LeMaitre®

LifeSpan® ePTFE Vascular Graft

LifeSpan® ePTFE Vascular Graft
Patient Information – English

LifeSpan® ePTFE Vascular Graft

Patient Information – English

a. Straight

Diameter	Length	Regular Wall Model Number	Thin Wall Model Number
6 mm	10 cm	R06010	
6 mm	20 cm	R06020	T06020
7 mm	20 cm	R07020	
8 mm	20 cm	R08020	
6 mm	50 cm	R06050	T06050
7 mm	50 cm	R07050	T07050
8 mm	50 cm	R08050	T08050
6 mm	80 cm		T06080
7 mm	80 cm	R07080	T07080
8 mm	80 cm	R08080	T08080
10 mm	80 cm		T10080

b. External Spiral Support

Diameter	Length	Spiral Support	Regular Wall	Thin Wall
6 mm	50 cm	50 cm	R06050C50	T06050C50
7 mm	50 cm	50 cm	R07050C50	T07050C50
8 mm	50 cm	50 cm	R08050C50	T08050C50
6 mm	80 cm	80 cm	R06080C80	T06080C80
7 mm	80 cm	80 cm	R07080C80	T07080C80
8 mm	80 cm	80 cm	R08080C80	T08080C80
10 mm	80 cm	80 cm	R10080C80	T10080C80

c. Center Spiral Support

Diameter	Length	Spiral Support	Regular Wall	Thin Wall
6 mm	50 cm	10 cm	R06050CS	
6 mm	50 cm	30 cm		T06050C30
7 mm	50 cm	30 cm		T07050C30
8 mm	50 cm	30 cm		T08050C30
6 mm	80 cm	50 cm		T06080C50
7 mm	80 cm	50 cm		T07080C50
8 mm	80 cm	50 cm		T08080C50

d. Stepped

Diameter	Length	Regular Wall
4-7 mm	50 cm	RS47050

e. Stepped with Center Spiral Support

Diameter	Length	Spiral Support	Model Number
4-7 mm	50 cm	10 cm	RS47050CS

f. Quick Tapered

Diameter	Length	Model Number
4-7 mm	50 cm	QT47040
4-7 mm	50 cm	QT47050

g. Quick Tapered with Center Spiral Support

Diameter	Length	Spiral Support	Model Number
4-7 mm	50 cm	10 cm	QT47045CS

Intended Use

- Grafts with external monofilament support in the middle of the graft may be used for the creation of an arteriovenous shunt for blood access; however, the graft must not be cannulated in the area of the external monofilament support.
- Stepped and tapered grafts are used for the creation of arteriovenous shunts for blood access. Stepped configurations may reduce the risk of steal syndrome and high cardiac output.
- The LifeSpan graft is used to repair damaged/diseased blood vessels, or to be used as a conduit in hemodialysis.

Intended Purpose

The Grafts are intended for bypass of occluded blood vessels, or for arteriovenous shunts for blood access.

Intended Patient population

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

Self-care Instructions

1. Your new device is 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 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 near the new graft.

NOTE: If you experience 2-5 above, 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, frequently elevate leg above your heart.
9. Protect your graft from any trauma (sharp or blunt) objects.
10. It is preferable to have the surgical site covered for the first week to protect skin and incisions. (Follow your provider's instructions)
11. Keep bandages or compression bandages on as per your provider's instructions.
12. Avoid tight clothing or bandages which can cause compression and clotting up the graft.
13. 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.
14. 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.
15. DO NOT soak in the bathtub, a hot tub, or a swimming pool. Ask your provider when you can start doing these activities again.
16. 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.
17. Clean your incision with soap and water every day once your provider says you can. Look carefully for any changes. Gently pat it dry.
18. DO NOT put any lotion, cream, or herbal remedy on your wound without first discussing with your provider.
19. Bypass surgery does not cure the cause of the blockage in your arteries. Your arteries may become narrow again.
20. 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.
21. Your provider may give you medicine to help lower your cholesterol.
22. If you are taking prescriptions for high blood pressure or diabetes, take them as prescribed.
23. Your provider may ask you to take aspirin or other over-the-counter or prescription medicine to prevent blood clots. 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 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.

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 check.

Post-surgical Monitoring

- Check your incision and rest of the implant extremity (arm or leg) every day to be sure it is in good condition. Pay attention to how you feel.
- Call your doctor or dialysis team 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 access
4. Numbness
5. Fever

- Check for signs of good circulation. Your foot or leg should not be cool, pale, experience pain, change colors, have sudden bulging around the access site, or have other symptoms similar to pre-surgery. Call your provider if you are experiencing any of these symptoms.
- Call your provider immediately if bleeding from your access site persists.

Lifetime of the Device

- The lifetime of the device has been shown to be safe and effective out to 9 years. Proper care and regular medical follow up may help make this device last much longer.
- 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 incisions
- Signs of infection, such as:
  1. Increased pain, swelling, warmth, or redness
  2. Red streaks leading from the incision
  3. Pus draining from the incision
  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 are what make up the LifeSpan graft. All materials have passed biocompatibility testing to ensure they are safe to use.

- PTFE: graft an monofilament
- Hydrocarbon lubricant
- Black ink

In Case of an Emergency

Please make sure any serious incident that occurs in relation to the device you have 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

- Any serious adverse reaction should immediately be reported to your doctor. You may also report the incident 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).

LeMaitre®

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

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

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

R4194-01 Rev. A 02/22

CE
1639