AORTIC PERICARDIAL
HEART VALVE

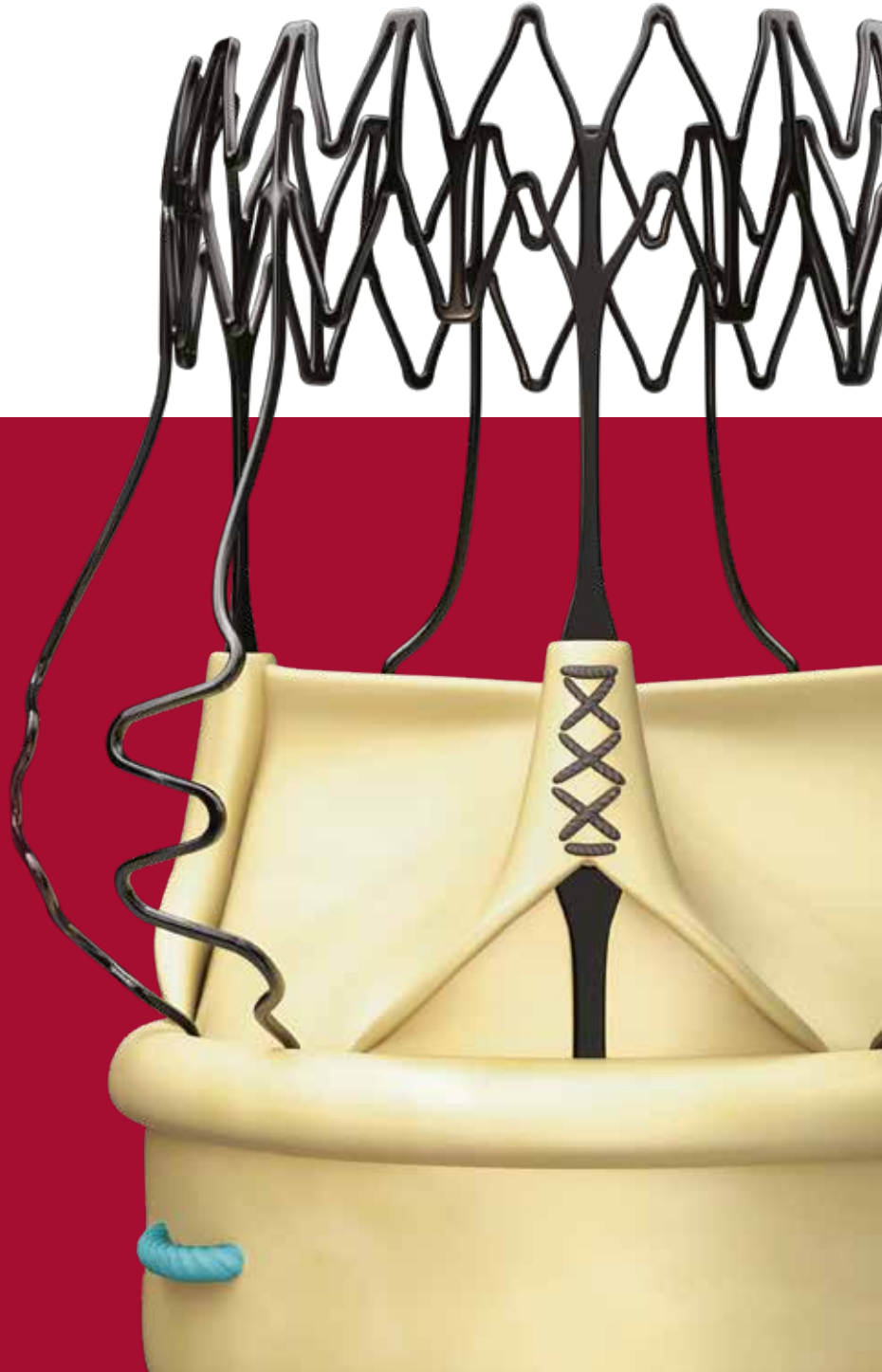
PERCEVAL™

Reducing the impact of surgery
and facilitating faster recovery[1,2]

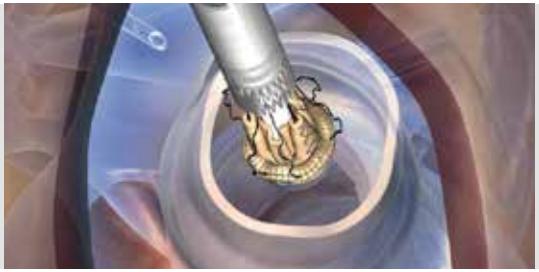
CORCYM
WE TAKE LIFE TO HEART

PERCEVAL™

CORCYM Perceval™ is a pericardial heart valve with a sutureless and collapsible design that simplifies the surgical implantation, reducing operative trauma and post-operative complications and enables faster Patient recovery[1,2].



The only truly sutureless surgical valve



PERCEVAL REDUCES THE SURGICAL IMPACT [3,4]

MAXIMIZED VISIBILITY

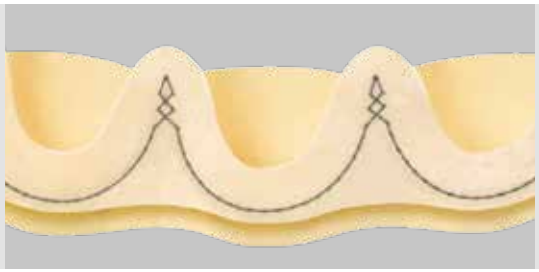
When collapsed, the valve allows the surgeon better visibility of the annulus and the anatomical structures during implantation.[2,5]

PRECISE POSITIONING

Three guiding sutures are used to position the valve in the aortic root which, together with the enhanced visibility, allow for precise and easy positioning[1].

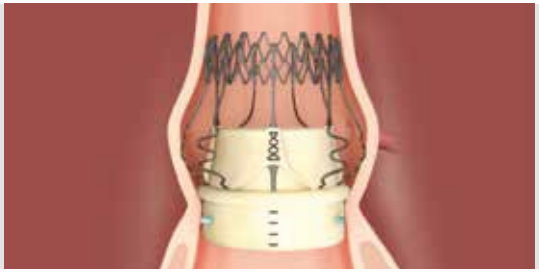
EASE OF IMPLANT

Traditional valves require multiple sutures. Perceval is a truly sutureless valve[2,6].



INNOVATION AND HERITAGE

The Perceval valve design has a long clinical heritage. Its proven double-sheet design has been used to manufacture biological prostheses since 1985.



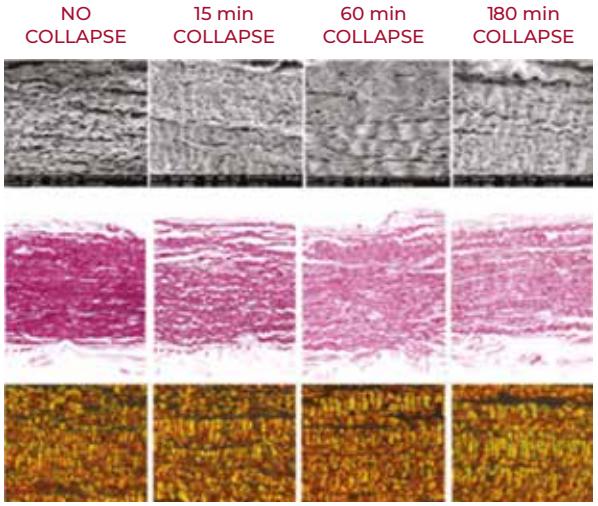
INNOVATION STARTS AT ITS CORE

Perceval is designed to provide favorable hemodynamics thanks to:

- the absence of sewing cuff providing less obstruction to blood flow
- the elastic stent able to adapt to the aortic root movement during the cardiac cycle.

The only truly sutureless surgical valve

FULLY ATRAUMATIC COLLAPSING[5]

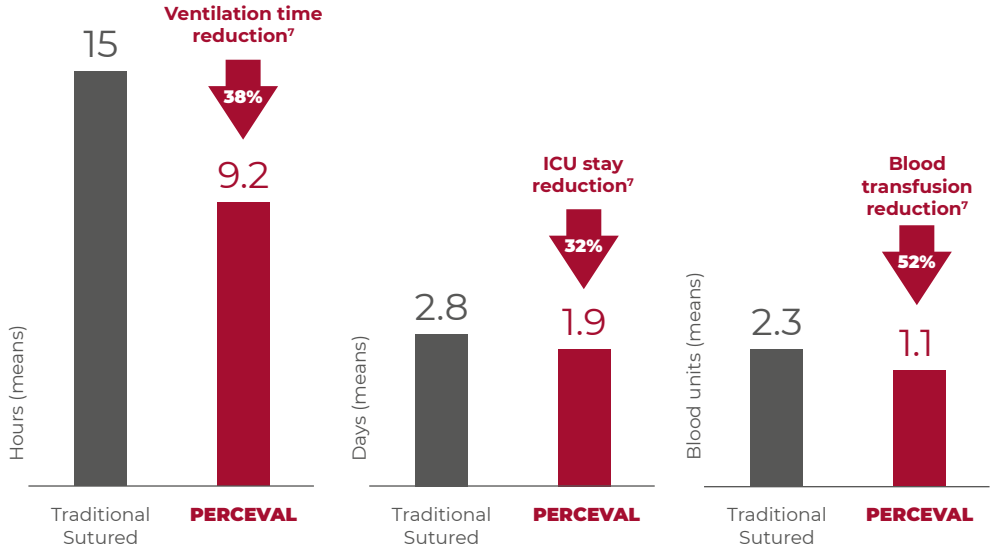


Pericardical Cusps: scanning electron microscopy. Elastic Van Gieson and Sirius Red stain at polarized light: collagen waviness in control and at different times of collapse.

COLLAPSING:

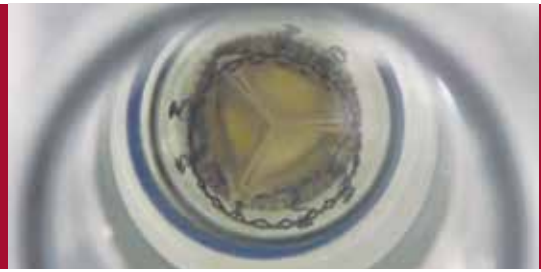
- Aids visualisation[3]
- Facilitates complex procedures[3]
- Prevents any possible damage to the tissue[8]

BETTER PATIENT OUTCOMES[7]



DID YOU KNOW THAT...

Perceval valve showed no failure after 2 Billion cycles, equivalent to 50-year heart cycles in-vivo[8].



PRODUCT SPECIFICATIONS

CODE		DESCRIPTION	USE
ICV	1208	Perceval size S	Single use
	1209	Perceval size M	
	1210	Perceval size L	
	1211	Perceval size XL	
	0218TS	Inflation Device	Single use
ICV	1219	Sizers kit	Re-usable
ICV	1232	Dual Collapser Base	Re-usable
ICV	1230	Accessory tray	Re-usable

SINGLE USE ACCESSORY KITS

STERNAL APPROACH

SIZE	KIT CODE		CONTAINS
S	ICV1345		ICV1235: Dual Collapser ICV1242: Dual Holder ICV1216: MICS Post-dilation Catheter
M	ICV1346		ICV1235: Dual Collapser ICV1242: Dual Holder ICV1217: MICS Post-dilation Catheter
L	ICV1347		ICV1236: Dual Collapser ICV1243: Dual Holder ICV1218: MICS Post-dilation Catheter
XL	ICV1348		ICV1236: Dual Collapser ICV1243: Dual Holder ICV1241: MICS Post-dilation Catheter

MICS APPROACH

SIZE	KIT CODE		CONTAINS
S	ICV1349		ICV1235: Dual Collapser ICV1244: Dual MICS Holder ICV1216: MICS Post-dilation Catheter
M	ICV1350		ICV1235: Dual Collapser ICV1244: Dual MICS Holder ICV1217: MICS Post-dilation Catheter
L	ICV1351		ICV1236: Dual Collapser ICV1245: Dual MICS Holder ICV1218: MICS Post-dilation Catheter
XL	ICV1352		ICV1236: Dual Collapser ICV1245: Dual MICS Holder ICV1241: MICS Post-dilation Catheter

REFERENCES

1. Santarpino et al. - **Sutureless aortic valve replacement: first-year single-center experience** - *Ann Thorac Surg. 2012 Aug;94(2):504-8*

2. Glauber M. et al. - **International Expert Consensus on Sutureless and Rapid Deployment Valves in Aortic Valve Replacement Using Minimally Invasive Approaches.** - *Innovations (Phila). 2016 May-Jun;11(3):165-73*

3. Phan K. et al. - **Sutureless aortic valve replacement: a systematic review and meta-analysis** - *Ann Cardiothorac Surg 2015;4(2):100-111.*

4. Powell R. et al. - **The Perceval Sutureless Aortic Valve: Review of Outcomes, Complications, and Future Direction** - *Innovations 2017 May/Jun;12(3):155-173.*

5. Della Barbera et al. - **Pre-implantation collapse in the Sorin Perceval S Sutureless prosthesis does not affect pericardial graft structure** - *Abstracts / Cardiovascular Pathology 22 (2013) e29–e52*

6. Aagaard et al. - **Midterm Evaluation of Hemodynamics of the Top Hat Supraannular Aortic Valve** - *Asian Cardiovasc Thorac Ann 2010;18:1–5*

7. Santarpino et al. - **The Perceval S Aortic Valve Has the Potential of Shortening Surgical Time: Does It Also Result in Improved Outcome?** - *Ann Thorac Surg 2013*

8. Corcym data on file

INTENDED USE/INDICATIONS

EUROPE: Perceval/Perceval Plus prosthesis is intended to replace a damaged native aortic heart valve or a malfunctioning aortic prosthesis via open heart surgery. The prosthesis is indicated for use in adult patients suffering from aortic valve stenosis or steno-insufficiency or with a previously implanted aortic valve prosthesis that is no longer functioning adequately and requires replacement. Physicians should give careful consideration to the use of this valve in patients less than 65 years of age, as sample size in clinical studies for this patient population is insufficient to demonstrate a clinical benefit

US: The Perceval/Perceval Plus bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves

CANADA: The Perceval/Perceval Plus bioprosthesis is intended for use in patients aged ≥ 65 years in which the aortic valve pathology is in an advanced stage to require the replacement of the native or malfunctioning previously implanted prosthesis.

AUSTRALIA: Perceval prosthesis is indicated for the replacement of a diseased native or a malfunctioning prosthetic aortic valve via open heart surgery. The prosthesis is indicated in patients who meet the following criteria: 1) subjects of age ≥ 65 years 2) subjects with aortic valve stenosis or steno-insufficiency.

KEY CONTRAINDICATIONS

Aneurysmal dilation or dissection of the ascending aortic wall; known hypersensitivity to nickel or cobalt alloys; ratio between the sinotubular junction and the annulus diameter greater than 1.3.

KEY WARNINGS

Do not under or oversize the prosthesis. This could result, in possible migration, excessive compression/ rupture of the aorta, suboptimal expansion or valve folding that may lead to fatal arrhythmia or hemorrhage, regurgitation or altered hemodynamics. Severe LVOT hypertrophy may prevent optimal expansion of the inflow portion of the stent.

TOP POTENTIAL SIDE EFFECTS

Potential adverse events associated with cardiac valve replacement with a bioprosthesis and the related surgical procedure include: bleeding, cardiac conduction disorders, endocarditis, heart failure, neurological events, non structural dysfunction, structural valve deterioration, thromboembolism.

MRI conditional

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

CORCYM

Manufactured by:

Corcym S.r.l.
Via Crescentino sn
13040 Saluggia (VC) Italy
Tel: +39 0161 487800

Corcym S.r.l. previously Sorin Group Italia S.r.l.

Corcym Canada Corp.
5005 North Fraser Way
Burnaby, BC V5J 5M1 Canada
Tel: +604 412-5650

Corcym Canada Corp. previously LivaNova Canada Corp.

CE 0123

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