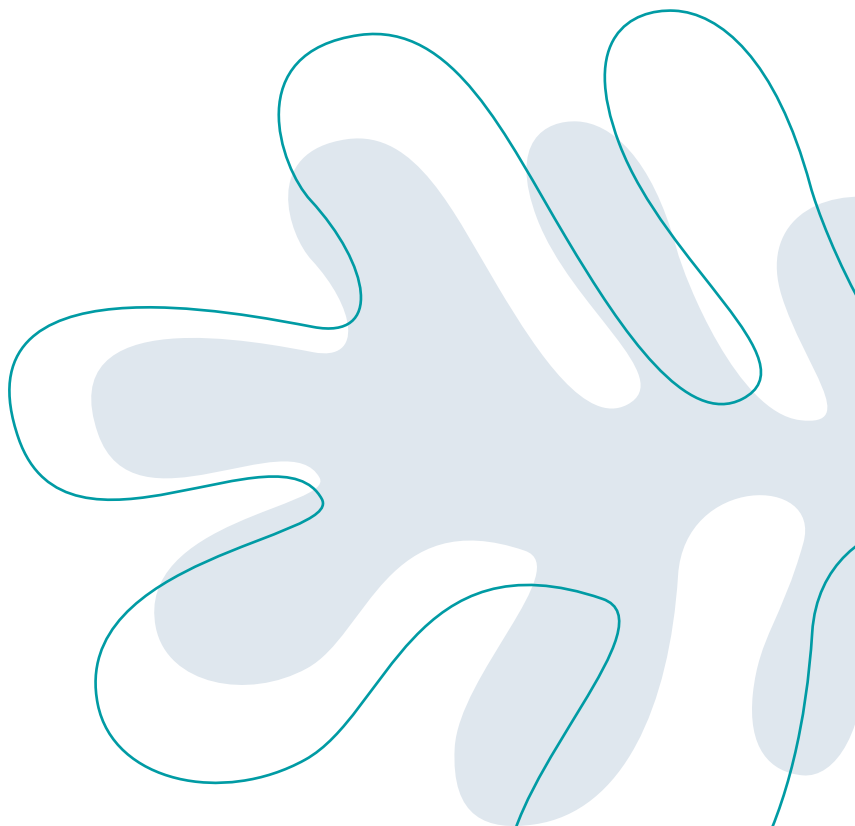
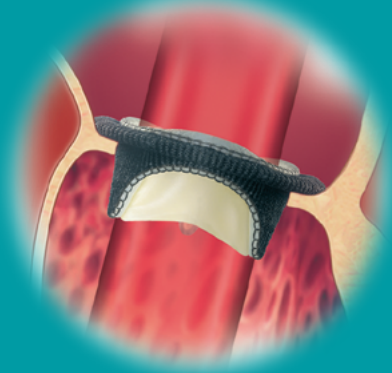




## **MITRAL STENTED HEART VALVE**

EXPERIENCED SOLUTIONS





The Pericarbon More mitral stented pericardial valve is the result of Sorin Group ceaseless commitment to achieving superior levels of quality and reliability in medical technology.

The long-term proven design<sup>1-6</sup> of the first generation of Carbofilm™ coated Pericarbon mitral valves combined with improved implantability and exclusive tissue treatment aimed at detoxifying the valve and mitigating the calcification process are proof of the success of Sorin's mission: to improve the quality of life for patients.

- PROVEN CLINICAL PERFORMANCE
- ROBUST AND SAFE DESIGN
- LOW PROFILE SCALLOPED STENT
- SOFT, COMPLIANT SEWING CUFF
- ANTI-LOOPING PROTECTION
- READY FOR USE, NO RINSING REQUIRED
- DETOXIFIED VALVE

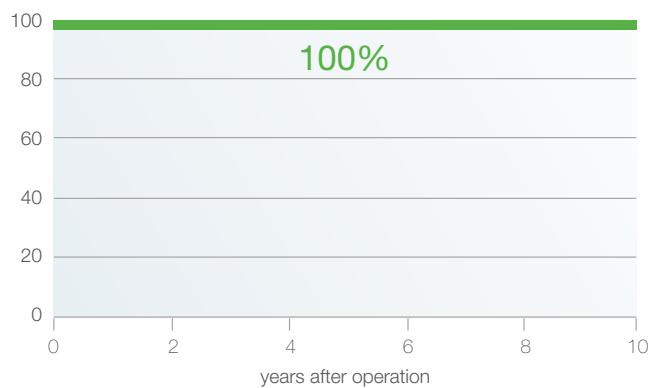
**EQUIPPED TO PERFORM**

T.A. Folliguet, E. Le Bret, J. Bachet, F.Laborde

## PERICARBON PERICARDIAL BIOPROSTHESIS: AN EXPERIENCE BASED ON THE LESSONS OF THE PAST

*Ann Thorac Surg. Mai 2001; 71(5 Suppl.) : S289-92*

### ACTUARIAL FREEDOM FROM STRUCTURAL VALVE DETERIORATION



## 100% FREEDOM FROM SVD AT 10 YEARS

Doenst T, Borger M.A., David T.E.

### LONG TERM RESULTS OF BIOPROSTHETIC MITRAL VALVE REPLACEMENT: THE PERICARDIAL PERSPECTIVE

*J. Cardiovasc Surg. (Turin). Oct. 2004 ; 45(5) : 449-54*

The currently available pericardial valves, particularly the Carpentier-Edwards pericardial and the Sorin Pericarbon, appear to provide an attractive option for the mitral valve replacement in older patients because they often out-live the patient and the need for reoperation is low.

Pericardial mitral valve can also be used in younger patients but frequent monitoring of valve performance is necessary because they may become stenotic with time and require years after operation.

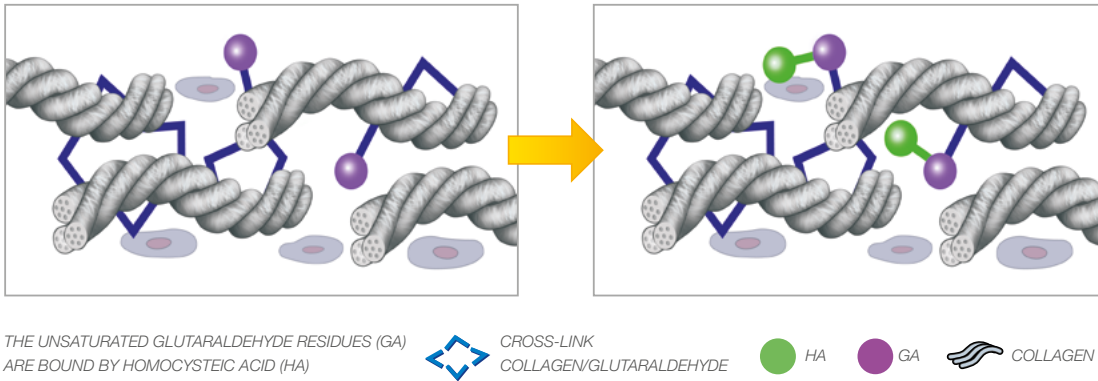
## CONCLUSION

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

## AORTOTOMY AND NATIVE VALVE EXCISION

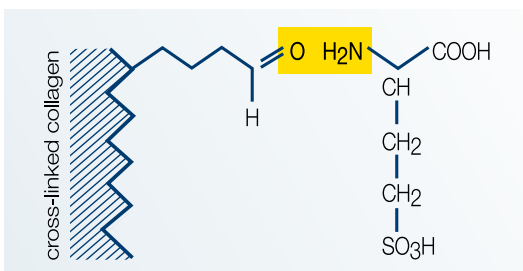
The exclusive detoxification treatment with homocysteic acid <sup>(14, 15)</sup>, neutralizes the residues of unbound glutaraldehyde groups (GA) left after the tissue fixation process.

Both sheets are made of the same pericardium material, hence, the detoxification 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 does not contain glutaraldehyde residues, thus the valve is ready to implant and does not require washing.



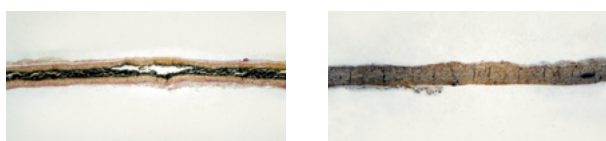
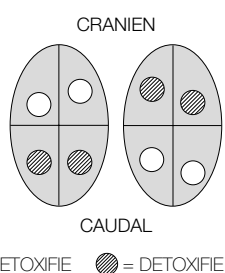
Comparative studies between detoxified and non-detoxified pericardial tissue samples show that the process maintains unchanged the tissue stability and the mechanical properties provided by the glutaraldehyde cross-linking <sup>(8)</sup>.

In-animal testings have been conducted in order to evaluate the anticalcification effects of the detoxification treatment. Both subcutaneous implants in rats of pericardial patches and valve replacements in sheep have shown a significant reduction in calcium contents of detoxified patches and valves vs non-detoxified (glutaraldehyde treated only) patches and valves.

## ETHEROTOPIC IN VIVO TEST

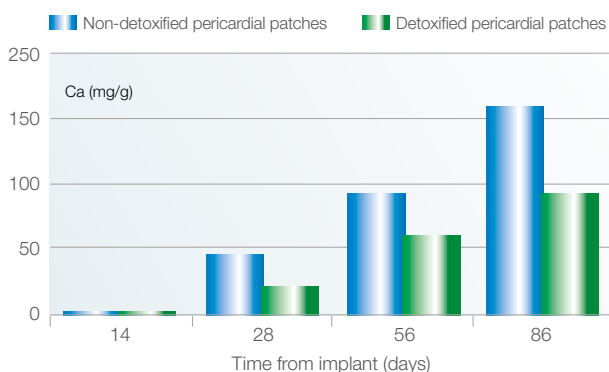
Subcutaneous implants in rats <sup>(16)</sup>

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



Calcium deposition detected histologically in the 86 days implanted specimens.

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

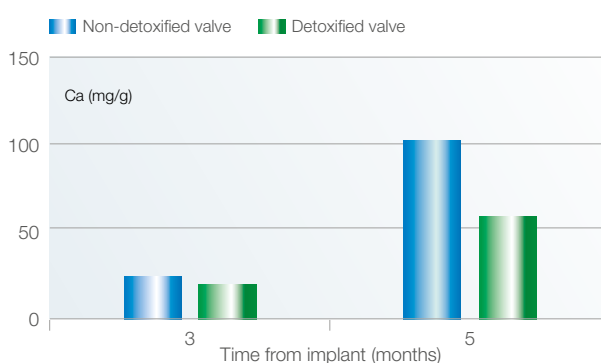


Mitigation of dystrophic mineralization in the detoxified sample is significant, even in longterm implants.

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

## ORTHOTOPIC IN VIVO TEST

Valve replacement in sheep <sup>(17)</sup>



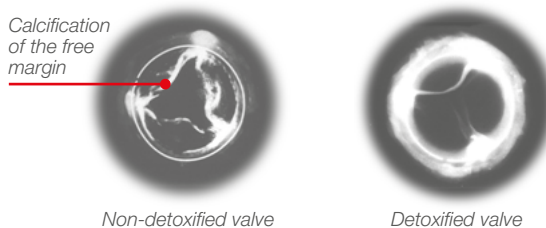
The homocysteic acid treated valves are significantly different in calcium content:

9.55 mg/g vs 16.26 mg/g at 3 months and  
50.89 mg/g vs 94.95 mg/g at 5 months.

For both detoxified and non detoxified 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.



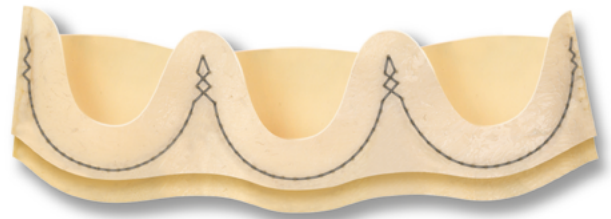
These results suggest that the treatment will further improve the already excellent long term valve performance.

## UNIQUE PROVEN DESIGN

### UNIQUE TWO-SHEET DESIGN

The bioprosthesis is attained by the unique two-sheet design: a tricuspid shaped pericardium sheet is sutured to a second flat sheet using thread coated with a thin film of turbostratic carbon (Carbofilm™).

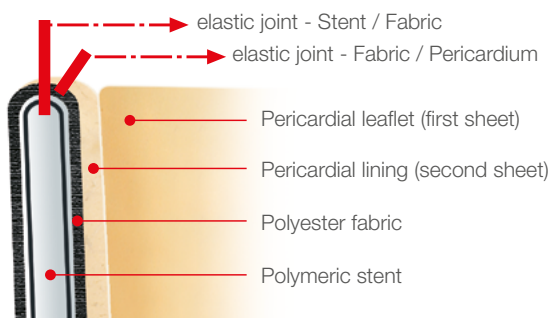
The commissural areas, designed to absorb and distribute the mechanical stress during leaflet motion, present a unique cross-stitch suturing pattern. The two sheets are superimposed in a flat position so when the leaflets open they recover their original cylindrical configuration, hence, they are completely stress-free.




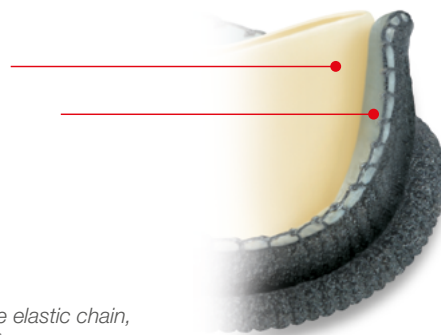
### THE ELASTIC CHAIN

The unique design creates a chain of smooth linkages with decreasing elasticity and represents the ideal condition for minimizing the concentration of tensional stress, especially during the closure phase. 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)



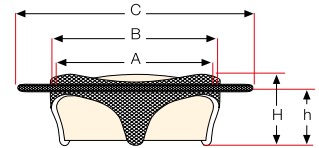
### THE FIXATION PROCESS

The bioprosthesis is constructed from glutaraldehyde-treated bovine pericardium.

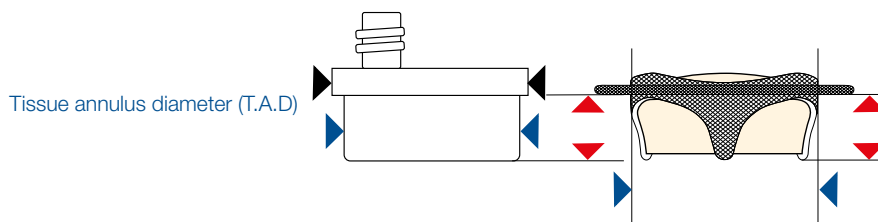
Simultaneous in-depth tissue fixation and shaping are achieved by means of a fluidic, hence atraumatic system at low pressure. The detoxification process is then applied to the valve.

## PRODUCT SPECIFICATIONS

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



A = Valve orifice diameter  
 B = External diameter (T.A.D.)  
 C = Sewing ring diameter  
 H = Total height  
 h = Ventricular protrusion

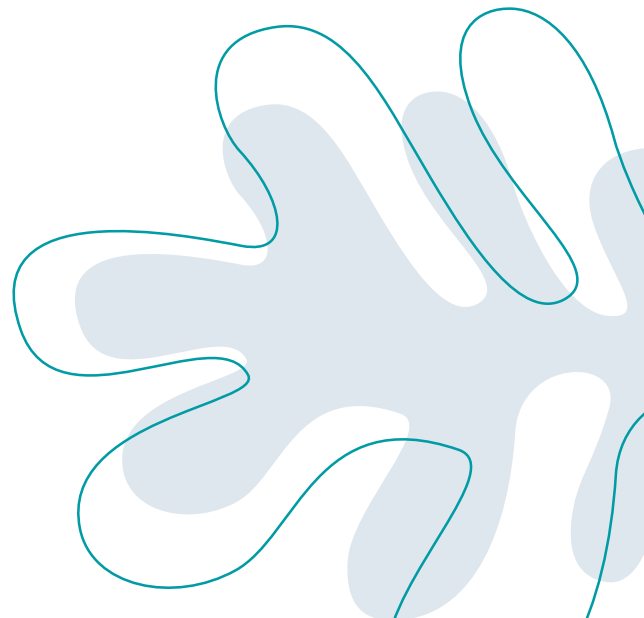


## ACCESSORIES

REF	ARTICLE	DESCRIPTION
ICV0782	Sizers set	8 intra-annular sizers for aortic and mitral valve models
ICV0664	UNI Handle	Universal, bendable handle for all valve models and sizers



All accessories are provided not sterile.



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The procedures described in this publication are provided for the convenience of the implanting medical professional, and for purposes of illustration alone. Accordingly, the procedures are not intended to be exhaustive and may not be the only procedures available at the time of implantation for performing bioprosthesis procedures. Sorin Group Italia S.r.l. therefore makes no representations as to the safety or effectiveness of the procedures. Sorin Group Italia S.r.l. relies on the medical professional to use his or her medical judgement and experience and know-how in implantation techniques for a particular patient. Detailed descriptions of indications, contraindications, precautions and potential side effects are to this end provided in the product's Instructions for Use manual.



Manufactured by:  
 SORIN GROUP ITALIA S.R.L.  
 Via Crescentino  
 13040 Saluggia (VC) Italy  
 Tel. +39 0161 487472  
 Fax +39 0161 487316  
 e-mail: info.cardiacsurgery@sorin.com



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