1.0 Device Identification and General Information

i) **Document Number:** MS-0072

ii) **Device trade names:** Omniflow II Biosynthetic Vascular Prosthesis

iii) **Manufacturer's name and address:**

Legal manufacturer name:	LeMaitre Vascular, Inc.
Address:	63 Second Avenue, Burlington, MA. 01803, USA

iv) **SRN:** US-MF-000016778

v) **Basic UDI-DI:** G1MS 0607250017

Registrations:	
Basic UDI-DI	08406631OmniflowJM
EMDN	P07010299

vi) **Device Item Codes, Descriptions, Basic UDI, GMDN Code and MDR Classification**

Manufacture Item Code	Description	GTIN-14 (UDI)
741-530	Omniflow II graft (curved) 30cm x 5mm	00840663110230
741-535	Omniflow II graft (curved) 35cm x 5mm	00840663110247
741-540	Omniflow II graft (curved) 40cm x 5mm	00840663110254
741-545	Omniflow II graft (curved) 45cm x 5mm	00840663110261
741-630	Omniflow II graft (curved) 30cm x 6mm	00840663107209
741-635	Omniflow II graft (curved) 35cm x 6mm	00840663107193
741-640	Omniflow II graft (curved) 40cm x 6mm	00840663107186
741-645	Omniflow II graft (curved) 45cm x 6mm	00840663107179
741-730	Omniflow II graft (curved) 30cm x 7mm	00840663110278
741-735	Omniflow II graft (curved) 35cm x 7mm	00840663110285
741-740	Omniflow II graft (curved) 40cm x 7mm	00840663110292
741-745	Omniflow II graft (curved) 45cm x 7mm	00840663110308
741-830	Omniflow II graft (curved) 30cm x 8mm	00840663107247
741-835	Omniflow II graft (curved) 35cm x 8mm	00840663107230
741-840	Omniflow II graft (curved) 40cm x 8mm	00840663107223
741-845	Omniflow II graft (curved) 45cm x 8mm	00840663107216
751-315	Omniflow II graft 15cm x 3mm	00840663110193
751-320	Omniflow II graft 20cm x 3mm	00840663110209
751-415	Omniflow II graft 15cm x 4mm	00840663110216
751-420	Omniflow II graft 20cm x 4mm	00840663110223
751-510	Omniflow II graft 10cm x 5mm	00840663107261
751-520	Omniflow II graft 20cm x 5mm	00840663106998
751-530	Omniflow II graft 30cm x 5mm	00840663109364
751-535	Omniflow II graft 35cm x 5mm	00840663106981
751-540	Omniflow II graft 40cm x 5mm	00840663106974
751-545	Omniflow II graft 45cm x 5mm	00840663106967

751-550	Omniflow II graft 50cm x 5mm	00840663106950
751-555	Omniflow II graft 55cm x 5mm	00840663106943
751-560	Omniflow II graft 60cm x 5mm	00840663106936
751-565	Omniflow II graft 65cm x 5mm	00840663106929
751-610	Omniflow II graft 10cm x 6mm	00840663107254
751-620	Omniflow II graft 20cm x 6mm	00840663107070
751-630	Omniflow II graft 30cm x 6mm	00840663109371
751-635	Omniflow II graft 35cm x 6mm	00840663107063
751-640	Omniflow II graft 40cm x 6mm	00840663107056
751-645	Omniflow II graft 45cm x 6mm	00840663107049
751-650	Omniflow II graft 50cm x 6mm	00840663107032
751-655	Omniflow II graft 55cm x 6mm	00840663107025
751-660	Omniflow II graft 60cm x 6mm	00840663107018
751-665	Omniflow II graft 65cm x 6mm	00840663107001
751-710	Omniflow II graft 10cm x 7mm	00840663109388
751-720	Omniflow II graft 20cm x 7mm	00840663109395
751-730	Omniflow II graft 30cm x 7mm	00840663109401
751-735	Omniflow II graft 35cm x 7mm	00840663109418
751-740	Omniflow II graft 40cm x 7mm	00840663109425
751-745	Omniflow II graft 45cm x 7mm	00840663109432
751-750	Omniflow II graft 50cm x 7mm	00840663109449
751-755	Omniflow II graft 55cm x 7mm	00840663109456
751-760	Omniflow II graft 60cm x 7mm	00840663109463
751-765	Omniflow II graft 65cm x 7mm	00840663109470
751-810	Omniflow II graft 10cm x 8mm	00840663107162
751-820	Omniflow II graft 20cm x 8mm	00840663107155
751-830	Omniflow II graft 30cm x 8mm	00840663109487
751-835	Omniflow II graft 35cm x 8mm	00840663107148
751-840	Omniflow II graft 40cm x 8mm	00840663107131
751-845	Omniflow II graft 45cm x 8mm	00840663107124
751-850	Omniflow II graft 50cm x 8mm	00840663107117
751-855	Omniflow II graft 55cm x 8mm	00840663107100
751-860	Omniflow II graft 60cm x 8mm	00840663107094
751-865	Omniflow II graft 65cm x 8mm	00840663107087

vii) Medical device nomenclature description / text

–P07010101 VASCULAR PATCHES, PERICARDIUM, Straight

–P07010102 VASCULAR PATCHES, PERICARDIUM, Bifurcated

viii) Class of device

Manufacture Name	GMDN Code	MDR Classification	Rule
Omniflow II Biosynthetic Vascular Prosthesis	37889	III	18

ix) Year when the first certificate (CE) was issued covering the device

Device Name	Date of Initial CE Mark	Date of 510(k)
Omniflow II Biosynthetic Vascular Prosthesis	1996	Not currently 510(k) cleared

x) Authorised representative if applicable; name and the SRN

EU Authorized Representative:	LeMaitre Vascular GmbH Otto-Volger-Str. 5 a/b 65843, Sulzbach/Ts Germany
SRN:	DE-AR-000013539

xi) NB's name (the NB that will validate the SSCP) and the NB's singleidentification number

BSI Group The Netherlands B.V.
Identification Number: 2797
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam, Netherlands

2.0 Intended use of the device

i) Intended purpose: The Omniflow II Vascular Prosthesis is intended for use as a blood conduit in the replacement, reconstruction, bypassing or patching of diseased vessels and as a vascular access graft in hemodialysis or AV access.

ii) Indication(s) and target population(s)

- Indication: The Omniflow II Straight Vascular Prosthesis is indicated to facilitate the treatment of renal disease which requires arteriovenous access for hemodialysis when a straight configuration is required. The device is also indicated for peripheral vessel disease (occlusion or aneurysm) to patch and repair vessels.

  The Omniflow II Curved Vascular Prosthesis is indicated for arteriovenous access when a looped configuration is required.

- Target Population: Patients of any gender, age or ethnicity who are in need of vessel replacing, reconstruction, bypassing, or patching of diseased vessels.

iii) Contraindications and/or limitations

- The prosthesis should not be used in patients with a known hypersensitivity to ovine material or glutaraldehyde.

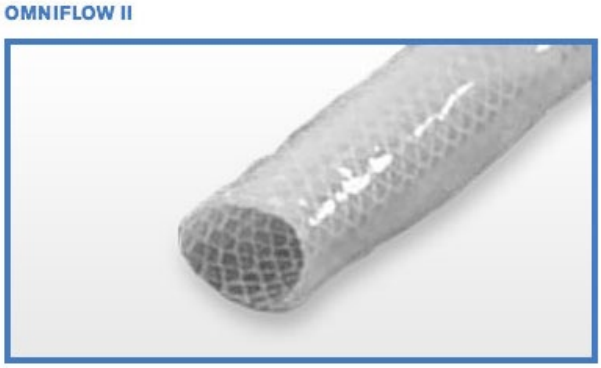
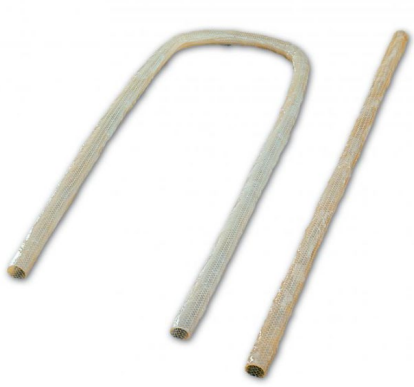
3.0 Device Description

i) Description of the device

Omniflow II is a biosynthetic compound prosthesis. The graft is composed of a polyester mesh endoskeleton set on a silicon mandrel that is implanted on a sheep's back to form a tube of

collagen that is sterilized in a glutaraldehyde solution after removal. The polyester mesh provides strength and durability while the ovine fibrocollagenous tissue matrix structure is biocompatible. The integrated structure allows for high compliance ("radial elasticity") which is close to matching the natural vessel, reducing compliance mismatch and associated intimal hyperplasia. The wall of the graft is impervious to tissue in-growth in the lumen, assisting with long-term patency. The device is biocompatible and thus integrates well with the host tissue. The associated micro-vascularization of the wall allows for access to the host's immune system and to treatment or prophylaxis with antibiotics, enabling resistance to infection. The device's mode of action is serving as a physical conduit between 2 points in a patient's vasculature so that blood can flow through this alternative conduit instead of the native vessel. Images of the device are provided in table below.

Images of the device

The Omniflow II device	
Two (2) pre-formed configurations of the Omniflow II device: • Omniflow II – Curved Prosthesis (left) • Omniflow II – Straight Prosthesis (right)	

The prosthesis is supplied sterile and nonpyrogenic in a solution of 50% ethanol. The prosthesis remains sterile unless the primary package is opened or damaged.

The Omniflow II Straight Vascular Prosthesis is mounted on a glass mandrel contained in a glass tube. The mandrel design prevents the prosthesis slipping off the mandrel when it is removed from the glass tube. The diameter and minimum length of the prosthesis is specified on the label applied to the glass tube.

The Omniflow II Curved Vascular Prosthesis is contained in a sterile flexible inner bag within an outer bag. The diameter and minimum length of the prosthesis is specified on the label applied to the outer surface of the outer bag.

The Omniflow II Vascular Prosthesis is considered magnetic resonance (MR) safe.

The lifetime of the device (per Product Lifetime Document PL0001) is set at 6 years, based on the graft's maximum lifespan for all indications having been demonstrated after repeated percutaneous de-clotting and surgical interventions. The graft lifespan was defined as the length of time from graft placement to any occlusion that could not be managed by means of percutaneous or surgical procedures, including thrombectomy and revision of the venous anastomosis.

ii) A reference to previous generation(s) or variants if such exist, and a description of the differences:

The Omniflow II is a mature product currently on the market for a well-established intended use. Omniflow II, which has been in clinical use since 1989, is the 3rd-generation prosthesis of a technology that has evolved since 1972. Design changes have resulted in a product with enhanced handling properties for the surgeon and improved performance outcomes for the patient. The history of this device is presented in table below. No significant design changes have been made to Omniflow II since product launch.

Device History

Generation	Product	Time period	Clinical history
1st generation	Omniflow clinical prototypes	1972 to 1984	Development, proof of concept, limited clinical evaluation. Manufacturing scale up.
2nd generation	Omniflow	1984 to 1989	Controlled clinical evaluation of peripheral and arteriovenous access applications, market release.
3rd generation	Omniflow II	1989 to date	Controlled clinical evaluation of peripheral application to ensure there were no unanticipated outcomes, followed by market release.

iii) Description of any accessories which are intended to be used in combination with the device: No accessories are supplied with this device.

iv) Description of any other devices and products which are intended to be used in combination with the device: No other devices or products are intended to be used in combination with this device.

4.0 Risks and Warnings

Potential device related complications:

Adverse event	Rate	Source from the CER

Infection	0-4%	Wang et al, 1996
Thrombosis	2-34.5%	De Siqueira et al 2020, Neufang et al 2020, Socrate et al 2021, Van de Laar et al 2022
Dilatation	10.5%	Palumbo et al.
Leakage	10.5%	Palumbo et al.
Suture pullout	-	Not reported
Wall integrity of the prosthesis may be adversely affected by collagenase-producing microorganisms	-	Not reported

Potential procedural and secondary complications:

Adverse event	**Rate**	**Source from the CER**
Aneurysm formation	0.06%	PMS data
Pseudoaneurysm formation	2%	Want et al., 1996
Adverse tissue responses	-	Not reported
Late aneurysm formation (more than 4 years after implantation)	-	Not reported

i) Residual risks and undesirable effects

- Residual risk evaluation is conducted as part of our FMEAs and risk management procedure. We essentially conclude that the benefits outweigh any residual risks and that the risk has been reduced as far as possible

ii) Warnings and precautions

Warnings

1. Do NOT re-sterilise the Omniflow II prosthesis. It is supplied sterile and pyrogen free. Use the prosthesis immediately after opening the package and discard any unused portions.
2. Do NOT use the prosthesis if the primary package is damaged as sterility may be compromised.
3. Do NOT use the prosthesis if the glass mandrel is broken.
4. Do NOT use the prosthesis if it is not completely covered by the storage solution.
5. Do NOT attempt to reposition the prosthesis after removal of the tunneling instrument.
6. Do NOT straighten the curved prosthesis during preparation or implantation, as this will cause disruption of the mesh tissue interface.
7. Do NOT use the straight prosthesis to fashion a looped arteriovenous access as this may cause kinking.
8. Do NOT pull, stretch, twist, squeeze or pinch the body of the prosthesis.

9. Do NOT use ablation techniques such as cutting balloons, laser, or radio frequency ablation with the Omniflow II prosthesis.
10. Do NOT attempt to dilate the prosthesis with balloon angioplasty or stenting procedures.
11. The Omniflow II prosthesis should only be implanted by trained surgeons.
12. The use of the Omniflow II prosthesis in the coronary artery has not been evaluated.

Precautions

- Ensure the rinsing procedure has been performed to remove the storage solution prior to implanting the prosthesis. Failure to do so may cause occlusion. Keep the prosthesis moist with sterile physiological saline during the procedure.
- The use of a hollow tunnelling instrument for the passage of the prosthesis is essential. Failure to do so may cause disruption to the biosynthetic material and lead to occlusion, dilatation or aneurysm formation. The inner diameter of the tunneler should be at least 3mm larger than the indicated inner diameter of the prosthesis.
- Ensure that the prosthesis does not become twisted when passing through the tunnelling instrument as this may lead to occlusion.
- Avoid cross clamping with metal instruments as this may damage the prosthesis and cause occlusion, dilatation or aneurysm formation. If clamping is necessary use only a-traumatic clamps and avoid repeated or excessive clamping in the same position on the prosthesis.
- The prosthesis has minimal longitudinal elasticity. Ensure the prosthesis is cut to the correct length. If it is too short it may cause suture pullout with a risk of anastomotic aneurysm. If it is too long it may kink and cause occlusion.
- Cut off the sections of the prosthesis which were clamped during rinsing. Ensure that the full wall thickness and a mesh eyelet are incorporated with each stitch when performing the anastomosis. Failure to do so may result in stitch pullout and anastomotic aneurysm formation.
- Do not implant Omniflow II into a site with an active infection unless the surgeon determines there is not a more suitable alternative for preventing amputation or death.

iii) Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable:

Worldwide complaints/sales per year

Year	# Complaints	# Devices sold	Complaint rate
2018	30	2,651	1.13%
2019	29	3,086	0.94%
2020	14	2,476	0.57%
2021	22	2,367	0.93%
2022	14	1,910	0.73%
Total Complaints	**109**	**12,490**	**0.87%**

Complaints by type/year

Complaint Category	2018	2019	2020	2021	2022	Total	Rate
Broken glass	24	25	12	21	5	87	0.697%

Aneurysm	3	2	0	0	3	8	0.064%
Infection	1	1	0	0	2	4	0.032%
Packaging issue	1	0	0	1	2	4	0.032%
Harder graft	0	1	0	0	1	2	0.016%
Shipping error	0	0	2	0	0	2	0.016%
Leaking graft	1	0	0	0	0	1	0.008%
Occlusion	0	0	0	0	1	1	0.008%

- The table below lists the 2 CAPAs relevant to the safety and performance of the subject device that were opened from 01 January 2018 to 31 December 2022.

CAPA summary

CAPA Number	Reason CAPA initiated	Corrective action taken	Status	Date initiated	Date closed
CAPA 2019-040	Calculating the particle counts in the cleanroom incorrectly from Q2 2015 to present.	Retrain (in person) and document training for all affected personnel regarding particulate monitoring and communicate the audit observation. Review all data from 2013 to 2015 Q1, which was calculated correctly.	Closed	17-Jan-19	29-Aug-21
CAPA 2021-003	Complaints of glass packaging breaking during shipment.	Plastic packaging was developed according to the BNI quality system.	Closed	04-Feb-21	19-Aug-21

There were 0 FSCAs / recalls that have been initiated or reported for the subject device from 01 January 2018 to 31 December 2022.

5.0 Summary of clinical evaluation and post-market clinical follow-up (PMCF)

i) Summary of clinical data related to equivalent device, if applicable:

– An equivalent device was not used for this clinical evaluation.

ii) Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

All published literature has been reviewed in the writing of the clinical evaluation report. The more recent publications are used in preference to older studies to ensure our knowledge base keeps up with the state-of-the-art.

iii) Summary of clinical data from other sources, if applicable

Performance Outcomes

The performance outcomes following use of subject device with Omniflow II for vascular bypass or repair were reported by 13 studies. Among these studies, 1 study reported in-situ reconstruction/ revascularization of an infected vein,[1] 4 studies reported reconstruction/ replacement of an infected vascular graft,[2-5] and 8 studies reported bypass surgeries for factors such as disabling claudication or chronic critical ischemia.[6,7,8-13] The primary performance outcomes reported were patency (primary and secondary), survival/ mortality, limb salvage/ amputation, and reintervention rates. Details regarding the performance outcomes reported in the studies are provided in the CER.

Primary patency rates for reconstruction/ revascularization appeared to be dependent on time since procedure and location. Within the 1st year post-procedure, primary patency rates ranged from 68% to 100%. At the 5th year post-procedure, primary patency rates had generally decreased, ranging from 14% to 78%. In terms of location, the average primary patency for procedures described as occurring above-knee was 74.7% (range=44-98%), which was higher compared to the average primary patency for procedures described as occurring below-knee, 56% (range=35-86%). The poorest primary patencies appeared to be associated with femorocrural implants or crural bypasses, for which primary patency ranged from 14-47%.

Secondary patency rates for reconstruction/ revascularization ranged from 36% (2 year follow-up for femorocrural implant) to 85% (1 year follow up for replacement of infected infrainguinal prosthetic graft). As with primary patency, secondary patency rates were better for above-knee procedures (mean=73%, range=65-78%) and poorer for below-knee procedures (mean=56%, range=46-63%).

Survival rate for the period from in-hospital to <30 days post-procedure was high, ranging from 87.5% to 100%. Survival rate beyond 30 days post-procedure ranged from 60% (at 5 years post-procedure for 1 study, and at median 50 months post-procedure for 1 study) to 95% (at 4 years post-procedure for 1 study). No graft-related causes were attributed to deaths during the early or late survival periods.

Limb salvage rates were dependent on procedure location. Limb salvage rates ranged from 83-100% for reconstruction/ replacement of infected vascular grafts, 81-91% for above-knee bypass procedures, 71-87% for below-knee procedures, and 60% for femorocrural or crural bypass procedures.

Surgical reinterventions were reported for 3 studies, all of which used bypass procedures. Reintervention rates ranged from 7.3-40%. The highest reintervention rates were for patients undergoing crural bypass without adjuvant distal AVFs (range=20-40%).

Performance outcomes with Omniflow II for vascular access indications were reported by 3 studies.[14-16] The primary performance outcomes reported were patency (primary and secondary), survival/ mortality, limb salvage/ amputation, and reintervention rates.

Primary patency rates varied widely across studies. Morosetti et al. reported a primary patency range of 21% at 2 years post-procedure to 55% at 6 months post-procedure; Wang et al. reported a range of 34.1% at 4 years post-procedure to 77.4% at 1 year post-procedure; and Palumbo et al. reported a range of 60% at 2 years post-procedure to 83% at 6 months post-procedure. Regardless of study, primary patency decreased over time.

Similarly, secondary patency rates varied across studies, and also showed a decrease over time: at 6 months post-procedure, Morosetti et al. reported 72% patency and Palumbo et al. reported 92% patency; at 2 years post-procedure, Morosetti et al. reported 34% patency and Palumbo et al. reported 75% patency.

Survival rates for the vascular access indication were high, ranging from 72-100%. Limb salvage rate was reported in only 1 study, which found 100% limb salvage (61/61 limbs) at up to 4 years post-procedure. Finally, reintervention rates were low for this indication, ranging from 8-14%.

Safety Outcomes

Safety outcomes with Omniflow II for vascular bypass or repair were reported by 12 studies. Graft aneurysm/ graft stenosis/ graft degeneration rates ranged from 0% (at median 28.5 months post-procedure for repair of infected groin pseudoaneurysm) to 12.6% (at mean 68 months post-procedure for bypass).

Graft occlusion rates ranged from 0% (at mean 38 months post-procedure for supra-aortic bypass) to 40% (“early” occlusion in patients with crural bypass without adjuvant distal AVF). Graft occlusions appeared to occur most frequently for bypasses in the femorocrural/crural location (mean=23.6%), followed by the below-knee location (mean=17.7%), infected graft replacement (mean=15.3%), and the above-knee location (mean=9.8%).

Graft infection or reinfection rates ranged from 0-4.8%. The study by Becker et al. reported a graft infection rate of 66.7% (4/6 patients), but this rate may be influenced by the high-risk population studied (i.e., drug abusers). Hemorrhage rates ranged from 1.6-4.3%, and it was unclear whether these hemorrhages were associated with the graft. Finally, 1 study reported a 1.6% rate for pseudoaneurysms, and 1 study reported a 4.3% rate of graft thrombosis within 24 hours of the bypass procedure.

Safety outcomes with Omniflow II for vascular access were reported by 3 studies. Graft aneurysm/ graft stenosis/ graft degeneration rates ranged from 0% (at median 39 months post-procedure) to 12% (at 1.5 and 2 years post-procedure).

Graft occlusions and hemorrhages were not reported among the 3 vascular access studies.

Infection/ reinfection rates were low, ranging from 0-1.9%. Pseudoaneurym rates ranged from <1% to 6.8%. Finally, graft thrombosis rates varied across studies: Palumbo et al. reported 0 events (at median 39 months), Wang et al. reported 18 cases of graft thrombosis (a rate of 29.5%), and Morosetti et al. reported a rate of 114%, without explanation for this large value.

iv) **An overall summary of the clinical performance and safety**

The clinical literature review identified 4 new articles relating to the safety and/or performance of the subject device when used as intended. A total of 216 patients representative of the intended population were treated with the subject device in these newly-identified studies. The clinical data on these patients was gathered from 3 uncontrolled studies[1,2,12] and 1 case series.[9] Controlled studies included comparisons to Intergard Synergy (Getinge AB),[2] Vascu-Guard (Baxter International, Inc.),[2] a composite of Vascu-Guard and Omniflow II,[2] bovine artery (Shelhigh, Inc.),[1] ProCol Vascular Bioprosthesis (LeMaitre Vascular),[1] autologous vein graft,[1] cryopreserved arterial homograft,6 and xeno-pericardial patch.[1]

Findings from the clinical literature support the performance of the subject device, which include patency, survival/mortality rate, limb salvage/ amputation rate, and reintervention rate. Safety outcomes with the subject device included device-related adverse events (graft aneurysm/stenosis, graft occlusion, and infection/reinfection). The outcomes relating to the safety and performance of the subject or equivalent device are consistent with those expected for this type of device when used as intended.

Based on this clinical evaluation, which includes both non-clinical and clinical data, there is sufficient data to demonstrate conformity to the applicable requirements and confirm that the subject device is safe and performs as intended and claimed and is state of the art device for use for vascular access or in vascular bypass or repair. Review of the post-market data, information materials and the risk management documentation confirms that the risks are appropriately identified and consistent with the state of the art, and that the risks associated with the use of the device are acceptable when weighed against the benefits.

v) **Ongoing or planned post-market clinical follow-up**

Ongoing post-market surveillance (PMS) of the subject device according to the following procedure, SOP-28-001. Post-Market Clinical Follow-up (PMCF) activities are planned for the subject device. A multi-stepped approach will be used to substantiate the performance claims of the device and ensure that the risk/benefit remains positive. First, a thorough literature review will be conducted to capture all relevant and up to date published information regarding the Omniflow device.

There is also an on-going study with the Universitair Medisch Centrum, Groningen looking at two aspects of treatment with the Omniflow. These include graft infection and the influence of diabetes on the outcome of patients treated with an Omniflow prosthesis.

Graft infection is one of the most severe complications in vascular surgery. Several small numbered studies showed the potential resistance to infection of Omniflow prostheses. The study will look at how Omniflow can be used for reconstructive surgery for patients with vascular graft infection.

The Omniflow prosthesis is used for different indications, for both central and peripheral indications (arterial replacement, bypass surgery, arteriovenous shunting). This study will list the results per indication and evaluate the influence of diabetes mellitus on the outcomes.

As part of the PMCF plan a prospective clinical study, #OMN-13-001, is being designed to investigate the efficacy endpoints of primary patency, secondary patency, and operation time at select locations and implant sites. The study will also collect safety information, specifically, the rates of thrombosis/ occlusion, limb salvage, infection, and survival. Any safety-related incident that occurs during the operation, as well as post-operatively at day 30, 6 months, and 1 year, will be recorded. Data will be analyzed to identify any previously unknown side-effects and contraindications, unforeseen trends, emergent risks, and unexpected device events. The study will also identify possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose of the device is correct.

The updated information will be used to design further on-going registry studies to begin collecting prospective registry data going forward. These studies will be designed to identify possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct. This will be completed through the safety assessment and the clinician survey. Finally, this study will be used to confirm the safety and performance throughout the expected lifetime of the device through the proactive and continuous collection of data.

6.0 Possible diagnostic or therapeutic alternatives:

Treatment options for peripheral vascular disease and vascular trauma include peripheral vascular repair and revascularization. Treatment options for end-stage renal disease include providing vascular access for hemodialysis treatment. These treatment options are described in detail below.

Peripheral Vascular Repair and Revascularization

Invasive treatments are not recommended for asymptomatic peripheral arterial disease. In many cases, intermittent claudication caused by peripheral arterial disease can be managed with medical treatment (e.g., smoking cessation interventions, statin therapy, or antiplatelet therapy) or exercise therapy. However, the Society of Vascular Surgery recommends invasive (endovascular or surgical) treatment for patients with "significant functional or lifestyle-limiting disability when there is a reasonable likelihood of symptomatic improvement with treatment, when pharmacologic or exercise therapy, or both, have failed, and when the benefits of treatment outweigh the potential risks."[17] Invasive treatment should be individualized to the patient. For instance, endovascular procedures are recommended over open surgery for focal occlusive disease of the superficial femoral artery, whereas surgical bypass is recommended as an initial revascularization strategy for patients with diffuse femoro-popliteal disease or extensive calcification of the superficial femoral artery (depending on patient anatomy).[17] European Society of Cardiology/ European Society of Vascular Surgery suggest endovascular therapy as the first choice of treatment for femoro-popliteal lesions <25 cm and surgical bypass (especially when using the great saphenous vein) for occlusion/stenosis >25 cm in length.[18]

The primary goals of interventional treatment for chronic lower limb ischemia are to relieve ischemic pain, heal ischemic ulcers, prevent limb loss, and improve patient's functional capacity and quality of life.[19] Femoro-popliteal bypass grafting for lower limb ischemia has been practiced since the 1940s and is one of the most common procedures performed by vascular surgeons. Femoro-popliteal bypass grafting involves a proximal anastomosis taken from the common, superficial, or profunda femoris artery, and a distal anastomosis to the popliteal artery either above or below the knee.[20] Autologous vein is typically recommended as the first choice of graft in bypass surgery, but the use of a prosthetic conduit for femoro-popliteal bypass is suggested in the absence of suitable vein.[17,18]

Non-autologous graft types include HUV and grafts constructed from PTFE, ePTFE, and Dacron (polyethylene terephthalate). Heparin-bonded synthetic grafts are also commercially available. Ambler et al. conducted a meta-analysis of RCTs that compared at least 2 different graft types for above-and below-knee femoro-popliteal bypass. For above-knee grafts, there was moderate-quality evidence from 3 RCTs showing that autologous vein grafts improve primary patency compared to prosthetic grafts by 60 months. There was no clear difference between Dacron and PTFE grafts in terms of primary patency at 60 months, but there was low-quality evidence to suggest that Dacron grafts improved secondary patency compared to PTFE at 24 months and 60 months. Both HUV and heparin-bonded Dacron grafts were found to be superior to PTFE in terms of primary patency for above-knee bypass, but these findings were based on single trials. For below-knee grafts, no graft type was found to be superior to any other in terms of primary patency.[20] A comparison of vein and prosthetic above-knee femoropopliteal by Sharrock et al. showed that primary patency, primary assisted patency, and secondary patency were significantly higher in patients treated with the vein grafts at up to 5 years.[21] Autologous grafts also showed higher patency compared to synthetic grafts for venous reconstruction following pancreatectomy.[22]

Endovascular techniques for the treatment of lower extremity ischemia include balloon angioplasty, stents and stent-grafts, plaque debulking, thrombolysis, and percutaneous thrombectomy. In a systematic review and meta-analysis, Antonopoulos et al. ranked treatment options for superficial femoral artery de novo lesions as follows (resulting in highest to lowest primary patency): drug-eluting stent, bypass surgery, nitinol stent, covered stent, drug-coated balloon, PTA with brachytherapy, stainless steel stent, cryoplasty, and balloon angioplasty.[23] In a meta-analysis of RCTs, Antoniou et al. found higher technical success rates but longer hospital stays with bypass surgery compared to PTA for critical lower limb ischemia. Primary patency at 1 year was higher after bypass surgery (61.2-85.7%) compared to PTA (43.3-72%), but there was no significant difference at 4 years. Additionally, there were no differences identified between endovascular and surgical treatment in terms of clinical improvement, quality of life, mortality, amputation rates, or reintervention rates, but periprocedural complications occurred more frequently in patients undergoing bypass surgery.[19]

Vascular Access

Vascular access can be accomplished with central venous catheterization, arterialization of a vein, or by interposition of a graft between an artery and a vein for the insertion of hemodialysis needles. An AVF is defined as an autogenous anastomosis between an artery and a vein.[24] A meta-analysis by Almasri, 2016 found that in terms of patency, infection, and mortality rates,

AVFs provided the best outcomes, followed by AVGs and then catheters. In general, patency was lower in women, the elderly, and those with diabetes.[25] Because AVFs generally provide superior outcomes, AVGs are typically used when creation or maintenance of an autologous fistula is not feasible. Grafts commonly used in vascular access surgery include biological (e.g., bovine carotid artery, bovine mesenteric vein) and synthetic (e.g., PTFE) options. Additionally, heparin-bonded grafts have been developed with the aim of preventing clotting and thereby increasing patency. Lazarides et al. conducted a meta-analysis comparing heparin-bonded PTFE grafts to standard PTFE grafts for hemodialysis vascular access. No significant differences between heparin-bonded and standard grafts in 6-month or 1-year patency was observed, suggesting no advantage of heparin-bonded grafts.[26] Compared to synthetic grafts, biological grafts have a greater resistance to infection, but there are concerns about long-term aneurysm formation and rupture.[24]

7.0 Suggested profile and training for users:

The Omniflow II Vascular Prosthesis is a surgical tool intended for use by experienced vascular surgeons trained in the procedures for which they are intended.

8.0 Reference to any harmonized standards and CS applied

Standard Title	Standard Reference: Revision Year
Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Part 2: Requirements for aseptically processed medical devices	EN 556-2:2015
Information supplied by the manufacturer of medical devices	EN 1041:2008
Cardiovascular implants and extracorporeal systems – Vascular prostheses -- Tubular vascular grafts and vascular patches	ISO 7198:2016
Biological evaluation of medical devices – Part 1: Evaluation and testing	ISO 10993-1:2009
Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	ISO 10993-3:2009
Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2006
Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	ISO 10993-5:2009
Biological evaluation of medical devices – Part 6: Tests for local effects after implantation	EN ISO 10993-6:2007
Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity	ISO 10993-10:2010
Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	ISO 10993-11:2018
Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances	EN ISO 10993-17:2008
Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	ISO 11607-1:2006
Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	ISO 11607-2:2006
Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products	ISO 11737-1:2006

Tests of sterility performed in the definition, validation and maintenance of a sterilization process	ISO 11737-2:2009
Aseptic processing of health care products – Part 1: General requirements	ISO 13408-1:2008
Medical devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485:2016
Sterilization of health care products – Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives – Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	ISO 14160:2011
Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness	ISO 14644-1:2015
Medical devices – Application of risk management to medical devices	EN ISO 14971:2012
Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements	EN ISO 15223-1:2016
Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management	ISO 22442-1:2015
Medical devices utilizing animal tissues and their derivatives – Part 2: Controls on sourcing, collection and handling	ISO 22442-2:2015
Medical devices utilizing animal tissues and their derivatives – Part 3: Validation of the elimination and/or inactivation of viruses and TSE agents	ISO 22442-3:2007

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9.0 Revision History

SSCP revision number	Date issued	Change description	Revision validated by the NotifiedBody
A	See last page	Initial release	☐ Yes Validation language: English ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
B	25 Apr 2023	Updated PMS data, SOTA literature, added patient section	☐ Yes Validation language:English ☐ No
C	24Jul2023	Updated lifetime to align with PL doc	☐ Yes Validation language:English ☐ No

10. Patient Information

A summary of the safety and clinical performance of the device, intended for patients, is given below.

Summary of safety and clinical performance

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document. The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare specialist in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

1. **Device general information**
    a. **Device trade name:** Omniflow II Vascular Prosthesis (subject device)
    b. **Producer; name and address:** LeMaitre Vascular, Inc. 32 Third Avenue, Burlington, MA 01803
    c. **Basic UDI-DI**: 08406631OmniflowJM
    d. **Year when the device was first CE-marked**: 1996
2. **Intended use of the device**
    a. **Used For**: the subject device is intended for use as a blood conduit in the replacement, repair, bypassing or patching of diseased vessels and as a vascular access graft in hemodialysis or AV access.
    b. **Indications and intended patient groups**: The Patch is indicated to help with the treatment of renal disease which requires artery or vein access for hemodialysis when a straight shape is required. The device is also indicated for peripheral vessel disease (occlusion or aneurysm) to patch and repair vessels.

The patches that are curved are indicated for artery or vein access when a looped shape is required.

    c. **Do not use for:** Not for use in patients with allergies to proteins derived from sheep.
3. **Device description**
    a. Device description and material/substances in contact with patient tissues: The patches are sterile flexible collagen-tissue patches cut from a uniform area of chemically-treated proteins derived from sheep. The patches are permanent implants in direct contact with vascular tissue and blood.
    b. Information about medicinal substances in the device, if any: NA
    c. Description of how the device is achieving its intended mode of action: Per regulations, the subject device achieves its affect through non-medicinal means. It achieves this goal as a physical barrier device as its mode of action.
    d. Description of accessories, if any: NA
4. **Risks and warnings**

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

a. **How potential risks have been controlled or managed:** Analysis have concluded that the benefits outweigh any residual risks and that the risk has been reduced as far as possible.

b. **Remaining risks and unwanted effects:** The data in this clinical report is adequate to determine if unwanted side effects exist for the subject device. It concludes that the device conforms to the requirement on how acceptable the side effects are. No gaps were identified in the clinical data. However, there was a limited operative performance data for the subject device. A future study will be completed to continue collecting safety and performance data on the device.

Warnings:

1. Your new device is a foreign body and therefore needs close monitoring and careful observation. It may take 6-8 weeks for full recovery. Your new device is a foreign body and therefore needs close monitoring and careful observation. It may take 6-8 weeks for full recovery.
2. After placement, the area maybe swollen and tender for up to a week.
3. Observe for any new redness or tenderness
4. Observe for any opening in the incisions.
5. Observe for numbness tingling or pain in the leg, the side of the new graft.
   - Any of the above (2-5) contact your provider.
6. Do not puncture or manipulate the graft.
7. You may shower according to your provider instructions.
8. Swelling in the extremity is expected because of increased blood flow. Move according to your provider's instructions, otherwise keep the leg elevated above your heart.
9. It is preferable to have the new graft covered for the first week to protect skin and incisions. (Follow your provider instructions)
10. Keep bandages or compression bandages on as per your provider.
11. If your staples have been removed, you will probably have Steri-Strips (small pieces of tape) across your incision. Wear loose clothing that does not rub against your incision.
12. You may shower or get the incision wet, once your doctor says you can. DO NOT soak, scrub, or have the shower beat directly on them. If you have Steri-Strips, they will curl up and fall off on their own after a week.
13. DO NOT soak in the bath tub, a hot tub, or swimming pool. Ask your provider when you can start doing these activities again.
14. Your provider will tell you how often to change your dressing (bandage) and when you may stop using one. Keep your wound dry. If your incision goes to your groin, keep a dry gauze pad over it to keep it dry.
15. Clean your incision with soap and water every day once your provider says you can. Look carefully for any changes. Gently pat it dry.
16. DO NOT put any lotion, cream, or herbal remedy on your wound without asking first if that is ok.
17. Bypass surgery does not cure the cause of the blockage in your arteries. Your arteries may become narrow again.
18. Eat a heart-healthy diet, exercise, stop smoking (if you smoke), and reduce stress. Doing these things will help lower your chances of having blocked artery again.
19. Your health care provider may give you medicine to help lower your cholesterol.

20. If you are taking medicines for high blood pressure or diabetes, take them as you have been told to take them.
21. Your provider may ask you to take aspirin or a medicine called clopidogrel (Plavix) when you go home. These medicines keep your blood from forming clots in your arteries. DO NOT stop taking them without talking to your provider first.

5. Summary of clinical assessment and post-market clinical follow-up

a. **Clinical background of the device:** The subject device is categorized as class III device in the EU. The graft is composed of a polyester mesh frame set on a silicon mandrel that is implanted on the sheep's back to form a tube of protein that is fixed by sterilizing formula after removal. The polyester mesh provides strength while the protein structure is biocompatible. The integrated structure allows for high compliance (radial stretchy) which is close to matching the natural vessel, reducing compliance mismatch and linked intimal hyperplasia. The wall of the graft is impervious to tissue in-growth in the lumen, assisting with long-term patency.
b. **The clinical evidence for the CE-marking:** The device was first approved for CE mark under LeMaitre Vascular in 1996. Studies were conducted to ensure the grafts were safe and effective. See the IFU for further details.
c. **Safety:** There are ongoing clinical trials on this graft that will be used to confirm the safety and performance throughout the expected lifetime of the device through the proactive and continuous collection of data.

6. Possible diagnostic or therapeutic alternatives: When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your personal situation.

7. Suggested training for users: This device is intended to be used by surgeons. Considering how complex this surgery is, it is left to the surgeon to decide proper surgery and graft type as well as the therapy to adopt before, during and after the operation.