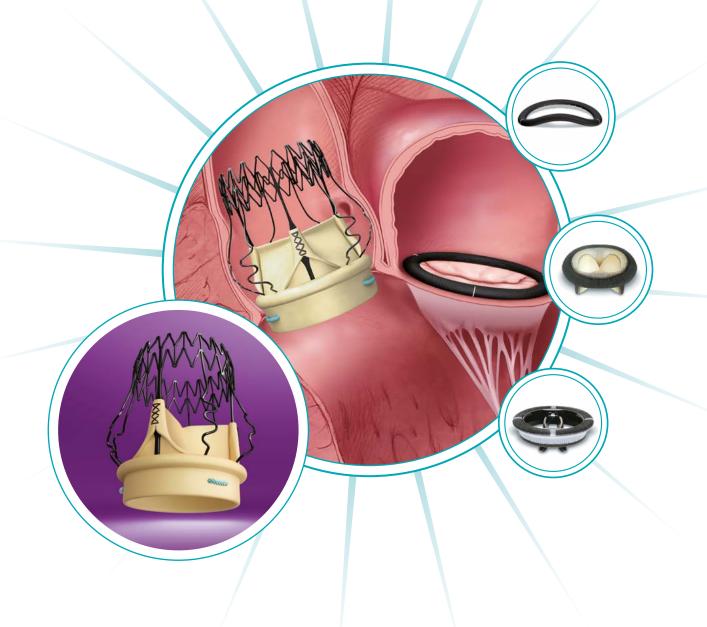


PERCEVAL® PLUS

Now a Viable Option for Multiple Valve Procedures



WHEN TIME REALLY MATTERS

The unique characteristics of PERCEVAL PLUS make it an ideal choice in complex implantations.

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Now a Viable Option for Multiple Valve Procedures

Tips & Tricks for a Multiple Valve Surgery°

Mitro-Aortic Continuity -

· A mitro-aortic continuity of 5-8 mm is recommended.⁷

 Attention must be payed to anterior mitral annulus stitching to avoid coronary sinus narrowing or distortion.

Aortic Valve Replacement

- · Check the aortic symmetry, evaluate potential distortion of non coronary sinus.
- Sizing, positioning, release and ballooning according to IFU.*
- Proper leaflet coaptation and valve functionality must be verified.
- If emergency cardiovascular procedures (such as cardiopulmonary resuscitation) are administered post-implant, an echocardiographic exam postprocedure is recommended, in order to verify the preserved position and function of the Perceval valve.

Mitral Valve Replacement or Repair

The mitral valve procedure must be performed prior to AVR.

MITRAL REPAIR

- Open annuloplasty bands do not interfere with the aortic root.
- In the case of closed rings, a semirigid ring is preferred, such as the MEMO 4D[®].
- For closed rings, caution must be taken to avoid deep bites and mitro-aortic continuity distortion.

TISSUE MITRAL REPLACEMENT

Attention should be given to the commissural struts so as not to protrude into the LVOT.

MECHANICAL MITRAL REPLACEMENT

Mechanical valves interfere less with the LVOT as they have a low profile design.



* The decision of using PERCEVAL PLUS in the patients should be based on a careful individual assessment and limited to cases in which the benefits of using PERCEVAL PLUS justify the risks.

The available clinical data indicate that using PERCEVAL PLUS 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.

PERCEVAL PLUS: WHEN TIME REALLY MATTERS

Extending the benefits of PERCEVAL PLUS to a wider patient population.



Because patients wish to return to a full and active life

Clinical evidences supporting the use of the PERCEVAL platform in Multiple Valve Procedures

Different clinical evidences already published to support the benefit of Perceval in concomitant procedures 1-8

Concomitant Perceval implantation and mitral valve repair/replacement is a feasible, safe and reproducible procedure 2, 3, 5, 6, 8

No interference between the aortic and mitral valves was observed in the published experiences^{5,8}

Minimally invasive surgery in combined procedures is a feasible approach that could be simplified with the use of Perceval⁷

Perceval in concomitant valve surgery can simplify patients' management, even in high-risk and elderly ones^{5,6,8}

REFERENCES:

- 1. "Sutureless aortic valve replacement in a calcified homograft combined with mitral valve replacement." Akca F, Lam K, Özdemir I, Tan E, J Cardiothorac Surg. 2017 Sep 7;12(1):82
- 2. "Valve Replacement with a Sutureless Aortic Prosthesis in a Patient with Concomitant Mitral Valve Disease and Severe Aortic Root Calcification." Lio A, Scafuri A, Nicolò F, Chiariello L, Tex Heart Inst J. 2016 Apr 1;43(2):186-8. doi: 10.14503/THIJ-15-5152. eCollection 2016 Apr. PMID:27127442
- 3. "Sutureless aortic valve and mitral valve repair in redo cases really an off-label approach?" Čanádyová J, Mokráček A, Kurfirst V, Kardiochir Torakochirurgia Pol. 2016 Dec;13(4):366-367. doi: 10.5114/kitp.2016.64885. Epub 2016 Dec 30. PMID: 28096837
- 4. "Aortic sutureless Perceval valve for small root in concomitant mitral valve replacement." Moriggia S, Trumello C, Buzzatti N, Laci G, Di Giannuario G, Alfieri O, J Heart Valve Dis. 2015 Mar; 24(2):187-9. PMID:26204683
- 5. "Expanding the indication for sutureless aortic valve replacement to patients with mitral disease." Minh TH, Mazine A, Bouhout I, El-Hamamsy I, Carrier M, Bouchard D, Demers P, J Thorac Cardiovasc Surg. 2014 Oct;148(4):1354-9. doi: 10.1016/j.jtcvs.2013.12.061. Epub 2014 Jan 15. PMID:25260274
- 6. "Sutureless Aortic Valve Replacement in the Setting of Triple-Valve Surgery." Mazine A, Vistarini N, El-Hamamsy I, Carrier M, Bouchard D, Demers P, Innovations (Phila). 2015 Jul- Aug; 10(4):291-3. doi: 10.1097/IMI.000000000000175. PMID: 26368034
- 7. "Minimally invasive approach for aortic and mitral valve surgery." Lio A, Miceli A, Ferrarini M, Glauber M, Eur J Cardiothorac Surg. 2016 Dec;50(6):1204-1205. doi:10.1093/ejcts/ezw208.
- 8. "Sutureless aortic valve replacement with concomitant valvular surgery." Baran C, Durdu MS, et al., J Thorac Cardiovasc Surg 2018;-:1-9

INDICATIONS: The PERCEVAL prosthesis is indicated for the replacement of diseased native or a malfunctioning prosthetic aortic valve via open heart surgery. The prosthesis is indicated for use in adult patients who are diagnosed to have aortic valve stenosis or steno-insufficiency.

TOP POTENTIAL SIDE EFFECTS: The risks or potential adverse events associated with cardiac valve replacement with a bioprosthesis include, but may not be limited to: cardiac arrhythmias, death, endocarditis, heart failure, hemorrhage, intravalvular and/or paravalvular leak, stroke or any related neurologic disorders, structural valve deterioration, reoperation and explant. Beyond the previously mentioned adverse events, specific events related to the implant of the PERCEVAL prosthesis may include, but not be limited to dislodgment and/or migration of the prosthesis.

MRI conditional.



Manufactured by: Sorin Group Italia Srl

A wholly-owned subsidiary of LivaNova PLC Via Crescentino - 13040 Saluggia (VC) Italy Tel: +39 0161 487472 - Fax: +39 0161 487316 info.cardiacsurgery@livanova.com **LivaNova Canada Corp.** 5005 North Fraser Way Burnaby BC V5J5M1 - Canada Tel: 1-604-412-5650 www.livanova.com



