LeMaitre®

XenoSure® Biologic Patch

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Patient Information – English

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Biologic Vascular Patch Sizes	Width	Length	Model #
Biologic Vascular Patch - Rounded	1 cm	6 cm	1P6
Biologic Vascular Patch - Tapered	0.8 cm	8 cm	0.8P8
Biologic Vascular Patch- Rounded	2 cm	9 cm	2P9
Biologic Vascular Patch - Tapered	1 cm	10 cm	1P10
Biologic Vascular Patch - Tapered	1.5 cm	10 cm	1.5P10
Biologic Vascular Patch - Tapered	1 cm	14 cm	1P14

Biologic Surgical Patch Sizes	Width	Length	Model #
Biologic Surgical Patch - Square	4 cm	4 cm	4P4
Biologic Surgical Patch - Rectangular	4 cm	6 cm	4P6
Biologic Surgical Patch - Rectangular	6 cm	8 cm	6P8
Biologic Surgical Patch - Rectangular	5 cm	10 cm	5P10
Biologic Surgical Patch - Rectangular	8 cm	14 cm	8P14
Biologic Surgical Patch - Rectangular	10 cm	16 cm	10P16
Biologic Surgical Patch - Rectangular	12 cm	25 cm	12P25

The intended purpose of the device:

- Indication: (vascular reconstruction, repair, and vessel patching)
    a. Australia: The XenoSure Biologic Patch is intended for use as a surgical patch material for cardiac and vascular reconstruction and repair.
    b. Europe: The XenoSure Biologic Patch is intended for use as a surgical patch material for vascular reconstruction or vessel patching during surgical procedures such as carotid endarterectomy.
- 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:

Patch used for vascular reconstruction, repair and vessel patching:

Self-Care

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.

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

6. Do not puncture or manipulate the patch.
7. You may shower according to your provider instructions.
8. Swelling in the extremity is expected because of increased blood flow. Move according to your provider's instructions, otherwise keep your leg elevated above your heart.
9. It is preferable to have the incision covered for the first week to protect skin and incisions. (Follow your provider's instruction)
10. Keep bandages or compression bandages on as per your provider.
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 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 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:

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

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

- Avoid protracted extreme extension of the arm if the patch was implanted in your 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.
- If the patch is implanted in your neck, take care not to overextend your neck by bending or twisting frequently.

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 patch 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 wounds and leg. Pay attention to how you feel. Call your provider 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 incisions
    d. Numbness
    e. Fever
- Check for signs of good circulation. It's a problem if your foot or leg is cool or pale or you are having pain in that foot or leg or symptoms similar to pre-surgery, call your provider.
- The nature and frequency of regular or preventive examination, monitoring or maintenance will determined by your provider. This will be based on your underlying medical condition and the status of your graft.
- If you have any symptoms of a stroke or neurological problems such as difficulty with speaking, your vision, or movement control etc. please check with your provider immediately.

The expected device lifetime:

- The lifetime of the device has been shown to be safe and effective out to 12 years. Proper care and regular medical follow up may help make this device last much longer.
- To ensure your patch functions as intended follow the guidance of your health care provider.

Other circumstances in which the patient should contact the health professional 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
    f. Any symptoms of stroke or neurological problems

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 arms or legs are swelling

Materials of this device:
The following materials are what make up the XenoSure patch. All materials have passed biocompatibility testing to ensure they are safe to use:

- Bovine pericardium tissue
- Small amount of residual Glutaraldehyde

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).

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