the anastomosis^{1,2}
- High suture retention strength and durability¹

The Fusion Bioline graft is available with a removable external support.¹

Getinge Bioline coating

Bioline coating is composed of recombinant human albumin and heparin¹ — a substance widely known as a safe and effective anti-thrombogenic.^{1,6} The Bioline process includes 3 layers of heparin and albumin on the graft which allows for a sustained effect.¹ Albumin, acting in a complementary role of bonding agent and facilitator, is a contributor to Bioline's exceptional performance.^{3,7} Covalent bonds between the heparin molecules and the albumin layer provide stability of the coating.¹



FINEST Trial Data — Patency

The Fusion Bioline graft was developed to improve the patency rate associated with standard prosthetic grafts. The FINEST Trial was designed to assess the clinical outcome of heparin-coated and standard vascular grafts in a prospective, randomized, controlled, multicenter trial.³

- 209 patients
- Prosthetic femoral to above-knee or below-knee popliteal bypass surgeries
- Randomized to receive a standard ePTFE graft or the Fusion Bioline vascular graft
- Grafts were assessed at 30 days, 6 months, and 12 months.

Primary patency at 12 months

Efficacy population	Standard ePTFE (n=100)	Fusion Bioline (n=103)	Difference	P-value
Patency	67.0%	76.5%	9.5%	0.05

	Standard PTFE (n=100)	Fusion Bioline (n=103)
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Site of Proximal Anastomosis

External Iliac	2 (2.0%)	2 (1.9%)
Common Femoral	94 (94.0%)	99 (96.1%)
Profunda Femoral	1 (1.0%)	0 (0.0%)
Superficial Femoral	2 (2.0%)	2 (1.9%)
Other	1 (1.0%)	0 (0.0%)

Site of Distal Anastomosis

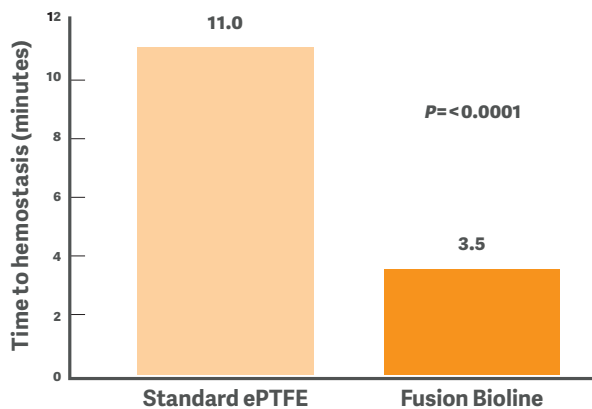
Above Knee (AK)	86 (86.0%)	88 (85.4%)
Below Knee (BK)	14 (14.0%)	14 (13.6%)
Other	0 (0.0%)	1 (%)

FINEST Trial Data — Hemostasis

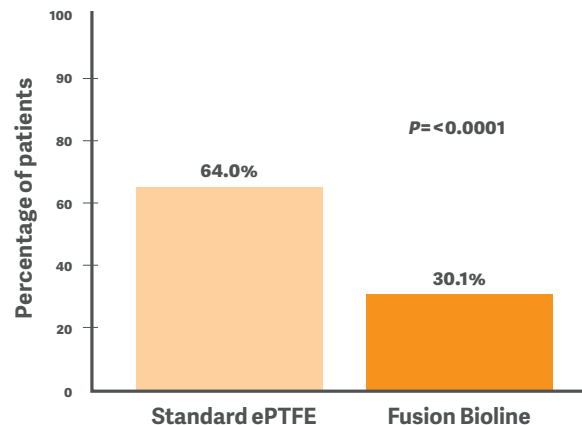
Fusion Bioline Vascular Graft demonstrated significantly shorter time to hemostasis³

- Suture-hole bleeding times were significantly shorter with Fusion Bioline ($P < 0.0001$); observed mean times to hemostasis were 3.5 minutes for Fusion Bioline Vascular Graft vs. 11.0 minutes for the Standard ePTFE graft.

Time to hemostasis



Use of hemostatic agent



Conclusions:

- Fusion Bioline Heparin Coated Vascular Graft demonstrated higher primary patency rates at 12 months as compared to Standard ePTFE in a prospective randomized controlled trial
- Fusion Bioline Heparin Coated Vascular Graft demonstrated significantly shorter time to hemostasis as compared to Standard ePTFE
- The percentage of subjects with any MALE (Major Adverse Limb Event) and POD (Periprocedural Death) was significantly higher in the Standard ePTFE group than in the Fusion Bioline group. MALE/POD occurred in 30.7% and 17.1% respectively for the Standard ePTFE and Fusion Bioline groups at 12 Months ($P = 0.033$)

Product Information

Straight



Diameter	Length	Reference
5 mm	40 cm	M00201501045B0
5 mm	80 cm	M00201501085B0
6 mm	20 cm	M00201501026B0
6 mm	40 cm	M00201501046B0
6 mm	60 cm	M00201501066B0
6 mm	80 cm	M00201501086B0
7 mm	40 cm	M00201501047B0
7 mm	80 cm	M00201501087B0
8 mm	40 cm	M00201501048B0
8 mm	60 cm	M00201501068B0
8 mm	80 cm	M00201501088B0
10 mm	40 cm	M00201501041B0
10 mm	80 cm	M00201501081B0

Straight Externally Supported



Diameter	Length	Reference
5 mm	40 cm	M00201503045B0
5 mm	80 cm	M00201503085B0
6 mm	40 cm	M00201503046B0
6 mm	60 cm	M00201503066B0
6 mm	80 cm	M00201503086B0
7 mm	40 cm	M00201503047B0
7 mm	80 cm	M00201503087B0
8 mm	40 cm	M00201503048B0
8 mm	60 cm	M00201503068B0
8 mm	80 cm	M00201503088B0
10 mm	40 cm	M00201503041B0
10 mm	80 cm	M00201503081B0

1. Data on file at Maquet.
2. Cronwett & Johnston, et al. *Rutherford's Vascular Surgery* 8th ed., Vol 2, Elsevier, 2014.
3. Lumsden, et al. Randomized controlled trial comparing the safety and efficacy between the FUSION BIOLINE Heparin-Coated Vascular Graft and EXXCEL Soft ePTFE (FINEST) Trial., *Journal of Vascular Surgery* Mar 2015.
4. Feyrer, et al. Reduction of Neuropsychological Dysfunction after Cardiac Surgery with Heparin-coated Cardiopulmonary Bypass Circuits: *Kardiotechnik* 01/1998.
5. Palatianos GM, Foroulis CN, Vassili MI, et al. A prospective, double-blind study on the efficacy of the bioline surface-heparinized extracorporeal perfusion circuit; *Ann Thoracic Surg* 2003 Jul;76(1):129-35.
6. Bosse D, Praus M, Kiessling P, et al. Phase I comparability of recombinant human albumin and human serum albumin. *J Clin Pharmacol.* 2005 Jan;45(1):57-67.
7. Amiji M, Park K. Surface modification of polymeric biomaterials with poly(ethylene oxide), albumin, and heparin for reduced thrombogenicity. *J Biomater Sci Polym Ed.* 1993;4(3):217-234.



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