

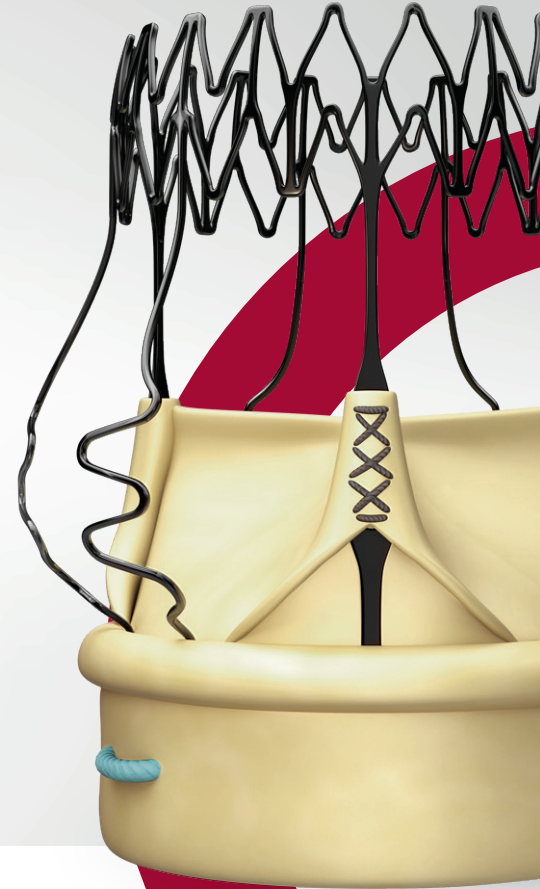


SUTURELESS AORTIC PERICARDIAL HEART VALVE

# PERCEVAL PLUS

THE VALVE FOR A

*lifetime*



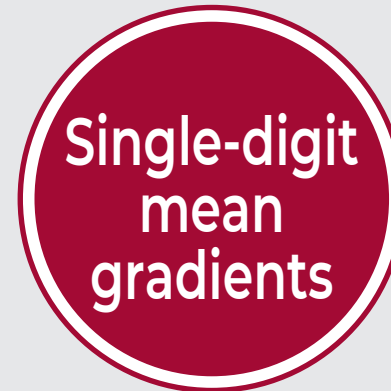
# Perceval Platform



vs control group



15 years max follow-up<sup>2</sup>



throughout 5-year follow-up<sup>3</sup>



greater than mild at 1 year<sup>3</sup>

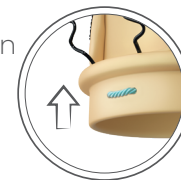


at 30 days<sup>4</sup>



at 30 days<sup>5</sup>

\* 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

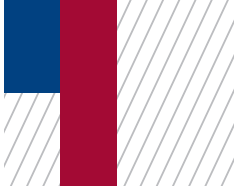




The Perceval Platform is based on a sutureless and collapsible design that simplifies the surgical implantation, reducing the impact of surgery and facilitating faster recovery.<sup>6,7</sup>

### Perceval is a trusted platform:

- First-in-human in **2007**
- Over **18 years** of successful clinical experience
- More than **600** publications
- Present in more than **100** countries worldwide
- More than **120.000** patients treated worldwide

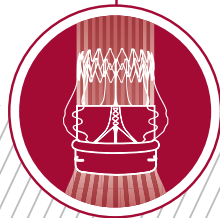


# Unique design: unique benefits

Durability



Hemodynamics



Valve-in-Valve



MICS



Ease of use





## Designed for durability: *FREE*dom to shape the future

The innovative *FREE tissue treatment* in Perceval Plus addresses both major causes of valve calcification, phospholipids and aldehydes.<sup>4</sup> 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.<sup>4</sup>

*FREE* is designed to improve durability.<sup>1</sup>

### ***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.<sup>13</sup>

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.<sup>13</sup>

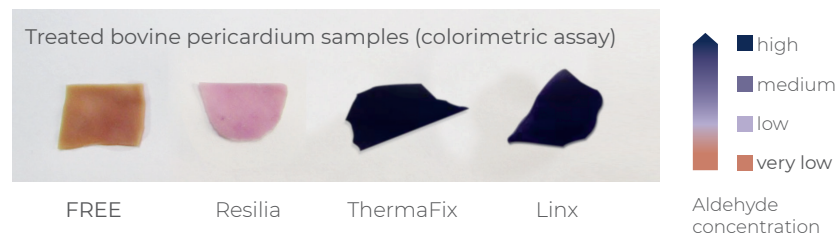
## ENHANCED

### Aldehyde neutralization

Free aldehydes are a consequence of the fixation process. They favor toxicity and calcification.<sup>13</sup>

Aldehydes are “capped” and neutralized during manufacturing

FREE tissue outperforms other treatments in terms of aldehyde neutralization.<sup>1\*</sup>



### 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.<sup>4</sup>

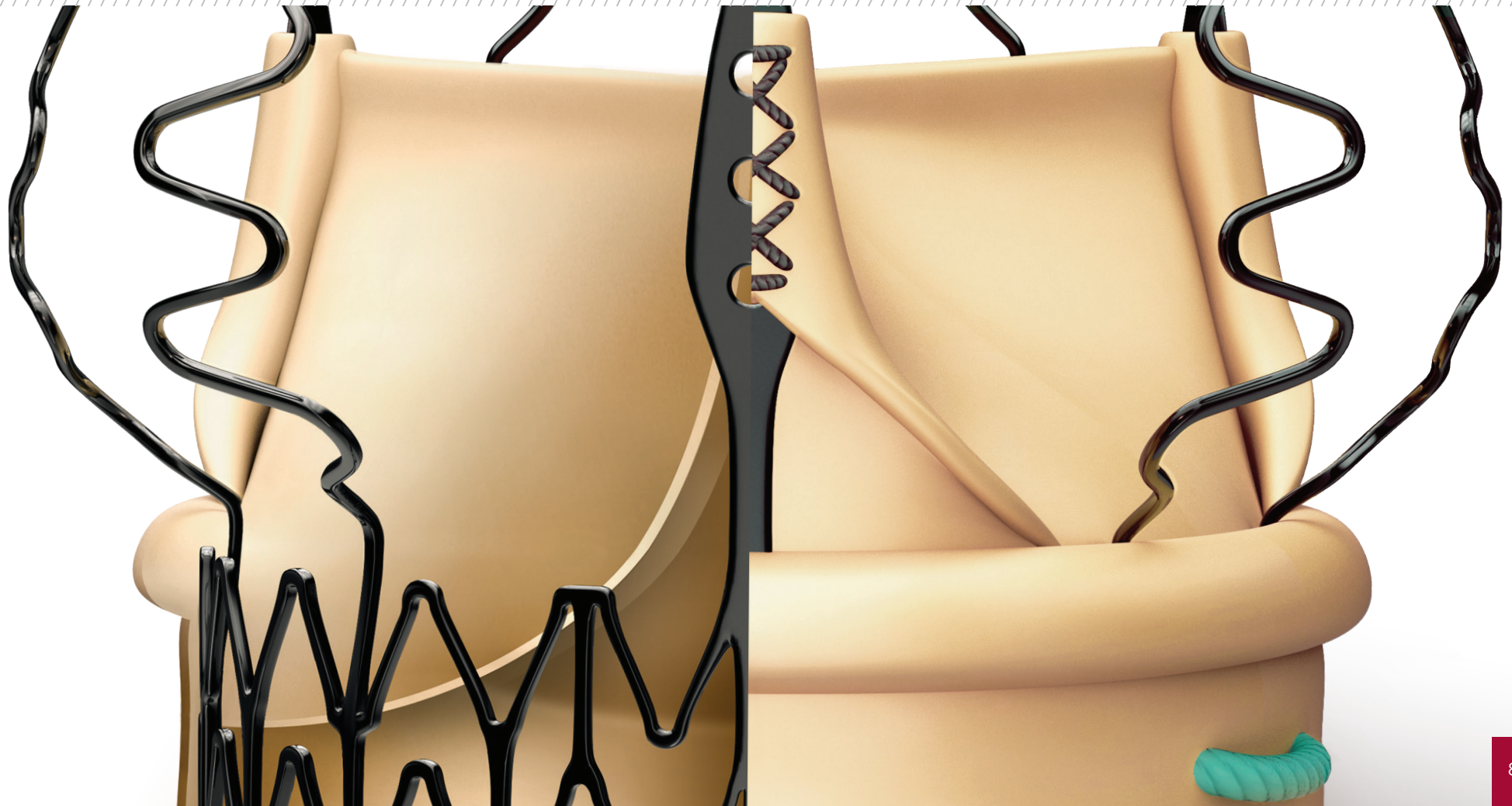
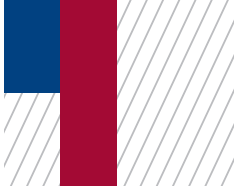
**READY  
TO USE**

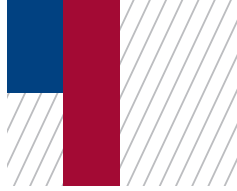
nearly **100%**  
calcification\*

\* vs control group

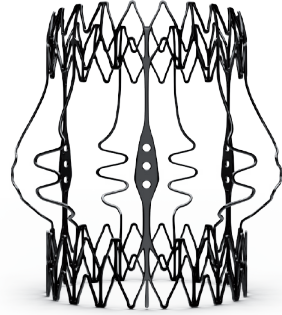


Designed for durability



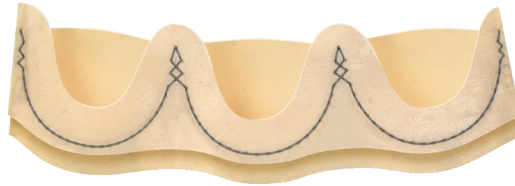


DESIGNED  
TO LAST  
**50**  
YEARS\*



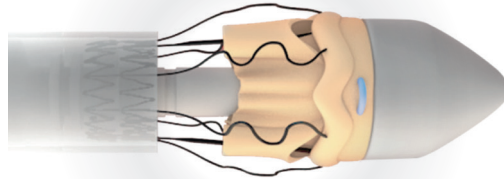
### Superelastic stent

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



### 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.<sup>12</sup>

Perceval Plus is based on the trusted Perceval Platform, that has shown a linearized rate of SVD of 0.74% per patient-years with a maximum follow-up of 15 years.<sup>2</sup>

**0.74%**  
p-y  
**SVD**

15 years max follow-up<sup>2</sup>

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

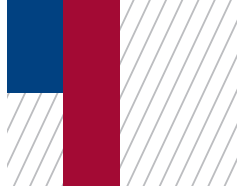
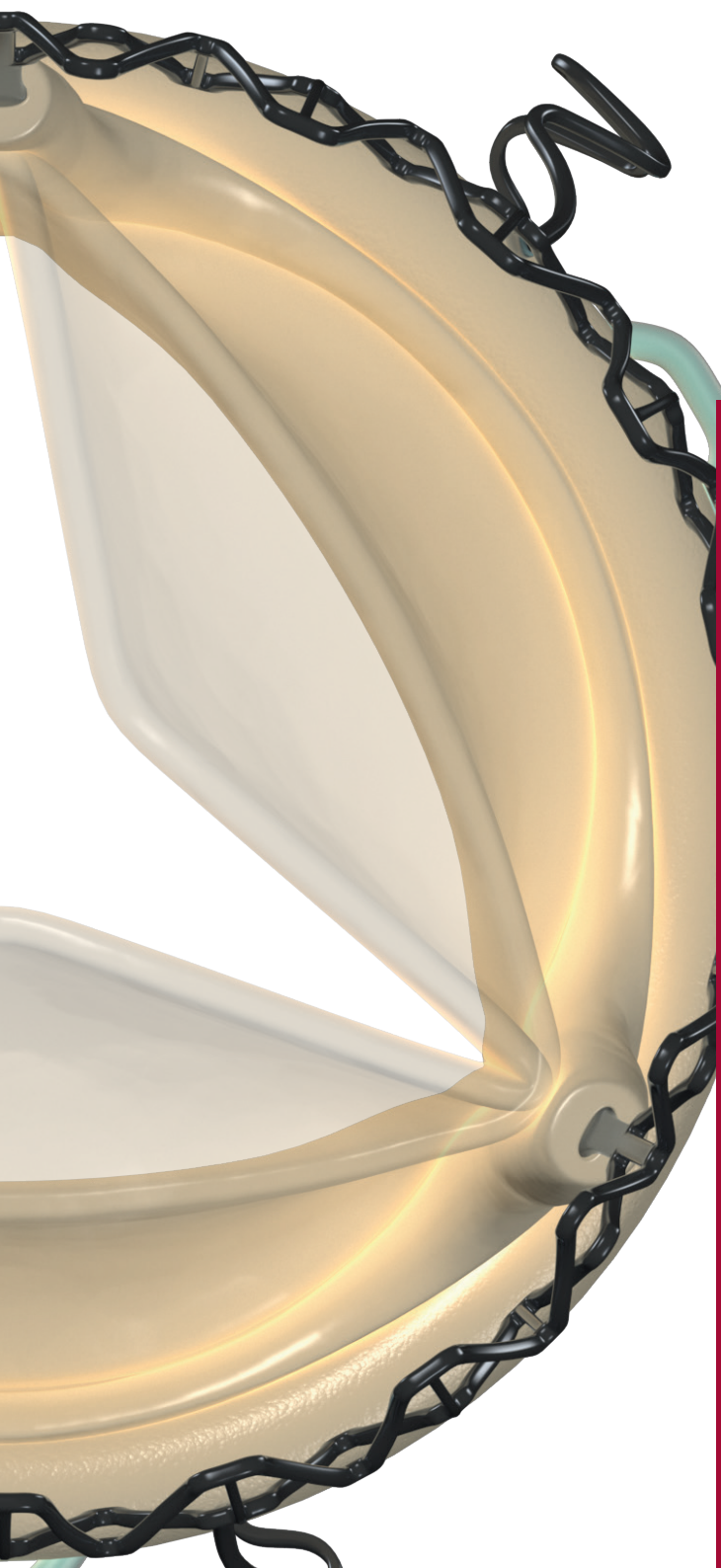


## Designed for excellent hemodynamics

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.<sup>7</sup>

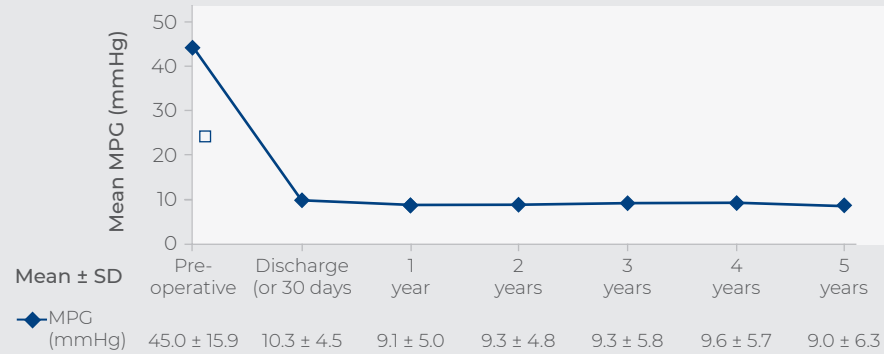
The Nitinol stent allows Perceval Plus to follow the physiological movement of the aortic root during the cardiac cycle, mimicking the native valve.<sup>3,4</sup>





### Stable hemodynamics<sup>3</sup>

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



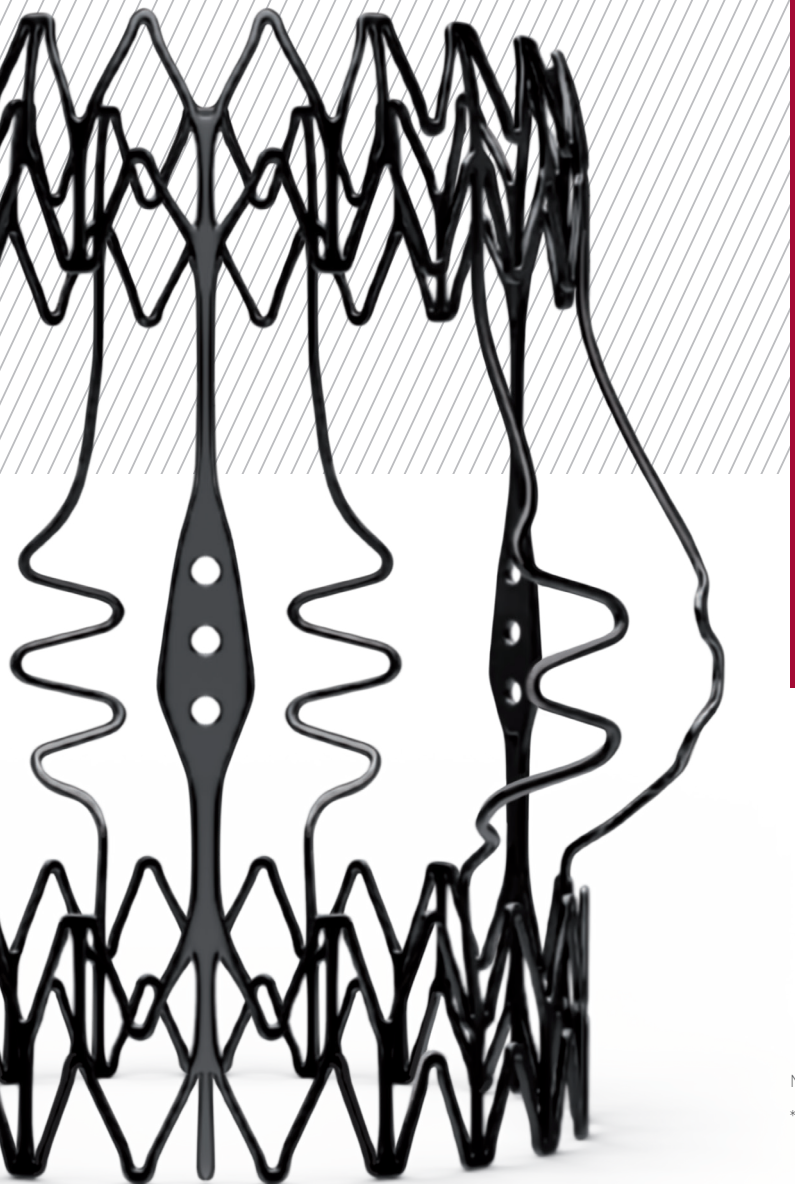
**Single-digit mean gradients**

**throughout 5-year follow-up<sup>3</sup>**

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



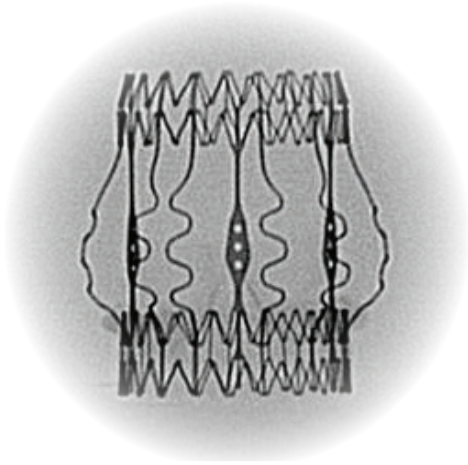
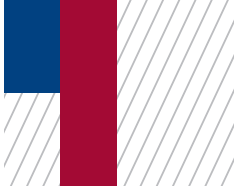
## Designed for the future: the ideal docking station for Valve-in-Valve



Perceval Plus is a valve designed for the future. Not only is it durable,<sup>2</sup> 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.\*\*<sup>14,15</sup>

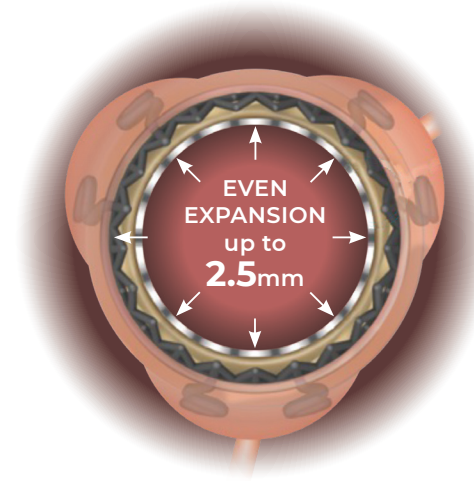
No data on potential interaction between the Perceval Plus stent and transcatheter devices or their delivery systems are available.

\*\* In compliance with product Instructions For Use.



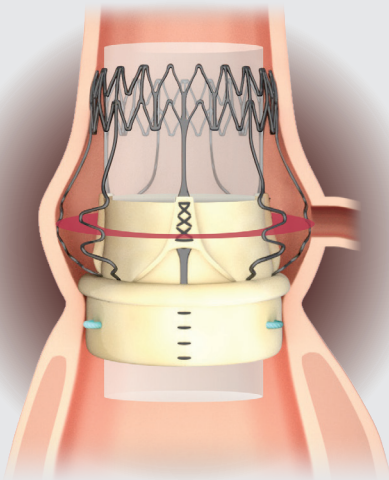
### Clear visibility

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



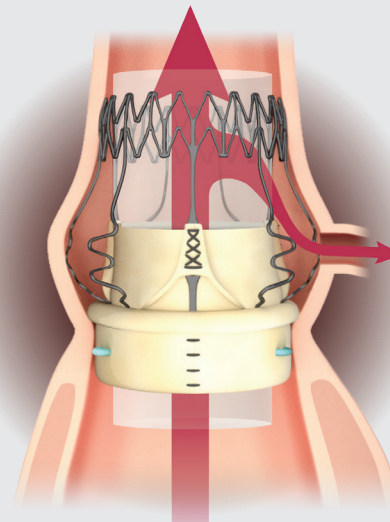
### Even circumferential expansion

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 which is preserved even after the TAVI deployment.

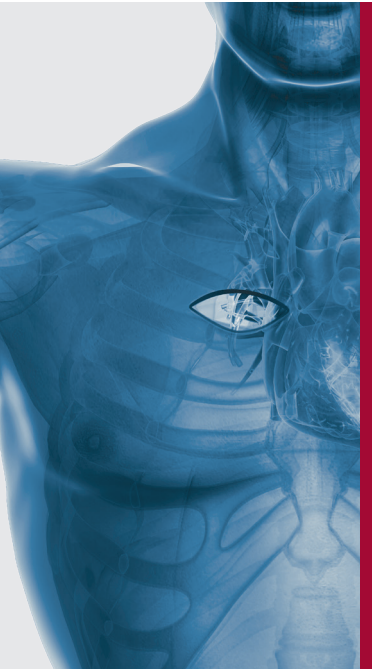


### Minimized risk of sinus sequestration

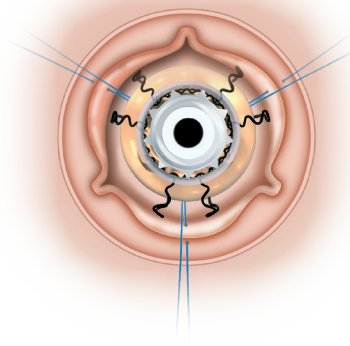
By design, the Perceval Plus leaflets, when open, do not touch the STJ, thus avoiding sinus sequestration.



## Designed for MICS

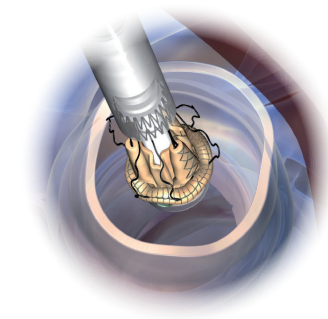


Perceval Plus RelyON System and Minimally Invasive Cardiac Surgery were made for each other thanks to the sutureless design of the valve and the length and diameter of the new Deliver System. The System allows for minimized incision,<sup>4,5</sup> maximized visibility,<sup>4,14</sup> faster learning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



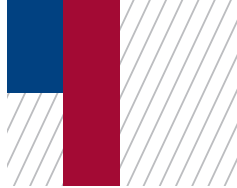
### Minimized incision<sup>4,14</sup>

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.<sup>4,7,18</sup>



### Maximized visibility during implantation<sup>4,14</sup>

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.<sup>7,12</sup>



# Designed for fast-track surgery

Fast-track surgery and ERAS have demonstrated many benefits for both the patient<sup>19-21</sup> and the hospital.<sup>19,21-24</sup> Perceval Plus's unique design and proven clinical benefits<sup>7,18</sup> 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.<sup>14,15,18</sup>





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, infographics, 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.

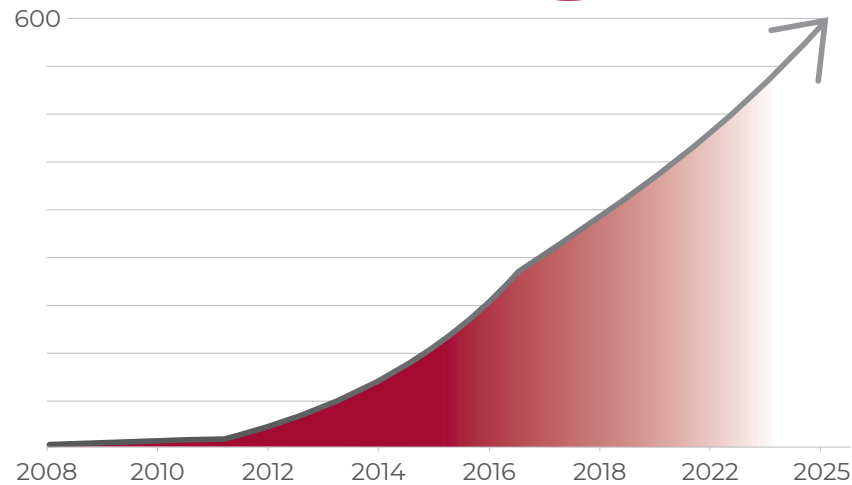
## Optimized for MICS procedures

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**

**>600**  
publications



**>600**  
publications

## WORLDWIDE

### **PERSIST-AVR study**

Inclusion: 910 patients in 47 centers



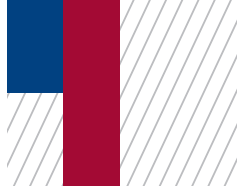
### **BELIEVE study**

Inclusion: 88 patients



### **IDE study**

Inclusion: 355 patients in 18 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



## **PILOT study**

Inclusion: 30 patients in 3 centers

## **PERCEVAL PMS**



Inclusion: 204 patients in 22 centers

## **PIVOTAL study**

Inclusion: 150 patients in 9 centers



## **PERFECT study**

Inclusion: 61 patients in 4 centers

## **CAVALIER study**

Inclusion: 658 patients in 26 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**

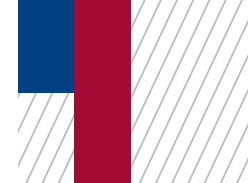


**Post-proctorship surveillance for monitoring overall effectiveness of the proctor program and customizing it depending on the trainee surgeon's needs**

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

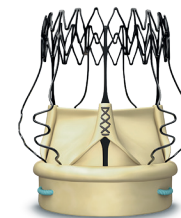


**Visit our website for more details:**  
[www.corcym.com](http://www.corcym.com)



## 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**	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".

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Technical claims are supported by CORCYM data on file.



#### 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  $\geq$  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.



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