Pericardial Patch
WITH ENCAP™ AC TECHNOLOGY

ENHANCED BIOCOMPATIBILITY FOR LASTING PERFORMANCE

The Pericardial Patch with EnCap AC Technology* combines strong, durable bovine pericardium with a proprietary anti-calcification treatment, making it suitable for a variety of cardiac repairs while offering improved handling and enhanced biocompatibility.

IMPROVED HANDLING AND SUTURABILITY SUPPORT CARDIOVASCULAR REPAIR

- Ready-to-use, rinseless preparation saves time during procedures.
- Bovine pericardium provides improved handling and suturability compared with synthetic patches.[1]
- The strength of glutaraldehyde-fixed tissue enhances durability and helps resist undesirable changes such as patch shrinkage and aneurysm formation, even in high-stress repairs.[2–6]
- Soft, pliable tissue conforms to anatomy and sutures into place with minimal leaking along suture line.

ANTI-CALCIFICATION TREATMENT ENHANCES BIOCOMPATIBILITY AND DURABILITY

- Proprietary EnCap AC Technology caps residual aldehydes to reduce antigenicity and cytotoxicity.[5,7,8]
- Resists calcification and promotes rapid binds, thorough healing with endothelial cell covering.[7–10]
- Improved endothelialization strengthens the reconstruction or repair, helping reduce calcification and other degeneration.[7–9]

APPROPRIATE FOR A WIDE RANGE OF CARDIAC AND VASCULAR REPAIRS[8]

- Annular reconstruction[3]
- Endocarditis leaflet repairs
- Septal defect repairs
- Aortic root enlargement
- Other vascular repairs.

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Location: Moldova

* There is no clinical data currently available which evaluates the long-term impact of anticalcification tissue treatment in humans.

Abbott

ORDERING INFORMATION

Pericardial Patch

Model Number	Patch Size (cm)	Nominal Thickness (mm)
C0205	2 x 5	0.20 – 0.40
C0405	4 x 5	0.15 – 0.25
C0510	5 x 10	0.20 – 0.40
C0914	9 x 14	0.20 – 0.40

All sizes not currently available in all markets.

References:

1. Crawford FA Jr, Sade RM, Spinale F. Bovine pericardium for correction of congenital heart defects. Ann Thorac Surg. 1986;41(6):602-5.
2. Frater RWM, Vetter HO, Zussa C, et al. Chordal replacement in mitral valve repair. Circulation. 1990;82[suppl IV]:IV-125-IV-130.
3. David TE, Feindel CM, Armstrong, S, et al. Reconstruction of the mitral annulus: a ten-year experience. J Thorac Cardiovasc Surg. 1995;110(5):1323-32.
4. Bjornstad K, Duran RM, Nassau KG, et al. Clinical and echocardiographic follow-up after aortic valve reconstruction with bovine or autologous pericardium. Am Heart J. 1996;132(6):1173-8.
5. Gong G, Seifter E, WD Lyman, et al. Bioprosthetic cardiac valve degeneration: role of inflammatory and immune reactions. J Heart Valve Dis. 1993;2(6):684-93.
6. Gong G, Ling Z, Seifter E, et al. Aldehyde tanning: the villain in bioprosthetic calcification. Eur J Cardiothorac Surg. 1991;5:288-99.
7. Frater RWM, Seifter E, Liao K, et al. Anticalcification, proendothelial, and anti-inflammatory effect of post-aldehyde polyol treatment of bioprosthetic material. In: Gabbay S, Wheatley DJ (eds.). Advances in Anticalcific and Antidegenerative Treatment of Heart Valve Bioprostheses. Austin, TX: Silent Partners Inc; 1997:105-14.
8. Frater RWM, Liao K, Seifter E. Stentless chordally supported mitral bioprosthetic valve. In: Gabbay S, Frater RWM (eds.) New Horizons and the Future of Heart Valve Bioprostheses. Austin, TX: Silent Partners Inc; 1994:103-19.
9. Hoffman D, Gong G, Liao K, et al. Spontaneous host endothelial growth on bioprostheses. Circulation. 1992;86[suppl II]:II-75-II-79.
10. Moritz A, Grimm M, Eybl E, et al. Improved spontaneous endothelialization by postfixation treatment of bovine pericardium. Eur J Cardiothorac Surg. 1991;5:155-9.

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DECLARATION OF CONFORMITY
Pericardial Repair Patches

GLYCAR S.A. (Pty) Ltd. Declare by our sole responsibility that the following products conform to the applicable provisions of the Medical Device Directive (MDD) 93/42/EEC, as amended by 2007/47/EC.

Manufacturer Address:	1 Albert Road Irene 0062 South Africa
European Representative:	St. Jude Medical Coordination Center BVBA. The Corporate Village Da Vincilaan11 Box F1 1935 Zaventem, Belgium
Product Type:	Pericardial Repair Patches
Product name (s):	SJM™ Pericardial Patch, with EnCap™ Technology
Description:	Bovine Pericardium Patches
Model #s:	C0205 – 20mm X 50mm C0405 – 40mm X 50mm C0510 – 50mm X 100mm C0914 – 90mm X 140mm
Classification:	Class III, per annex IX rule 8 and 17
GMDN CODE:	35273
Annex II, excluding clause 4	Certificate No: 50275-16-07
Annex II, clause 4 & Commission Regulation 722/2012	Certificate No: 50275-53-A5
Applicable Quality System Standards:	EN ISO 13485: 2016
Notified Body:	DEKRA Certification GmbH Medizinprodukte / Medical Devices Zentrale / Headquarters: Handwerkstr. 15 D-70565 Stuttgart
Notified Body Number:	0124
Original CE Mark Date:	27 October 1999
This declaration will expire on:	27 April 2022

Signature: _____

Mr. Aaron Baloyi
Quality Management Representative
GLYCAR S.A. (Pty) Ltd

Issue Date: 15 May 2019

EC CERTIFICATE

for the Quality Assurance System

according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Glycar S.A. (Pty) Ltd.

Certified location/s:

1, Albert Road, 0062 Irene, South Africa

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50275-Z6-00, the decision dated 2019-04-25 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-04-28 to 2024-04-27

Registration No.: 50275-16-07

DEKRA Certification GmbH * D-70565 Stuttgart, Handwerkstraße 15 *

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-05-03
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

84460

Annex to the EC Certificate No. 50275-16-07

Valid from 2019-04-28 to 2024-04-27

Revision status of the annex: 0 dated 2019-04-25

Devices/device categories included in the certificate:

Class III:

- Pericardial Tissue Repair Patches

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

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Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-05-03
Notified Body ID-number: 0124

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EC Design-ExaminationCertificate

according to directive 93/42/EEC, annex II (4) and commission regulation no. 722/2012

As a notified body of the European Union, DEKRA Certification GmbH certifies for the manufacturer

Glycar S.A. (Pty) Ltd.

1 Albert Road, 0062 Irene, South Africa

that the design dossier for the product(s) described in the annex complies with the requirements of the directive 93/42/EEC and the commission regulation no. 722/2012. This certificate is based on the result of the examination of the design dossier according to the directive 93/42/EEC annex II.4 and commission regulation no. 722/2012 as documented in the report mentioned in the Annex.

Product: PERICARDIAL TISSUE REPAIR PATCHES

This certificate is valid from 2018-04-28 to 2023-04-27

Registration No.: 50275-53-A5

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-03-20
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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Annex to the EC Design Examination Certificate No. 50275-53-A5

Revision status: 0

valid from 2018-04-28 to 2023-04-27

Report number: 50275-P1-12

Product: Pericardial Tissue Repair Patches

Intended use:

The Pericardial Tissue Repair Patches are intended for the repair of congenital, traumatic, iatrogenic, ischemic and septal defects of the heart, pericardium and great vessels.

Technical data:

Model no.:	**C0205**	**C0510**	**C0914**	**C0405**
Patch Material:	Bovine Pericardium			
Patch dimensions (length x width) [mm]:	20x50	50x100	90x140	40x50
Sterilization process:	Chemical sterilization			

Tissue or derivate of animal origin which was subject of the assessment procedure:

Bovine Pericardium

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