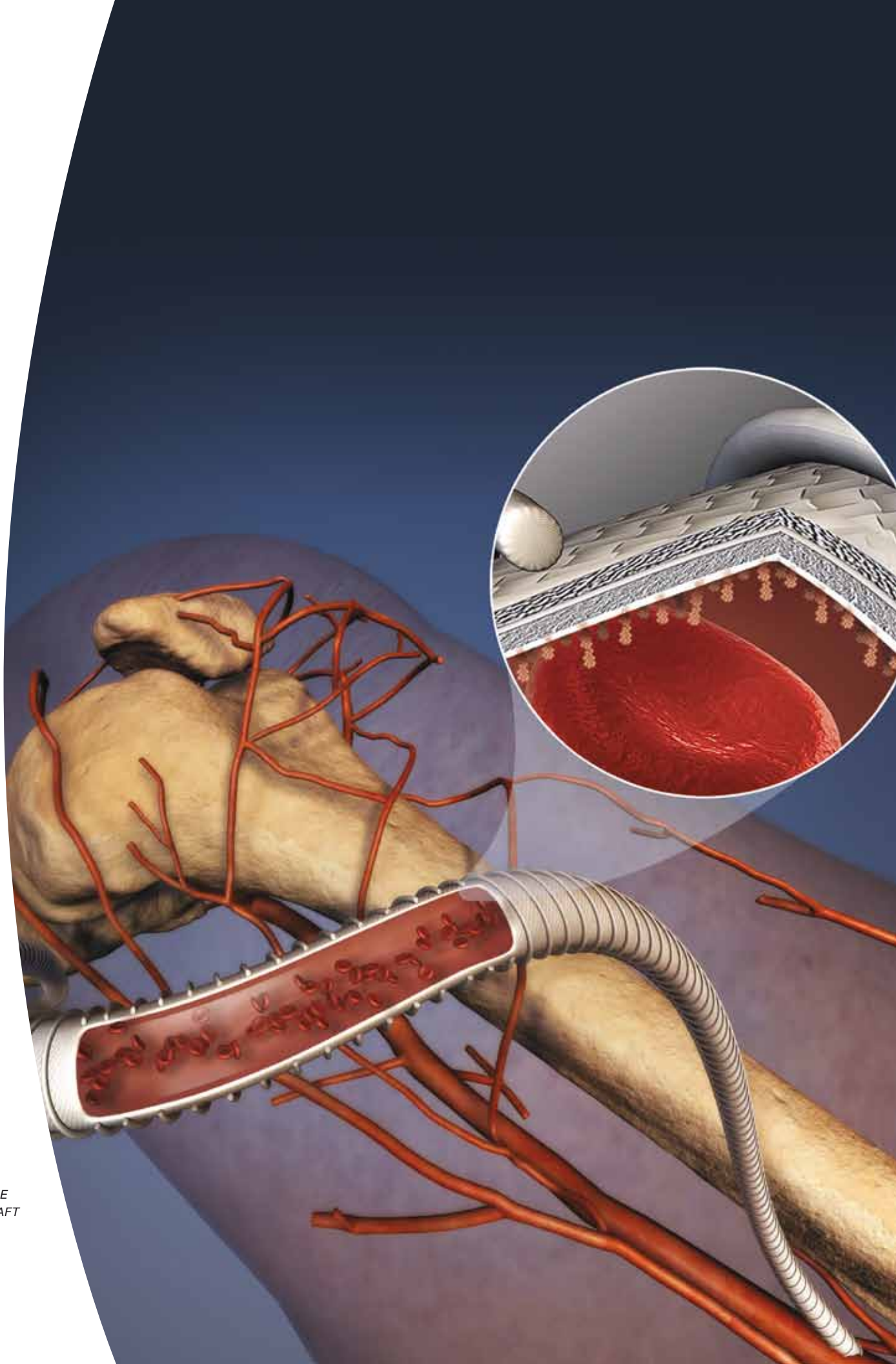


MAQUET
GETINGE GROUP

FUSION BIOLINE VASCULAR GRAFT
AN EVOLUTION IN HEPARIN
COATED GRAFTS





FUSION BIOLINE
VASCULAR GRAFT
*Revolutionizing
Vascular Grafts,
Inside and Out*

FUSION BIOLINE VASCULAR GRAFT

ENHANCING GRAFT PERFORMANCE

The **MAQUET line of FUSION grafts** merges ePTFE with PET to offer vascular surgeons the best of both materials:

- Easy handling of polytetrafluoroethylene (ePTFE)
- Minimal suture hole bleeding compared to ePTFE grafts

FUSION BIOLINE vascular grafts build on this revolutionary design with the addition of a heparin coating designed to enhance thromboresistance.

MAQUET BIOLINE coating

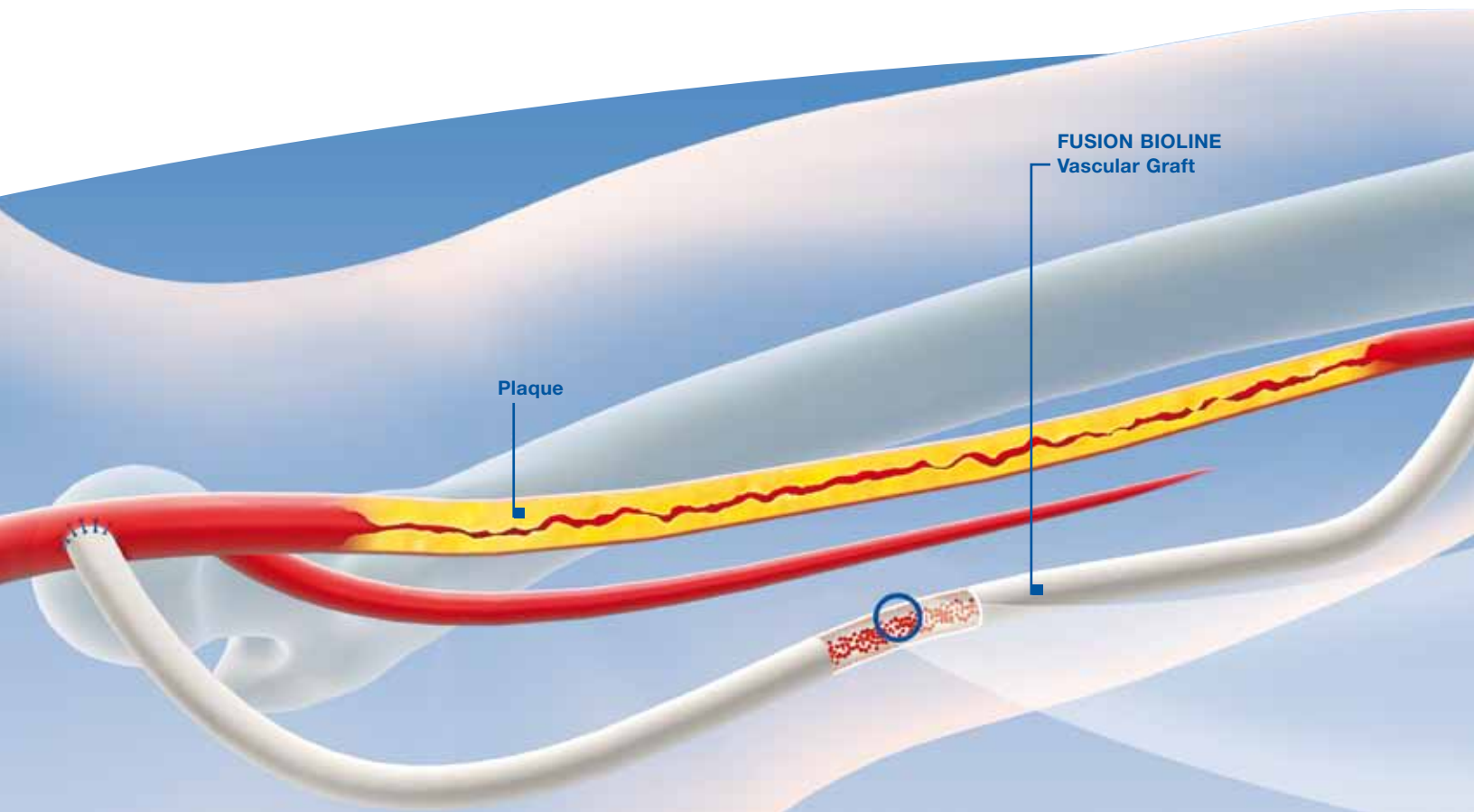
BIOLINE coating is composed of recombinant human albumin and heparin—a substance widely known as a safe and effective anti-thrombogenic. Covalent bonds between the heparin molecules and the albumin layer provide stability of the coating.

The BIOLINE coating has successfully been used on MAQUET's Cardiopulmonary line since 1995. BIOLINE coating on the Cardiopulmonary products has demonstrated a reduction in clotting activity¹ and a reduction of platelet adhesion and thrombi creation.^{2,3}

By adding the benefits of heparin to the unique FUSION dual-layer construction, the FUSION BIOLINE graft sets a new standard for peripheral bypass treatment.



Grafts after 1 hour in blood loop study using hypercoagulable blood model



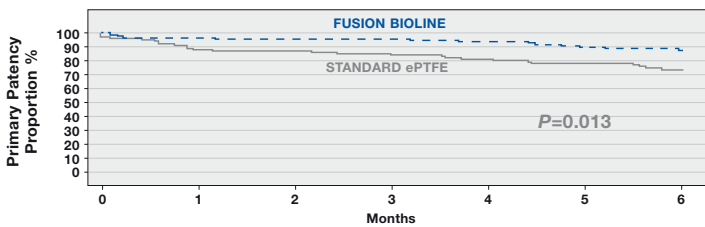
FUSION BIOLINE Vascular Graft Demonstrates Clinically Improved Patency⁵

Primary Patency at 6 Months

EFFICACY POPULATION	STANDARD ePTFE (n=100)	FUSION BIOLINE (n=103)	DIFFERENCE	P-VALUE
Patency	70.0%	86.4%	16.4%	<0.0001

Study design included Fem Pop AK & BK patients.

Kaplan-Meier 6 Month Primary Patency (Efficacy Analysis Population)



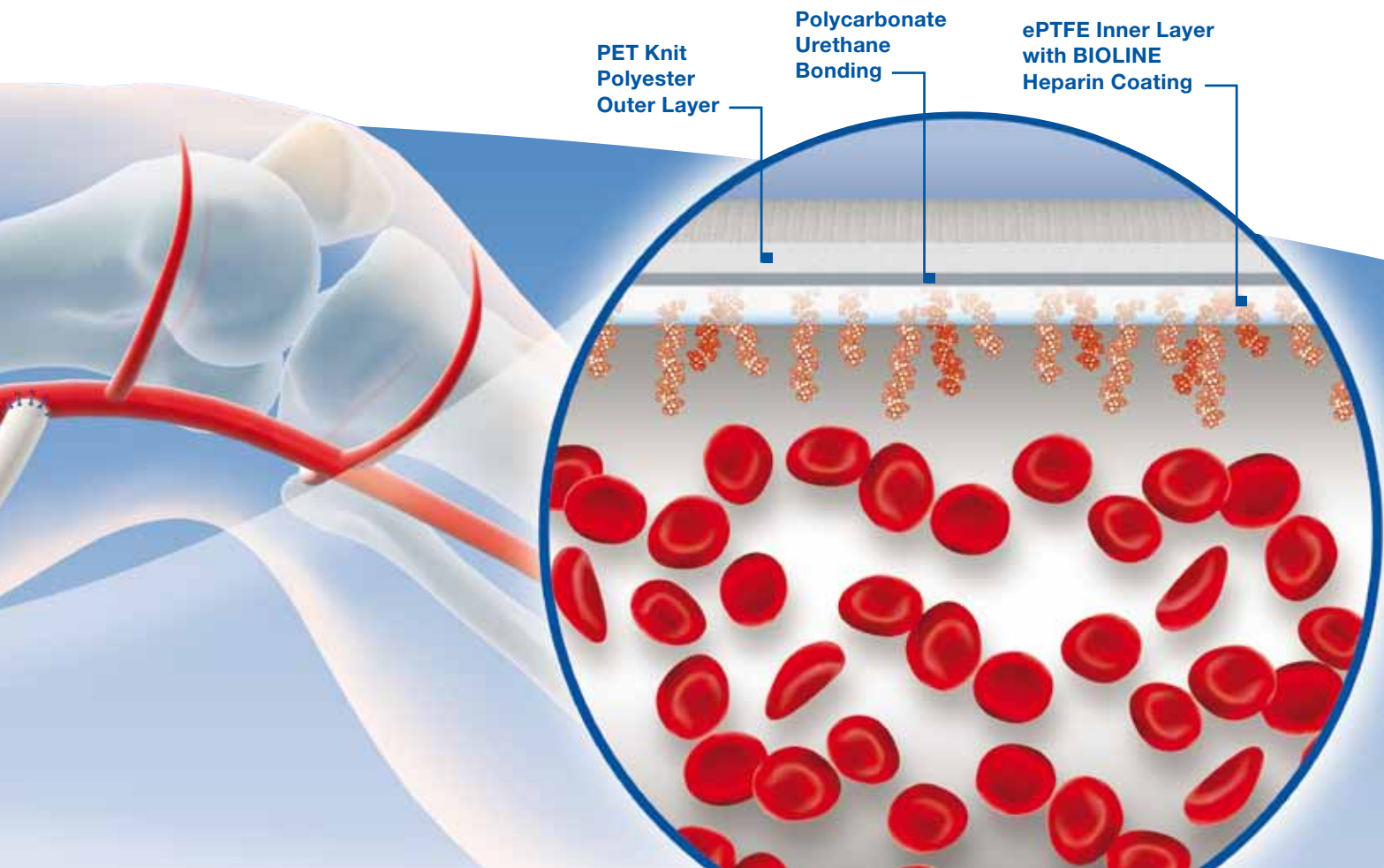
FUSION BIOLINE Vascular Grafts:

Delivering benefits during and after surgery⁴

- Axial compliance designed to help reduce tension on the anastomoses⁴
- High suture retention strength and durability⁴
- Kink resistant to help maintain blood flow across joints and bends⁴
- Minimal suture hole bleeding for improved hemostasis⁴
- Crush resistant to help enhance flow dynamics⁴

Dual-layer Construction: ePTFE and PET Layers

FUSION BIOLINE vascular graft is constructed of two layers. The inner layer is comprised of ePTFE. The BIOLINE heparin coating is bonded to this inner layer with albumin, the main blood protein. The outer layer is a knit polyester textile. These two layers are fused together with a proprietary polycarbonate-urethane adhesive.

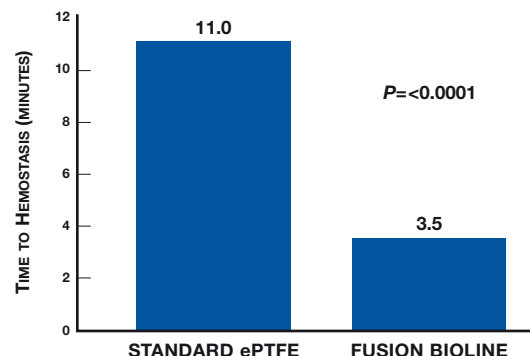


FUSION BIOLINE VASCULAR GRAFT

TIME TO HEMOSTASIS

FUSION BIOLINE Vascular Graft Demonstrated Significantly Shorter Time to Hemostasis

- 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 group



CONCLUSIONS

- FUSION BIOLINE heparin coated vascular graft demonstrated significantly higher primary patency rates at 6 months as compared to Standard ePTFE
- 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 29.7% and 14.3% respectively for the Standard ePTFE and FUSION BIOLINE groups at 6 Months ($P = 0.011$)

PRODUCT INFORMATION

STRAIGHT GRAFTS

UPN	Order Number	Diameter (mm)	Length (cm)
M00201501045B0	501045B	5	40
M00201501085B0	501085B	5	80
M00201501026B0	501026B	6	20
M00201501046B0	501046B	6	40
M00201501066B0	501066B	6	60
M00201501086B0	501086B	6	80
M00201501047B0	501047B	7	40
M00201501087B0	501087B	7	80
M00201501048B0	501048B	8	40
M00201501068B0	501068B	8	60
M00201501088B0	501088B	8	80
M00201501041B0	501041B	10	40
M00201501081B0	501081B	10	80

STRAIGHT EXTERNALLY SUPPORTED GRAFTS

UPN	Order Number	Diameter (mm)	Length (cm)
M00201503045B0	503045B	5	40
M00201503085B0	503085B	5	80
M00201503046B0	503046B	6	40
M00201503066B0	503066B	6	60
M00201503086B0	503086B	6	80
M00201503047B0	503047B	7	40
M00201503087B0	503087B	7	80
M00201503048B0	503048B	8	40
M00201503068B0	503068B	8	60
M00201503088B0	503088B	8	80
M00201503041B0	503041B	10	40
M00201503081B0	503081B	10	80

All grafts are fully supported except 3 cm on one end.

1. Fraedrich, et al. A New Covalent Heparin Bonding Process of Extracorporeal Circuits Improves the Hemocompatibility of Cardiopulmonary Bypass Equipments: Clinical study presented at the 23rd Congress of the German Society for Thoracic and Cardiovascular Surgery, Germany, 1995.
 2. Feyrer, et al. Reduction of Neuropsychological Dysfunction after Cardiac Surgery with Heparin-coated Cardiopulmonary Bypass Circuits: *Kardiotechnik 01/1998*.
 3. 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.
 4. Data on file at MAQUET.
 5. FUSION BIOLINE IFU
- FUSION BIOLINE vascular grafts are designed to repair or replace peripheral arteries.

MAQUET

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