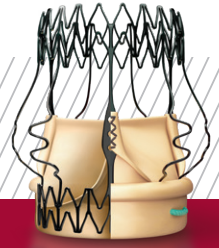


SUTURELESS AORTIC PERICARDIAL HEART VALVE

PERCEVAL™ PLUS

RELY ON SYSTEM

The Optimal Mix

FEATURING THE INNOVATIVE

FREE TISSUE TREATMENT

CORCYM

WE TAKE LIFE TO HEART

Perceval Platform

nearly –100% calcification
vs control group

0.54% p-y SVD
13 years max follow-up[2]

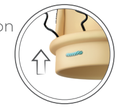
Single-digit mean gradients
throughout 5-year follow-up[3]

0.5% PVL
greater than mild at 1 year[3]

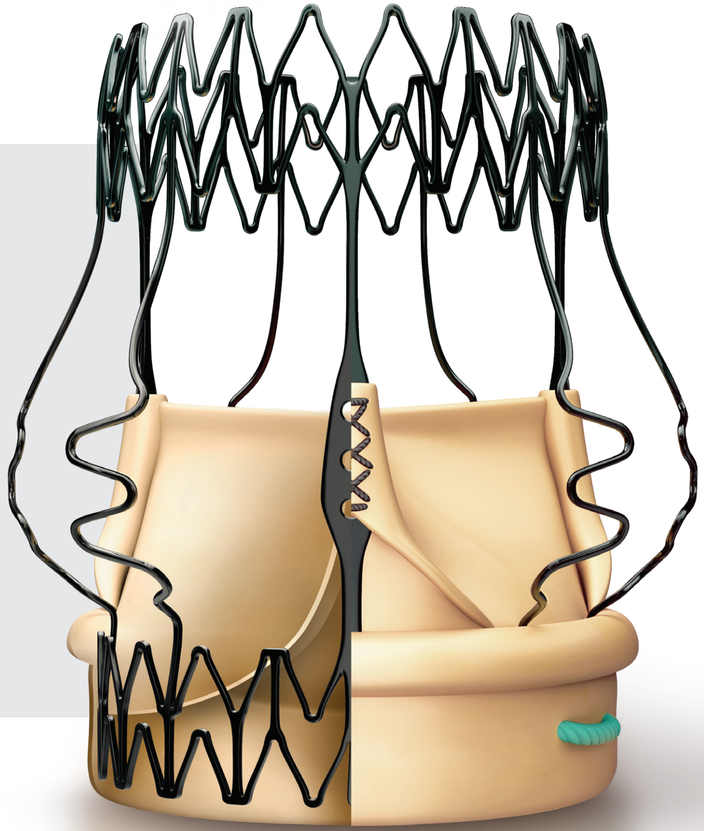
0.8% mortality
at 30 days[4]

3.3% PPI rate*
at 30 days[5]

* Perceval Plus features a reduced ventricular protrusion. The reduction of the protrusion of the valve below the aortic annulus is expected to reduce permanent pacemaker implant (PPI) rates even further and improve patient outcomes.



Technical claims are supported by Corcym data on file



The Perceval Platform is based on a sutureless and collapsible design that simplifies the surgical implantation, reducing the impact of surgery and facilitating faster recovery.[6,7]

Perceval is a trusted platform:

- First-in-human in **2007**
- Over **15 years** of successful clinical experience
- More than **500** publications
- Present in more than **100** countries worldwide
- More than **100.000** patients treated worldwide

Unique design: unique benefits

Durability

Hemodynamics

Valve-in-Valve

MICS

Ease of use

Designed for durability: Innovative *FREE tissue treatment*

The innovative *FREE tissue treatment* in Perceval Plus addresses both major causes of valve calcification, phospholipids and aldehydes.[4]
The technology also allows the valve to be stored in an aldehyde-free solution, resulting in negligible toxicity for the patient and a faster procedure for the surgeon as no rinsing is required.[4]

FREE is designed to improve durability.[1]

FREE is a next-generation tissue treatment

- NEW PHOSPHOLIPIDS REMOVAL
- GLUTARALDEHYDE FIXATION AND STERILIZATION
- ENHANCED ALDEHYDE NEUTRALIZATION
- ALDEHYDE-FREE STORAGE SOLUTION
- READY TO USE

-96% phospholipid content*

NEW

Phospholipids removal

Phospholipids are intrinsically present in biological tissue.
They are potential binding sites for calcium.[13]

During the manufacturing process phospholipids are dissolved and eliminated

Glutaraldehyde fixation and sterilization

After the phospholipids removal, the tissue undergoes a fixation process to stabilize its mechanical properties, get sterilized and reduce immune response.[13]

≈0% aldehyde toxicity*

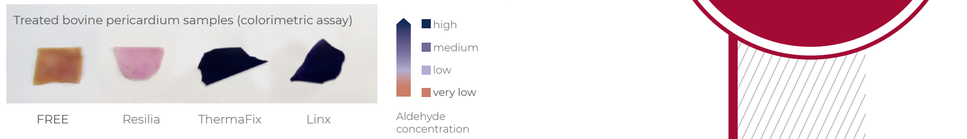
ENHANCED

Aldehyde neutralization

Free aldehydes are a consequence of the fixation process.
They favor toxicity and calcification.[13]

Aldehydes are “capped” and neutralized during manufacturing

FREE tissue outperforms other treatments in terms of aldehyde neutralization.[1*]



READY TO USE

Aldehyde-free storage solution

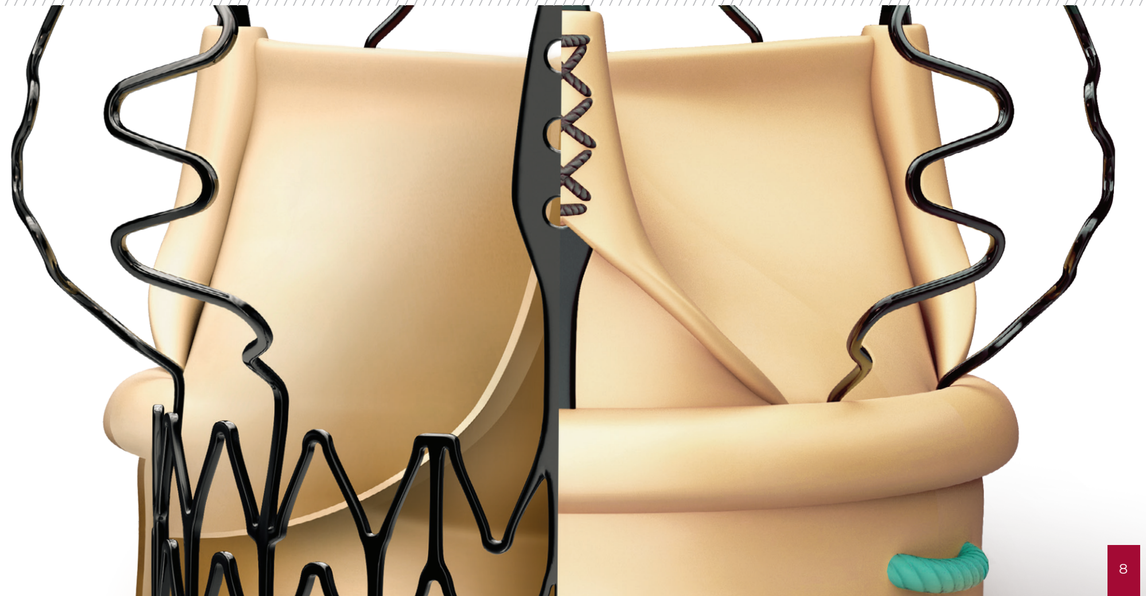
Before packaging, the valve undergoes an industrialized rinsing process.

The valve is stored in an aldehyde-free solution, resulting in negligible toxicity for the patient and a faster procedure for the surgeon as no rinsing is required.[4]

nearly 100% calcification*

* vs control group
Technical claims are supported by Corcym data on file

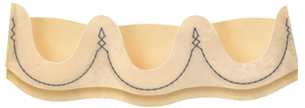
Designed for durability



DESIGNED TO LAST 50 YEARS*

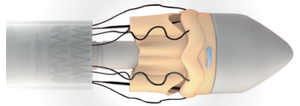
Superelastic stent

- Self-expands in place (no need to knot the sutures), ensuring optimal valve sealing.[7]
- Reduces the stress transferred to the leaflets.[8]
- Carbofilm™ coated to reduce inflammatory reaction and favor a gentle endothelialization.[9,10,11]



Double sheet design

An outer sheet acts as a cushion that minimizes the stress transferred to the leaflets.



Fully atraumatic collapsing

The collapsing procedure does not affect the leaflets preventing any possible damage to the tissue.[12]

Perceval Plus is based on the trusted Perceval Platform, that has shown a linearized rate of SVD of 0.54% per patient-years with a maximum follow-up of 13 years.[2]

0.54% p-y SVD

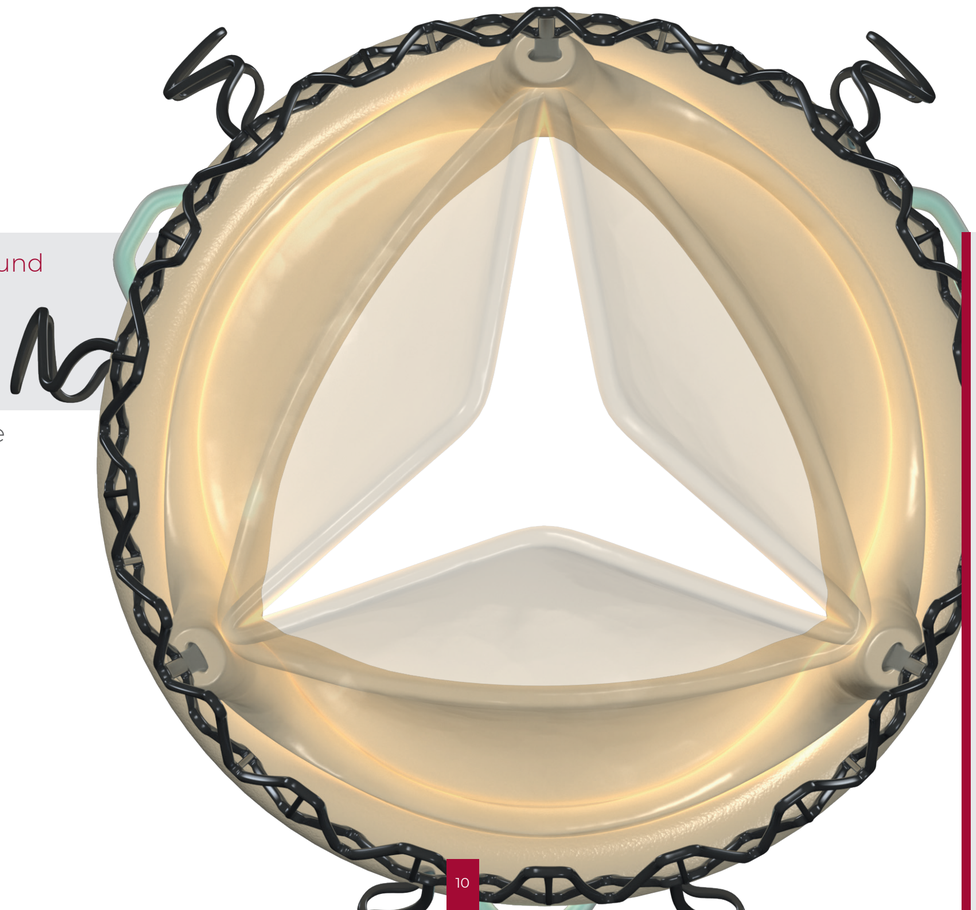
13 years max follow-up[2]

(*) Technical claims are supported by CORCYM data on file. Data related to bench tests

Designed for excellent hemodynamics

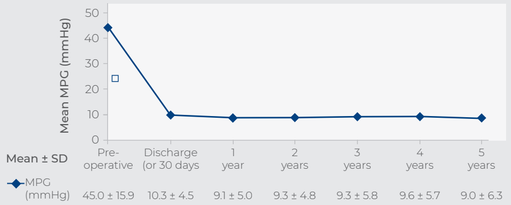
Perceval Plus boasts a distinctive design built around a superelastic stent that self-expands in place (no need to knot the sutures), ensuring optimal valve sealing.[7]

The Nitinol stent allows Perceval Plus to follow the physiological movement of the aortic root during the cardiac cycle, mimicking the native valve.[3,4]



Stable hemodynamics[3]

The radial force at the inflow ring and the design of the superelastic stent allow for excellent hemodynamics with stable results over time.[3,8]

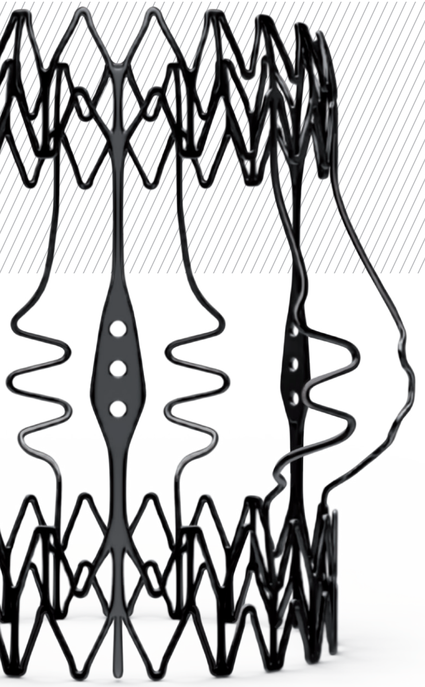


Single-digit mean gradients

throughout 5-year follow-up[3]

MPG, mm Hg	Preoperative	5 years
Size S		
Mean ± SD	45.6 ± 15.4	9.2 ± 5.4
Size M		
Mean ± SD	45.1 ± 15.8	10.3 ± 6.6
Size L		
Mean ± SD	44.8 ± 16.3	8.3 ± 6.1
Size XL		
Mean ± SD	43.4 ± 15.9	4.3 ± 3.0

Designed for the future: the ideal docking station for Valve-in-Valve

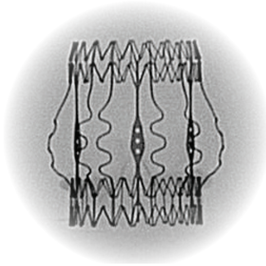


Perceval Plus is a valve designed for the future. Not only is it durable,[2] but it also gives patients even broader treatment options for their future. Its exclusive stent design allows even circumferential expansion to accommodate future transcatheter valves, making Perceval Plus ViV friendly by design.

Thanks to its unique features, all patients eligible for biological AVR may benefit from a Perceval Plus implant.**[14,15]

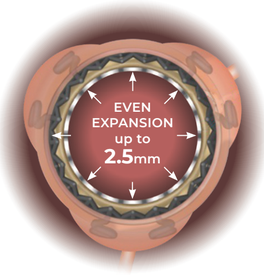
No data on potential interaction between the Perceval Plus stent and transcatheter devices or their delivery systems are available.

** In compliance with product Instructions For Use.



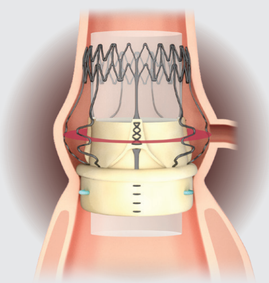
Clear visibility

The Nitinol stent provides clear visibility under fluoroscopy and CT scan to identify landmarks which facilitate the ViV procedure.



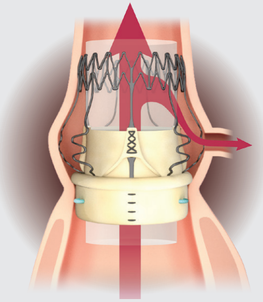
Even circumferential expansion

The inflow ring can be evenly and circumferentially expanded up to 2.5mm above its nominal size, which allows for hemodynamic advantages and greater compatibility with TAVI models and sizes.



Minimized risk of coronary obstruction

Perceval Plus leaflets remain open when a TAVI is deployed inside it. The sinusoidal struts and the open leaflets create a space between the coronary ostia and the leaflets themselves wich is preserved even after the TAVI deployment.

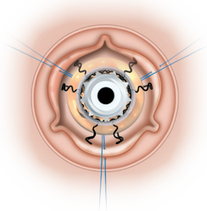


Minimized risk of sinus sequestration

By design, the Perceval Plus leaflets, when open, do not touch the STJ, thus avoiding sinus sequestration.

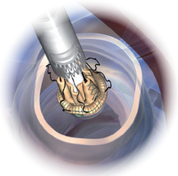
Designed for MICS

Perceval Plus RelyON System and Minimally Invasive Cardiac Surgery were made for each other thanks to the sutureless design of the valve and the length and diameter of the new Deliver System. The System allows for minimized incision,[4,5] maximized visibility,[4,14] faster learning curve[5,16] and a reduced manipulation of the aortic root.[4,5,17]



Minimized incision[4,14]

Thanks to the unique collapsible profile and sutureless design of the valve and the design of the Delivery System, Perceval Plus RelyON System allows a reduced incision size and less surgical trauma.[4,7,18]



Maximized visibility during implantation[4,14]

The collapsible profile of the valve and the small diameter of the Delivery System allow the surgeon full visibility of the annulus and of the anatomical structures during implantation and deployment for great confidence and fast, precise positioning at the implantation site.[7,12]

Designed for fast-track surgery

Fast-track surgery and ERAS have demonstrated many benefits for both the patient[19-21] and the hospital.[19,21-24] Perceval Plus's unique design and proven clinical benefits[7,18] are expected to enhance the advantages of fast-track and ERAS (Enhanced Recovery After Surgery) protocols even further. Compared to conventional valves, Perceval Plus has shown many advantages, both in full sternotomy and MICS approaches:[14,15,18]

- **-30%** cross-clamp time[10]
- **-25%** CPB time[10]
- **-50%** ICU stay[25]
- **-60%** Ventilation time[25]
- **-23%** Blood transfusions[25]
- Up to **-26%** Hospital costs[24-28]

Designed for ease of use

RELYON

Take sutureless AVR to the next level with Perceval Plus RelyON System.
Perceval Plus is now accompanied by RelyON creating a comprehensive System that allows for a smooth experience for the whole OR team.
RelyON has been designed in partnership with surgeons and nurses to ensure an easy and fast Perceval Plus procedure, from unboxing to deployment.

Precise

The RelyON Delivery System delivers Perceval Plus with a single movement of the hand allowing to maintain a firm hold on the device, which in turn facilitates a precise positioning of the valve in the aortic root.

User-friendly

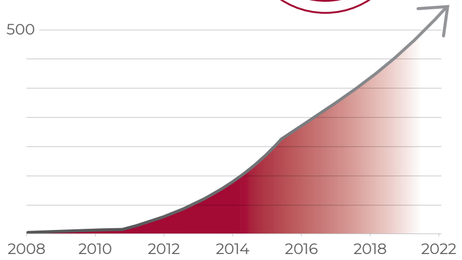
Top-loading valve, self-locking lever, infrographics, open-close guide, all-in-one packaging allow for a calm procedure and empower any user to prepare the valve in a quick and effective way.

Optimized for MICS procedures

The design of the Delivery System is optimized for MICS. Both the length and the small diameter of the shaft, together with the collapsible design of Perceval Plus, allow for a minimized incision and facilitated access to and visualization of the implantation site.

Robust body of evidence

PERCEVAL PLATFORM >500 publications



>500 publications

WORLDWIDE

PERSIST-AVR *study*
Inclusion: 910 patients in 47 centers

SURE-AVR *registry*
Inclusion: 1655 patients

MANTRA *study*
Enrollment ongoing (started in 2021)
Inclusion: 1,250 patients in Aortic Sub-study,
500 patients in Mitral/tricuspid Sub-study
200 patients in Memo 4D Sub-study
Follow-up at 30 days, annually up to 10 years

BELIEVE *study*
Inclusion: 88 patients

IDE *study*
Inclusion: 355 patients in 18 centers

PILOT *study*
Inclusion: 30 patients in 3 centers

PIVOTAL *study*
Inclusion: 150 patients in 9 centers

CAVALIER *study*
Inclusion: 658 patients in 26 centers

PERCEVAL PMS
Inclusion: 204 patients in 22 centers

PERFECT *study*
Inclusion: 61 patients in 4 centers

Perceval Training Journey

CORCYM offers a full range of training and education programs for cardiac surgeons, at all experience levels to share best practices and deepen expertise.

Perceval proctorship is composed of several elements

In-person or virtual training including product presentation, step-by-step implantation, dry lab or wet lab

Review and discussion of selected patients

In-person or remote support in the OR

Post-proctorship surveillance for monitoring overall effectiveness of the proctor program and customizing it depending on the trainee surgeon's needs

Visit CORCYM Academy, our online training platform dedicated to Healthcare Professionals where you can see the Perceval Platform in action during many cases perfomed by some of our top users and attend Webinars: **www.corcym-academy.com**

Visit our website for more details:
www.corcym.com

PRODUCT ORDERING INFORMATION

CODE	DESCRIPTION	USE
PVF-S	PERCEVAL PLUS size S	Single use
PVF-M	PERCEVAL PLUS size M	
PVF-L	PERCEVAL PLUS size L	
PVF-XL	PERCEVAL PLUS size XL	

ACCESSORIES ORDERING INFORMATION

CODE	DESCRIPTION	SIZE	USE
ICV 1219	Sizer Set		Re-usable
0218TS*	Inflation Device		Single use
PAK-S	RelyON PAK Accessories Kit** • Collapser System • Delivery System • Postdilation Catheter	S	Single use
PAK-M		M	
PAK-L		L	
PAK-XL		XL	
ICV1230	Empty Tray		Re-usable

* Not available in all geographies.
** In this brochure, "RelyON PAK Accessories Kit" is referred to as "RelyON".

REFERENCES

1. Meuris B. et al., **"A novel tissue treatment to reduce mineralization of bovine pericardial heart valves."** *J Thorac Cardiovasc Surg. 2018 Jul;156(1):197-206*
2. Lamberigts M. et al., **"Sutureless aortic valves in isolated and combined procedures: 13 years of experience in 784 patients."** *J Thorac Cardiovasc Surg. (2022); doi: https://doi.org/10.1016/j.jtcvs.2022.09.053*
3. Fischlein T. et al., **"Midterm outcomes with a sutureless aortic bioprosthesis in a prospective multicenter cohort study."** *J Thorac Cardiovasc Surg 2021;-:1-9*
4. Solinas et al., **"Right anterior mini-thoracotomy and sutureless valves: the perfect marriage."** *Ann Cardiothorac Surg 2020;9(4):305-313*
5. Glauber et al., **"Minimally Invasive Aortic Valve Replacement With Sutureless Valves: Results From an International Prospective Registry."** *Innovations 2019, 15(2), 120–130*
6. Santarpino et al., **"Sutureless aortic valve replacement: first-year single-center experience."** *Ann Thorac Surg. 2012 Aug;94(2):504-8*
7. 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*
8. Shrestha M. et al., **"European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up to 5 years in over 700 patients."** *Eur J Cardiothorac Surg. 2015; 1–8*
9. Vallana et al., **"Carbofilm: Present and future applications in biomedical devices."** *Ceramics International 1993; 19: 169-179*
10. Di Bacco L. et al., **"Rapid Explantation of Rapid-Deployment Sutureless Valve in Case of Acute Endocarditis: How to Remove Safely Sutureless Perceval S Prostheses."** *Innovations (Phila). 2017 Nov/Dec;12(6):483-485*
11. Aebischer P. et al., **"Tissue reaction to fabrics coated with turbostratic carbon: subcutaneous versus vascular implants."** *Biomaterials 1988; 9: 80-85*
12. Bejko et al., **"Morphologic investigation on perceval S, a sutureless pericardial valve prosthesis: Collagen integrity after collapsing-ballooning and structural valve deterioration at distance."** *Int J Cardiol. 2021 Oct 15;341:62-67*
13. Thiene et al., **"Anticalcification strategies to increase bioprosthetic valve durability."** *The Journal of Heart Valve Disease 2011 Jan;20(1) 37-44*
14. Gersak B. et al., **"Sutureless, rapid deployment valves and stented bioprosthesis in aortic valve replacement: recommendations of an International Expert Consensus Panel."** *European Journal of Cardio-Thoracic Surgery (2015) 1–10 doi:10.1093/ejcts/ezv369*
15. Fischlein T. et al., **"Sutureless versus conventional bioprostheses for aortic valve replacement in severe symptomatic aortic valve stenosis."** *J Thorac Cardiovasc Surg 2021 Mar;161(3):920-932*
16. Murzi et all., **"Exploring the learning curve for minimally invasive sutureless aortic valve replacement."** *J Thorac Cardiovasc Surg 2016*
17. Szecel et al., **"Perceval sutureless aortic valve implantation: mid-term outcomes."** *The Annals of Thoracic Surgery, Volume 111, Issue 4, April 2021, Pages 1331-1337*
18. Powell R. et al., **"The Perceval Sutureless Aortic Valve: Review of Outcomes, Complications, and Future Direction."** *Innovations 2017 May/Jun;12(3):155-173*
19. Williams et al., **"One-year results from the first US-based enhanced recovery after cardiac surgery (ERAS Cardiac) program."** *J Thorac Cardiovasc Surg 2019;157(5):1881–8*
20. Fleming et al., **"Aggregation of Marginal Gains in Cardiac Surgery: Feasibility of a Perioperative Care Bundle for Enhanced Recovery in Cardiac Surgical Patients."** *Journal of Cardiothoracic and Vascular Anesthesia, Vol 30, No 3 (June), 2016: pp 665–670*
21. Zaouter et al., **"Reduced Length of Hospital Stay for Cardiac Surgery-Implementing an Optimized Perioperative Pathway: Prospective Evaluation of an Enhanced Recovery After Surgery Program Designed for Mini-Invasive Aortic Valve Replacement."** *J Cardiothoracic and Vascular Anesthesia, 2019 Nov;33(11):3010-3019*
22. Li et al., **"Enhanced recovery after surgery pathway for patients undergoing cardiac surgery: a randomized clinical trial."** *Eur J Cardiothorac Surg 2018;54:491–7*
23. Petersen et al., **"Economic impact of enhanced recovery after surgery protocol in minimally invasive cardiac surgery."** *BMC Health Services Research (2021) 21:254*
24. Yazdchi et al., **"Enhanced Recovery After Cardiac Surgery: A Propensity-Matched Analysis."** *Semin Thorac Cardiovasc Surg. 2021 Jun 2;S1043-0679(21)00261-6*
25. Pollari F. et al., **"Better short-term outcome by using sutureless valves: a propensity-matched score analysis."** *Ann Thorac Surg. 2014 Aug;98(2):611-6; discussion 616-7*
26. Minami et al., **"Hospital Cost Savings and Other Advantages of Sutureless vs Stented Aortic Valves for Intermediate-Risk Elderly Patients."** *Surgery Today 2017 Apr 6. doi: 10.1007/s00595-017-1516-8*
27. Laborde et al., **"Sutureless Valves Reduce Hospital Costs Compared to Traditional Valves."** *JHVD Jan 2017, 26(1):1-8*
28. Panagiotopoulos et al., **"Perceval S, sutureless aortic valve: cost-consequence analysis"** *KardiochirTorakochirurgia Pol 2022 Mar;19(1):22-27*
29. Engelman et al., **"Guidelines for Perioperative Care in Cardiac Surgery Enhanced Recovery After Surgery"** *- Society Recommendations JAMASurg. 2019;154:755–66.*

Technical claims are supported by CORCYM data on file.

NOTES

INTENDED USE/INDICATIONS

EUROPE: The Perceval/Perceval Plus prosthesis is intended to replace a damaged native aortic heart valve or a malfunctioning aortic prosthesis via open- heart surgery in adult patients:

- suffering from aortic valve stenosis or steno-insufficiency;

- with a previously implanted aortic valve prosthesis that is no longer functioning adequately and requires replacement.

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

CANADA: Perceval Plus bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.

AUSTRALIA: Perceval Plus bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves. 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
WE TAKE LIFE TO HEART

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