LeMaitre®

CardioCel® Bioscaffold Patch

CardioCel® Bioscaffold Patch
Instructions for Use - English

CardioCel® Bioscaffold Patch
(Model Numbers - UC0202, UC0404, UC0508, UC0614C, UC0404N, UC0508N)
Instructions for Use - English

STERILE PO Rx only

Storage
The CardioCel Bioscaffold Patch should be stored at room temperature, never below 2°C or above 25°C, and away from direct heat source. The implant should not be re-sterilized.

Description
The CardioCel Patch consists of one piece of bovine pericardial tissue that has been selected for minimal tissue blemishes. The pericardium is procured from cattle originating in Australia, New Zealand, and the US.
The CardioCel Patch is liquid chemical sterilized and packaged in a plastic jar containing sterile propylene oxide sterilization solution. The sterilization solution converts to propylene glycol storage solution in the jar prior to product release.
The CardioCel patch comes in a range of sizes from 4cm^2 to 84cm^2. The CardioCel average thickness is 0.5mm. The CardioCel Neo average thickness is 0.3mm.
The CardioCel Bioscaffold Patches come in the following sizes:

Product	Model	Size (cm)		Product	Model	Size (cm)
CardioCel	UC0202*	2x2		CardioCel Neo	UC0404N	4x4
	UC0404	4x4			UC0508N	5x8
	UC0508	5x8				
	UC0614C	6x14				

* Not available in the United States or Canada

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

Intended User
The intended users of this device are qualified Cardiothoracic, Vascular and General Surgeons.

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.

Contraindications
- None

Warnings
1. Use of the device following a compromise in sterility may result in infection.

Precautions
1. Store the package right-side up.
2. The outside of the jar is not sterile and must not be placed in the sterile field.
3. Do not use the device if the tamper-evident seal is broken.
4. Do not use the device if the Freeze indicator has been tripped.
5. Do not use the device if there is evidence of damage to, or leakage from, the jar, or if the solution appears turbid as sterility of the product may have been compromised.
6. Do not expose the patch to any solutions, chemicals, antibiotics, antimycotics, or other drugs except for the storage solution or sterile physiological saline, as irreparable damage to the patch may result that is not apparent under visual inspection.
7. Prior to surgery, prospective patients or their representatives should be informed about possible complications which may be associated with the use of this device.
8. As with any surgical procedures, infection is a possible complication. Monitor patient for infection and take appropriate therapeutic action.

Adverse Events
1. Device damage by exposure to chemicals, freezing, extreme heat, or chemical sterilization by the user has not been investigated. Therefore the long term surgical outcome after exposure is unknown.
2. Cases of epicardial inflammatory reactions have been reported when bovine pericardium has been used for pericardial closure.
3. Other adverse events associated with bioprosthetic pericardial patches that have been reported in the literature have included: calcification; haemolysis; flow obstruction; thromboembolism; endocarditis; pericardial adhesions; inflammation; degeneration of the implants; and formation of clinically significant fibrous tissue.

Potential Complications
- restenosis
- stenosis
- pseudo-aneurysm formation
- infection
- thrombosis
- calcification
- fibrosis
- vessel occlusion
- patch rupture
- dilatation
- myocardial infarction
- bleeding
- stroke
- death

How Supplied
One CardioCel Patch is provided sterile and non-pyrogenic in a sealed container; DO NOT RESTERILIZE. The patch is stored in a sterile propylene glycol storage solution. Sterility is assured if the package is unopened and has an undamaged seal. Unused sections should be considered non-sterile and discarded.

Directions for Use
Choose the required CardioCel Patch model as appropriate for the type of procedure being performed. The CardioCel Patch can be cut to a size appropriate for a given repair. CardioCel is for SINGLE USE ONLY.

Patch Preparation
Rinse surgical gloves to remove glove powder prior to touching CardioCel.
Examine the information of the jar label to verify selection of the correct CardioCel Patch size.
DO NOT USE THE CARDIOCEL PATCH IF THE JAR IS DAMAGED OR IF THE SEAL IS BROKEN. Do not discard the product. Please contact your distributor for further instructions.
Remove the tamper-evident outer plastic seal and unscrew the jar cap. The contents of the jar are sterile and must be handled aseptically to prevent contamination. The outside of the jar is not sterile and must not enter the sterile field. From the jar, remove the CardioCel Patch by grasping its corners with sterile, atraumatic forceps.
Immerse in physiological saline. No extensive rinsing is required. Allow the CardioCel Patch to remain in saline to avoid dehydration until required by the surgeon.

Implantation
The surgeon may cut and shape CardioCel to suit the requirements of the procedure.
Care should be taken when handling the device, for example by using atraumatic forceps, to avoid tearing or otherwise damaging the patch.

The device should be visually examined for damage noting it may have a smooth and a rough side.
CardioCel may be cut, folded or layered as required. If layering, it is preferable to cut the material into separate sheets, creating edges rather than to fold it, presenting the maximum number of cut surfaces to body tissue, to enhance penetration by cells and blood vessels.
CardioCel may be sutured or stapled in place. Being a strong material, it will take and hold sutures easily and firmly, and will remain in situ while it is incorporated into surrounding tissue.
When implanting by suture, suture bites should be taken 2 to 3 millimeters from the edge of the patch.
Note: After removal from its jar, all unused pieces of CardioCel should be discarded.
The solution in which the CardioCel is stored can be disposed of according to hospital procedures for non-hazardous materials.

Surgical Technique
It is beyond the scope of this Instructions for Use booklet to instruct the surgeon in specific repair procedures. LeMaitre Vascular, Inc. assumes that any surgeon performing the above operations has received adequate training and is thoroughly familiar with the pertinent scientific literature.

Patient Implant Resources
For patients located in Australia, the CardioCel Patch is supplied with a Patient Implant Card (PIC) and Patient Implant Leaflet (PIL). Please supply the patient with the PIL and the completed PIC (instructions below) after implantation:
1. The front of the PIC supplied is to be completed by the operating surgeon/team.
2. There are 3 lines of information to be completed. Line #1 is for patient identification (e.g. patient name). Line #2 is for the operation date. Line #3 is for the address of the health care center or doctor where medical information about the patient may be found.
3. The back of the PIC contains the product and Manufacturer information.

Safe Handling and Disposal
If serious medical incidents should arise during use of this medical device, users should notify both LeMaitre Vascular and the Regulatory Authority of the country where the user is located.
This product contains no sharps, heavy metals or radioisotopes, and is not infectious or pathogenic. No special requirements for disposal are evident. Please consult local regulations to verify proper disposal.
The storage solution can be disposed of according to hospital procedures for non-hazardous materials.
Packaging and shipping of explanted CardioCel:
Return of the shipment to LeMaitre Vascular depends on 3 crucial questions:
1. Is the explant obtained from a patient with a known or presumed pathogenic condition at the time of the explant?
2. Is the explant obtained from a patient that has a known treatment history that involves therapeutic radionuclides within the last 6 months?
3. Has the clinician obtained consent from the patient for the sample to be returned to the manufacturer for research purposes?

In the event that the response to question 1 or 2 is affirmative, LeMaitre Vascular does not provide adequate guidance for shipment. THESE EXPLANTS SHOULD NOT BE RETURNED TO LEMAITRE VASCULAR UNDER ANY CIRCUMSTANCES. In these cases, the explant should be disposed of according to local regulations.

For explants that do not have pathogenic or radiologic hazards, please use the following:
Pre-explantation:
1. If possible, perform a CT or Ultrasound scan of the device to document patency.
2. LeMaitre Vascular can accept clinical information that is patient-anonymized. LeMaitre Vascular requests information including:
   a. The original diagnosis which resulted in use of the implant.
   b. The patient's medical history relevant to the implant, including the hospital or clinic at which the device was implanted.
   c. The patient's implant experience prior to implant removal.
   d. The hospital or clinic at which the explantation was done, and date of retrieval.

Explantation:
1. Explanted CardioCel patches should be directly transferred to a sealable container filled with a solution of alkaline buffered 2% glutaraldehyde or 4% formaldehyde prior to shipment.
2. Cleaning of explanted patches should be minimal if necessary. Proteolytic digestion should not be used in any circumstances.
3. CardioCel explants should not be decontaminated under any circumstances. DO NOT autoclave the sample or use ethylene oxide gas to decontaminate.

Packaging:
1. Explants should be sealed and packed in a manner that minimizes potential for breakage, contamination of the environment or exposure to those handling such packages during transit. Material that is absorbent and is cushioning should be selected for isolating the sealable container inside the secondary packaging. Primary and secondary packaging must then be packaged inside an outer package.
2. Explants in sealed primary containers should be labeled with an ISO 7000-0659 Biohazard symbol. The same symbol should be attached to the secondary packaging and to the outer packaging. Outer packaging should also be labelled with Name, Address and Telephone Number of Sender, and the statement, "Upon discovery of damage or leakage, the package should be isolated and sender notified".
3. Packages prepared in the above manner may be shipped to:

LeMaitre Vascular
Attn: Complaint Lab
63 Second Avenue
Burlington, MA 01803, USA

Limited Product Warranty; Limitation of Remedies
LeMaitre Vascular, Inc., warrants that reasonable care has been used in the manufacture of this device and that this device is suitable for the indication(s) expressly specified in these instructions for use. Except as explicitly provided herein, LEMAITRE VASCULAR (AS USED IN THIS SECTION, SUCH TERM INCLUDES LEMAITRE VASCULAR, INC., ITS AFFILIATES, AND THEIR RESPECTIVE EMPLOYEES, OFFICERS, DIRECTORS, MANAGERS, AND AGENTS) MAKES NO EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THIS DEVICE, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND HEREBY DISCLAIMS THE SAME. This limited warranty does not apply to the extent of any abuse or misuse of, or failure to properly store, this device by the purchaser or any third party. The sole remedy for a breach of this limited warranty shall be replacement of, or refund of the purchase price for, this device (at LeMaitre Vascular's sole option) following the purchaser's return of the device to LeMaitre Vascular. This warranty shall terminate on the expiration date for this device.

IN NO EVENT SHALL LEMAITRE VASCULAR BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES. IN NO EVENT WILL THE AGGREGATE LIABILITY OF LEMAITRE VASCULAR WITH RESPECT TO THIS DEVICE, HOWEVER ARISING, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EXCEED ONE THOUSAND DOLLARS (US$1,000), REGARDLESS OF WHETHER LEMAITRE VASCULAR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY. THESE LIMITATIONS APPLY TO ANY THIRD-PARTY CLAIMS.

These limitations do not apply to consumers in Australia or to the extent they are precluded by local law in any other jurisdiction.

A revision or issue date for these instructions is included on the back page of these Instructions for Use for the user's information. If twenty-four (24) months has elapsed between this date and product use, the user should contact LeMaitre Vascular to see if additional product information is available.

Symbol Legend

	Distributed By:	REF	LOT		US					Rx only	
English	Distributed By	Catalogue Number	Batch Code	Use by date	Date/ Country of Manufacture	Wall thickness	Do not re-use	Do not resterilize	Do not use if package is damaged	Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician.	Consult Instructions for Use

	25°C 2°C	STERILE PO		STORED IN PROPYLENE GLYCOL		BIO	
English	Temperature Limits	Sterilized using Propylene Oxide	Single sterile barrier system with protective packaging outside	Stored in Propylene Glycol	Keep Away from Sun	Contains biological material of animal origin	Non-pyrogenic

	MR	MD	120 mmHg ≤0.1 mL / (min x cm²)	UDI	UKRP	?	31		
English	MR Safe	Medical Device	Water permeability	Unique Device Identifier	UK Responsible Person	Patient Name	Implant Date	Healthcare Institution	Patient Information Website

LeMaitre®

Distributed By:

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

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, USA

UKRP

LeMaitre Vascular, Ltd.
Stirling House, Centenary Park
Skylon Central
Hereford HR26FJ
England UK
Tel: 01432513125

AUS

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

R4248-01 Rev. B 02/24