LivaNova

Health innovation that matters

PERCEVAL – Important Safety Information

INDICATIONS
EUROPE: Perceval prosthesis is intended to replace a damaged native aortic heart valve or a malfunctioning aortic prosthesis via open heart surgery. The prosthesis is indicated for use in adult patients suffering from aortic valve stenosis or steno-insufficiency or with a previously implanted aortic valve prosthesis that is no longer functioning adequately and requires replacement. Physicians should give careful consideration to the use of this valve in patients less than 65 years of age, as sample size in clinical studies for this patient population is insufficient to demonstrate a clinical benefit.
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. The safety and efficacy of Valve-in-Valve procedures in a Perceval valve have not been established. Valve-in-Valve procedures in a Perceval valve should be performed according to indications provided by the transcatheter valve manufacturer. The decision of using Perceval in patients should be based on a careful individual assessment and limited to cases in which the benefits of using Perceval justify the risks. The available clinical data indicate that using Perceval 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.

TOP POTENTIAL SIDE EFFECTS: Potential adverse events associated with cardiac valve replacement with a bioprosthesis and the related surgical procedure include: bleeding, cardiac conduction disorders, death, endocarditis, heart failure, (stroke, transient ischemic attack), non-structural dysfunction, structural valve deterioration, thromboembolism, reoperation. Beyond the previously mentioned adverse events, specific events related to the implant of the Perceval prosthesis may include dislodgment and migration of the prosthesis.

MRI conditional.

For professional use. Please click here to find instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Consult your labeling.