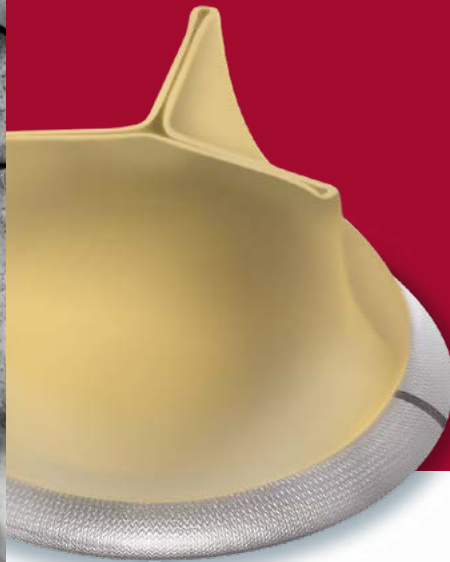




CROWN PRT™

AORTIC PERICARDIAL
STENTED HEART VALVE

Experience designs
performance

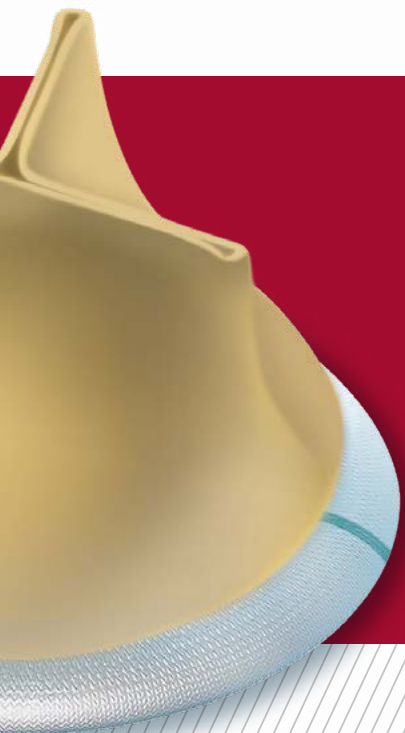


 **CORCYM**
WE TAKE LIFE TO HEART



CROWN PRT™

The Crowning touch



CROWNING DESIGN:

- Smooth handling
- Straight forward implantability
- Ample versatility¹

CROWNING PERFORMANCE:

- Favorable hemodynamics³⁻⁶

FEATURES

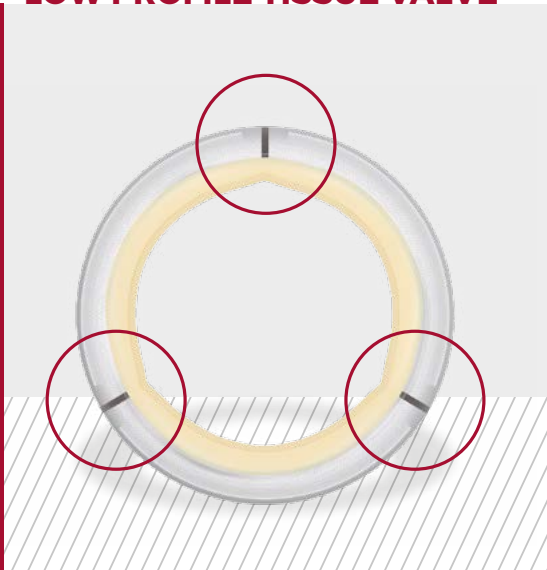
Easy to handle and implant

FLEXIBLE STENT



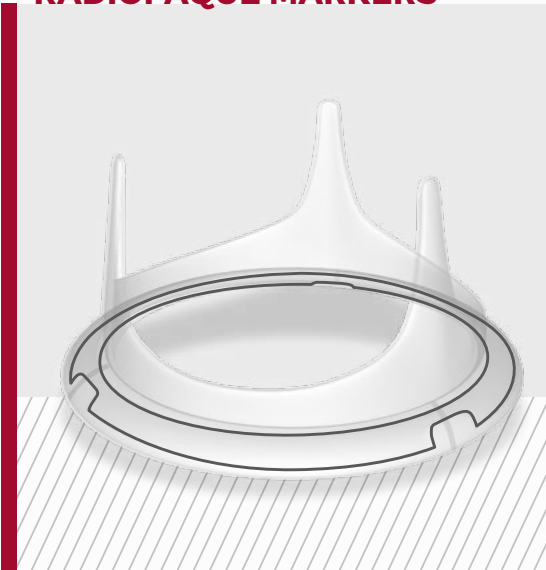
CROWN PRT's flexible stent provides resilience towards possible deformations during implant and robustness towards creep over time.*

LOW PROFILE TISSUE VALVE



CROWN PRT's sewing cuff visible markers are aimed to help precise valve placement and evenly distribute sutures.

RADIOPAQUE MARKERS



CROWN PRT's sewing cuff offers radiopaque information on its precise position through a specially shaped insert, impregnated with tungsten powder.

* CORCYM data on file

FEATURES

Versatile

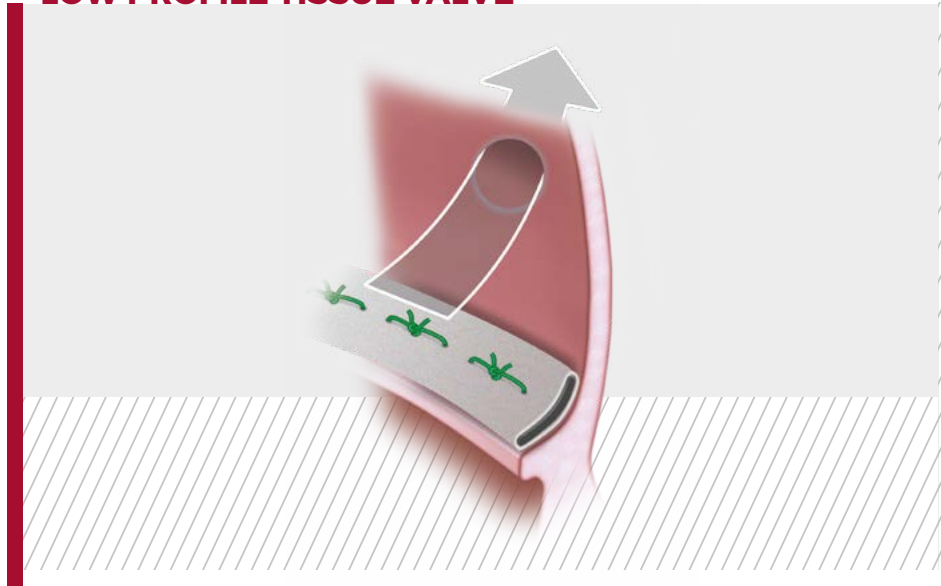
SLIM, ELASTIC SEWING CUFF



The malleable sewing cuff facilitates implantation by allowing conformability to different types of annuli, even stiff/calcified and/or irregular roots.

*"The slim sewing ring also serves this goal and is slightly malleable so that implantation in stiff roots is facilitated."*¹

LOW PROFILE TISSUE VALVE



Clearance of both coronary ostia and sino-tubular junction is assured, even in narrow aortic roots. The low/flat profile also allows the Surgeon great visibility of the aortic anatomy during the procedure.

*"Coronary clearance is ensured by the flat profile, which also facilitates knot lowering."*¹

FEATURES

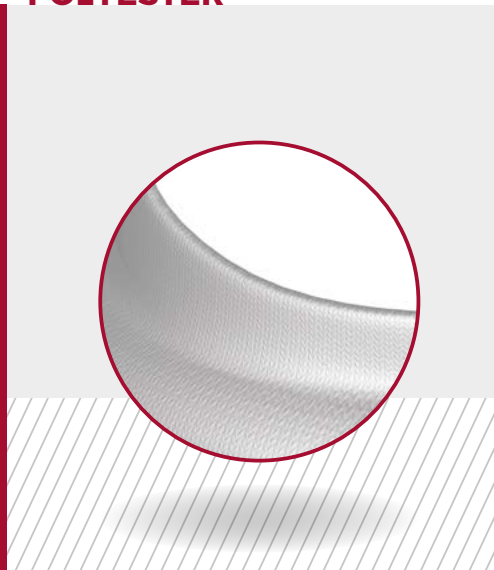
Valve design

SINGLE BOVINE PERICARDIUM OUTER LAYER



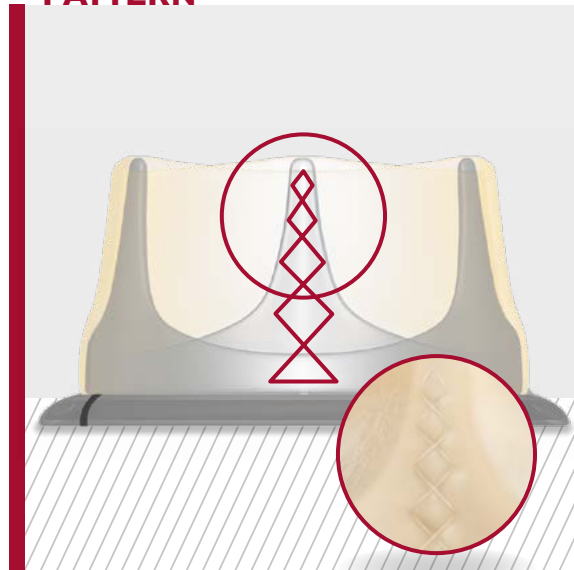
CROWN PRT's single bovine pericardium layer is mounted outside the stent. This optimizes hemodynamic performance by maximizing the flow area through a synchronous and unimpeded opening of the leaflets.²

ONE-SEAM KNIT POLYESTER



It allows for a smooth contact surface between pericardium and synthetic material. Cushioned leaflet contact may reduce pericardium wear, enhancing valve durability.

CROSS-STITCH PATTERN



By distributing stress on the commissures, pressure forces on the valve posts may be relieved during the cardiac cycle.

FEATURES

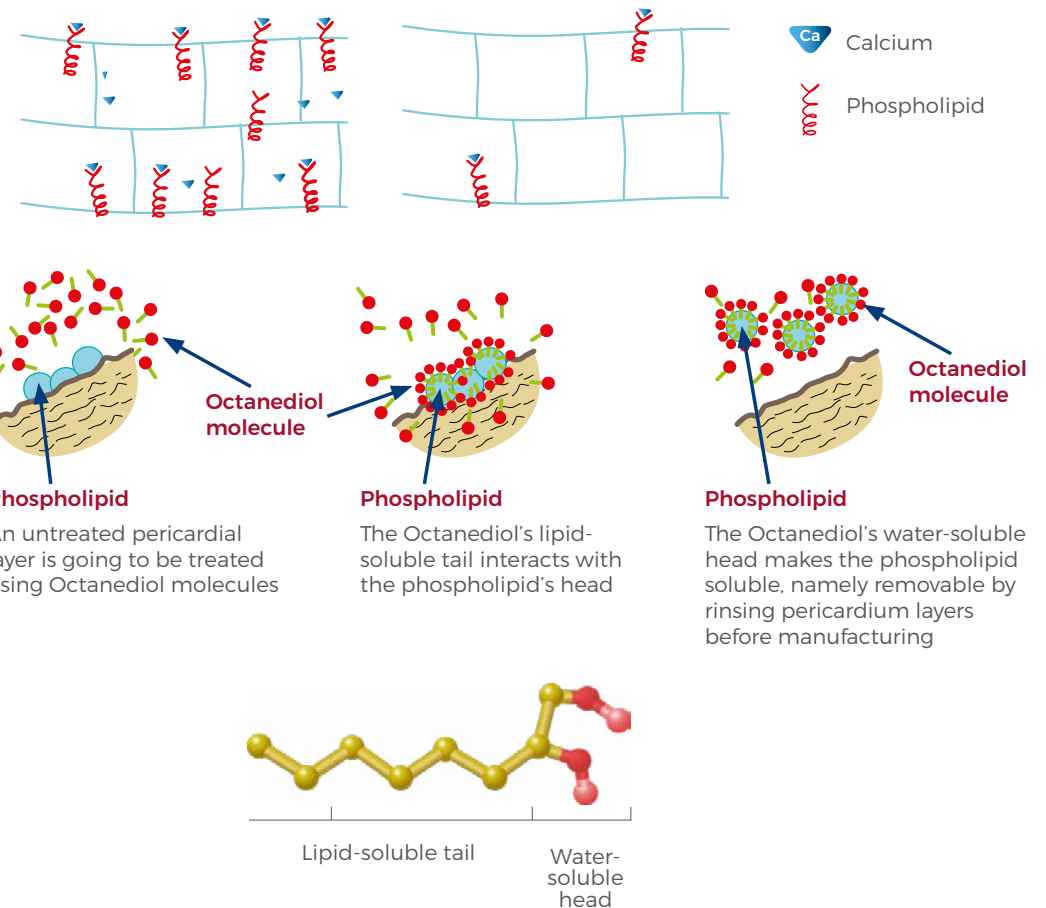
Treated to last

PHOSPHOLIPID REDUCTION TREATMENT (PRT)

The presence of phospholipids in the pericardial tissue play a key role in the calcification process of bioprostheses as their phosphate heads are potential binding sites for circulating calcium ions.

Crown PRT features CORCYM's patented PRT which has proved to decrease phospholipid content in pericardial tissue leading to a remarkable reduction of calcium uptake compared to control tissue.*

The PRT process removes phospholipids using Octanediol, a long chain alcohol that possesses a lipid-soluble tail to aid its solubility in phospholipids heads and a water-soluble head to allow removal by rinsing pericardial layers before valve manufacturing.



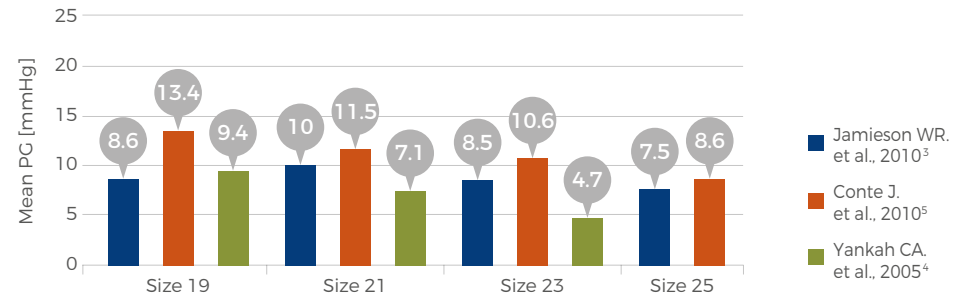
* CORCYM data on file

CLINICAL EVIDENCE

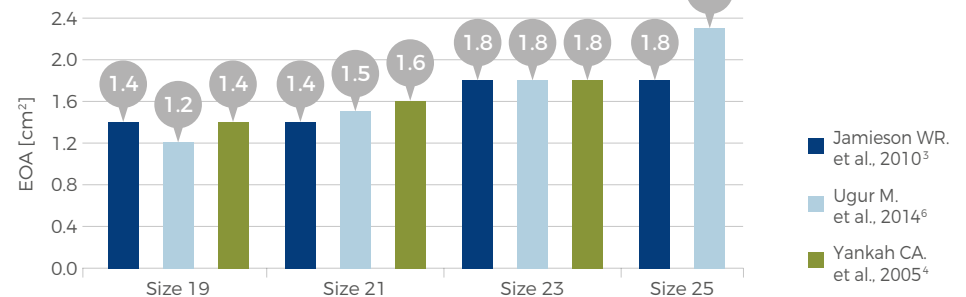
Hemodynamics

The capability of CORCYM's single bovine pericardial outer layer design to maximize flow areas through leaflets that open uniformly and wide has demonstrated favorable *in-vivo* hemodynamic performance since its introduction in the market in 1982. Literature overviews highlight low pressure gradients, large effective orifice areas and a remarkable regression on the left ventricular mass.

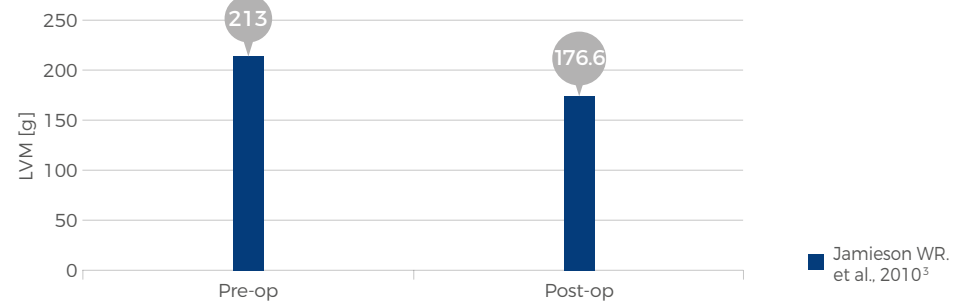
Low Pressure Gradient (PG)



Large Effective Orifice Area (EOA)



Remarkable Regression of Left Ventricular Mass (LVM)



CLINICAL EVIDENCE

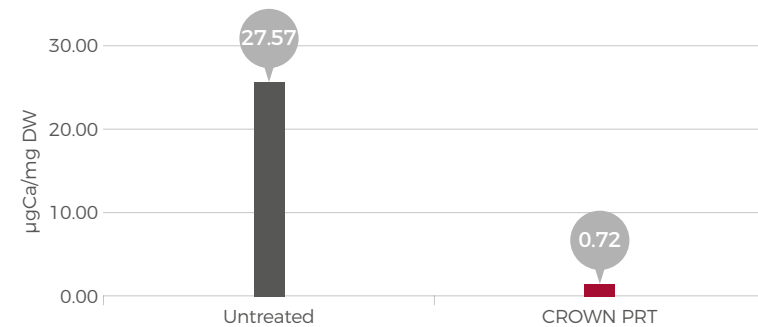
Mitigation testing

IN-ANIMAL CALCIUM ABSORPTION MITIGATION TESTING

By reducing the nucleation sites for calcium deposition - the phospholipids in the pericardial tissue - PRT directly addresses the origin of tissue calcification which may lead to an enhanced valve durability.

Tests in subcutaneous rat implants at 60 days demonstrate a significant reduction of calcium content in PRT-treated bovine pericardium patches compared to control.

The Phospholipid Reduction Treatment (PRT) process is intended to enhance already proven resilient durability by reducing calcium absorption up to 97% compared to control.*

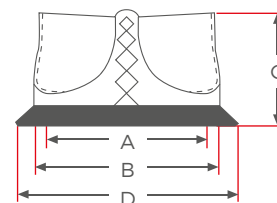


* CORCYM data on file

CROWN PRT™ AORTIC PERICARDIAL STENTED HEART VALVE

PRODUCT ORDERING INFORMATION

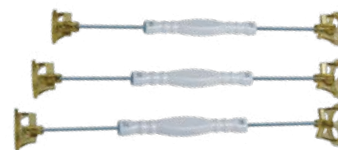
SIZE	A Inside Diameter (mm)	B Outside Diameter (mm)	C Overall Height (mm)	D Sewing Ring Width (mm)	CODE
19	15.4	18.6	11	21	CNA19
21	17.3	20.7	13	23	CNA21
23	19.0	22.7	14	26	CNA23
25	21.0	25.1	15	29	CNA25
27	22.9	27.3	16	31	CNA27
29	24.7	29.5	16	33	CNA29



A = Inside Diameter
B = Outside Diameter
C = Overall Height
D = Sewing Ring Width

ACCESSORIES ORDERING INFORMATION (not provided sterile)

CODE	NAME	DESCRIPTION
ICV1353	Bendable dual-ended sizers set	3 bendable dual-ended sizers: 19-21 mm 3-25 mm 27-29 mm
AH-11	Aortic Handle	1 Aortic handle to be used with all sizers



CROWN PRT™
The Crowning touch



REFERENCES

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Favorable gradients with the mitroflow aortic valve prosthesis in everyday surgery.
Thorac Cardiovasc Surg. 2012 Jul;60(5):326-33; discussion 333-4.
 2. von Knobelsdorff-Brenkenhoff F. et al.,
In vitro assessment of heart valve bioprostheses by cardiovascular magnetic resonance: four-dimensional mapping of flow patterns and orifice area planimetry.
Eur J Cardiothorac Surg. 2011 Sep;40(3):736-42.
 3. Jamieson WR. et al.,
Hemodynamic performance of mitroflow aortic pericardial bioprosthesis-optimizing management for the small aortic annulus.
Thorac Cardiovasc Surg. 2010 Mar;58(2):69-75.
 4. Yankah CA. et al.,
Seventeen-year clinical results of 1,037 Mitroflow pericardial heart valve prostheses in the aortic position.
J Heart Valve Dis. 2005 Mar;14(2):172-9; discussion 179-80.
 5. Conte J. et al.,
A North American, prospective, multicenter assessment of the Mitroflow aortic pericardial prosthesis.
Ann Thorac Surg. 2010 Jul;90(1):144-152.
 6. Ugur M. et al.,
Comparison of early hemodynamic performance of 3 aortic valvebioprostheses.
J Thorac Cardiovasc Surg. 2014 Jan 15. pii: S0022-5223(14)00027-0.
- Technical claims supported by CORCYM data on file

INTENDED USE/INDICATIONS

The Crown PRT valve is intended for the replacement of malfunctioning native or prosthetic aortic valves.

KEY CONTRAINDICATIONS AND WARNINGS

There are no absolute contraindications for the use of the Crown PRT valve. Clinical experience described in the medical literature suggests that patients who are undergoing chronic haemodialysis, or with parathyroid disease, impaired calcium metabolism, or who are 55 years of age or less may have an increased tendency toward calcification of valvular bioprostheses. For single use only. Adequate rinsing with sterile physiological saline is mandatory before implantation to reduce the formaldehyde concentration. Do not allow the tissue to dry during handling and implantation of the valve as this could render the valve unfit for use. Sizers and handles from other manufacturers are not suitable for use with the Crown PRT valve and should not be used.

TOP POTENTIAL SIDE EFFECTS

The risks or potential adverse events associated with cardiac valve replacement with a bioprosthesis include, but may not be limited to: non-structural valve dysfunction including valvular regurgitation and periprosthetic leakage, death, endocarditis, thrombosis and thromboembolism, haemolysis, bleeding associated with anticoagulant therapy, structural valve deterioration, reoperation and explant.

MRI conditional

For professional use. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Not approved in all geographies. Consult your labeling.



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Corcym Canada Corp. previously LivaNova Canada Corp.

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