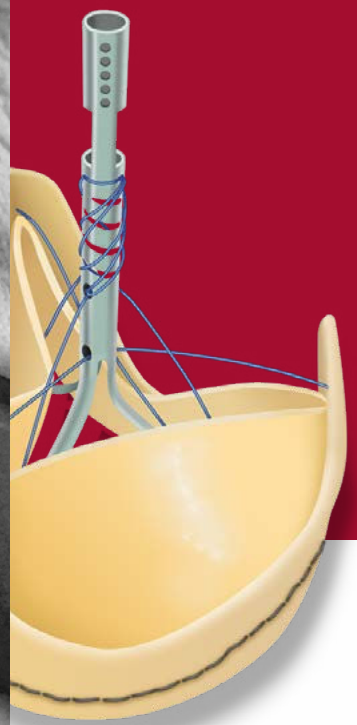
AORTIC PERICARDIAL
HEART VALVE

SOLO SMART™



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]

Technical claims are supported by CORCYM data on file.

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 SURGERY[5]

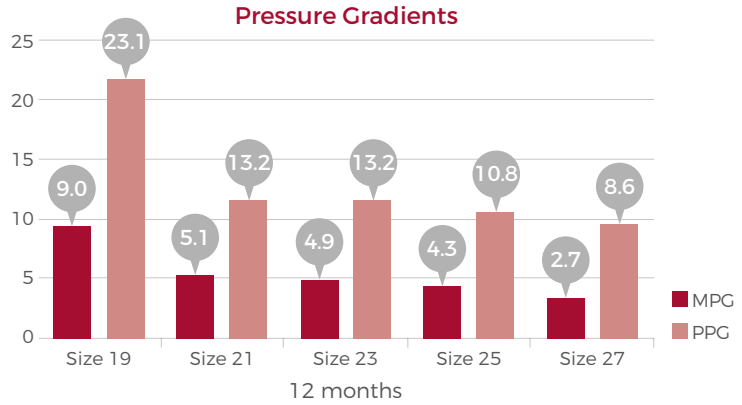
Patients requiring a concomitant procedure can result with a smaller effective aortic area and reduced dynamics due to a constrictive effect of the annuloplasty ring or mitral prosthesis.[6]

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 Bioprostheses 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.*

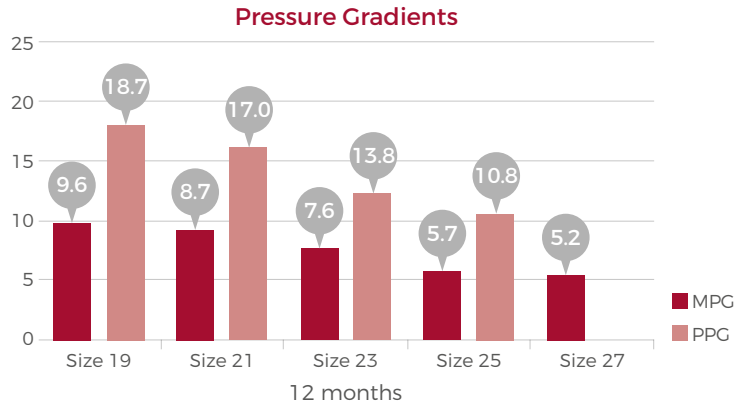
Purposefully designed for patients needing excellent hemodynamic performance.*

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]



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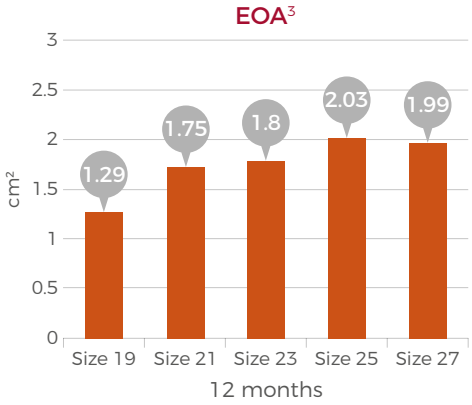
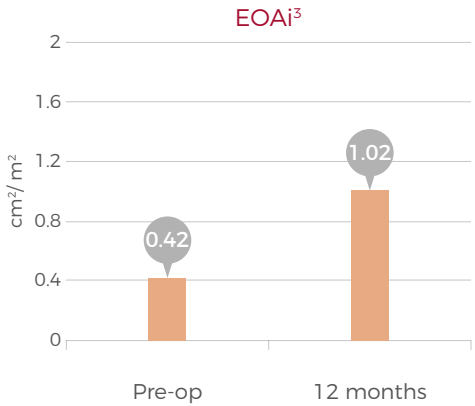
1. Repossini et al., Early clinical and hemodynamic results after aortic valve replacement with the Freedom SOLO bioprosthesis (experience of Italian multicenter study), Eur J Cardiothorac Surg (2012) 41(5): 1104-1110.
2. Beholz et al., The Freedom SOLO Valve for Aortic Valve Replacement: Clinical and Hemodynamic Results from a Prospective Multicenter Trial. The Journal of Heart Valve Disease 2010;19:115-123.

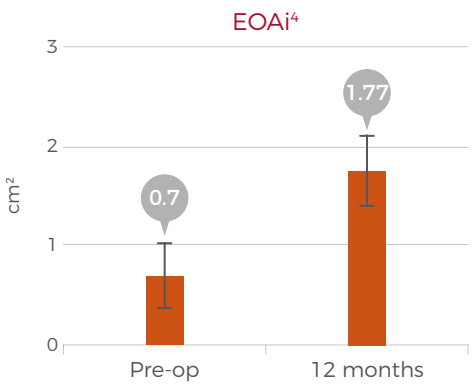
Solo Smart provides hemodynamic performances, EOA and EOAi close to those of healthy native-valves, ensuring excellent results and low risk of mismatch.*

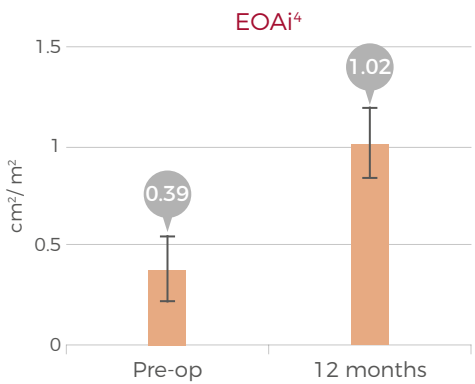
"The EOA indices were about 1.0 cm²/m² for all valve sizes after 12 months, which suggested almost normal hemodynamics at the valvular level, without any need for annular enlargement procedures".[3]

"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]









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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.

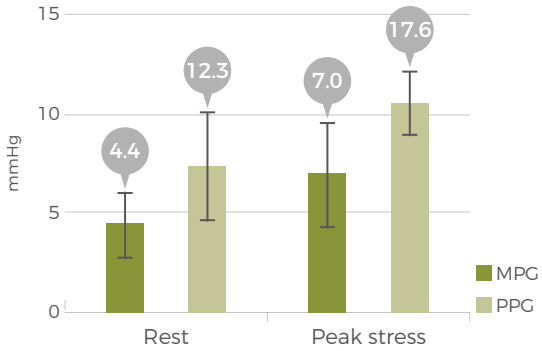
Meeting the needs of an active lifestyle

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

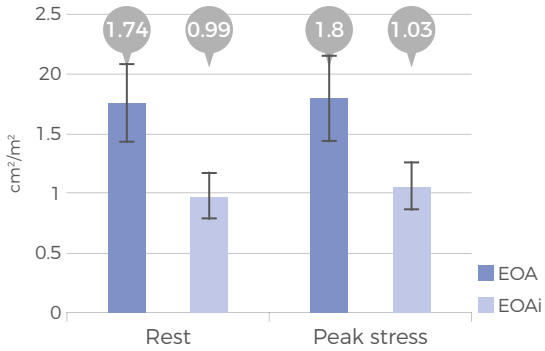
Solo Smart has no rigid support and is placed supra-annularly, meaning it does not restrict blood flow, offering excellent hemodynamic results, even during exercise.* Hemodynamic performance of Solo Smart under exercise is characterized by:[5,6]

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

Gradients at rest and peak stress[5]



EOA and EOAi at rest and peak stress[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.

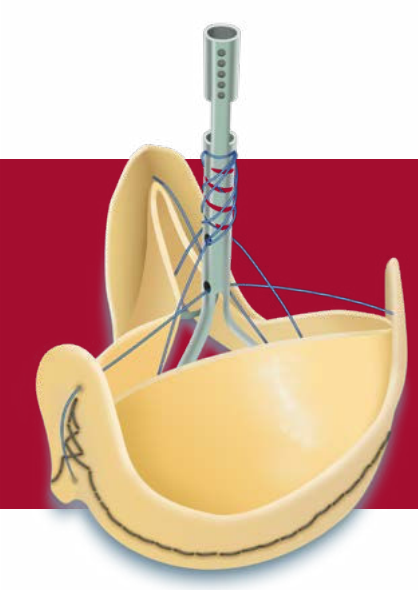
A native-like valve* design with stented-like implantability

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

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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.

INDICATIONS US, Canada
The Solo Smart prosthesis is indicated for the replacement of damaged native aortic heart valves or malfunctioning prostheses. A biological prosthesis is particularly indicated in cases where chronic anticoagulant therapy is contraindicated or difficult to manage.

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.

KEY WARNINGS Europe
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. Use only the supplied sizers ICV1237 to determine the appropriate valve size. The use of other accessories could result in failure to implant and impair the prosthesis integrity. Do not attempt to clean, resterilize, or reuse the prosthesis. Keep the prosthesis moist. If allowed to dry, even partially or briefly, the tissue will be irreversibly damaged.

KEY CONTRAINDICATIONS AND WARNINGS US, Canada
A biological prosthesis should not be used in young patients, 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. For single use only. Extensive calcification of the root of the aorta 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 oversize the prosthesis. Do not undersize the prosthesis: if the annulus size falls between two consecutive prosthesis sizes, choose the larger prosthesis. 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. Cases of thrombocytopenia have been observed in patients implanted with the Solo valve. Hence, it is recommended that the use of this device in patients with lower than normal preoperative platelet levels be carefully considered.

TOP POTENTIAL SIDE EFFECTS Europe
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.

TOP POTENTIAL SIDE EFFECTS US, Canada
The risks or potential adverse events associated with cardiac valve replacement with a bioprosthesis include, but may not be limited to: non-structural valve dysfunction including valvular regurgitation and periprosthetic leakage, death, endocarditis, thrombosis and thromboembolism, haemolysis, bleeding associated with anticoagulant therapy, thrombocytopenia, structural valve deterioration, reoperation and explant.

MRI safe

For professional use. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Not approved in all geographies. Consult your labeling.

CORCYM
WE TAKE LIFE TO HEART

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