

Omniflow® II

Biosynthetic Vascular Prosthesis



Omniflow® II

Biosynthetic Vascular Prosthesis

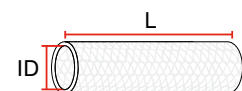
The Biosynthetic Solution for Peripheral Revascularization and Arteriovenous Vascular Access

Omniflow II - The biosynthetic solution

The Omniflow II Biosynthetic Vascular Prosthesis is an innovative graft that is composed of cross-linked ovine collagen and a polyester mesh endoskeleton. The graft offers a solution for peripheral reconstruction and vascular access for haemodialysis when vein is not available.

Omniflow II VASCULAR PROSTHESIS - STRAIGHT

- For peripheral revascularisation or straight arteriovenous access.
- Available in diameters of 5, 6, 7* and 8 mm and lengths of 20 - 65 cm.

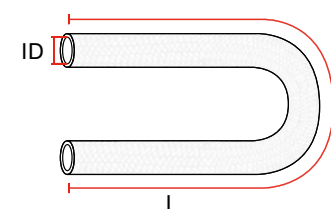


Minimum Length (L)	Model # [REF]	Model # [REF]	Model # [REF]	Model # [REF]
Internal Diameter (ID)	5 mm	6 mm	7 mm*	8 mm
20 cm	751-520	751-620	751-720	751-820
30 cm	751-530	751-630	751-730	751-830
40 cm	751-540	751-640	751-740	751-840
50 cm	751-550	751-650	751-750	751-850
60 cm	751-560	751-660	751-760	751-860
65 cm	751-565	751-665	751-765	751-865

* 7 mm coming soon, please contact your local sales representative.

Omniflow II VASCULAR PROSTHESIS - CURVED

- For looped arteriovenous access.
- Available as preformed loop in diameter of 6 mm and lengths of 30 - 45 cm.



Minimum Length (L)	Internal Diameter (ID)	Model # [REF]
30 cm	6 mm	741-630
35 cm	6 mm	741-635
40 cm	6 mm	741-640
45 cm	6 mm	741-645

LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts. · Germany
T +49 (0)6196 659230
F +49 (0)6196 527072

LeMaitre Vascular SAS
79 avenue de Villiers
75017 Paris · France
T +33 (0)3 44 26 00 41
F +33 (0)3 44 26 07 31

LeMaitre Vascular S.r.l.
Via Leone Tolstoj 86
20098 San Giuliano Milanese (MI)
Italy
T +39 02 988 48 51
F +39 02 984 97 059

LeMaitre Vascular Spain S.L.
Calle Basauri 17
28023 Madrid · Spain
T +34 902 500 037
F +34 91 184 98 71

LeMaitre Vascular Switzerland GmbH
Neuhofstrasse 5A
CH-6340 Baar · Switzerland
T 0800 561 761
F +41 415 608 236

LeMaitre Vascular AS
Dronning Eufemias gt. 16
NO-0191 Oslo · Norway
T +49 (0)6196 659230
F +47 21 54 74 67

LeMaitre Vascular, Inc.
63 Second Avenue
Burlington, MA 01803 · USA
T +1 781 221 2266
F +1 781 221 2223

LeMaitre Vascular GK · Japan
T +81 (0)3 5215 5681
F +81 (0)3 5215 5682

LeMaitre Vascular ULC · Canada
T +1 905 832 8077
F +1 905 303 3903

LeMaitre Vascular PTY LTD · Australia
T +61 (0) 3 9330 4775
F +61 (0) 3 9330 4772

LeMaitre Medical Technology
(Shanghai) Co., Ltd · China
T +86 21 61357276
F +86 21 61357100

When vein is not available

- Haemocompatible flow surface
- Good long term patency rates
- Excellent incorporation in host tissue
- Resistance to infection



Omniflow® II

Biosynthetic Vascular Prosthesis

Omniflow II - The biosynthetic solution

The Omniflow II Biosynthetic Vascular Prosthesis is an innovative graft that is composed of cross-linked ovine collagen and a polyester mesh endoskeleton. The graft offers a solution for peripheral reconstruction and vascular access for haemodialysis when vein is not available.

The benefits of this innovative graft design include:

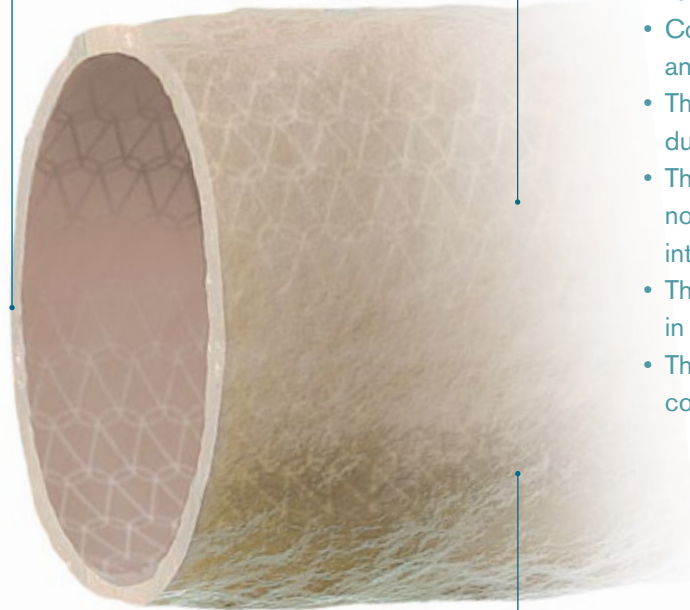
- High patency and limb salvage rates compared to synthetic prostheses in below-knee or crural settings or with poor peripheral run-off (1-5)
- A solution for patients when there is concomitant diabetes and no vein available (6;7)
- High primary and secondary patency rates and low infection rate in AV-Access for hemodialysis (8;9;10)
- Low reported infection rates in peripheral applications (1-5)
- Low reported re-infection rates in peripheral, aortic and AV-Access applications (11-17)

Literature references:

- (1) Koch G, Gutsch S, Pascher O, Fruhwirth J, Hauser H. [Femoropopliteal vascular replacement: vein, ePTFE or ovine collagen?]. Zentralbl Chir 1996;121(9):761-7.
- (2) Koch G, Gutsch S, Pascher O, Fruhwirth H, Glanzer H. Analysis of 274 Omniflow Vascular Prostheses implanted over an eight-year period. Aust N Z J Surg 1997 Sep;67(9):637-9
- (3) Duenschede F, Youssef M, Stabrauskaite J, Ahmed S, Espinola-Klein C, Dorweiler B, et al. [Omniflow-II for critical limb ischemia. Long-term results]. Chirurg. 2017;88(3):233-8.
- (4) Neufang A, Dorweiler B, Espinola-Klein C, Savvidis S, Doemland M, Schotten S, et al. Outcomes of complex femorodistal sequential autologous vein and biologic prosthesis composite bypass grafts. J Vasc Surg. 2014;60(6):1543-53.
- (5) Duenschede F, Stabrauskaite J, Doemland M, Vahl CF, Dorweiler B. [The Omniflow® II biograft. Long term experience with implantation infemoropopliteal position]. Gefäßchirurgie 2015;20(5):343-9.
- (6) Perretti B, Trani A, Gasparre A, Bonanno F. The biosynthetic prosthesis in ovine collagen, Omniflow II, in the treatment of severe critical ischemia of the lower limb: short- and medium-term results. 9th National Congress of the Societa Italiana di Chirurgia Vascolare Ed Endovascolare (SICVE), Siena, September 26-29, 2010.
- (7) Vlachovsky R, Staffa R, Kriz Z. Our Experience with Biosynthetic Graft Implantation - Prospective Study of 35 Patients. 16th Slovak Congress of Vascular Surgery with International Participation, Jasna, Slovakia, March 29 - April 1, 2012.
- (8) Palumbo R, Niscola P, Calabria S, Fierimonte S, Bevilacqua M, Scaramucci L, et al. Long-term favorable results by arteriovenous graft with Omniflow II prosthesis for hemodialysis. Nephron Clin Pract 2009;113(2):c76-c80.
- (9) Frosini F, Romano E, Ercolini E, Barbanti E, Lenzi A, Passuello F, et al. Seven years of Prosthetic Arteriovenous Grafts for Hemodialysis. Our Experience with Omniflow II. 7th Congress of the Vascular Access Society, Istanbul, May 5-7, 2011.
- (10) Berardinelli L. Modern Biological and Semi-Biological Materials for Hemodialysis Arterio-Venous Grafts: Better Long Term Patency, Lower Rate of Infection and of Steal Syndrome. NDT Plus. 2010;3(Suppl 3):iii160.
- (11) Briner L, Mentz M, Jobin AC, Kruse A, Widmer M. The risk of re-infection after surgical vascular access revision using a biosynthetic vascular graft. VAS, 8th Intl Congress, April 2013, Abstracts, J Vasc Access. 2013;14(1):12.
- (12) Al Shakarchi J, McGrogan D, Yates PJ, Inston N. Use of biosynthetic grafts (Omniflow II) for high infection risk haemodialysis vascular access. J Vasc Access. 2016;17(2):151-4.
- (13) Chaudhry A, Shetty R, Crimmin S, Singh-Ranger R. Bio-synthetic Graft Repair of Mycotic Aneurysm of the Common Femoral Artery. Eur J Vasc Endovasc Surg EXTRA 2009 Jul 1;18(1):1-2.
- (14) Wittberger G, Matia I, Schmelzle M, Krenzien F, Hau HM, Freitas B, et al. Mid and long-term results after replacement of infected peripheral vascular prosthetic grafts with biosynthetic collagen prosthesis. J Cardiovasc Surg (Torino) 2014;55(5):693-8.
- (15) Krasznai AG, Snoeijis M, Siroen MP, Sigterman T, Korsten A, Moll FL, et al. Treatment of aortic graft infection by in situ reconstruction with Omniflow II biosynthetic prosthesis. Vascular. 2016;24(6):561-6.
- (16) Töpel I, Stigler T, Ayx I, Betz T, Uhl C, Steinbauer M. Biosynthetic Grafts to Replace Infected Prosthetic Vascular Bypasses: A Single Center Experience. Surg Infect (Larchmt). 2017;18(2):202-5.
- (17) Wozniak W, Bajno R, Swider M, Ciostek P. The Usefulness of Biosynthetic Vascular Graft Omniflow II and Autologous Veins for the Treatment of Massive Infection of Dacron Vascular Graft with Enterococcus faecalis HLAR. Polish Journal of Microbiology. 2016;65(4):471-4.

The Omniflow II – PRE-HEALED FLOW SURFACE

- The Omniflow is pre-healed resulting in a haemocompatible flow surface.



The Omniflow II - COMPOSITE STRUCTURE

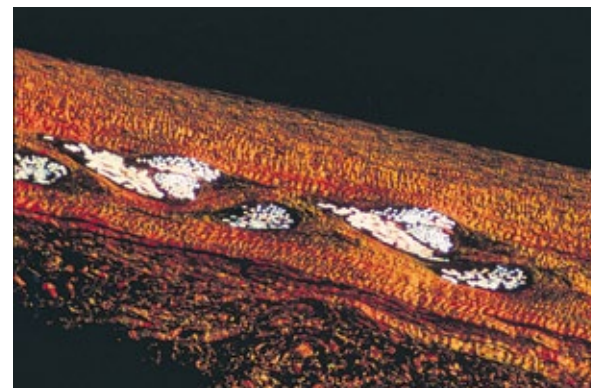
- Composite of a cross-linked ovine collagen and a polyester mesh endoskeleton.
- The polyester mesh provides strength and durability.
- The collagen structure is stabilized, non-antigenic and remains structurally intact many years after implantation.
- The wall is impervious to tissue ingrowth in the lumen, assisting long-term patency
- The rapid incorporation into the host tissue contributes to infection resistance.

The Omniflow II - HANDLES LIKE A VEIN

- Cuts, trims and shapes with ease
- No need for cuffs or jump grafts at the distal anastomosis
- Minimal suture hole bleeding with standard vascular sutures
- Excellent suture retention

The Omniflow II - RESISTANCE TO INFECTION

- The collagen structure is biocompatible, which encourages rapid incorporation into host tissue. The associated micro-vascularization of the Omniflow wall contributes to infection resistance.



CROSS SECTION of Omniflow II composite structure showing the polyester mesh integrated with collagen.



The Omniflow II - FOR AV-ACCESS

- Preformed loop graft prevents kinking
- Ease of puncturing
- Rapid hemostasis with minimal pressure



TISSUE INGROWTH and retention of smooth flow surface shown in an explant after 7 years in the femoro-popliteal position.



PRE-FORMED CONFIGURATIONS are available in straight for peripheral and AV-Access applications, as well in a pre-formed U-shape for AV-Access loop grafts.