

IMPORTANT SAFETY INFORMATION

PERCEVAL/PERCEVAL PLUS

INTENDED USE/INDICATIONS

EUROPE: Perceval/Perceval Plus 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

US: The Perceval/Perceval Plus bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves

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

AUSTRALIA: Perceval 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; ratio between the sinotubular junction and the annulus diameter greater than 1.3.

KEY WARNINGS

Do not under or oversize the prosthesis. This could result, in possible migration, excessive compression/rupture of the aorta, suboptimal expansion or valve folding that may lead to fatal arrhythmia or hemorrhage, regurgitation or altered hemodynamics. Severe LVOT hypertrophy may prevent optimal expansion of the inflow portion of the stent.

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, endocarditis, heart failure, neurological events, non structural dysfunction, structural valve deterioration, thromboembolism.

MRI conditional

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