Glycar

Physician's Manual
Glycar Pericardial Patch with Aldecap™ Technology

DEVICE DESCRIPTION
The Glycar Pericardial Patch with Aldecap is made in South Africa of selected specially treated Bovine Pericardium. The pericardium is sourced from a specific abattoir in Namibia which is recognised as BSE free by the EU. The animals are hormone free, range fed and traceable back to their birth. The initial cleaning and fixing of the pericardium is started soon after slaughter at the abattoir by Glycar Personnel.

The process is continued at the Glycar plant in Irene which has FDA Good Manufacturing Procedure approval from the FDA which conducts inspections biannually and is ISO approved by the EU which conducts annual inspections. The pericardial patch has been sold since 1999 in the USA with approval from the FDA. It has been sold under the CE mark in Europe for the same period.

The pericardium is selected for thickness, strength and flexibility. The basic crosslinking is achieved with glutaraldehyde and the basic component of the detoxifying and anticalcification treatment is propylene glycol.

FDA, CE & ISO Certificates are available at Glycar SA PTY LTD.

Manufactured in S. Africa by:
Glycar S.A. (Pty.) Ltd.,

CE 0124

Glycar S.A.
1 Albert Rd.,
IRENE
South Africa
0062
Tel: +27 -12-667-1615
Fax: +27-12-667-3574
E-mail: Glycar@glycar.co.za

Customer Service
Tel: +27-12-667-1615
Fax: +27-12-667-3574
Cell: +27 72 172 6796

GLYCAR Inc.
Glycar Inc.
17 Gladwin Place
Bronxville
NEW YORK
USA
10708
Tel: 001-914-779-8878
Fax: 001-914-779-1083
E-mail: Rwmfglycar@aol.com
Cell: 001-914-309-5862

REF	Model Number
LOT	Lot Number
MR	MR Safe
	Use Before Date
	Single Use Only!
	Consult Instructions For Use
STERILE A	Processed Using Aseptic Technique

INDICATIONS
The Glycar Pericardial Patch with Aldecap™ treatment is indicated for:

- ✦Pericardial closure
- ✦Cardiac and vascular reconstruction and repair.

PACKAGING
The patches are packaged in plastic or glass jars encased in shrinkwrap. The contents of the undamaged, unopened jar are sterile. Moisture under the shrinkwrap indicates possible damage to the jar and lid or failure of the seal between them. The patch should **not** be used if there is any evidence of damage to the container.
The storage solution in the jar starts as 2% propylene oxide. By the time of release from quarantine this has converted to 2% propylene glycol which is a harmless biocompatible solution.
Precautions: The outside of the jar is NOT sterile and must not be placed in the sterile field. Each device is delivered with heat (temps. > 45 Celsius) and freeze (temps. < 0 Celsius) indicators. If either has turned red, do not use the patch.

GENERAL HANDLING INSTRUCTIONS
1. The Glycar Pericardial patch with Aldecap™ treatment should be stored before use at room temperature. It may be stored in a refrigerator but not in a freezer.
2. The Glycar Pericardial Patch with Aldecap™ treatment must NOT be subject to Steam or Ethylene oxide sterilization.
3. Atraumatic forceps may be used to remove the patch from its container. Toothed forceps and clamps should be avoided.
4. All powder should be washed off gloves before handling the patch.
5. Upon removal from the container the patch should be placed in sterile water or saline solution. No formal rinse is needed.
6. Should the patch inadvertently dry it may rapidly be rehydrated in sterile water or saline solution.
7. Tests in experimental animals have shown that the patch may be soaked in Gentamycin solution without changing the host response. Tests using other antibiotics have NOT been performed.

RECOMENDATIONS FOR USE
1. The patch is cut to shape by the surgeon according to the specific repair being performed. Approximately 2mm should be allowed for suture placement.
2. If opposite sides of the rectangular patch are held between finger and thumb and pulled away from each other, it is commonly found that the pericardium is stiff in one direction and yielding in the other. This identifies collagen fibers that run in the direction in which stiffness was felt. When the pericardium yields it implies that the pull is across the fibres. Occassionally the surgeon cutting a piece from the patch for insertion into the heart may find this property useful.
3. The patch is sutured to the surrounding tissue by interruped or continuous sutures. Cutting needles should not be used. Use nonabsorbable suture.
4. The 5cm X 4cm patch is thinner than the other patches and is intended for use in infants.

WARNINGS
The Glycar pericardial patch with Aldecap™ treatment is for SINGLE USE ONLY. Once the jar has been opened the patch should either be used or discarded. On no account may it be returned to its container. No attempt must be made to resterilise it. Portions not used should NOT be used except during the same operative period.

POSSIBLE ADVERSE REACTIONS
In the past regular aldehyde tanned pericardium used without post tanning treatment has been associated with calcification particularly in juvenile patients and, in some patients, formation of excesivce fibrous tissue.

DISCLAIMER OR WARRANTIES
Glycar SA Pty Ltd. Warrants that due diligence has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties whether expressed, implied, written or oral, including but not limited to, any implied warranties or merchantability or fitness.

No product is 100% effective under all circumstances under which the device is used. We do not warrant either a good effect or against any ill effects following its use.

Glycar SA Pty Ltd. shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of this device. We will replace any device which was found defective upon delivery. The use of this device is restricted to qualified medical practitioners.