AORTIC PERICARDIAL
HEART VALVE

PERCEVAL™ PLUS

The optimal mix

CORCYM
WE TAKE LIFE TO HEART

PERCEVAL™ PLUS

An ideal solution for minimally invasive surgery, makes sutureless aortic[1] valve replacement available to a wide patient population*[2]

PERCEVAL™ IS A TRUSTED PLATFORM THAT HAS ACHIEVED THE FOLLOWING MILESTONES:

- First-in-human performed in 2007
- More than 13 years of successful clinical use[3]
- Solid clinical evidence
- Truly global reach

* The Perceval Plus is an improvement of the proven Perceval technology. Perceval clinical data can be used as reference for Perceval Plus.

THE OPTIMAL MIX - Unique Valve Design

Based on a clinically proven technology

FACILITATES MINIMALLY INVASIVE SURGERY

DESIGNED FOR DURABILITY

FREE

Innovative FREE tissue treatment

Uniquely suited for future ViV* procedures**

AVAILABLE TO A WIDE PATIENT POPULATION[2]

Simplifies complex procedures[14,16]

Viable for multiple valve procedures***[4,5]

* Valve-in-Valve.

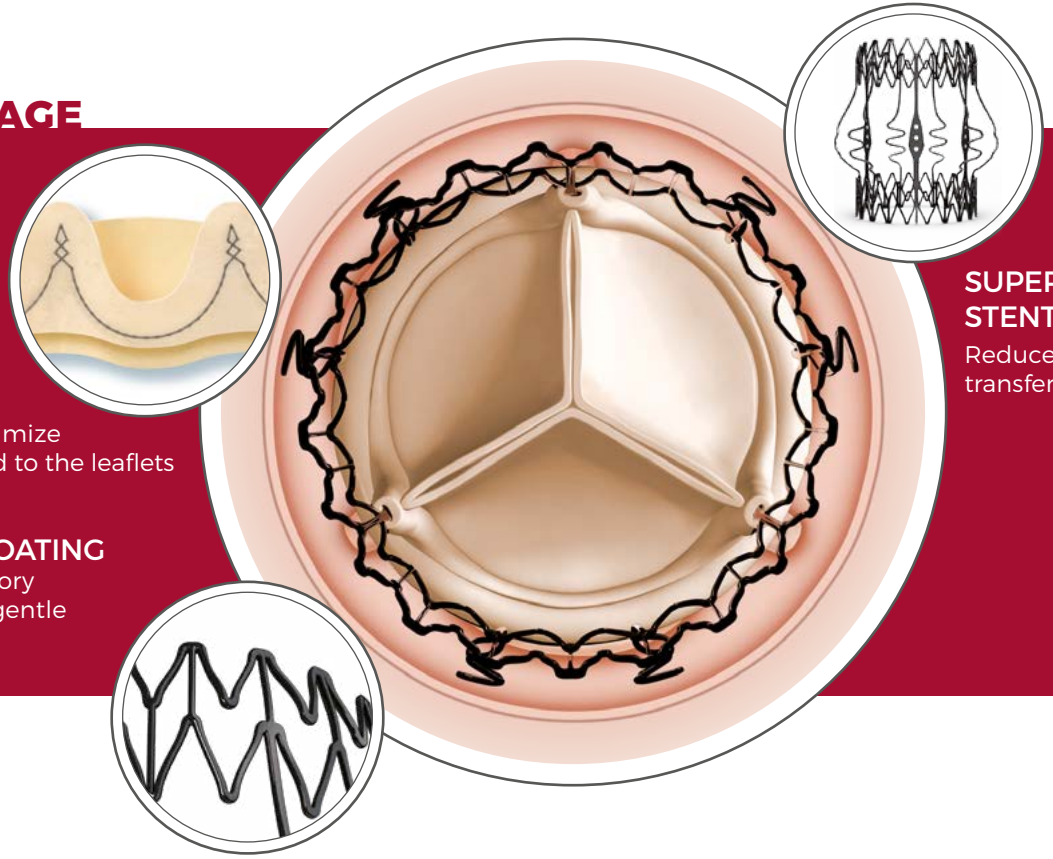
** The decision to make a transcatheter aortic valve implantation in Perceval Plus compared to other options should be done by the Heart team based on individual assessment of the patient's conditions. The safety and efficacy of Valve-in-Valve procedures in a Perceval Plus valve have not been established.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

*** The decision of using Perceval in patients should be based on a careful individual assessment and limited to cases in which the benefits of using Perceval justify the risks.
The available clinical data indicate that using Perceval in patients with other prostheses may result in intraoperative valve misplacement or insufficient leaflet coaptation leading to valve replacement, due to possible interference with the other prostheses.

Unique Valve Design

THE PERCEVAL VALVE DESIGN HAS A LONG CLINICAL HERITAGE. Its proven double-sheet design has been used to manufacture biological prostheses since 1985, while the super elastic stent provides unique characteristics and mechanical behavior. With Perceval Plus, the valve is enhanced with a reduced ventricular protrusion feature, designed to further improve patient outcomes.

PERCEVAL HERITAGE



DOUBLE SHEET DESIGN

An outer sheet acts as a cushion to minimize the stress transferred to the leaflets

CARBOFILM™ COATING

Reduces inflammatory reaction favoring a gentle endothelialization[7]

SUPER ELASTIC STENT

Reduces the stress transferred to the leaflets[6]

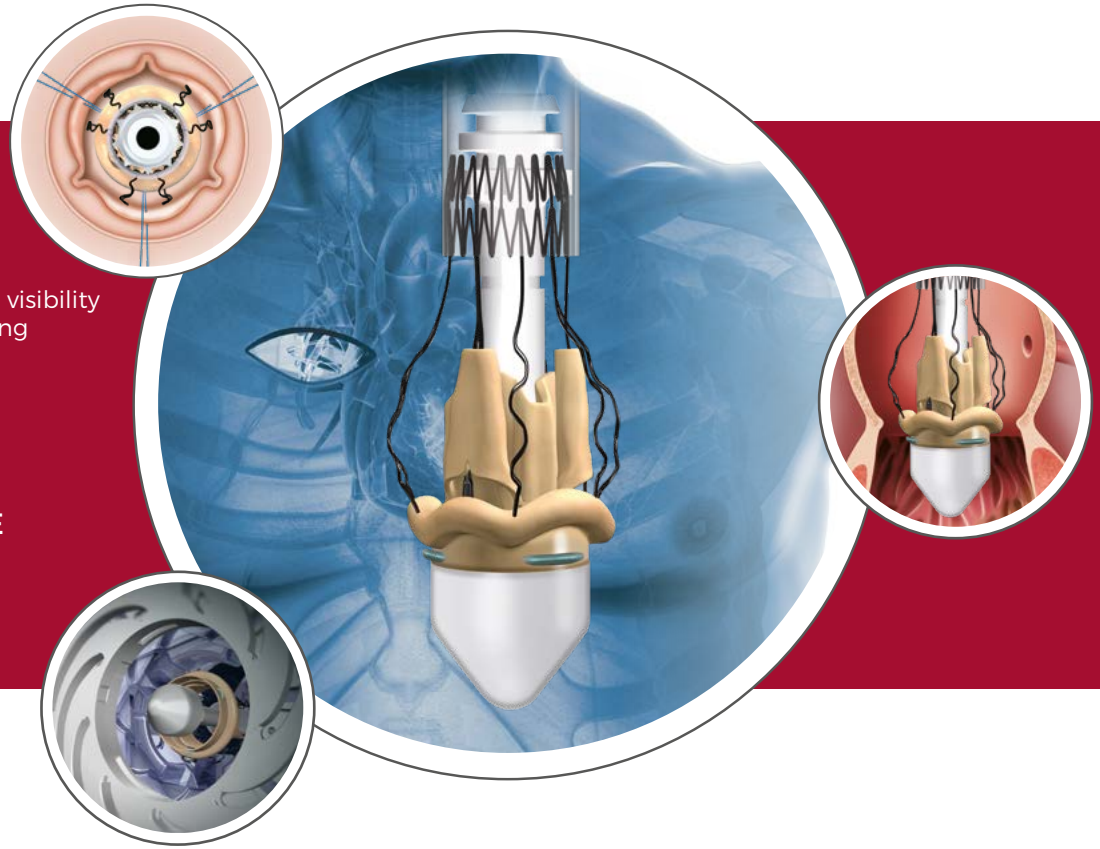
Exclusive to **PERCEVAL PLUS**

Reduced valve ventricular protrusion

The reduction of the protrusion of the valve below the aortic annulus is expected to decrease the risk of impairment of the atrio-ventricular conduction system.

Facilitates Minimally Invasive Surgery

THE ATRAUMATIC COLLAPSING DOES NOT IMPAIR LEAFLET FUNCTIONALITY,[8] PREVENTING POSSIBLE DAMAGE TO THE TISSUE.[2] When collapsed, the valve allows the surgeon better visibility of the annulus and the anatomical structures during implantation and deployment, for greater confidence and faster, more precise positioning at the implantation site.[1]



COLLAPSED PRIOR TO IMPLANTATION

Collapsible design allows visibility of critical structures during implantation[1]

ATRAUMATIC VALVE COLLAPSING

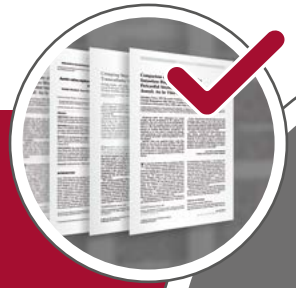
Does not impair leaflet functionality[8]

MAXIMIZED VISIBILITY DURING IMPLANTATION[4]

Faster, more precise positioning[1]

Designed for Durability

BASED ON A CLINICALLY PROVEN TECHNOLOGY. Perceval Plus is based on the trusted Perceval platform supported by more than 13 years of clinical experience that demonstrates excellent results in terms of durability.[3]

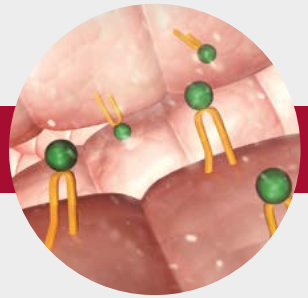


0.76%
SVD
at **13 years**[3]

INNOVATIVE FREE TISSUE TREATMENT. The innovative FREE tissue treatment in Perceval Plus addresses both major causes of valve calcification, phospholipids and aldehydes.[9]
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.[9]

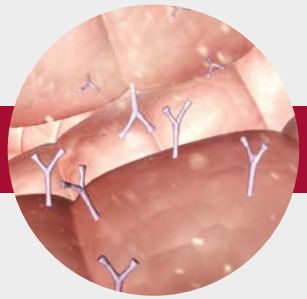
THE MAJOR CAUSES OF CALCIFICATION

Phospholipids and aldehydes contribute to calcification as they are calcium binding sites.[10-14]



PHOSPHOLIPIDS

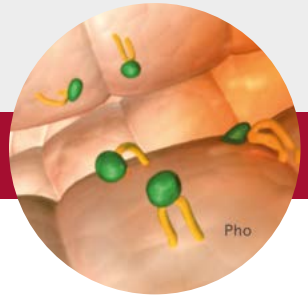
Phospholipids are intrinsically present in biological tissue



ALDEHYDES

Aldehydes are a consequence of the fixation process

FREE ADDRESSES CALCIUM BINDING SITES[15]



PHOSPHOLIPIDS

During the manufacturing process phospholipids are dissolved and eliminated[15]

ALDEHYDES

Aldehydes are also “capped” and neutralized during manufacturing[15]

SUPPORTING EVIDENCE FOR THE FREE TISSUE TREATMENT

-96%
phospholipid content*[9]

NEGLIGIBLE
aldehyde content[9]

* vs control group[9]

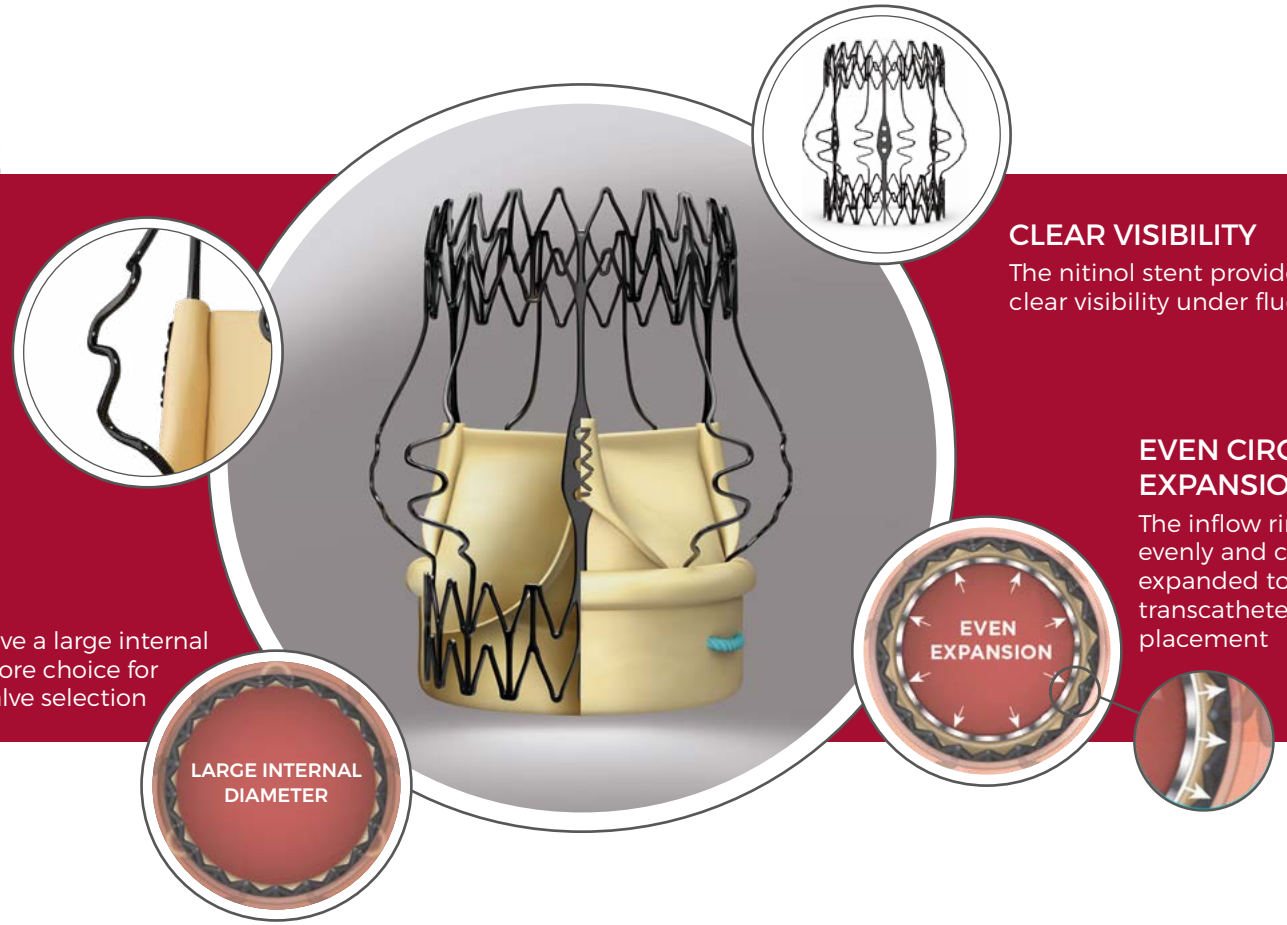
Available to a Wide Patient Population

PERCEVAL PLUS 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.*

VALVE-IN-VALVE

CLEAR LANDMARKS
The sinusoidal struts enable identification of clear landmarks which may help avoid coronary ostia obstruction

MORE CHOICE
Perceval Plus valves have a large internal diameter, providing more choice for future transcatheter valve selection



CLEAR VISIBILITY
The nitinol stent provides clear visibility under fluoroscopy

EVEN CIRCUMFERENTIAL EXPANSION (at annulus level)
The inflow ring can be evenly and circumferentially expanded to accommodate transcatheter aortic valve placement

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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.

Multiple Valve and Complex Procedures

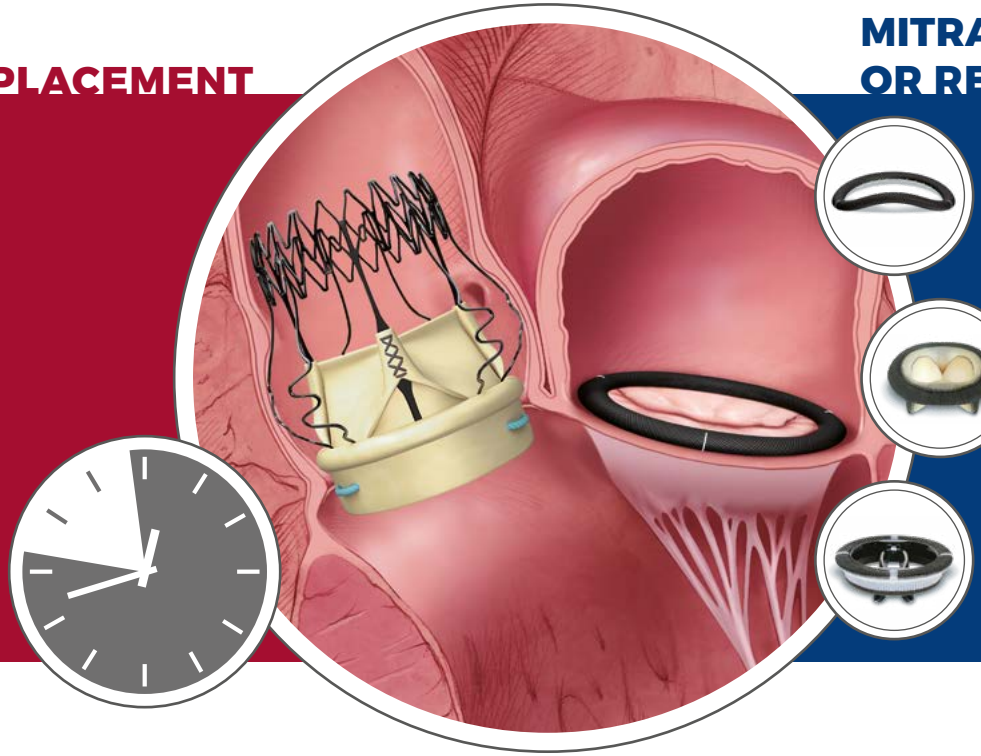
PERCEVAL PLUS: WHEN TIME REALLY MATTERS. The unique characteristics of Perceval Plus make it an ideal choice in complex implantations[5] while extending the benefits to a wider patient population.**

Whether using an open or a minimally invasive cardiac surgery (MICS) approach, Perceval Plus enables a faster procedure and reduced cross-clamp time compared to traditional valve prostheses.[5,16]

AORTIC VALVE REPLACEMENT

25-60%
Faster procedures

vs traditional approaches
Clinically significant reduction in cross-clamp time[5,16]



MITRAL VALVE REPLACEMENT OR REPAIR

MITRAL REPAIR

TISSUE MITRAL REPLACEMENT

MECHANICAL MITRAL REPLACEMENT

Perceval Plus helps reduce complexity even in challenging and time consuming procedures, while maintaining good hemodynamic outcomes.[4,5]

Perceval Plus is safe and effective, even in cases of concomitant cardiac procedures.** [4,5]

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The available clinical data indicate that using Perceval in patients with other prostheses may result in intraoperative valve misplacement or insufficient leaflet coaptation leading to valve replacement, due to possible interference with the other prostheses.

Providing a Professional Support Network for Surgeons

CORCYM OFFERS A FULL RANGE OF TRAINING AND EDUCATION PROGRAMS FOR CARDIAC SURGEONS, AT ALL EXPERIENCE LEVELS TO SHARE BEST PRACTICES AND DEEPEN EXPERTISE.

The Perceval proctorship is a unique opportunity to gain first-hand experience and exchange knowledge with a network of expert Perceval users.

Educational opportunities include: dry-labs, in-OR proctorship and lectures.

A number of online and offline training and educational resources are also available to support surgeons in each step of their experience with Perceval Plus.

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

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15. **Corcym data on file**
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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

Manufactured by:

Corcym S.r.l.
Via per 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

corcym
.com

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