MITRAL STENTED PERICARDIAL
HEART VALVE

PERICARBON MORE™

CORCYM
WE TAKE LIFE TO HEART

PERICARBON MORE™

- Proven clinical performance[1-2]
- Low profile scalloped stent
- Soft, compliant sewing cuff
- Anti-looping protection
- Ready for use, no rinsing required
- Aldehyde neutralization treatment

Long-term proven design[1-2] of the first generation of Carbofilm™ coated Pericarbon mitral valves combined with a tissue treatment aimed at neutralizing aldehydes and mitigating the calcification process.

Technical claims are supported by CORCYM data on file.

Actuarial freedom from structural valve deterioration[1]

100% freedom from SVD at 10 years[1]

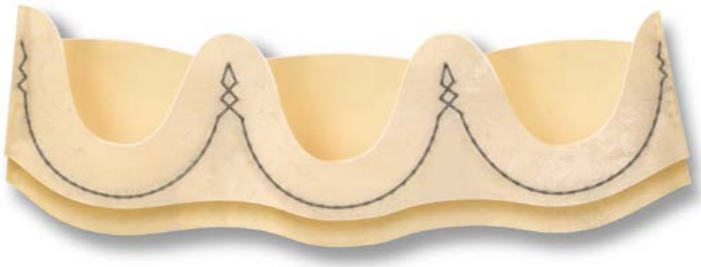
Conclusion

"These results show that over a period of up to 10 years, the Pericarbon pericardial bioprosthesis is an excellent and safe valve substitute."[1]

Unique design

Unique two-sheet design

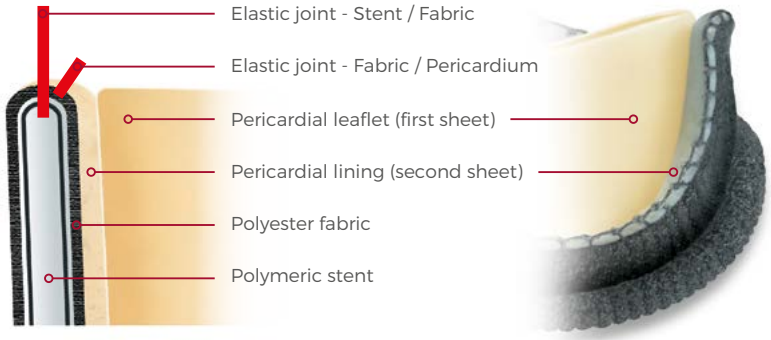
The bioprosthesis is attained by the unique two-sheet design: a tricusp shaped pericardium sheet is sutured to a second flat sheet using thread coated with a thin film of turbostratic carbon (Carbofilm™).
The commissural areas, designed to absorb and distribute the mechanical stress during leaflet motion, present a unique cross-stitch suturing pattern.
The two sheets are superimposed in a flat position so when the leaflets open they recover their original cylindrical configuration.



The elastic chain

The unique design creates a chain of smooth linkages with decreasing elasticity to minimize stress concentration. The presence of the second pericardium sheet (pericardial lining) is significant and makes the valve unique in that:

- its use contributes to the elastic chain
- it avoids contact and abrasion between the three leaflets and the fabric covered stent (synthetic material).



Indicates the union between two different elements of the elastic chain, from less elastic (stent) to more elastic (pericardial leaflet).

The fixation process

The bioprosthesis is constructed from glutaraldehyde-treated bovine pericardium.
Simultaneous in-depth tissue fixation and shaping are achieved by means of a fluidic, system at low pressure. The aldehyde neutralization process is then applied to the valve.

Technical claims are supported by CORCYM data on file.

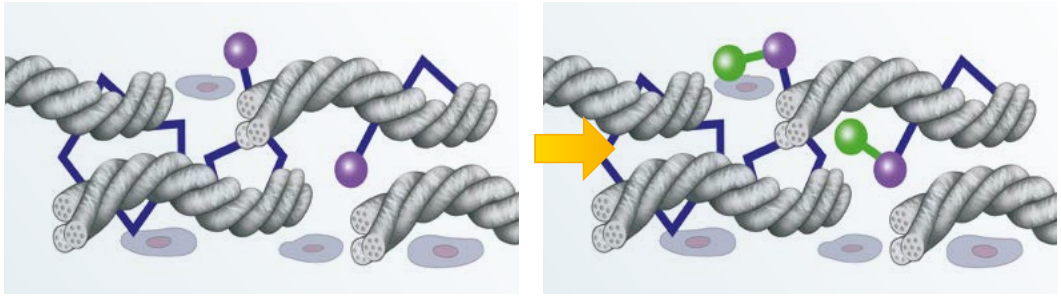
Neutralized and ready to implant

The tissue treatment with homocysteic acid,[3,4] neutralizes the residues of unbound glutaraldehyde groups (GA) left after the tissue fixation process.

Both sheets are made of the same pericardium material, hence, the aldehyde neutralization treatment acts on the leaflets and wall in exactly the same manner.

The prosthesis is then stored in a sterile, aldehyde-free solution.

The final product shows negligible aldehydes content in the tissue, thus the valve is ready to implant and does not require rinsing.



Comparative studies between neutralized and non-neutralized pericardial tissue samples show that the tissue stability and mechanical properties provided by the glutaraldehyde cross-linking are maintained unchanged through the process.[5]

Anticalcification effects of the neutralization treatment were evaluated in vivo.[6*]
A significant reduction in calcium content of neutralized tissue vs non-neutralized (glutaraldehyde treated only) tissue was shown in both rats and sheeps.[6*]

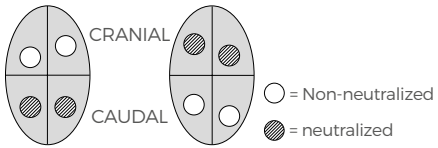
* CORCYM data on file

Technical claims are supported by CORCYM data on file.

Etherotopic in vivo test

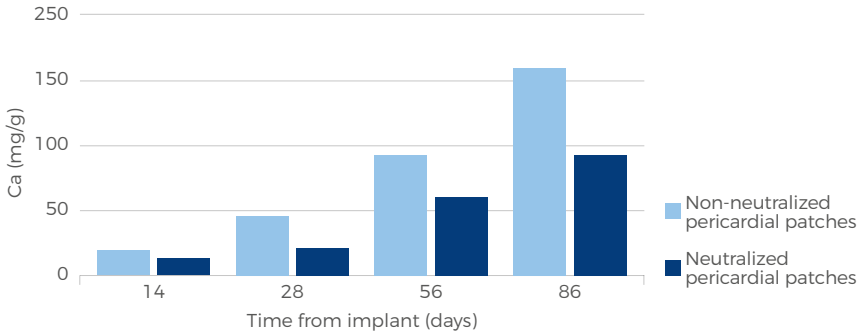
Subcutaneous implants in rats[6]

Four samples of pericardium, two neutralized and two non-neutralized, were randomly implanted in the back of rats, as shown in the figure.



Calcium deposition detected histologically in implanted specimens at Day 86.

There is heavy calcification in non-neutralized samples (left), but absent or only focal calcification in neutralized samples (right).

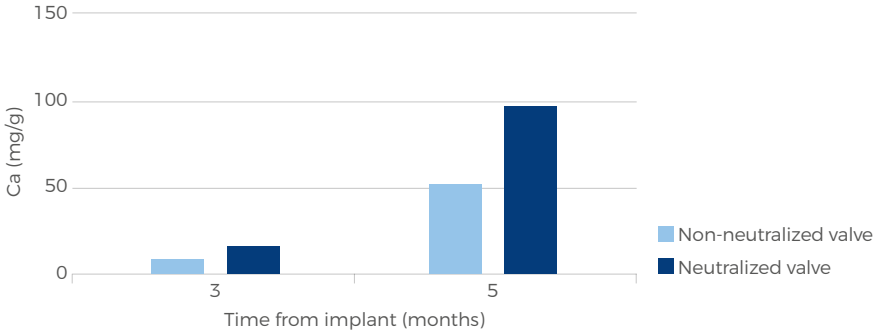


Mitigation of dystrophic mineralization in the neutralized sample is significant, even in longterm implants.

No difference in cells and collagen preservation was found between the neutralized and non-neutralized samples when retrieved, even on a long-term basis.

Orthotopic in vivo test

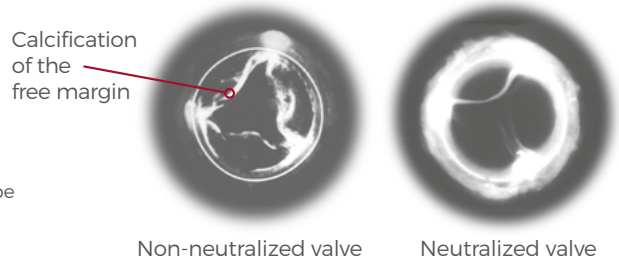
Valve replacement in sheep*



For both neutralized and non-neutralized valves:

- the reendothelization on both inflow and outflow surfaces was observed by SEM.
- elasticity and preservation of collagen fibres were satisfactory.

Radiographic visualization of calcium deposits in retrieved valves after 5 months.



SEM:
Scanning Electron Microscope

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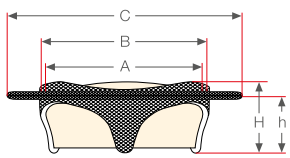
PRODUCT ORDERING INFORMATION

Size	A (mm)	B (mm)	C (mm)	H (mm)	h (mm)	Ref.	Code
19	15	19	24	12	9	PS 19	ICV0766
21	17	21	27	13	10	PS 21	ICV0767
23	19	23	31	14	11	PS 23	ICV0768
25	21	25	34	15	12	PS 25	ICV0769
27	23	27	38	17	13	PS 27	ICV0770
29	25	29	41	18	14	PS 29	ICV0771
31	27	31	45	19	15	PS 31	ICV0772
33	29	33	48	20	16	PS 33	ICV0773



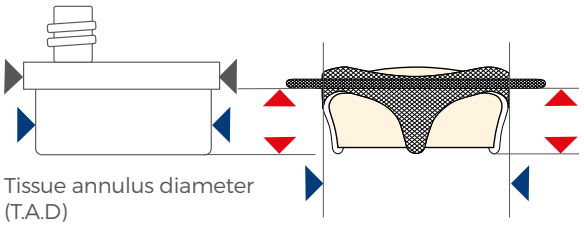
A = Valve orifice diameter

B = External diameter (T.A.D.)

C = Sewing ring diameter

H = Total height

h = Ventricular protrusion



Tissue annulus diameter (T.A.D)

ACCESSORIES ORDERING INFORMATION (not provided sterile)

CODE	NAME	DESCRIPTION
ICV0782	Sizer set	8 uni profile sizer
ICV0664	UNI Handle	Bendable handle for valve holder

REFERENCES

1. Folliguet et al., **"Pericarbon™ pericardial bioprosthesis: an experience based on the lessons of the past".** *Ann. Thorac. Surg, 2001;71:289-92.*
2. Caimmi et al., **"Twelve years follow up with the Sorin Pericarbon™ stented bioprosthesis in mitral position: Clinical and Morphological observations".** *The Journal of Heart Valve Disease, 1998;7:400-6.*
3. Schoen et al., "**Calcification of Tissue Heart Valve Substitutes: Progress Toward Understanding and Prevention".** *Ann Thorac Surg 2005;79:1072– 80.*
4. Thiene et al., **"Anticalcification Strategies to Increase Bioprosthetic Valve Durability".** *The Journal of Heart Valve Disease 2011;20:37-44.*
5. Stacchino et al., **"Detoxification process for glutaraldehyde-treated bovine pericardium: biological, chemical and mechanical characterization".** *The Journal of Heart Valve Disease 1998;7:190-194.*
6. Valente et al., **"Detoxified glutaraldehyde cross-linked pericardium: tissue preservation and mineralization mitigation in a subcutaneous rat model".** *The Journal of Heart Valve Disease 1998;7:283-291.*

INTENDED USE/INDICATIONS

The Pericarbon More Mitral prosthesis is intended to replace a damaged native mitral heart valve or a malfunctioning mitral prosthesis via open heart surgery. The Pericarbon More Mitral prosthesis is indicated for use in: patients suffering from mitral valvular heart disease, that is a condition involving obstruction of the mitral heart valve or stenosis; leakage of the mitral valve, known as regurgitation, incompetence, or insufficiency; and combinations of the two; or patients with a previously implanted mitral valve prosthesis that is no longer functioning adequately and requires replacement.

KEY CONTRAINDICATIONS

A biological prosthesis should not be used in young patients, in patients with chronic renal impairment or calcium metabolism disorders, or in patients receiving chronic drug treatment with preparations containing calcium due to the increased risk of premature valve tissue calcification.

KEY WARNINGS

For single use only. Keep the holder attached to the valve during the suturing procedures. In this way the aseptic handling is preserved and the anti-loop protection over the cusps is kept working. Do not attempt to clean, resterilize, or reuse any the prosthesis. Keep the prosthesis moist. If allowed to dry, even partially or briefly, the tissue will be irreversibly damaged. Use only the supplied accessories. The use of other accessories could result in failure to implant and impair the prosthesis integrity.

TOP POTENTIAL SIDE EFFECTS

Potential adverse events (in alphabetical order) associated with cardiac valve replacement with a bioprosthesis and the related surgical procedure include: acute/recurrent fever, allergic reaction, anaphylactic shock, anatomical structures damage, anemia, bleeding, cardiac conduction disorder, cardiac failure, cardiac tamponade, embolism, endocarditis, genotoxic response, haemolisis, infection, inflammatory response, multiorgan failure, myocardial infarction, neurological events (stroke, transient ischemic attack), nonstructural dysfunction, structural valve deterioration, thrombocytopenia, thromboembolism, TSE transmission leading to spongiform encephalopathy, valve dehiscence, valve insufficiency/stenosis, valve thrombosis. It is possible that these complications may lead to: death or permanent impairment, reoperation, medical therapy.

MRI conditional

For professional use. Instructions for Use are available upon request through the manufacturer's website. Not approved in all geographies. Follow your labeling.

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WE TAKE LIFE TO HEART

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