

SOLO SMART – Important Safety Information

INDICATIONS:

The Solo Smart prosthesis is indicated for the replacement of damaged native aortic heart valves or malfunctioning prostheses. A biological prosthesis is particularly indicated in cases where chronic anticoagulant therapy is contraindicated or difficult to manage.

KEY CONTRAINDICATIONS AND WARNINGS:

A biological prosthesis should not be used in young patients, in patients with chronic renal impairment or calcium metabolism disorders, or in patients receiving chronic drug treatment with preparations containing calcium due to the increased risk of premature valve tissue calcification. For single use only. Extensive calcification of the root of the aorta may prevent correct suturing. In native bicuspid valve replacement, it may be difficult to align the prosthesis cusps correctly in the implant site. In both these cases, the use of another type of prosthesis is preferable. Do not oversize the prosthesis. Do not undersize the prosthesis: if the annulus size falls between two consecutive prosthesis sizes, choose the larger prosthesis. Do not use the prosthesis if there is an excessive mismatch between the valve annulus and the sino-tubular junction diameters (dilated aorta), unless surgically corrected, as this may give rise to central regurgitation due to defective leaflet coaptation. Cases of thrombocytopenia have been observed in patients implanted with the Solo valve. Hence, it is recommended that the use of this device in patients with lower than normal preoperative platelet levels be carefully considered.

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: non-structural valve dysfunction including valvular regurgitation and periprosthetic leakage, death, endocarditis, thrombosis and thromboembolism, haemolysis, bleeding associated with anticoagulant therapy, thrombocytopenia, structural valve deterioration, reoperation and explant.

MRI safe.

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.