## 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:** 08406631OmniflowJM

**vi) Device Item Codes and Descriptions**

| UDI-DI | Catalog | Description |
|---|---|---|
| 00840663111916 | 751-320M | Omniflow II graft 20cm x 3mm |
| 00840663111923 | 751-420M | Omniflow II graft 20cm x 4mm |
| 00840663111503 | 751-520M | Omniflow II graft 20cm x 5mm |
| 00840663111510 | 751-530M | Omniflow II graft 30cm x 5mm |
| 00840663111527 | 751-540M | Omniflow II graft 40cm x 5mm |
| 00840663111534 | 751-550M | Omniflow II graft 50cm x 5mm |
| 00840663111541 | 751-560M | Omniflow II graft 60cm x 5mm |
| 00840663111558 | 751-565M | Omniflow II graft 65cm x 5mm |
| 00840663111565 | 751-620M | Omniflow II graft 20cm x 6mm |
| 00840663111572 | 751-630M | Omniflow II graft 30cm x 6mm |
| 00840663111589 | 751-640M | Omniflow II graft 40cm x 6mm |
| 00840663111596 | 751-650M | Omniflow II graft 50cm x 6mm |
| 00840663111602 | 751-660M | Omniflow II graft 60cm x 6mm |
| 00840663111619 | 751-665M | Omniflow II graft 65cm x 6mm |
| 00840663111626 | 751-720M | Omniflow II graft 20cm x 7mm |
| 00840663111633 | 751-730M | Omniflow II graft 30cm x 7mm |
| 00840663111640 | 751-740M | Omniflow II graft 40cm x 7mm |
| 00840663111657 | 751-750M | Omniflow II graft 50cm x 7mm |
| 00840663111664 | 751-760M | Omniflow II graft 60cm x 7mm |
| 00840663111671 | 751-765M | Omniflow II graft 65cm x 7mm |
| 00840663111688 | 751-820M | Omniflow II graft 20cm x 8mm |
| 00840663111695 | 751-830M | Omniflow II graft 30cm x 8mm |
| 00840663111701 | 751-840M | Omniflow II graft 40cm x 8mm |
| 00840663111718 | 751-850M | Omniflow II graft 50cm x 8mm |
| 00840663111725 | 751-860M | Omniflow II graft 60cm x 8mm |
| 00840663111732 | 751-865M | Omniflow II graft 65cm x 8mm |

**vii) Medical device nomenclature description / text**

–P07010299 VASCULAR PATCHES, PERICARDIUM, Straight

**viii) Class of device**

| Manufacturer Name | MDR Classification | Rule |
|---|---|---|
| Omniflow II Biosynthetic Vascular Prosthesis | III | 8 & 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<br>Otto-Volger-Str. 5 a/b<br>65843, Sulzbach/Ts<br>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.
- Target Population: Adults of any gender, 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 |  |

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 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

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

Potential device-related complications:

| Adverse event | Rate | Follow-up | Source from the CER |
|---|---|---|---|
| Infection | 0-4% | 9 months to 2 years | Morosetti, 2011; Palumbo, 2009; Wang, 1996; Muller et al. |
| Thrombosis | 4-16% | ≤6 weeks | De Siqueira et al 2020, Neufang et al 2020, Socrate et al 2021, Van de Laar et al 2022 |
| Dilatation | - | - | Not reported |

| | | | |
|---|---|---|---|
| Leakage | - | - | Not reported |
| Suture pullout | - | - | Not reported |
| Wall integrity of the prosthesis may be adversely affected by collagenase-producing microorganisms | - | - | Not reported |

Potential procedure-related complications:

| **Adverse event** | **Rate** | **Follow-up** | **Source from the CER** |
|---|---|---|---|
| Aneurysm formation<br>Pseudoaneurysm formation | 1-25% | 72 months – 5 years | Costantini, 2012; Koch, 1997; Neufang, 2020; Socrate, 2021; Toktas, 2018;van de Laar, 2022 |
| Adverse tissue responses | - | - | Not reported |
| Late aneurysm formation (more than 4 years after implantation) | - | - | Not reported |

ii) Warnings and precautions

**Warnings**

1. Do NOT re-sterilise the Omniflow II prosthesis. 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 it is not completely covered by the storage solution.
4. Do NOT use the prosthesis if the solution level in the vertical position is below the anti-roll nubs on the tube.
5. Do NOT attempt to reposition the prosthesis after removal of the tunnelling instrument.
6. Do NOT use the prosthesis to fashion a looped arteriovenous access as this may cause kinking.
7. Do NOT pull, stretch, twist, squeeze or pinch the body of the prosthesis.
8. Do NOT use ablation techniques such as cutting balloons, laser, or radio frequency ablation with the Omniflow II prosthesis.
9. Do NOT attempt to dilate the prosthesis with balloon angioplasty or stenting procedures.
10. The Omniflow II prosthesis should only be implanted by trained surgeons.
11. The use of the Omniflow II prosthesis in the coronary artery has not been evaluated.
12. Ethanol is a highly flammable liquid and vapor. Keep away from heat, sparks, and open flames.

**Precautions**

1. 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.

2. 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.
3. Ensure that the prosthesis does not become twisted when passing through the tunnelling instrument as this may lead to occlusion.
4. 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.
5. 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.
6. 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.
7. 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.
8. When the prosthesis is used for arteriovenous access some redness and swelling may be present over the implant area for a few days following implant.
9. Insufficient data is available on which to base any conclusions regarding the use of the Omniflow II vascular prosthesis for aortocoronary bypass procedures.
10. Failure to heparinize the prosthesis (i.e., in the case of patients who cannot tolerate heparin) may result in a higher likelihood of thrombosis or occlusion post-implantation, the extent of which has not been established.
11. Omniflow II cannot grow in diameter or length and thus should not be implanted into infants or children unless a plan for its replacement is established and that no other suitable alternative treatment option exists.

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

During 01 January 2018 to 30 November 2023, there were no FSCAs or recalls for the subject device known to the manufacturer or identified through a search of the recall and FSCA databases (Germany's BfArM Field Corrective Actions, Switzerland's SWISSMEDIC database, UK's MHRA Alerts and Recalls database, and France's ANSM database). The device is not on the market in the US; therefore, the FDA recalls database was not searched.

During 01 January 2018 to 30 November 2023, there were a total of 124 complaints associated with the subject device and a total of 14,650 devices sold, resulting in an overall cumulative complaint rate of 0.846%. The tables below provide the complaint and sales rate for each year.

*Sales per year*

| Region | 2018-Nov 2023 | 2018 | 2019 | 2020 | 2021 | 2022 | Jan-Nov 2023 |
|---|---|---|---|---|---|---|---|
| Europe | 13,167 | 2291 | 2488 | 2291 | 2246 | 1803 | 2048 |
| ROW | 1,483 | 387 | 621 | 184 | 103 | 96 | 92 |
| Worldwide Total | 14,650 | 2678 | 3109 | 2475 | 2349 | 1899 | 2140 |

*Complaints per year*

| Region | Year | # Complaints | # Devices sold | Complaint rate |
|---|---|---|---|---|
| Europe | 2018 | 28 | 2291 | 1.222% |
| | 2019 | 26 | 2488 | 1.045% |
| | 2020 | 13 | 2291 | 0.567% |
| | 2021 | 22 | 2246 | 0.980% |
| | 2022 | 15 | 1803 | 0.832% |
| | 2023 | 12 | 2048 | 0.586% |
| | Total | 116 | 13167 | 0.881% |
| ROW | 2018 | 2 | 58 | 3.448% |
| | 2019 | 3 | 98 | 3.061% |
| | 2020 | 1 | 109 | 0.917% |
| | 2021 | 0 | 48 | 0.000% |
| | 2022 | 0 | 48 | 0.000% |
| | 2023 | 2 | 46 | 4.348% |
| | Total | 8 | 407 | 1.966% |
| WorldWide | 2018 | 30 | 2,678 | 1.120% |
| | 2019 | 29 | 3,109 | 0.933% |
| | 2020 | 14 | 2,475 | 0.566% |
| | 2021 | 22 | 2,349 | 0.937% |
| | 2022 | 15 | 1,899 | 0.790% |
| | 2023 | 14 | 2,140 | 0.654% |
| **Total Complaints** | **2018- Nov 2023** | **124** | **14,650** | **0.846%** |

12. The table below lists the 3 CAPAs relevant to the safety and performance of the subject device that were opened from 01 January 2018 to 30 November 2023.

**CAPA summary**

| CAPA # | Description | Date Initiated | Date Closed | Status |
|---|---|---|---|---|
| CAPA 2019-040 | Complaints of broken glass during shipment. | 17-Jan-19 | 29-Aug-21 | Closed |

| CAPA # | Description | Date Initiated | Date Closed | Status |
|---|---|---|---|---|
| CAPA 2021-003 | Complaints of glass packaging breaking during shipment.<br>Plastic packaging was developed according to the BNI quality system. | 04-Feb-21 | 19-Aug-21 | Closed |
| CAPA-207 | Complaints of broken mandrel and broken glass<br>Non-conformity associated with CAPA 2021-003 and CAPA 2019-040. | 17-Jan-19 | 29-Aug-21 | Closed |

## 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

***Summary of literature supporting the device under evaluation***

| Timeframe | # Include Articles | Protocol | Report |
|---|---|---|---|
| 01 January 2023 – 18 December 2023 | 3 articles:<br>Müller, 2023[70]<br>Liesker, 2023a[71]<br>Liesker, 2023b[72] | Attachment A | Section **Error! Reference source not found.** |
| January 2021-February 2023 | 3 articles:<br>Caradu, 2022[73]<br>El-Diaz, 2022[74]<br>Pinero, 2021[75] | Clinical Evaluation Plan Omniflow II Biosynthetic Vascular Prosthesis, Rev. G | Clinical Evaluation Report Omniflow II Biosynthetic Vascular Prosthesis, Rev. G |
| 2020-2022 | 6 articles<br>Betz, 2022[76]<br>El Beyrouti, 2022[77]<br>Evans, 2022[78]<br>Keschenau, 2021[65]<br>Socrate, 2021[79]<br>Van de Laar, 2022[58] | Clinical Evaluation Plan Omniflow II Biosynthetic Vascular Prosthesis, Rev. F | Clinical Evaluation Report Omniflow II Biosynthetic Vascular Prosthesis, Rev. F |
| 2019-2020 | 16 articles<br>Betz, 2019[80]<br>Becker, 2019[45]<br>Constantini, | Clinical Evaluation Plan Omniflow II Biosynthetic Vascular Prosthesis, Rev. E | Clinical Evaluation Report Omniflow II Biosynthetic Vascular Prosthesis, Rev. E |

| | | | |
|---|---|---|---|
| | 2012[81]<br>De Siqueira, 2020[82]<br>Dunschede, 2016[83]<br>Koch, 1997[84]<br>Morosetti, 2011[35]<br>Neufang, 2014[55]<br>Neufang, 2020[85]<br>Ozpak, 2015[67]<br>Palumbo, 2009[86]<br>Polichetti, 2012[57]<br>Toktas, 2018[87]<br>Topel, 2017[88]<br>Wang, 1996[39]<br>Wiltberger, 2014[89] | | |
| TOTAL: 28 articles with 1414 patients | | | |

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

Clinical Benefits associated with the Omniflow are:

- Increased survival rates or lower mortality rates
- Improved limb salvage rates or decrease amputation rates (peripheral vessel disease indication only)

*Arteriovenous access*

There were 4 literature studies with a total of 124 patients performed using the subject device for arteriovenous access. There were 2 randomized controlled trials and 2 retrospective observational studies. The randomized controlled trials compared Omniflow to PTFE grafts and brachial-basilic AVF.

| **Outcome** | **Follow up** | **Omniflow range** | **Omniflow weighted average** |
|---|---|---|---|
| Primary patency | <1 year | 55-92% | 76.6% |
| | 1 year | 32-80% | 67.3% |
| | 2 years | 21-68% | 52.7% |
| | >2 years | 34.1 | NA |
| Secondary patency | <1 year | 72% | NA |
| | 1 year | 52-83% | 70.1% |

| | | | |
|---|---|---|---|
| | 2 years | 34-65% | 52.9% |
| Reintervention | Any | - | - |
| Survival | ≤ 6 weeks | 100% | NA |
| | >6 weeks to 1 year | 72% | NA |
| | ≥2 years | 33.1-81% | 70.4% |
| Thrombosis | ≤6 weeks | - | - |
| | >6 weeks or not specified | 0-114% | 47.7% |
| Infection | ≤6 weeks | - | - |
| | >6 weeks or not specified | 0-66.7% | 3.5% |
| Pseudoaneurysm | ≤6 weeks | - | - |
| | >6 weeks or not specified | 0-7.4% | 1.3% |
| Other adverse events | ≤6 weeks | - | - |
| | >6 weeks or not specified | 7.4-12% | 10.3% |

*Peripheral vascular repair/ revascularization*

There were 24 literature studies with a total of 1290 patients performed using the subject device. There were 7 retrospective comparative studies, 16 retrospective observational studies, and 1 systematic review. Comparative studies included comparisons to bovine vein, homograft, bovine mammary artery, autologous vein, pericardium, bovine pericardium, HUV, PTFE and ePTFE.

| **Outcome** | **Follow up** | **Omniflow range** | **Omniflow weighted average** |
|---|---|---|---|
| Primary patency | <1 year | 75-100% | 81.3% |
| | 1 year | 36-77% | 69.4% |
| | 2 years | 28.7-73% | 58.5% |
| | >2 years | 30-87.5% | 54.9% |
| Secondary patency | 1 year | - | - |
| | 2 years | 66.8-92% | 78.4% |
| | >2 years | 36.4-91% | 66.3% |
| Reintervention | ≤6 weeks | 46.1%-66.8% | 69.8 |
| | >6 weeks or not specified | 6.9-50% | 10.5% |
| Survival | ≤6 weeks | 87.5-100% | 95.3% |
| | >6 weeks-1 year | 75-96% | 90.1% |
| | ≥2 years | 60-98.9% | 86.0% |
| Limb salvage | ≤6 weeks | 94.7-98.5% | 97.9% |

| | | | |
|---|---|---|---|
| | >6 weeks or not specified | 75-96% | 90.8% |
| | ≤6 weeks | 20-100% | 82.2% |
| Thrombosis | >6 weeks or not specified | 6.7% | NA |
| | ≤6 weeks | 3.8-20% | 7.2% |
| Infection | >6 weeks or not specified | 0.7-10.9% | 5.1% |
| | ≤6 weeks | 0-15% | 4.4% |
| Pseudoaneurysm/ aneurysm | >6 weeks | - | - |
| Other adverse events | ≤6 weeks | 1.1-25.2% | 8.1% |
| | >6 weeks or not specified | 1.0-17.2% | 5.5% |

The device under evaluation is a biosynthetic composite of cross-linked ovine collagen with a polyester mesh endoskeleton. Based on the outcomes of the 28 clinical studies included in this CER, it is inferred that patients will experience a substantial benefit in terms of primary patency, secondary patency, survival and limited reinterventions. The literature identified thrombosis, infection, pseudoaneurysm formation and biodegeneration of the graft wall as risks. These risks are identified in the IFU. Aneurysms and infection were also identified in the PMS data as being among the top 5 reasons for complaints. No new risks were identified in the literature or from the PMS data the performance is in line with the state of the art. All residual risks have been minimized as far as possible. Together, these data suggest an acceptable benefit-risk profile for the Omniflow II Vascular Prosthesis

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

The manufacturer conducts ongoing post-market surveillance (PMS) of the subject device according to the following plans, #PMCF0014, Revision B (PMCF plan) A PMCF study is currently in progress or planned for the device.

As part of the PMCF plan, 3 activities for the collection of clinical data pertaining to Omniflow II Vascular Prosthesis have been initiated. The first activity involves a manufacturer-sponsored research grant for the comparative assessment of the use of biologic vascular prostheses (i.e., XenoSure Biologic Patch and Omniflow II) from multicenter cohorts in Groningen, Netherlands. The aims of this study are to 1) assess the use of Omniflow II in the prevention or treatment of vascular graft infections, or 2) assess the use of Omniflow II in central and peripheral indications and evaluate the influence of diabetes mellitus on the primary endpoints. Both studies will collect data for the early, mid-, and long-term (30 days, 6 months, and annual up to 10 years) outcomes. Graft re-infection and

patency are the primary performance endpoints. Secondary endpoints include any adverse events and mortality rates.

The second ongoing activity involves establishing a clinical registry of patients in Italy who have undergone infrainguinal bypass with the Omniflow II Vascular Prosthesis with anastomosis distal located at the level of the supragenicular popliteal artery (above-the-knee, ATK), subgenicular popliteal (below-the-knee, BTK), of the tibioperoneal trunk, of one of the 3 tibial vessels (anterior tibial artery, tibial artery posterior, interosseous artery) or one of the arteries of the foot. The registry will have retrospective and prospective phases. For the prospective phase, study patients 150) will have undergone the procedure within a 2-year span beginning in January 2022 and will be followed for 2 years post-procedure. For the retrospective phase, study participants 150) will have undergone procedures between January 2019 and December 2021. The study will confirm the safety of the medical device through collecting rates of mortality, infection, loss of limb, surgical complications, and other adverse effects. Technical success and patency rates are anticipated to be used to confirm the performance of the device under evaluation. Final study endpoints will be determined by a panel of clinical and area experts to ensure the appropriate data is captured to confirm safety and performance. Evaluation of outcomes with univariate (Kaplan-Meier curves) and multivariate (Cox regression) analysis factors influencing the results with 1, 3, and 5 year results estimates (short, medium, and long term).

The third ongoing activity is a clinical registry of patients in Spain who have undergone femoropopliteal bypass surgery with the Omniflow II Vascular Prosthesis.

## 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 | 19/04/2023 | Initial release | ☐ Yes<br>Validation language: English<br>☐ 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 | 25/04/2023 | Updated PMS data, SOTA literature, added patient section | ☐ Yes<br>Validation language:English<br>☐ No |
| C | 11/06/2024 | Updated lifetime to align with PL doc, removed curved variant from scope, updated catalog numbers | ☒ Yes<br>Validation language: English<br>☐ 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. 63 Second 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.
    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 effect 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 limited operative performance data for the subject device. A future study will be completed to continue collecting safety and performance data on the device.

***Potential device-related complications:***

| Adverse event | Rate | Follow-up |
|---|---|---|
| Infection | 0-4% | 9 months to 2 years |
| a blood clot within blood vessels that limits the flow of blood (Thrombosis) | 4-16% | ≤6 weeks |
| the action of dilating a vessel or opening (Dilatation) | NR | NR |
| Leakage | NR | NR |
| Suture pullout | NR | NR |
| Wall integrity of the prosthesis may be adversely affected by collagenase-producing microorganisms | NR | NR |

***Potential procedure-related complications:***

| Adverse event | Rate | Follow-up |
|---|---|---|
| Abnormal swelling or bulge in the wall of a blood vessel, such as an artery (Aneurysm formation) | 1-25% | 72 months – 5 years |
| When a blood vessel wall is injured. Blood leaking from the vessel collects in surrounding tissue (Pseudoaneurysm formation) | | |
| Adverse tissue responses | NR | NR |
| Abnormal swelling or bulge in the wall of a blood vessel, such as an artery (more than 4 years after implantation) (Late aneurysm formation) | NR | NR |

*NR= not reported*

## 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.
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. If the graft was implanted in your leg, swelling in the extremity is expected because of increased blood flow. Elevate or move the extremity according to your provider's instructions.

8. It is preferable to have the new graft covered for the first week to protect skin and incisions. (Follow your provider's instructions)
9. Keep bandages or compression bandages on as per your provider's instructions.
10. If you have adhesive surgical tape or strips across your incision(s), wear loose clothing that does not rub against your incision(s). The adhesive surgical tape or strips will curl up and fall off on their own after a week.
11. 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.
12. DO NOT soak in the bath tub, a hot tub, or swimming pool. Ask your provider when you can start doing these activities again.
13. 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.
14. Clean your incision with soap and water every day once your provider says you can. Look carefully for any changes. Gently pat it dry.
15. DO NOT put any lotion, cream, or herbal remedy on your wound without first discussing it with your provider.
16. Consult your provider on taking any prescription or over-the-counter medications after your surgery.

**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.