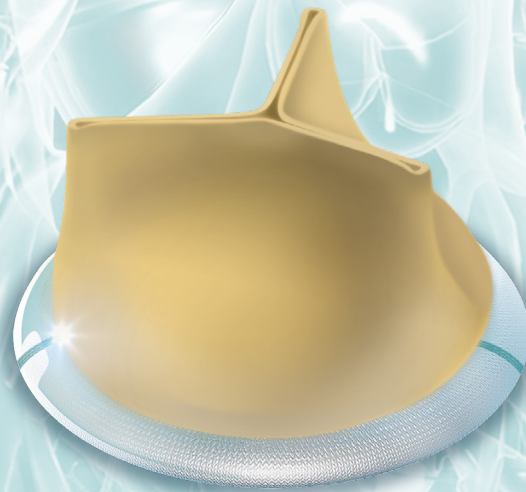


LivaNova

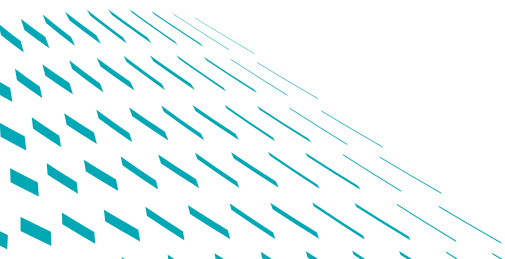
Health innovation that matters

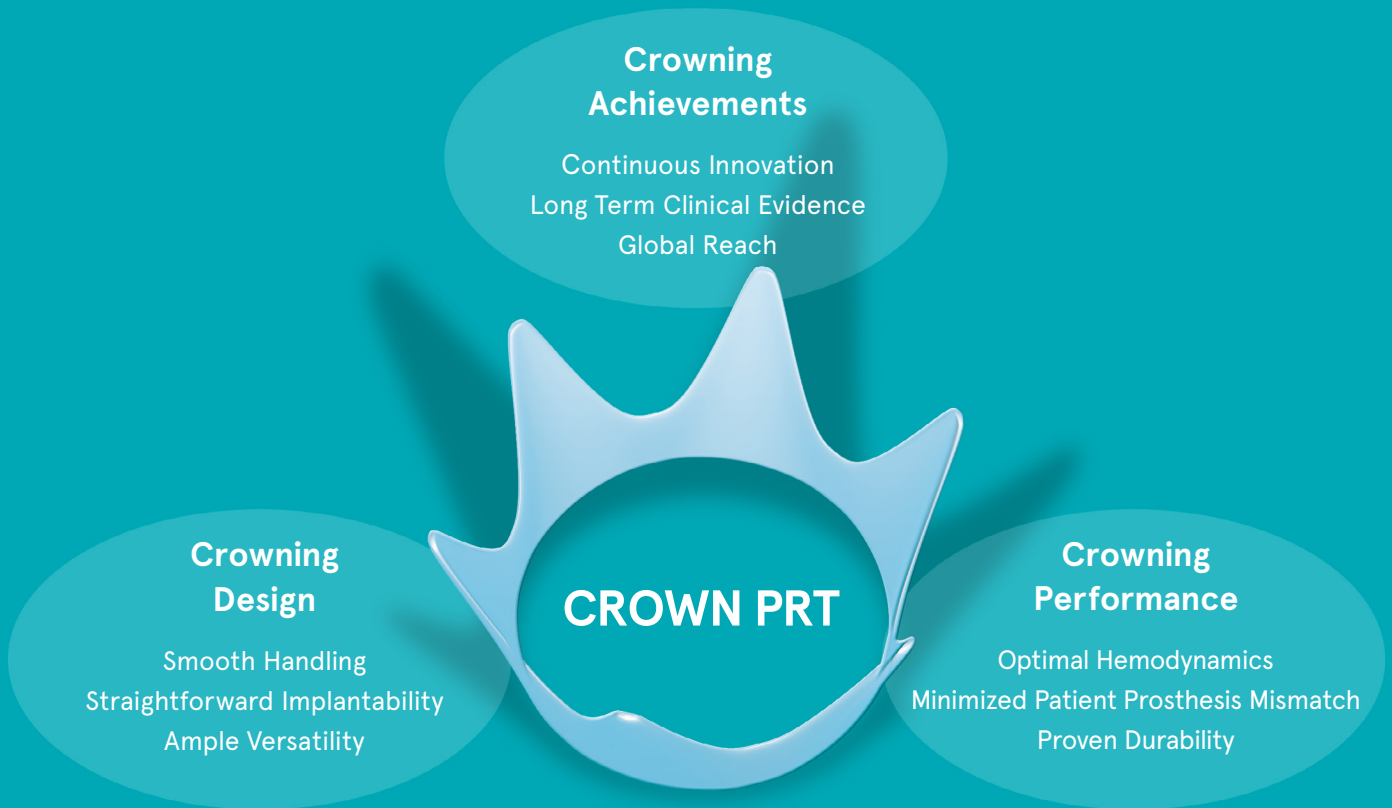
CROWN PRT[®]

The crowning touch



Experience designs performance





In the treatment of aortic valve disease, the replacement of the native aortic valve with a stented bioprosthesis represents a standard technique to provide older patients with a performing and durable solution, while relieving them from the discomfort of lifelong oral anticoagulation therapy.

CROWN PRT is the latest advancement in stented aortic bioprosthesis technology, featuring surgeon-friendly design and state-of-the-art performance.

Crowning achievements

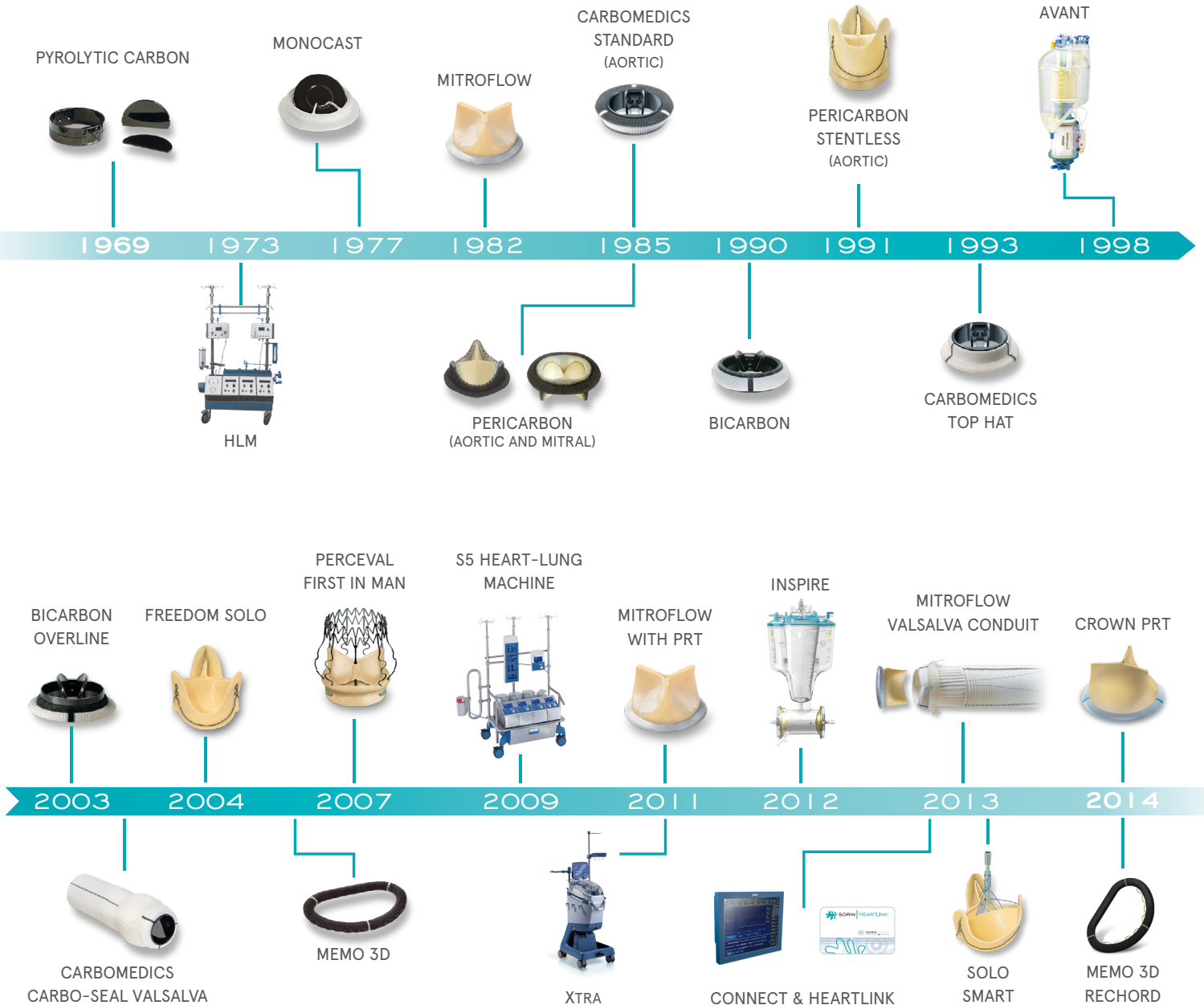
Pioneering innovative clinical solutions



CROWN PRT is part of LivaNova's cardiac surgery offering, a full suite of innovative solutions, supported by strong clinical evidence and adopted by healthcare providers worldwide.

Innovative

CROWN PRT stems from LivaNova's 45 year-long commitment to developing breakthrough innovations, an experience that has brought the company to become market leader in cardiac surgery.



Proven

100 Study Trials*
40,000 Patient Treatments*



CROWN PRT is part of LivaNova's array of Aortic Solutions which encompass both mechanical and biological prostheses.

LivaNova's mechanical and biological stented solutions have been successfully implanted since the eighties while its more recent biological stentless and sutureless solutions since the nineties and the turn of the century.

The proven clinical performance of these products is substantiated by the remarkable number of study trials and patient treatments reported in literature.

**LivaNova aortic prostheses to date.*

Global

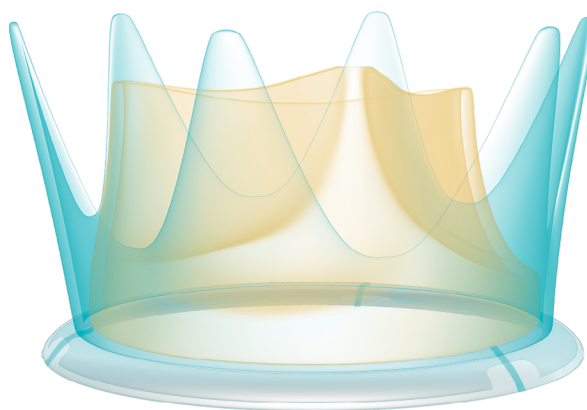


LivaNova's stented biological solutions are successfully used
in more than 80 countries throughout the world.

LivaNova's R&D structures in Canada and Italy systematically integrate the progress
of science and technology into products with the objective of developing
efficient and safe therapies for patients and healthcare providers.

Crowning design

Surgeon friendly design for straightforward
implantability and versatility



CROWN PRT's surgeon-friendly design further supports LivaNova's commitment
to continuous innovation.

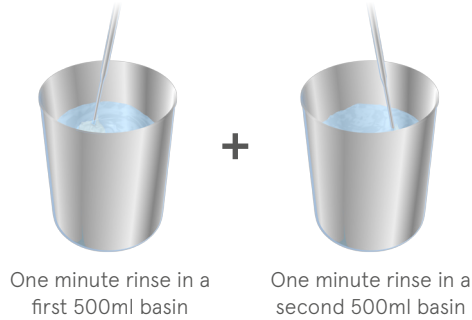
The visible markers provide precise positioning.

The radiographic markers allow sharp visualization during X-ray imaging.

EASY TO HANDLE AND IMPLANT

Short rinse time for streamlined procedures

CROWN PRT's two-minute rinse time makes intra-operative valve preparation fast and help save on aortic clamp time.



Flexible stent for easy manipulation and structural resistance

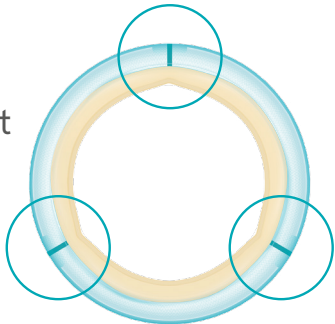
CROWN PRT's flexible stent provides resilience towards possible deformations during implant and robustness towards creep over time. valve preparation fast and help save on aortic clamp time.

“Under back-pressures of 2.000 mmHg - ten times higher than the maximal physiological ones - Stent adapts by bending its posts and then comes back to its original design once back-pressures are released.”*



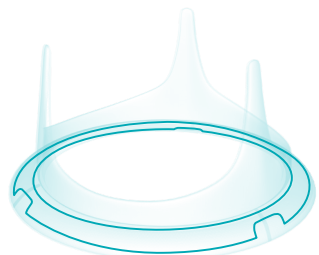
Visible markers for precise orientation and even suture placement

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



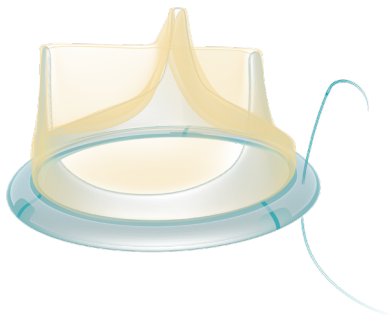
Radiographic markers for sharp X-ray imaging

CROWN PRT's sewing cuff offers radio-opaque information on the precise position of commissures through a specially shaped insert, impregnated with tungsten powder.



Low friction sewing cuff for soft suture placement

CROWN PRT's sewing cuff facilitates suturing by reducing friction.

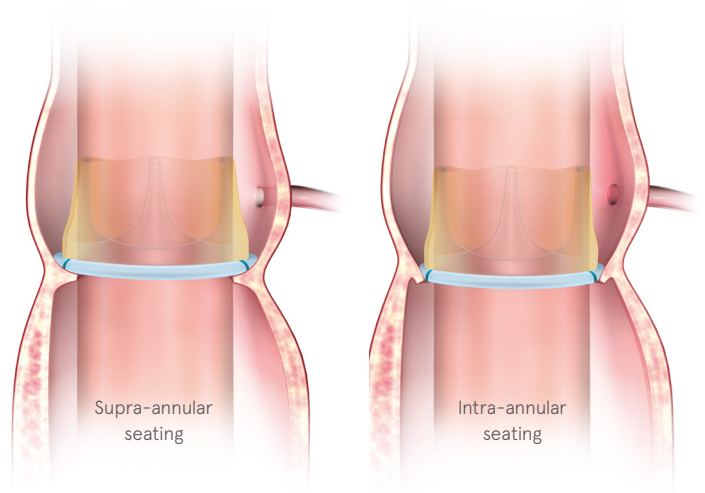


*LivaNova 2014. Data on file.

VERSATILE

Supra-intra annular positioning for adaptability to diverse anatomies and surgeon preferences

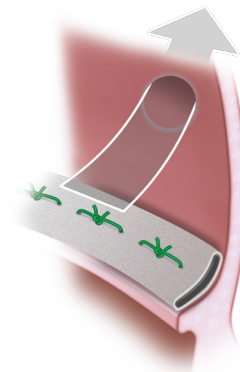
CROWN PRT valve offers surgeons the option of supra or intra-annular valve placement based on patient anatomy and surgeon practice.



The lowest profile tissue valve for clearance of coronary ostia and sino-tubular junction

Clearance of both coronary ostia and sino-tubular junction is assured, even in narrow aortic roots.

The low/flat profile also allows the surgeon greater visibility of the aortic anatomy during the procedure.

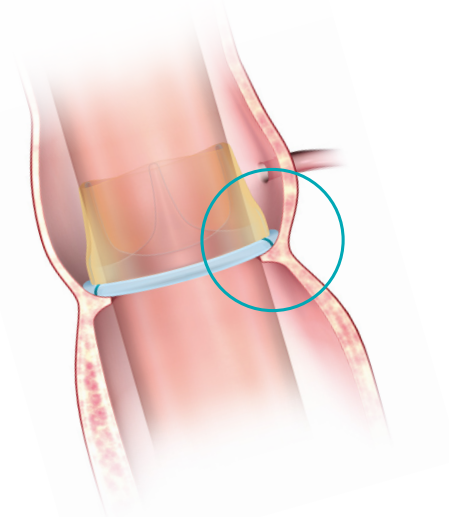


“Coronary clearance is ensured by the flat profile, which also facilitates knot lowering.”

Slim, elastic sewing cuff for full conformability to the native annulus

The malleable sewing cuff facilitates implantation by allowing full conformability to all 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.”



Crowning performance

Optimal hemodynamics and proven durability



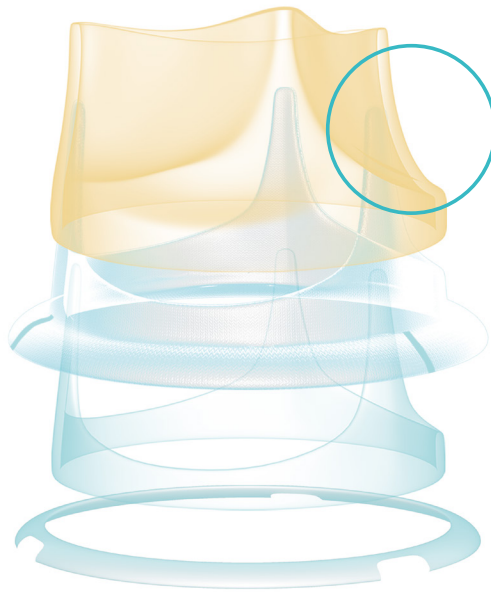
CROWN PRT's state-of-the-art performance is the result of LivaNova's long standing experience in heart valve design and cutting edge science of materials.

The wide open design provides optimal hemodynamics. The patented Phospholipid Reduction Treatment (PRT) is intended to enhance durability through mitigation of calcium absorption.*

DESIGNED TO OPEN WIDE

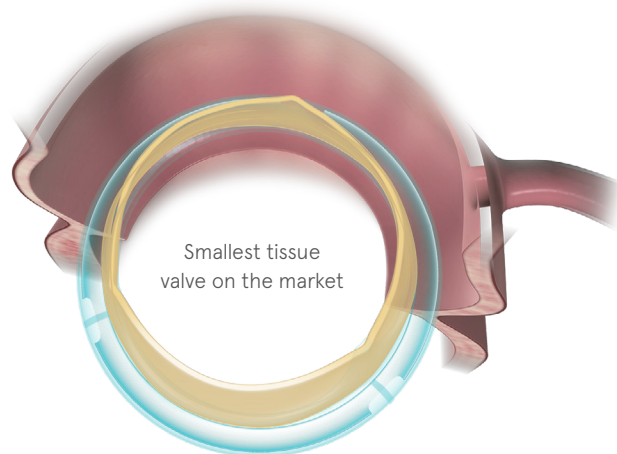
Single bovine pericardium outer layer for maximized flow areas

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



Smallest tissue valve on the market as an alternative option to aortic root enlargement

By providing favorable transvalvular pressure gradients even in small aortic annuli, CROWN PRT minimizes occurrence of patient-prosthesis mismatch and thus represents an alternative to aortic root enlargement, which is known to be associated with an increase of surgical risk.³



OPTIMAL HEMODYNAMICS

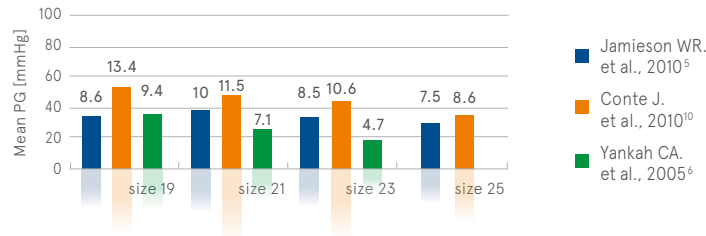
In-vivo hemodynamics

The capability of LivaNova’s single bovine pericardial outer layer design to maximize flow areas through leaflets that open uniformly and wide has demonstrated excellent 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.

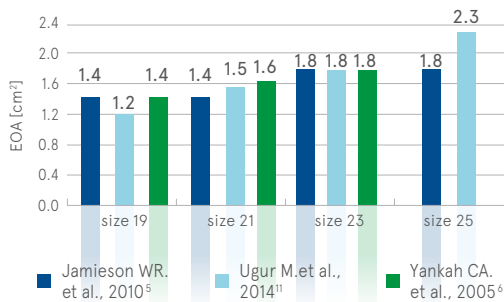
Synchronous and Unimpeded Valve Opening



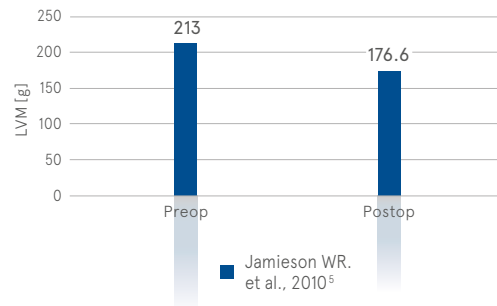
Low Pressure Gradient (PG)



Large Effective Orifice Area (EOA)



Remarkable Regression of Left Ventricular Mass (LVM)



“It exhibits a flat, native-like velocity profile.¹”

“Recovery of the left ventricle is thus enhanced and longterm outcome improved.¹”

OPTIMAL HEMODYNAMICS

Patient-Prosthesis Mismatch

The single bovine pericardial outer layer design reflects into in-vivo measurements of large effective orifice area indexed values and therefore minimized patient prosthesis mismatch.⁴

Large Effective Orifice Areas
Index for Minimized Patient-Prostheses Mismatch

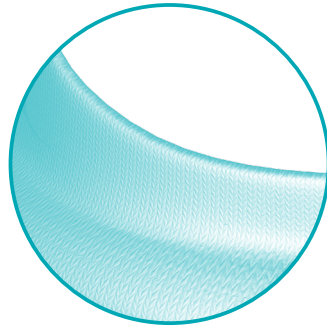
		Effective Orifice Area Indexed ¹¹			
Valve size		19mm	21mm	23mm	25mm
EOA* (cm ²)		1.2	1.5	1.8	2.3
BSA (m ²)	1	1.20	1.50	1.80	2.30
	1.1	1.09	1.36	1.64	2.09
	1.2	1.00	1.25	1.50	1.92
	1.3	0.92	1.15	1.38	1.77
	1.4	0.86	1.07	1.29	1.64
	1.5	0.80	1.00	1.20	1.53
	1.6	0.75	0.94	1.13	1.44
	1.7	0.71	0.88	1.06	1.35
	1.8	0.67	0.83	1.00	1.28
	1.9	0.63	0.79	0.95	1.21
	2	0.60	0.75	0.90	1.15
	2.1	0.57	0.71	0.86	1.10
	2.2	0.55	0.68	0.82	1.05
	2.3	0.52	0.65	0.78	1.00
	2.4	0.50	0.63	0.75	0.96
	2.5	0.48	0.60	0.72	0.92

- EOI ≥ 0.85 No Patient-Prosthesis Mismatch⁴
- 0.65 < EOI < 0.85 Moderate Patient-Prosthesis Mismatch⁴
- EOI ≤ 0.65 Severe Patient-Prosthesis Mismatch⁴

DESIGNED AND TREATED TO LAST

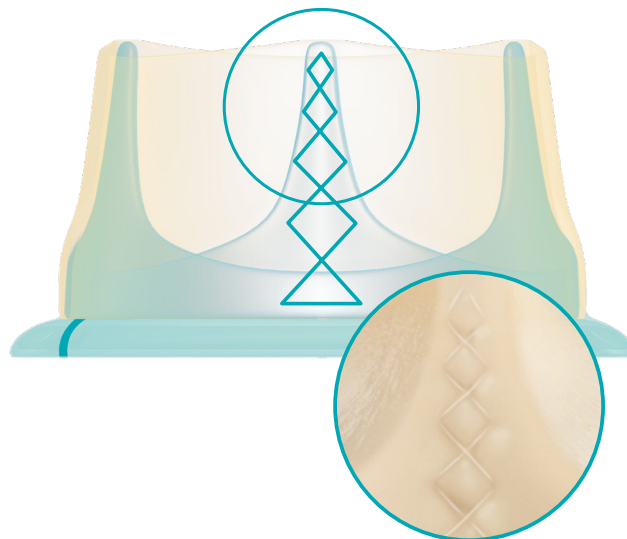
One-seam knit polyester for smooth contact surface between pericardium and synthetic material

Cushioned leaflet contact reduces pericardium wear, enhancing valve durability.



Cross-stitch pattern for even stress distribution on commissures

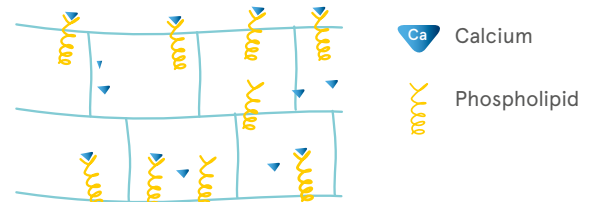
The presence By optimally distributing stress on the commissures, pressure forces on the valve posts are relieved during the cardiac cycle.



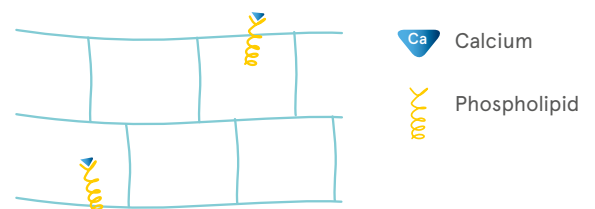
DESIGNED AND TREATED TO LAST

Phospholipid Reduction Treatment for mitigated calcium absorption

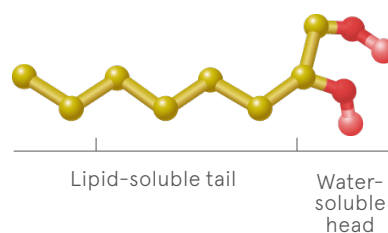
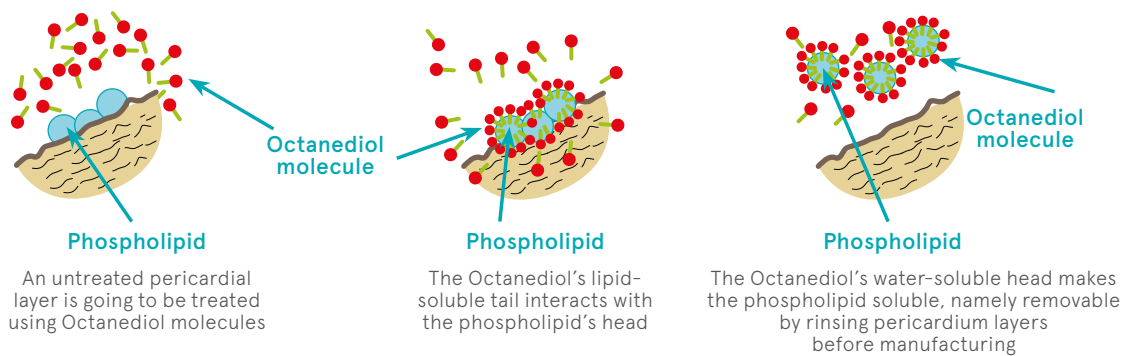
The presence of phospholipids in the pericardial tissue play a key role in the calcification process of bioprostheses as their phosphate heads are potential binding sites for circulating calcium ions.



Crown PRT features LivaNova's patented Phospholipid Reduction Treatment (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's heads and a water-soluble head to allow removal by rinsing pericardial layers before valve manufacturing.



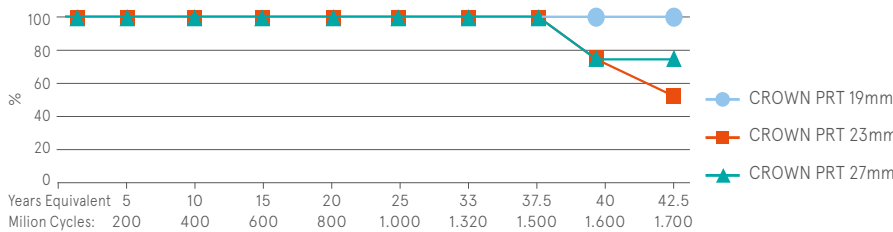
*LivaNova 2014. Data on file.

PROVEN DURABILITY

In-vitro durability

CROWN PRT's unique design shows outstanding resistance during accelerated wear testing at ISO 5840 conditions.

Freedom from structural valve degeneration (as per ISO 5840)

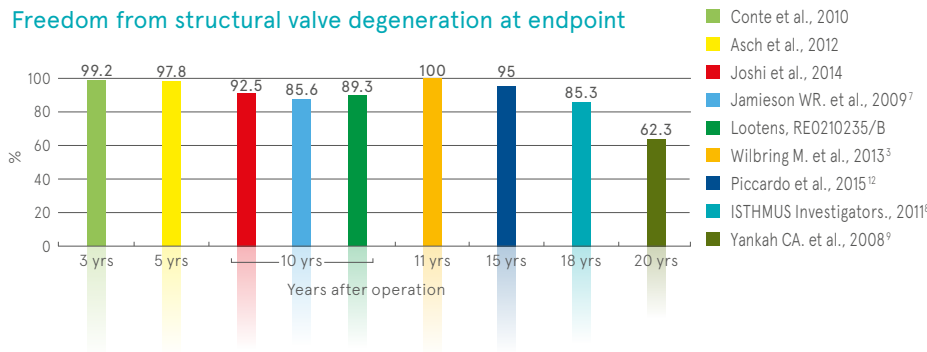


“ No failures up to 1.5 billion cycles, equivalent to 37.5 years. Over 6 times the minimum requirement.* ”

In-vivo durability

LivaNova's single bovine pericardial outer layer design has over 21 years of published clinical data proving already excellent durability without anti-calcification treatment.

Freedom from structural valve degeneration at endpoint

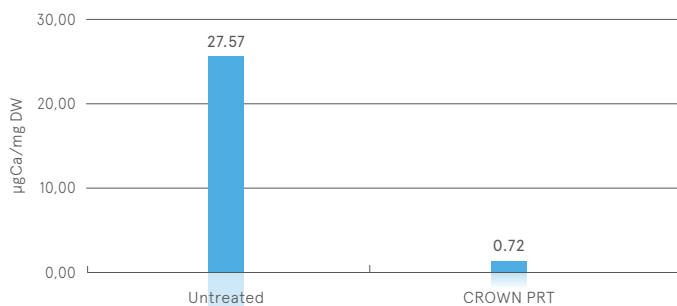


“ During the whole follow-up, which ranged up to 11 years, we recorded no reoperation because of failed prosthesis.³ ”

In-animal calcium absorption mitigation testing

By reducing the nucleation sites for calcium deposition - the phospholipids in the pericardial tissue - the Phospholipid Reduction Treatment (PRT) addresses directly 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.

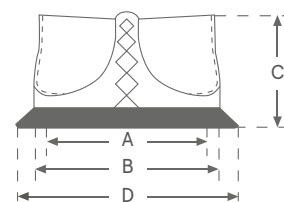


“ The Phospholipid Reduction Treatment (PRT) process is intended to enhance already proven resilient durability by reducing calcium absorption up to 97% compared to control.* ”

*LivaNova 2014. Data on file.

Product ordering information

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

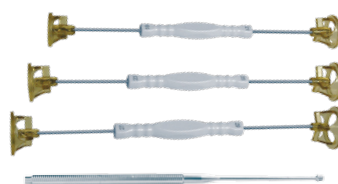


A = Inside Diameter
B = Outside Diameter
C = Overall Height
D = Sewing Ring Width



Accessories ordering information

Cat. #	Description
ICV1353	Bendable dual-ended sizers
	19–21mm
	23–25mm
AH-11	Handle



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LivaNova

Health innovation that matters

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Please always refer to the Instructions For Use (IFU) manual provided with each product for detailed information, warnings, precautions and possible adverse side effects.

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