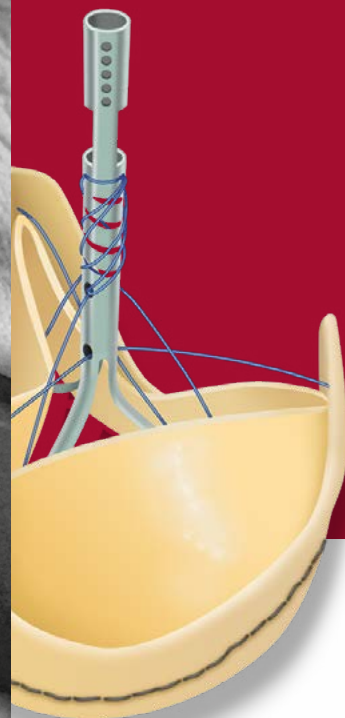




SOLO SMART™

AORTIC PERICARDIAL
HEART VALVE



Native-like
hemodynamic performance*
designed for a stented-like
implantability

 **CORCYM**
WE TAKE LIFE TO HEART

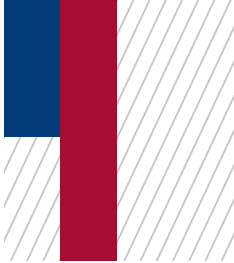
*Comparison made considering hemodynamic data on Solo Smart (Repossini et al., Eur J Cardiothorac Surg (2012) 41(5): 1104-1110) and data on native valves (Hanke et al., European Journal of Cardio-Thoracic Surgery (2013) 1-7).

SOLO SMART™

**Designed for both surgeons
and patients to provide
an easy and fast procedure
also thanks
to a “temporary stent”
that improves implantability**



**MANY PATIENTS NEED
EXCELLENT HEMODYNAMIC
PERFORMANCE TO RETURN
TO THEIR NORMAL LIFESTYLE.¹**



SOLO SMART IS PARTICULARLY SUITED FOR PATIENTS...

...WITH AN ACTIVE LIFESTYLE^{2,3}

During exercise or even during normal daily activities, where there's an increasing cardiac output, some prostheses can obstruct the blood flow. This can lead to higher pressure gradients which are not apparent at rest.²

...AT RISK OF PPM^{3,4}

When implanting a prosthesis, the presence of PPM can have an impact on patient outcomes. PPM is associated with less improvement in symptoms and functional class, impaired exercise capacity, less regression of LV hypertrophy, and more adverse cardiac events.^{3,4}

...REQUIRING CONCOMITANT AVR AND MV SURGERY⁵

Patients requiring a concomitant procedure can result with a smaller effective aortic area and reduced dynamics due to a constrictive effect of the annuloplasty ring or mitral prosthesis.⁶

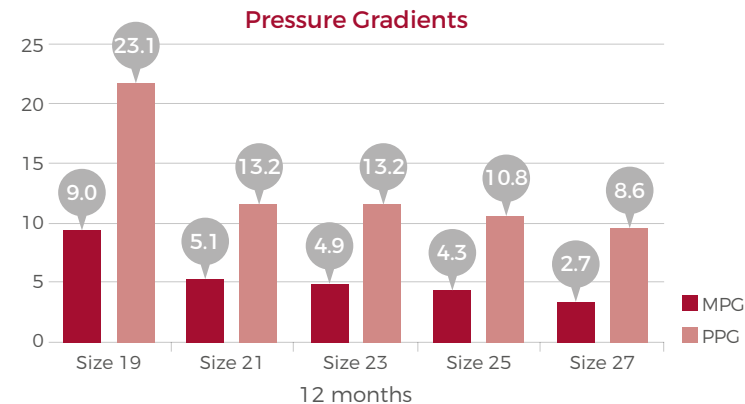


1. P. Pibarot et al., Prosthetic Heart Valves: Selection of the Optimal Prosthesis and Long-Term Management. *Circulation* 2009;119:1034-1048
2. Silberman et al., Exercise Hemodynamics of Aortic Prostheses: Comparison Between Stentless Bioprotheses and Mechanical Valves, *Ann Thorac Surg* 2001;72:1217-21.
3. Repossini et al., Early clinical and hemodynamic results after aortic valve replacement with the Freedom SOLO bioprosthesis (experience of Italian multicenter study), *Eur J Cardiothorac Surg* (2012) 41(5): 1104-1110.
4. Wollersheim et al., Midterm Follow-Up of the Stentless Freedom Solo Bioprosthesis in 350 Patients, *Ann Thorac Surg*. 2016 Jul;102(1):86-92.
5. Repossini et al., Single-suture line placement of a pericardial stentless valve, *J Thorac Cardiovasc Surg* 2005;130:1265-9.
6. Veronesi et al., Effect of Mitral Valve Repair on Mitral-Aortic Coupling: A Real-Time Three-Dimensional Transesophageal Echocardiography Study, *Journal of the American Society of Echocardiography* Vol. 25 N. 5.

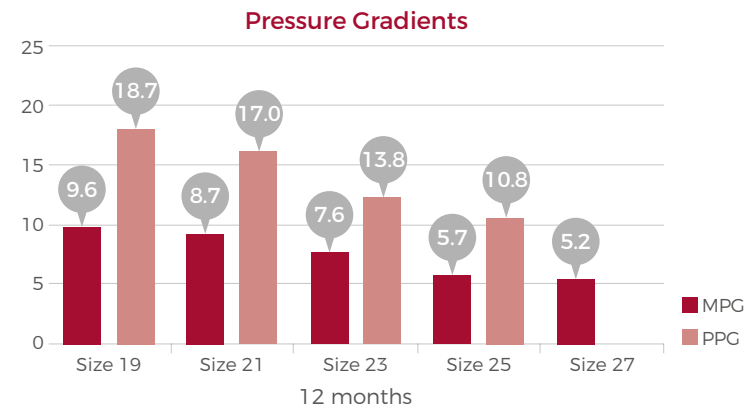
Purposefully designed for patients needing excellent hemodynamic performance.*

Solo Smart provides excellent hemodynamic performance for all valve sizes, even the smallest.*

Early clinical and hemodynamic results after aortic valve replacement with the Freedom SOLO bioprosthesis (experience of Italian multicenter study).¹



The Freedom SOLO Valve for Aortic Valve Replacement: Clinical and Hemodynamic Results from a Prospective Multicenter Trial.²



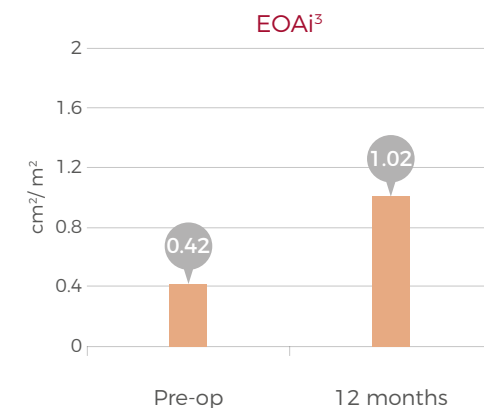
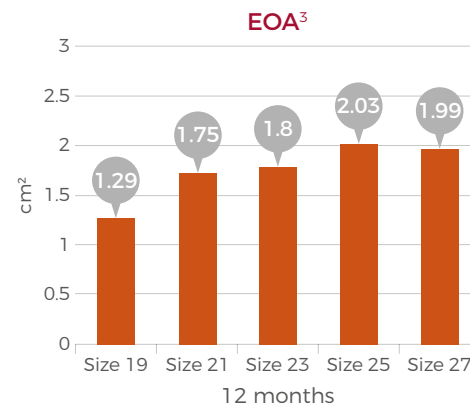
*Comparison made considering hemodynamic data on Solo Smart (Repossini et al., Eur J Cardiothorac Surg (2012) 41(5): 1104-1110) and data on native valves (Hanke et al., European Journal of Cardio-Thoracic Surgery (2013) 1-7).

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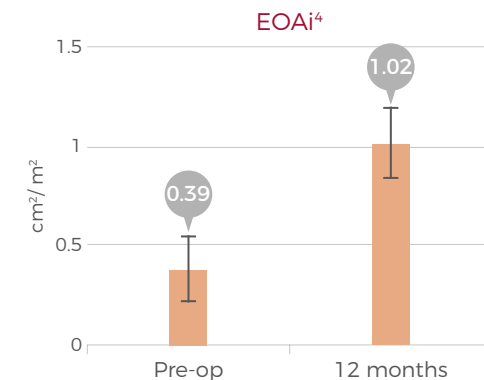
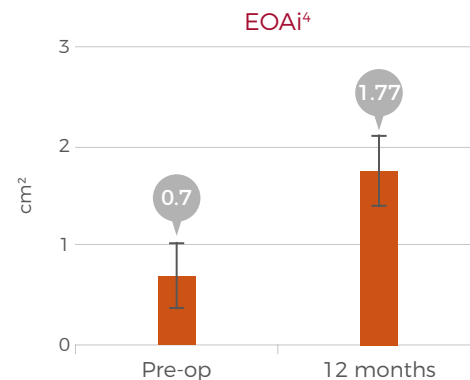
2. Beholz et al., The Freedom SOLO Valve for Aortic Valve Replacement: Clinical and Hemodynamic Results from a Prospective Multicenter Trial. The Journal of Heart Valve Disease 2010;19:115-123.

Solo Smart provides hemodynamic performances, EOA and EOAI close to those of healthy native-valves, ensuring excellent results and low risk of mismatch.*

“The EOA indices were about 1.0 cm²/m² for all valve sizes after 12 months, which suggested almost normal hemodynamics at the valvular level, without any need for annular enlargement procedures”.³



“The present study showed that large EOAs and EOAI’s remained substantially stable after the first post-operative year. Our data are consistent with previous studies, which demonstrated excellent early clinical and hemodynamic results”.⁴



*Comparison made considering hemodynamic data on Solo Smart (Repossini et al., Eur J Cardiothorac Surg (2012) 41(5): 1104-1110) and data on native valves (Hanke et al., European Journal of Cardio-Thoracic Surgery (2013) 1-7).

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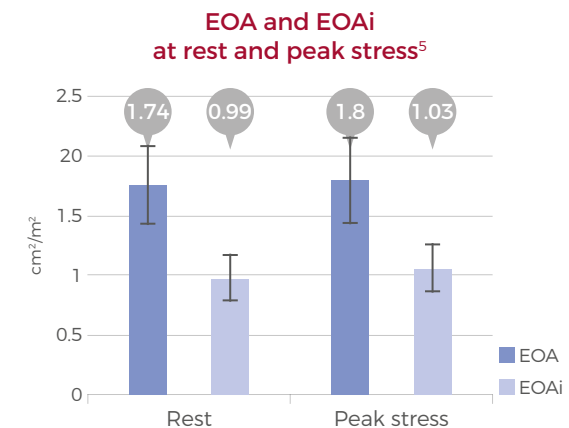
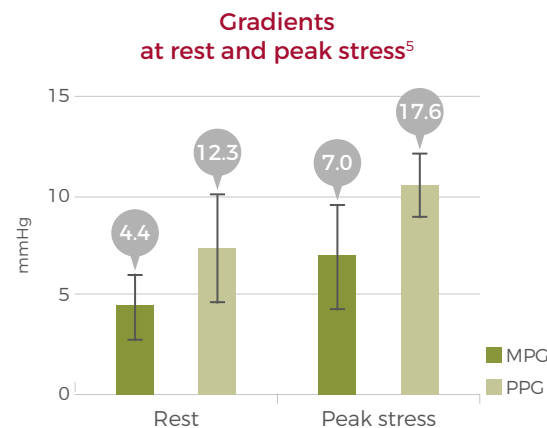
4. Repossini et al., Early clinical and hemodynamic results after aortic valve replacement with the Freedom SOLO bioprosthesis (experience of Italian multicenter study). Eur J Cardiothorac Surg (2012) 41(5): 1104-1110.

Meeting the needs of an active lifestyle

The valve mimics the physiology of a native valve with the ability of increasing its EOA to respond to increasing physiological demands.*

Solo Smart has no rigid support and is placed supra-annularly, meaning it does not restrict blood flow, offering excellent hemodynamic results, even during exercise.* Hemodynamic performance of Solo Smart under exercise is characterized by:^{5,6}

- Low gradients under stress
- Modest mean gradients increase from rest to stress
- EOA and EOAI increase during exercise



Early clinical and hemodynamic results after aortic valve replacement with the Freedom SOLO bioprosthesis (experience of Italian multicenter study).⁵

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5. Repossini et al., Early clinical and hemodynamic results after aortic valve replacement with the Freedom SOLO bioprosthesis (experience of Italian multicenter study). Eur J Cardiothorac Surg (2012) 41(5): 1104-1110.

6. Pisarik et al, Clinical experience with the Freedom Solo stentless aortic valve in 277 consecutive patients, Ann Thorac Surg 2014;98:1301-7.

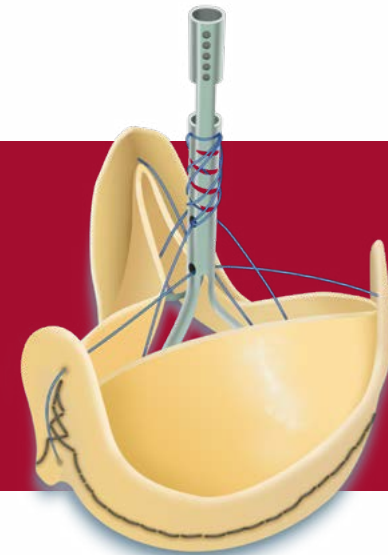
A native-like valve* design with stented-like implantability

Solo Smart is engineered for those surgeons who want to implant a valve with a native-like design and a stented-like implantability.

An easy and fast implant procedure improves confidence during implantation.^{1,2}

Solo Smart features a "temporary stent" that:

- Provides proper visibility of implantation site during valve positioning and suturing.
- Gives support and facilitates Solo valve implantation.
- Makes it possible to complete valve suturing in less time.
- Is designed to reduce the learning curve in first-time users.



SOLO SMART

AORTIC-BOVINE PERICARDIAL TISSUE VALVE
WITH STENTED-LIKE IMPLANTABILITY

Sizes 19-27 mm

Product specifications

Size	Ref.	Code
19	ART 19 SMT	ICV1246
21	ART 21 SMT	ICV1247
23	ART 23 SMT	ICV1248
25	ART 25 SMT	ICV1264
27	ART 27 SMT	ICV1265

Accessories

Article	Code	Description
Bendable ended sizers set	ICV1237	2 dual-ended sizers: - 19-21 mm - 23-25 mm
		Stand alone sizer: - 27 mm
Empty tray	ICV1230	Empty accessory tray



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2. Wollersheim et al, Aortic Valve Replacement With the Stentless Freedom SOLO Bioprosthesis: A Systematic Review, Ann Thorac Surg. 2015 Oct;100(4):1496-504.

INTENDED USE/INDICATIONS

Europe: The Solo Smart prosthesis is intended to replace a damaged native aortic heart valve or a malfunctioning aortic prosthesis via open heart surgery. The Solo Smart prosthesis is indicated for use in adult patient: suffering from aortic valvular heart disease, that is a condition involving obstruction of the aortic heart valve or stenosis; leakage of the aortic valve, known as regurgitation, incompetence, or insufficiency; and combinations of the two; or with a previously implanted aortic valve prosthesis that is no longer functioning adequately and requires replacement.

US, Canada: The SOLO Smart prosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.

KEY CONTRAINDICATIONS

Europe: A biological prosthesis should not be used in young patients or in patients with chronic renal impairment or calcium metabolism disorders, or in patients receiving chronic drug treatment with preparations containing calcium due to the increased risk of premature valve tissue calcification.

US, Canada: None known

KEY WARNINGS

For single use only. Use of another type of prosthesis is preferable if there is extensive calcification of the root of the aorta, as this may prevent correct suturing. In native bicuspid valve replacement, it may be difficult

to align the prosthesis cusps correctly in the implant site. In both these cases, the use of another type of prosthesis is preferable. Do not use the prosthesis if there is an excessive mismatch between the valve annulus and the sino-tubular junction diameters (dilated aorta), unless surgically corrected, as this may give rise to central regurgitation due to defective leaflet coaptation; do not undersize the prosthesis.

TOP POTENTIAL SIDE EFFECTS

Potential adverse events (in alphabetical order) associated with cardiac valve replacement with a bioprosthesis and the related surgical procedure include: acute/recurrent fever, allergic reaction, anaphylactic shock, anatomical structures damage, anemia, bleeding, cardiac failure, cardiac tamponade, coronary ostia obstruction, embolism, endocarditis, genotoxic response, hemolysis, infection, inflammatory response, multiorgan failure, myocardial infarction, neurological events (stroke, transient ischemic attack), non-structural dysfunction, structural valve deterioration, thrombocytopenia, thromboembolism, TSE transmission leading to spongiform encephalopathy, valve dehiscence, valve insufficiency/stenosis, valve thrombosis. It is possible that these complications may lead to: death or permanent impairment, reoperation, medical therapy.

MRI safe

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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Corcym Canada Corp. previously LivaNova Canada Corp.



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