Perceval Clinical Evidence

Key Published Experience by Topic
Up to December 2018
GENERAL OVERVIEW


7. Shrestha M. et al. - European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up to 5 years in over 700 patients - Eur J Cardiothorac Surg. 2015 Mar 6; PMID: 25750010


HEMODYNAMIC BEHAVIOUR


7. Shrestha M. et al. - European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up to 5 years in over 700 patients - Eur J Cardiothorac Surg. 2015 Mar 6; PMID: 25750010


DURABILITY

1. Meuris B. - The Sutureless AVR Experience in a Single Center: 11 Years of Use in 468 Patients - Oral presentation AATS 2019


5. Della Barbera M. et al. - Pre-implantation collapse in the Sorin Perceval S Sutureless prosthesis does not affect pericardial graft structure - Cardiovascular Pathology 22 (2013); http://dx.doi.org/10.1016/j.carpath.2013.01.052
PERMANENT PACEMAKER IMPLANTATION (PPI) FOLLOWING AVR


3. Laborde F. et al. - Sutureless Valves Reduce Hospital Costs Compared to Traditional Valves - J Heart Valve Dis. 2017 Jan; PMID: 28544824


4. Lio A. et al. - *Valve Replacement with a Sutureless Aortic Prosthesis in a Patient with Concomitant Mitral Valve Disease and Severe Aortic Root Calcification* - *THI J.* 2016 Apr 1; PMID: 27127442


SPECIAL CASES


5. Durand E. et al. - Emergency Transcatheter Aortic Valve Implantation for Acute and Early Failure of Sutureless Perceval Aortic Valve - Can J Cardiol. 2015 Sep; PMID: 26095935

PERCEVAL® PLATFORM – Clinical evidence

PERCEVAL VS. TRADITIONAL STENTED VALVES

1. Meco M. et al. - Sutureless Perceval Aortic Valve Versus Conventional Stented Bioprostheses: Meta–Analysis of Postoperative and Midterm Results in Isolated Aortic Valve Replacement - J Am Heart Assoc. 2018 Feb 16; PMID: 29453309


2. Folliguet T. - Sutureless aortic valve and TAVI: pros and cons - Minerva Cardioangiol. 2018 Apr; PMID: 29160046

2. Villa E. et al. - *Sutureless aortic valve replacement in high risk patients neutralizes expected worse hospital outcome: A clinical and economic analysis* - Cardiol J. 2018 Sep 20; PMID: 30234906


4. Laborde F. et al. - *Sutureless Valves Reduce Hospital Costs Compared to Traditional Valves* - J Heart Valve Dis. 2017 Jan; PMID: 28544824


3. Laborde F. et al. - Sutureless Valves Reduce Hospital Costs Compared to Traditional Valves - J Heart Valve Dis. 2017 Jan; PMID: 28544824


5. Shrestha M. et al. - European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up to 5 years in over 700 patients - Eur J Cardiothorac Surg. 2016 Jan; PMID: 25750010


INDICATIONS

EUROPE: 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.

USA: The Perceval bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.

CANADA: The Perceval S bioprosthesis is intended for use in patients aged ≥ 65 years when the aortic valve pathology is in an advanced stage to require the replacement of the native or malfunctioning previously implanted prosthesis.

AUSTRALIA: Perceval S 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; STJ/annulus diameter ratio greater than 1.3.

KEY WARNINGS: It is strongly recommended that the Perceval valve not be used in children, adolescents, or young adults, in patients with increased risk of accelerated valve tissue calcification. Do not under or oversize the prosthesis. The guiding sutures must not be tied. The decision to make a transcatheter aortic valve implantation in Perceval compared to other options should be done by the Heart team based on individual assessment of the patient’s conditions. Valve-in-Valve procedures in a Perceval valve should be performed according to indications provided by the transcatheter valve manufacturer.

TOP POTENTIAL SIDE EFFECTS: central and paravalvular leak, cardiac disorders, structural valve deterioration, thromboembolism, reoperation.

MRI conditional.

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.