

PERCEVAL – Important Safety Information

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 safety and efficacy of valve-in-valve procedures in a Perceval valve have not been established. 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:

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.

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.