LeMaitre®

Omniflow® II Vascular Prosthesis

Omniflow® II Vascular Prosthesis
Patient Information – English

Omniflow® II Vascular Prosthesis

Patient Information – English

i. Omniflow II - Straight Prosthesis

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

ii. Omniflow II - Curved Prosthesis

Length	6 mm Diameter
30 cm	741-630
35 cm	741-635
40 cm	741-640
45 cm	741-645

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 recovery.
2. After placement, the implant area may be 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 new graft.

NOTE: If you experience any of the above (2-5) please contact your provider.

6. Do not puncture or manipulate the graft.
7. You may shower according to your provider's instructions.
8. Swelling in the extremity is expected because of increased blood flow. Move according to your provider's instructions. If the graft was implanted in your leg, keep the leg elevated above your heart.
9. It is preferable to have the graft covered for the first week to protect skin and incisions. (Follow your provider's instructions)

10. Keep bandages or compression bandages on as per your provider's instructions.
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 provider 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 bathtub, a hot tub, or a 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 your provider 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 developing a blocked artery again.
19. Your provider may give you medicine to help lower your cholesterol.
20. If you are taking prescriptions for high blood pressure or diabetes, take them as prescribed.
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.

Intended Performance

- Patient monitoring is essential when the graft is used for vascular access to prevent excessive damage from complications.
- This is your graft and part of your body. If there is any evidence of bulge, redness, tenderness, or skin changes, immediately tell your provider.

Long Term Protection Measures for Your Graft

- Avoid protracted extreme extension of the arm or leg. Prolonged extreme extension may 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.

Electrical and Magnetic Sensitivity

- The device is not affected by electrical, magnetic or electro-magnetic interference. No precautions need to be taken when in the vicinity of these devices.
- There is no interaction of the graft with metal detectors and devices used at airport security checks.

Post-Surgical Monitoring

- Check your incision and the rest of the implant extremity (arm or leg) every day. Pay attention to how you feel.

- Call your provider immediately if you have any signs of a blood clot, swelling, unusual skin color or infection such as:
    a. Increased pain
    b. Swelling, redness, or red streaks
    c. Blood or pus draining from the incisions
    d. Numbness
    e. Fever
- Check for signs of good circulation. Your foot or leg should not be cool, pale, experience pain, or have other symptoms similar to pre-surgery. Call your provider if you are experiencing any of these symptoms.
- Check for signs of good circulation. It is a problem if your hand or arm is cool or pale, if it changes color, or if you have sudden bulging around your access.
- Call your provider immediately if bleeding from your access lasts longer than usual.
- 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 6.5 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 opens
- extensive bleeding from the incision
- signs of infection, such as:
    a. Increased pain, swelling, warmth, or redness
    b. Red streaks leading from the incision
    c. Pus draining from the incision
    d. A fever over 101°F (38.3°C)
    e. 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 make up the Omniflow II Prosthesis. All materials have passed biocompatibility testing to ensure they are safe to use:

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

In Case of an Emergency

Please make sure any serious incident that occurs in relation to the graft is reported to the manufacturer and to the Therapeutic Goods Administration (or other local Medical Device regulatory agency) at the address of the Therapeutic Goods Administration website (https://www.tga.gov.au/).

- Any serious adverse reaction should immediately be reported to your provider. You may also report the incident to the manufacturer, LeMaitre Vascular, Inc. (+1 781-221-2266 or; https://www.lemaitre.com/contact-us/email-us).

LeMaitre®

Distributed By:

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

LeMaitre Vascular GK
1F Kyodo Bldg. Ichibancho
16-1 Ichibancho, Chiyoda-ku
Tokyo 102-0082, Japan
Tel: +81-(0)3-5215-5681

LeMaitre Vascular ULC
9135 Keele Street, Suite B6
Vaughan, Ontario
Canada L4K 0J4
Tel: 855 673-2266

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

R4197-00 Rev. A 11/21

CE
2797