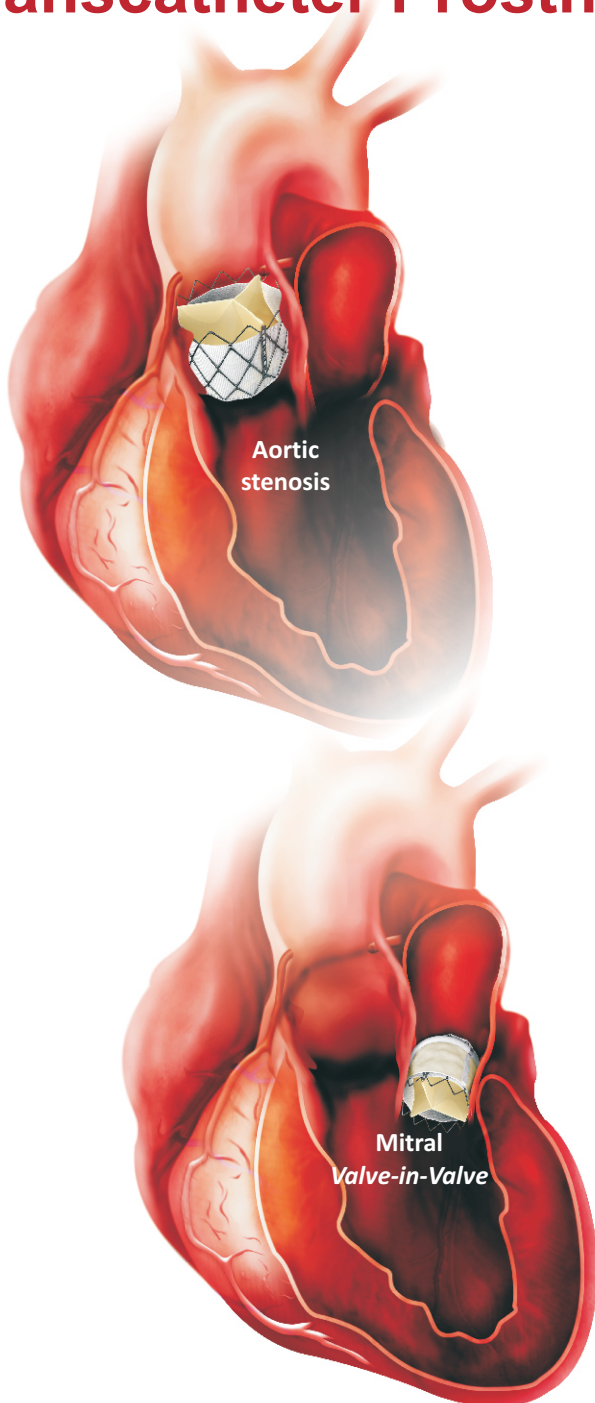


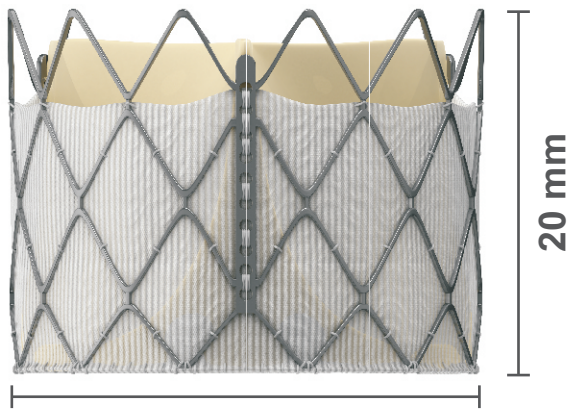
INOVARE[®] Transcatheter Prosthesis



INDICATIONS

- For patients who are inoperable and those whose conventional valve replacement is contraindicated due to high surgical risk.
- Replacement of the calcified native aortic valve or the dysfunctional aortic bioprosthesis via transapical transcatheter implant.
- Replacement of the dysfunctional mitral bioprosthesis via transapical transcatheter implant.
- Replacement of the calcified native aortic valve or the dysfunctional aortic bioprosthesis via transaortic transcatheter implant without extracorporeal circulation (ECC).
- Replacement of the calcified native aortic valve or the dysfunctional aortic bioprosthesis via transaortic transcatheter implant with ECC.

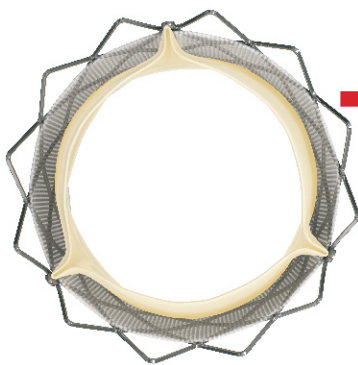
INOVARE[®] is distinguished by several features from other transcatheter bioprostheses, mainly:



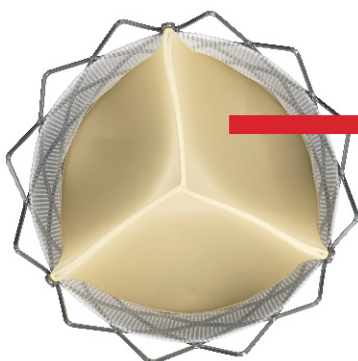
20, 22, 24, 26, 28 and 30mm → **Only one with six size options**

- Greater variety of diameters available in the market, enabling better size selection and, therefore, avoiding undersizing or oversizing

- Improved durability
- Lower risk of paravalvar leakage



- More vertexes in the losangular metallic cage, contributing to a better stress distribution and ring housing



- One single pericardium membrane for all leaflets, reducing the number of sutures and the valve profile

IMPLANT VIA TRANSAPICAL ACCESS

- Performed by minithoracotomy (opening on the rib cage region) followed by a purse-string suture to insert the valve guide through the heart apex. There is minimal manipulation of the aortic arch and ascending aorta, enabling accurate prosthesis positioning.
- Enables aortic stenosis treatment in a calcified native valve and a valve-in-valve* treatment of the dysfunctional aortic or mitral bioprosthesis with dysfunction.
- Currently, transapical access to the transcatheter valve implant is effective, successful and has satisfactory results. It is performed in patients with no possibility of a percutaneous procedure and also in those with no indications for transaortic implant without ECC for having a porcelain aorta.

IMPLANT VIA TRANSAORTIC ACCESS

- Occurs by ministernotomy, a small incision in the patient's sternum region.
- Enables treatment of the aortic bioprosthesis dysfunction or calcified native aortic valve with or without ECC.
- In a procedure where there is no need for a ECC, implantation is performed by inserting the introducer in the ascending aorta. It is an alternative to the transapical implant.
- In surgeries where ECC use is required, the transcatheter valve implantation is often performed in combination with other procedures, such as additional valvar replacement or myocardium revascularization.

RESERVATION

- The option for the transcatheter therapy, as well as the access to the valve implant, depends on each patient's conditions and the thorough assessment of the case by the Heart Team.
- For all procedures where **INOVARE**[®] is indicated, it is required that the surgery be performed by a medical surgeon responsible, skilled and qualified to carry out the transcatheter procedure.
- The materials required to perform an **INOVARE**[®] implantation are: transesophageal echocardiography, appropriate fluoroscopy equipment for transcatheter interventions, contrast injector pump and materials for cardiac surgery (in standby) and hemodynamics materials.

* *Valve-in-valve*: With the transcatheter therapy experience in native valves, that treatment also became an option for patients with surgical biological prosthesis with some degree of dysfunction. Thus, this type of technique, known as valve-in-valve, become viable and is becoming established as an attractive alternative for the reoperation of degenerate bioprosthesis in high risk patients.

Native Aortic Transapical

Off-pump trans-apical trans-catheter aortic valve implantation: First successful case report in India. Indian J Thorac Cardiovasc Surg 2011; 27(2):99-102.

New Braile Inovare transcatheter aortic prosthesis: Clinical results and follow-up. EuroIntervention 2015;11:682-689.

Transapical Aortic Valve-in-Valve

Transcatheter aortic valve-in-valve implantation: A selection change? Rev Bras Cir Cardiovasc 2012;27(3):355-61.

Native Aortic Transapical and Valve-in-Valve Aortic

Off-pump transapical balloon-expandable aortic valve endoprosthesis implantation. Rev Bras Cir Cardiovasc 2009; 24(2): 233-238.

Transapical aortic valve implantation: Results of a Brazilian prosthesis. Rev Bras Cir Cardiovasc 2010; 25(3): 293-302.

Transcatheter aortic valve implantation: Results of the current development and implantation of a new Brazilian prosthesis. Rev Bras Cir Cardiovasc 2011;26(3):338-47.

Transapical Mitral Valve-in-Valve

Mitral implant of the Inovare transcatheter heart valve in failed surgical bioprostheses: a novel alternative for valve-in-valve procedures. Interact Cardiovasc Thorac Surg. Jan 2017;1-7.

Transapical mitral valve implant for the treatment of degenerated bioprosthesis. Arq Bras Cardiol. 2013; 100(5):e62-e64.

Transapical mitral valve-in-valve implant: An alternative for high risk and multiple reoperative rheumatic patients. Intern J Cardiol 2012; 154:e6–e7.

Transapical Aortic Valve-in-Valve and Mitral Valve-in-Valve

Double transapical aortic and mitral valve-in-valve implant: An alternative for high risk and multiple reoperative patients. Intern J Cardiol 2013; 164:e32–e34.

Transaortic Without ECC

Implantation of transcatheter aortic valve prosthesis through the ascending aorta concomitant with coronary artery bypass grafting without cardiopulmonary bypass. Rev Bras Cir Cardiovasc 2014;29(4):650-3

Transaortic With ECC

Experimental study and early clinical application of a sutureless aortic bioprosthesis. Braz J Cardiovasc Surg 2015;30(5):515-9.