Edwards

Duravess Bovine Pericardial Vascular Patch

Instructions for Use

For Single Use Only

Description

The Edwards Duravess bovine pericardial vascular patch consists of a piece of bovine pericardium that has been processed using Edwards' proprietary XenoLogiX method. The pericardium is stored in a buffered glutaraldehyde solution which reduces the antigenicity of heterologous tissue and increases the stability of the tissue. Three configurations are available to be used in surgical procedures to repair and reconstruct blood vessels. Common procedures include carotid endarterectomy, profundaplasty, arteriovenous access revisions, femoral, iliac, renal and tibial endarterectomy. The vascular patches may be tailored during surgery to meet the specific configuration needs of individual circumstances.

Model Number	Dimensions
DP08X8	0.8 cm x 8 cm
DP1X6	1 cm x 6 cm
DP2X9	2 cm x 9 cm

Indications

The bovine pericardial vascular patch is intended for use as a surgical patch material for: vascular reconstruction and repairs; peripheral vascular reconstruction and repairs; and suture-line buttressing.

Warnings

The safety and efficacy of this device for procedures other than those stated in the Indications section have not been demonstrated.

The decision to use a vascular patch must ultimately be made by the physician on an individual basis after a careful evaluation of the short- and long-term risks and benefits to the patient and consideration of alternative methods of treatment. A full explanation of the benefits and risks should be given to each prospective patient before surgery. Careful and continuous medical follow-up is advised so that complications, particularly those related to material failure, can be diagnosed and properly managed to minimize danger to the patient.

Adequate rinsing with sterile physiological saline, as described in the Technique section, is mandatory before implantation to reduce the glutaraldehyde concentration. No other solutions, drugs, chemicals, or antibiotics should ever be added to the glutaraldehyde or rinse solution as irreparable damage to the tissue, which may not be apparent under visual inspection, may result.

Recipients of the vascular patch who are undergoing dental procedures should receive prophylactic antibiotic therapy to minimize the possibility of systemic infection. The vascular patch must be kept moist at all times. Drying out will cause irreversible damage to the tissue. To prevent drying out during implantation, the vascular patch should be irrigated periodically on both sides with sterile physiological saline.

Storage between 10 ° and 25 °C (50-77 °F) is recommended. Care should be exercised to avoid freezing or extreme heat, which may damage the tissue.

Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat, and may also cause skin sensitization. Avoid prolonged or repeated contact as well as prolonged breathing of the vapor.

Use only with adequate ventilation. In case of contact, immediately flush the affected area with water. In the event of contact with the eyes, seek medical attention. For more information about glutaraldehyde exposure refer to the Material Safety Data Sheet available from Edwards Lifesciences.

Surgical Precautions

Gentle handling is required for all implantable devices. If the patch is dropped, damaged, or mishandled in any way, it must not be used for human implantation. Visually examine both sides of the vascular patch. If one side appears smoother, implant the smoother surface so that it faces the blood flow.

Caution: To avoid damage to the patch, suture needles with cutting edges should not be used during implantation.

Caution: Because of the intense temperature and lighting conditions in the operating field during implantation, the tissue should be irrigated (approximately every 1 to 2 minutes) on both sides with sterile physiological saline to keep it moist.

Complications

As with all surgery, serious complications, sometimes leading to death, may result. In addition, complications due to individual patient reaction to an implanted device, or to physical or chemical changes in the components, particularly those of biological origin, may occur at varying intervals (hours or days), necessitating reoperation and replacement of the prosthetic device.

Complications associated with glutaraldehyde-preserved bovine pericardium have been reported in the literature. These complications include: inflammatory reaction, sterile abscess, infection, fibrous thickening, and severe hemorrhaging.

Technique

Preparation for Implantation

Caution: It is strongly recommended that the container not be opened unless it is reasonably certain that the patch will be implanted shortly thereafter. This is necessary to minimize the risk of contamination because it has been established that glutaraldehyde alone is not 100 percent effective as a sterilant against all possible contaminants. No attempts should be made to resterilize a vascular patch.

The vascular patch is packaged sterile in a plastic container with a screw-cap closure and seal. Before opening, inspect the container for evidence of damage

(such as a cracked container or lid), leakage, and broken or missing seals. As long as the container and its seals remain intact, the tissue will remain sterile.

After opening, inspect the contents of the container. The container should contain a sufficient quantity of buffered glutaraldehyde storage solution to cover the tissue and prevent it from drying out.

Caution: Vascular patches from containers found to be damaged, leaking, or without adequate glutaraldehyde, or broken or missing seals must not be used for human implantation.

Caution: The pericardium and glutaraldehyde storage solution are sterile. The outside of the container is not sterile and must not be placed in the sterile field.

Handle the contents of the container in an aseptic manner to prevent contamination. By grasping one edge with atraumatic forceps, immediately transfer the tissue to a sterile rinse basin containing 500 ml of sterile physiological saline. Be sure the fluid level is sufficient to completely submerge the tissue.

Caution: Unprotected forceps must never be used in handling the tissue.

Note: Care should be exercised during handling and rinsing operations to avoid contact of the tissue or the rinse solution with towels, linens, or other sources of lint and particulate matter which may be transferred to the tissue.

To rinse the pericardium, gently agitate the patch by hand for at least 1 minute in a basin containing 500ml of sterile physiological saline. Discard the rinse solution. Repeat this process a minimum of one additional time, using fresh rinse solution each time. The tissue should be left in the final rinse solution until needed to prevent drying out.

Surgical Procedure

Because of the complexity and variation in cardiac surgery techniques, the choice of surgical technique, appropriately modified in accordance with the included **Warnings, Precautions, and Technique**, is left to the discretion of the individual surgeon.

How Supplied

The Edwards bovine pericardial vascular patch is provided sterile and nonpyrogenic packaged in glutaraldehyde in a plastic container to which a seal has been applied.

Each container is shipped in a Styrofoam enclosure containing a temperature sensor to determine immediately upon receipt if the patch has been exposed to extreme temperatures during transit.

Note: Indicators are for transit only and in no way intended for purposes of monitoring temperatures a product is exposed to during its shelf life.

Upon receipt, immediately remove the Styrofoam and inspect the indicator.

If the indicator has been activated, do not use the vascular patch. Immediately contact the local supplier or representative of Edwards Lifesciences LLC to make arrangements for return and replacement.

Note: Products found to have been subjected to freezing or excessive heat later than 3 days following receipt will be considered to have resulted from environmental conditions within the control of the customer, and subject to replacement at customer's expense.

Warning: The vascular patch must be carefully inspected before implantation for evidence of temperature and other damage regardless of the inactivation of the temperature indicator.

The Styrofoam and temperature indicator should be discarded after opening and inspecting, except in the case of an activated sensor. Any vascular patch to be returned to the company following authorization, as outlined above, should be shipped in the same Styrofoam enclosure in which it was received.

Due to the biological nature of these devices, and their sensitivity to physical handling and environmental conditions, the vascular patch cannot be returned, except as noted above.

Storage

The vascular patch should be stored at 10 °C to 25 °C (50-77 °F). Stock inspection and rotation at regular intervals are recommended to ensure that the patch is used by the date indicated on the package label.

Caution: Do not freeze. Always store patches in a dry, contamination free area. Any patch that has been frozen, or is suspected of having been frozen, should not be used for human implantation.

Case History

Implant Patient Record

The vascular patch is packaged with patient record stickers containing product information including model number and lot number. These patient record stickers are provided for hospital and surgeon records.

Recovered Clinical Patches

Edwards is extremely interested in obtaining recovered clinical specimens of pericardial patches for analysis. A written report summarizing our findings will be provided upon completion of our evaluation. The explanted patches should be placed into a suitable histological fixative such as 10% formalin or 2% glutaraldehyde and returned to the company. Refrigeration is not necessary under these circumstances.

Technical Assistance

For technical assistance, please call Edwards Technical Support at the following telephone numbers:

Inside the U.S. and Canada
(24 hours): 800.822.9837
Outside the U.S. and Canada
(24 hours): 949.250.2222
In the UK: . . . . . 0870 606 2040 - Option 4
In Ireland: . . . . . 01 8211012 Option 4

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Prices are subject to change without notice.

Refer to the symbol legend at the end of this document.

Symbol Legend

	English		English		English
REF	Catalogue Number		Manufacturer		Use By
	Single use		Date of Manufacture	SZ	Size
25 °C 10 °C	Temperature Limitation	LOT	Lot Number		Do not use
Rx only	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.	#	Quantity	Use OK	Use
STERILE	Sterile		Non-pyrogenic	eifu.edwards.com + 1 888 570 4016	Consult Instructions for Use on the website eifu.edwards.com
	Do not use if package is opened or damaged		Do not resterilize		

Note: Not all symbols may be included in the labeling of this product.

VPEM1SL8x11.1

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Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA
Made in USA

Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

WEB IFU
10018936001 A
DOC-0063639 A