



XenoSure® Biologic Patch
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

Intended Use

Indication: (vascular reconstruction, repair, and vessel patching).

- Australia: The XenoSure Biologic Patch is intended for use as a surgical patch material for cardiac and vascular reconstruction and repair.
- 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 health 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 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 patch.
- NOTE: If you experience 2-5 above, please contact your provider.**
6. Do not puncture or manipulate the patch.
 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 patch 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. 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.
 13. You may shower or get the incision wet, once your doctor 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.
 14. DO NOT soak in the bath tub, a hot tub, or swimming pool. Ask your provider when you can start doing these activities again.
 15. 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.
 16. Clean your incision with soap and water every day once your provider says you can. Look carefully for any changes. Gently pat it dry.
 17. DO NOT put any lotion, cream, or herbal remedy on your wound without first discussing with your provider.
 18. Bypass surgery does not cure the cause of the blockage in your arteries. Your arteries may become narrow again.
 19. 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.

20. Your health care provider may give you medicine to help lower your cholesterol.

21. If you are taking medicines for high blood pressure or diabetes, take them as you have been told to take them.

22. 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 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.

Long Term Protection Measures for Your Patch

- 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.
- If the patch is implanted on 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.

Post-surgical Monitoring

- Check your incision and rest of the implant extremity 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.
- 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.

Lifetime of the Device

- 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.

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 sick to your stomach or cannot keep fluids down.
- Any symptoms of stroke or neurological problems. 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 XenoSure patch. All materials have passed biocompatibility testing to ensure they are safe to use:

- Bovine pericardium tissue
- Small amount of residual Glutaraldehyde

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>).



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