LeMaitre®

CardioCel® Bioscaffold Patch

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English – Patient Information

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CardioCel Bioscaffold Patch	Width	Length	Model #
Collagen Bioscaffold Patch	2 cm	2 cm	UC0202
Collagen Bioscaffold Patch	4 cm	4 cm	UC0404
Collagen Bioscaffold Patch	5 cm	8 cm	UC0508
Collagen Bioscaffold Patch	6 cm	14 cm	UC0614C

CardioCel Neo Bioscaffold Patch	Width	Length	Model #
Collagen Bioscaffold Patch	4 cm	4 cm	UC0404N
Collagen Bioscaffold Patch	5 cm	8 cm	UC0508N

Indication
The CardioCel Bioscaffold Patch is indicated for use as a patch in pericardial closure and the repair of cardiac and vascular defects including intra-cardiac defect, septal defects, valve and annulus repair, great vessel reconstruction, peripheral vascular reconstruction and suture line buttressing.

Intended Patient Population
Patients of any gender, age or ethnicity in need of cardiac or vascular repair. There is limited data for the use of this device on pregnant women. It is at the surgeon's discretion on whether to use it on this population.

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 maybe swollen and tender for up to a week.
3. Watch for any new redness or tenderness.
4. Watch for any opening in the incision(s).
5. Watch for numbness, tingling or pain.

NOTE: If you experience any symptoms described in 3, 4 or 5 above please contact your provider.

6. Do not puncture or manipulate the patch.
7. If the patch was implanted in your leg, swelling in the extremity is expected because of increased blood flow. Elevate or move the extremity according to your provider's instructions.
8. It is preferable to have the surgical site covered for the first week to protect skin and incision(s). (Follow your provider's instructions.)
9. Keep bandages or wound covering on as per your provider's instructions.
10. If you have adhesive surgical tape or strips across your incision(s), wear loose clothing that does not rub against your incision(s). The adhesive surgical tape or strips will curl up and fall off on their own after a week.
11. You may shower or get the incision(s) wet, once your provider says you can. DO NOT soak, scrub, or have the shower beat directly on the incision(s).
12. DO NOT soak in the bathtub, a hot tub, or a swimming pool. Ask your provider when you can start doing these activities again.
13. Your provider will tell you how often to change your wound covering and when you may stop using one. Keep your incision(s) dry. If your incision(s) goes to your groin, keep a dry gauze pad over it to keep it dry.
14. Clean your incision(s) with soap and water every day once your provider says you can. Look carefully for any changes. Gently pat it dry.
15. DO NOT put any lotion, cream, or herbal remedy on your incision(s) without first discussing with your provider.
16. Consult your provider for instructions on taking any prescription or over-the-counter medications after surgery.

Intended Performance
- The patch is intended to repair cardiac and vascular defects.

Undesirable Side Effects
- calcification: tissue hardening
- haemolysis: rupture of blood vessels
- flow obstruction: blockage
- thromboembolism: blockage of blood vessel by clot
- endocarditis: heart becomes swollen, hot and can be painful.
- pericardial adhesions: swelling and irritation of heart tissue
- inflammation: localized reddening and swelling and may be hot and painful
- degeneration of the implant: become less functional
- formation of clinically significant fibrous tissue: toughening of tissue that may impact your health

Long-term Protection Measures for Your Patch
- For cardiac implants there are no long term protection measures. Please contact your provider for further guidance.
- If implanted in an extremity:
  - 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 patch implantation side of your body as it may cause compression.

Risks Related to Interactions with Other Equipment
- None

Post-surgical Monitoring
- Check your incision(s) every day.
- Call your provider 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 incision(s)
    4. Numbness
    5. Fever
- The nature and frequency of regular or preventative examination, monitoring or maintenance of the patch will be determined by your provider. This will be based on your underlying medical condition and the status of your patch.

Lifetime of the Device
- The lifetime of the device has been shown to be safe and effective up to 12 years. Proper care and regular medical follow up may extend the life of the device.
- To ensure your patch functions as intended, follow the guidance of your healthcare 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(s) opens
- Extensive bleeding from the incision(s)
- Signs of infection, such as:
    1. Increased pain, swelling, warmth, or redness
    2. Red streaks leading from the incision(s)
    3. Pus draining from the incision(s)
    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 and substances could potentially pose a risk to patients:
- Bovine pericardium
- Low levels of residual glutaraldehyde
- Low levels of residual propylene

The CardioCel patch has passed biocompatibility testing to ensure it is safe to use.

In Case of an Emergency

Any serious adverse reaction should immediately be reported to your provider. Please make sure any serious incident that occurs in relation to the patch is reported to:
- The Therapeutic Goods Administration website (https://www.tga.gov.au/)
- LeMaitre Vascular, Inc. (+1 781-221-2266 or https://www.lemaitre.com/contact-us/email-us).

Symbol Legend

									
English	Symbol Legend	Patient Name	Implant Date	Healthcare Institution	Patient Information Website	Explanation of Unique Device Identifier	Medical Device	Batch Code	Manufacturer

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