LeMaitre®

# Omniflow™ II Vascular Prosthesis

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Patient Information – English

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| Length | 5 mm Diameter | 6 mm Diameter | 7 mm Diameter | 8 mm Diameter |
|---|---|---|---|---|
| 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 |

**Intended Use**

The Omniflow II Vascular Prosthesis is used to replace diseased or damaged blood vessels or used as a conduit for hemodialysis.

**Intended Purpose**

- The Omniflow II 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 vessel reconstruction, bypassing or patching.
- When a vein is not available the graft offers a solution for vascular access for hemodialysis.

**Intended Patient Population**

The graft is designed for patients with variable ages, weights, diagnoses and heath statuses.

**Self-Care Instructions**

1. Your new device is a foreign body and therefore needs close monitoring and careful observation. It may take 6-8 weeks for full healing.
2. After placement, the implant area may be swollen and tender for up to a week.
3. Watch for any new redness or tenderness.
4. Watch for any opening in the incisions.
5. Watch for numbness, tingling, or pain in the arm or leg near the new graft.

***NOTE: If you experience any symptoms described in 3, 4 or 5 above please 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 surgical site covered for the first week to protect skin and incision(s). (Follow your provider's instructions)
9. Keep bandages or wound coverings 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(s) wet, once your provider says you can. DO NOT soak, scrub, or have the shower beat directly on the incision(s).
12. DO NOT soak in the bathtub, a hot tub, or a swimming pool. Ask your provider when you can start doing these activities again.
13. Your provider will tell you how often to change your wound covering and when you may stop using one. Keep your incision(s) dry. If your incision(s) goes to your groin, keep a dry gauze pad over it to keep it dry.
14. Clean your incision(s) 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 with your provider.
16. Consult your provider on taking any prescription or over-the-counter medications after your surgery.

**Clinical Benefits**

- Greater survival rates or lower mortality rates.
- Better limb rescue rates or lesser limb loss rates (diseases in the arm, hands, feet or legs).

**Undesirable Side Effects**

1. Some chemicals (glutaraldehyde) may attack your immune system. The benefits of use of the Omniflow II Vascular Prosthesis have been weighed against the possible risk of late tissue weakening.

**Long-term Protection Measures for Your Graft**

- Avoid prolonged extreme extension of the arm or leg with the implantation as it could lead to nerve damage.
- Avoid extreme or abrupt movements of the arm, shoulder, or legs during a post-operative period of 1.5 to 2 months. Specifically, you should not reach out in front, raise arms above shoulder level, throw, pull, stride, or twist.
- Avoid sleeping on the graft implantation side of your body or crossing your legs for prolonged periods as it may cause compression.

**Risks Related to Interactions with Other Equipment**

- None

**Post-surgical Monitoring**

- Check your incision(s) every day.
- Call your provider immediately if you have any signs of a blood clot, swelling, unusual skin color or infection such as:
    1. Increased pain
    2. Swelling, redness, or red streaks
    3. Blood or pus draining from the incisions
    4. Numbness
    5. Fever
- The nature and frequency of regular or preventive examination, monitoring or maintenance will be determined by your provider. This will be based on your underlying medical condition and the status of your graft.

**Additional Post-surgical Monitoring for Hemodialysis**

Check your access site for a pulse or "thrill" vibration. To feel it, place your first two fingers over the graft, or listen with a stethoscope. If you are able to listen with a stethoscope, you should be able to hear a repetitive whooshing sound. If you do not hear it or feel a pulse, the graft may be malfunctioning. Contact your provider with any concerns.

**Lifetime of the Device**

- The lifetime of the device has been shown to be safe and effective up to 6 years on average. Proper care and regular medical follow up may extend the life of the device.
- To ensure your graft functions as intended, follow the guidance of your health care provider.

**When to Contact Your Provider**

Closely watch for any changes in your health. Seek emergency care anytime you experience:

- Lost consciousness
- Trouble breathing
- Extremity has severe pain or becomes cold, pale, blue, tingly, or numb.
- Pain that does not get better after you take pain medicine.
- Loose stitches or your incision(s) opens.
- Extensive bleeding from the incision(s).
- Signs of infection, such as:
    1. Increased pain, swelling, warmth, or redness
    2. Red streaks leading from the incision(s)
    3. Pus draining from the incision(s)
    4. A fever over 101°F (38.3°C)
    5. You are nauseous or cannot keep fluids down.
- You have chest pain, dizziness, problems thinking clearly, or shortness of breath that does not go away when you rest
- You are coughing up blood or yellow or green mucus
- You have chills
- You experience abdominal pain or bloating

**Device Materials**

The following materials and substances could potentially pose a risk to patients:

- Ovine fibrocollagenous tissue reinforced with polyester mesh.
- Low levels of residual Glutaraldehyde.

**In Case of an Emergency**

- Any serious adverse reaction should immediately be reported to your provider.
- Any device related emergency that occurs in Australia should be reported to the Therapeutic Goods Administration via their website (https://www.tga.gov.au/) and the manufacturer, LeMaitre Vascular, Inc. (+1 781-221-2266 or; https://www.lemaitre.com/contact-us/email-us).
- Any device related emergency that occurs in the EU should be reported to the Competent Authority of the country where you are located and the manufacturer, LeMaitre Vascular, Inc. (+1 781-221-2266 or; https://www.lemaitre.com/contact-us/email-us).

**Symbol Legend**

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|---|---|---|---|---|---|---|---|---|---|---|
| | |  |  |  |  |  |  |  |  |  |
| English | Symbol Legend | Patient Name | Implant Date | Healthcare Institution | Patient Information Website | Explanation of Unique Device Identifier | Medical Device | Batch Code | Serial Number | Manufacturer |

LeMaitre®

Distributed By:
LeMaitre Vascular, Inc.
Customer Service:
Tel: 781 221-2266
Fax: 781 221-2223

EC REP
LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts., Germany
Tel: +49-(0)6196-659230

LeMaitre Vascular, Inc.
63 Second Avenue
Burlington, MA 01803
Tel: 781 221-2266

AUS
Australian Sponsor
Emergo Australia
Level 20, Tower II, Darling Park
201 Sussex Street
Sydney, NSW 2000, Australia

UKRP
LeMaitre Vascular, Ltd.
Stirling House, Centenary Park
Skylon Central
Hereford HR26FJ
England UK
Tel: 01432513125

CH REP
MedEnvoy Switzerland
Gotthardstrasse
6302 Zug
Switzerland

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