LeMaitre®

LifeSpan® ePTFE Vascular Graft
Patient Information – English

LifeSpan® ePTFE Vascular Graft

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

The intended purpose of the device:
The grafts are intended for bypass of occluded blood vessels, or for arteriovenous shunts for blood access.

a. Intended purpose: (Grafts used for Arteriovenous Shunt)
   - 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 (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.

b. Patient population: Product is designed for patients with variable ages, weights, diagnoses and heath statuses

Special operating instructions for the use and care of your device:
Intended Purpose: (Grafts used for bypass or for hemodialysis access)

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 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 your hand on the side of 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 instructions.
8. Protect your graft from any trauma (sharp or blunt) objects.
9. It is preferable to have the new graft covered for the first week to protect skin and incisions. (Follow your provider's instruction)
10. Avoid tight clothing or bandages which can cause compression and clotting of the graft.
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 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 your provider first if that is okay.

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.

The intended performance of the device and any undesirable side effects that could be caused by use of the device:

- Avoid protracted extreme extension of the arm. 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 side with graft as it may cause compression.

Any residual risks that could arise due to any shortcomings of the protection measures adopted:

- 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.

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 graft with metal detectors and devices used at airport security check.

The nature and frequency of regular or preventive examination, monitoring or maintenance of the device and other measures that should be taken by you:

- Every day, check your access to be sure it is in good condition. Pay attention to how you feel. Call your doctor or dialysis team right away if you have any signs of infection or a blood clot, swelling, or unusual skin color.
- Be alert for signs of infection, such as:
    a. Increased pain
    b. Swelling, redness, or red streaks
    c. Blood or pus draining from the access
    d. Numbness
    e. Fever
- Check for signs of good circulation. It is a problem if your hand or arm is cool or pale or changes color, or if you have sudden bulging around your access.
- Call your doctor right away if bleeding from your access lasts longer than usual.

The expected device lifetime:

- 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.

Other circumstances in which you should contact your provider in relation to the operation of the device:
Seek immediate care anytime you think you may need emergency care.
For example, call if:
- You passed out (lost consciousness).
- You have trouble breathing.
- You have severe pain in your leg, or it becomes cold, pale, blue, tingly, or numb.
- You have pain that does not get better after you take pain medicine.
- You have loose stitches, or your incisions come open.
- You are bleeding a lot from the incisions.
- You have 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
    e. You are sick to your stomach or cannot keep fluids down

Watch closely for any changes in your health, and be sure to contact your doctor or nurse call line if:
- 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 have a fever over 101°F (38.3°C)
- Your belly hurts or is bloated
- There are signs of infection around the incision such as redness, pain, warmth, welling, or greenish discharge
- The bandage is soaked with blood
- Your arm or legs are swelling

Materials of this device:
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

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

R4194–00 Rev. A 12/21

CE
1639