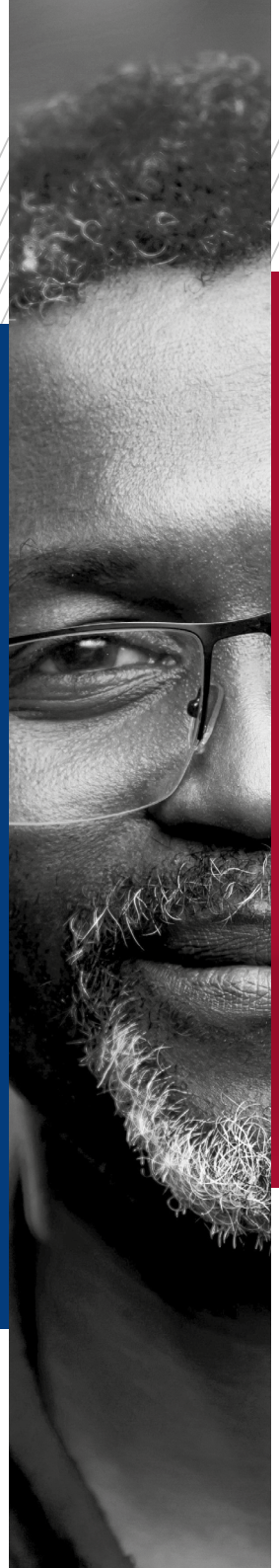
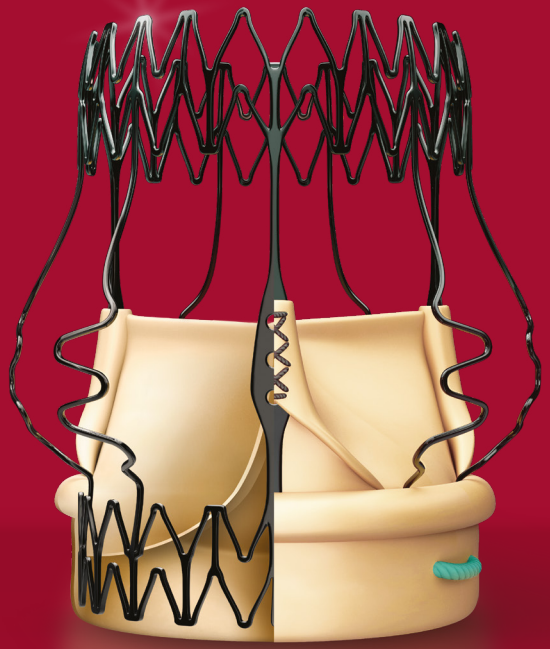


SUTURELESS AORTIC PERICARDIAL HEART VALVE

PERCEVAL™ PLUS

The Optimal Mix



FEATURING THE INNOVATIVE

FREE TISSUE TREATMENT

CORCYM

WE TAKE LIFE TO HEART

Perceval Platform

-99% calcification
vs control group[1]

0.76% SVD
at 13 years[2]

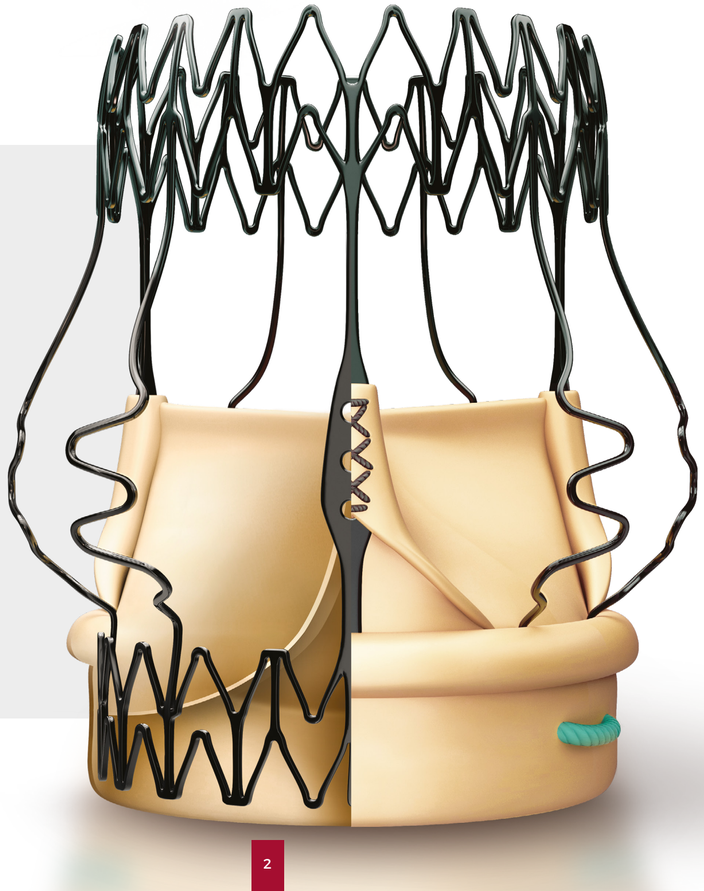
Single-digit mean gradients
throughout 5-year follow-up[3]

0.5% PVL
greater than mild at 1 year[5]

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.



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 **13 years** of successful clinical results
- More than **400** publications
- Present in more than **100** countries worldwide
- More than **75.000** patients treated worldwide

Unique design: unique benefits

Durability

Hemodynamics

Valve-in-Valve

MICS

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]

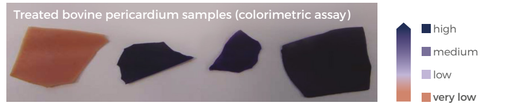
≃0% aldehyde toxicity*

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



READY TO USE

Aldehyde-free storage solution

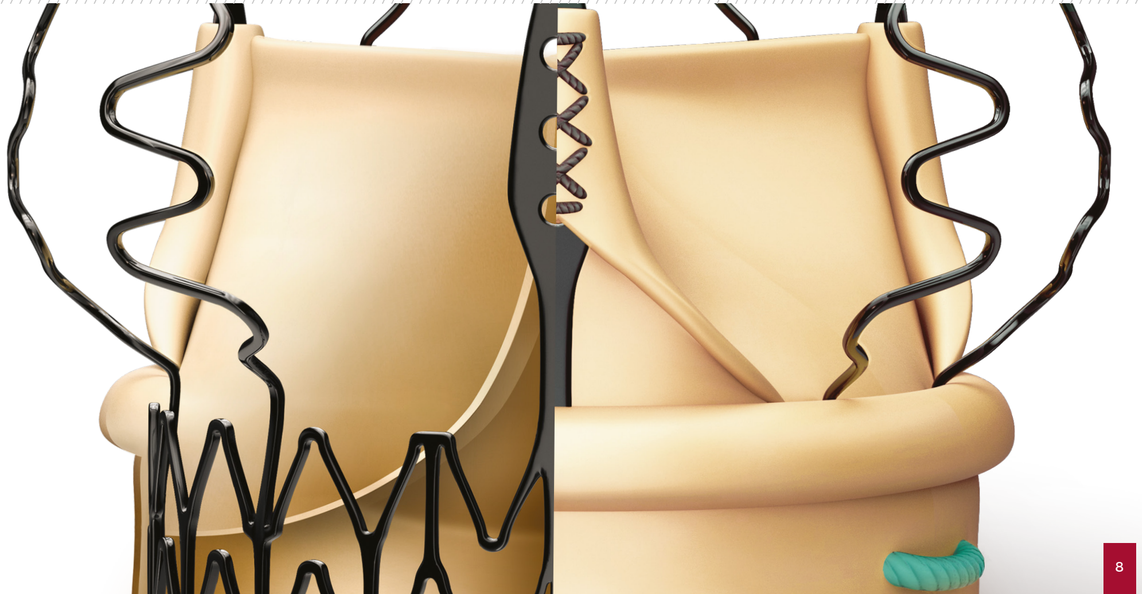
Before packaging, the valve undergoes an industrialized rinsing process.

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]

-99% calcification*

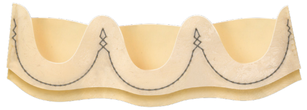
* vs control group[4]

Designed for durability



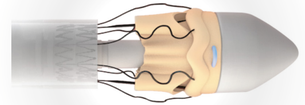
Superelastic stent

- Self-expands in place (no need to knot the sutures), ensuring optimal valve sealing.[7]
- Reduces 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 stress transferred to the leaflets.



Fully atraumatic collapsing

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

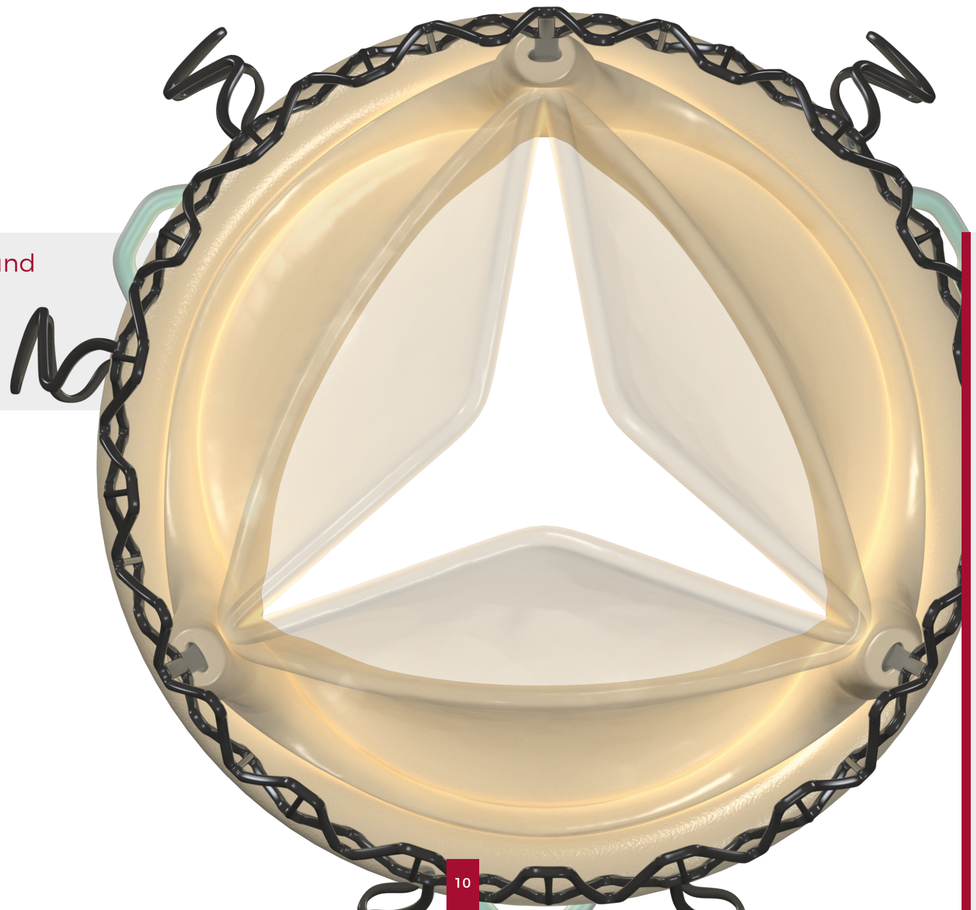
0.76%
SVD at
13 years[2]

Perceval Plus is based on the trusted Perceval Platform supported by more than 13 years of clinical experience that show excellent results in terms of durability.[2]

Designed for excellent hemodynamics

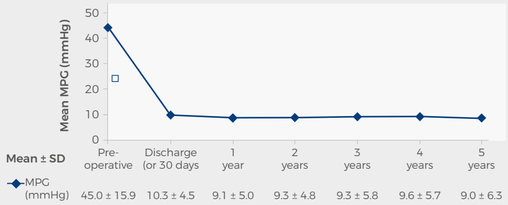
Perceval Plus boasts a distinctive design built around a superelastic stent that self-expands in place (no need to knot the sutures), ensuring optimal valve sealing.[7]

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]

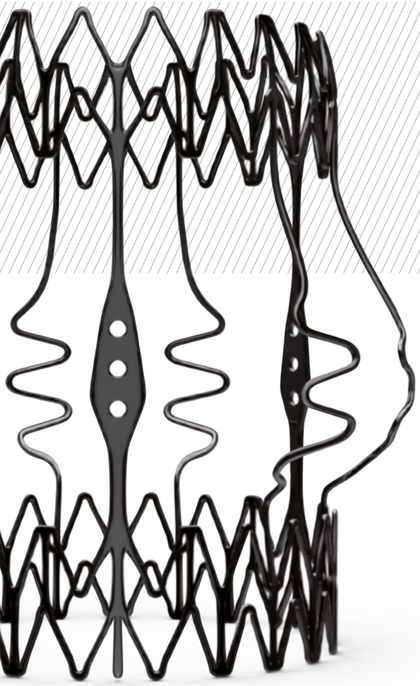


Single-digit mean gradients

throughout 5-year follow-up[3]

MPG, mm Hg	Preoperative	5 y
Size small		
Mean ± SD	45.6 ± 15.4	9.2 ± 5.4
Size medium		
Mean ± SD	45.1 ± 15.8	10.3 ± 6.6
Size large		
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: uniquely suited 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 a unique foundation for Valve-in-Valve procedures.*

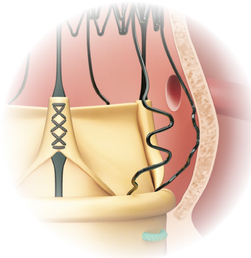
Thanks to its unique features, all patients eligible for biological AVR may benefit from a Perceval Plus implant.**[14,15]

* The decision to make a transcatheter aortic valve implantation in Perceval Plus compared to other options should be done by the Heart team based on individual assessment of the patient's conditions.
The safety and efficacy of Valve-in-Valve procedures in a Perceval Plus valve have not been established. Valve-in-Valve procedures in a Perceval Plus valve should be performed according to indications provided by the transcatheter valve manufacturer.

** In compliance with product Instructions For Use.

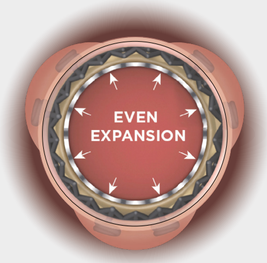
Clear visibility

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



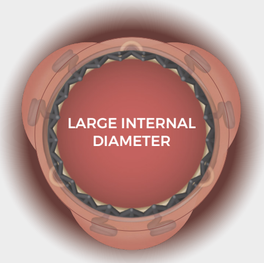
Coronary ostia patency

The stent design (sinusoidal struts and columns) are intended to minimize the risk of coronary obstruction during Valve-in-Valve procedures.



Even circumferential expansion (at annulus level)

The inflow ring can be evenly and circumferentially expanded to accommodate transcatheter aortic valve placement.



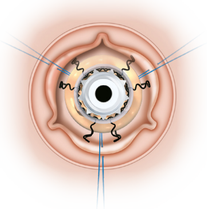
More choice

Perceval Plus's internal diameter can be expanded by up to 2.5mm above its nominal size allowing for a greater choice of transcatheter valve models and sizes.

Designed for MICS

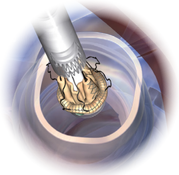
Perceval Plus's sutureless design and Minimally Invasive Cardiac Surgery were made for each other, allowing for minimized incision,[4,5] maximized visibility[4,14], faster learning curve[5,16] and a reduced manipulation of the aortic root.[4,5,17]

MICS



Minimized incision[4,14]

Thanks to its unique collapsible profile and its sutureless design, Perceval Plus allows a reduced incision size and less surgical trauma.[4,7,18]



Maximized visibility during implantation[4,14]

The collapsible profile allows 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]

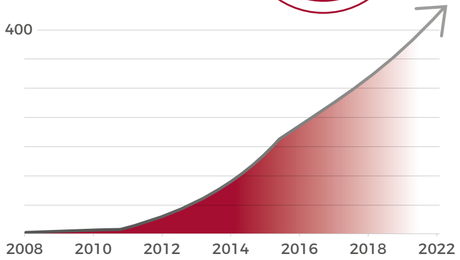
Designed for fast-track surgery

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]

- **Allows for shorter surgical times (significant shorter CCT and CPB time), both in isolated and combined AVR**[15,18]
- **Facilitates MICS procedures**
- **Involves shorter ICU and in-hospital stay, less ventilation time and fewer blood transfusions**[14,18,25]
- **Reduces hospital costs**[25-27]

Robust body of evidence

PERCEVAL PLATFORM >400 publications



>400 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
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		USE
ICV 1232	Dual Collapser base S/M/L/XL		Re-usable
ICV 1219	Sizer S/M/L/XL		Re-usable
0218TS*	Inflation Device S/M/L/XL		Single use
ICV1345	ACCESSORY KIT (Dual Collapser, Dual Holder, MICS Post-dilation Catheter)	S	Single use
ICV1346		M	
ICV1347		L	
ICV1348		XL	
ICV 1349	MICS ACCESSORY KIT (Dual Collapser, Dual MICS Holder, MICS Post-dilation Catheter)	S	Single use
ICV 1350		M	
ICV 1351		L	
ICV 1352		XL	
ICV1230	Empty Tray		Re-usable

*Not available in all countries

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Technical claims are supported by 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
WE TAKE LIFE TO HEART

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