

CROWN PRT – Important Safety Information

INDICATIONS:

The Crown PRT valve is intended for the replacement of malfunctioning native or prosthetic aortic valves.

KEY CONTRAINDICATIONS AND WARNINGS:

There are no absolute contraindications for the use of the Crown PRT valve. Clinical experience described in the medical literature suggests that patients who are undergoing chronic haemodialysis, or with parathyroid disease, impaired calcium metabolism, or who are 55 years of age or less may have an increased tendency toward calcification of valvular bioprostheses. For single use only. Adequate rinsing with sterile physiological saline is mandatory before implantation to reduce the formaldehyde concentration. Do not allow the tissue to dry during handling and implantation of the valve as this could render the valve unfit for use. Sizers and handles from other manufacturers are not suitable for use with the Crown PRT valve and should not be used.

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, structural valve deterioration, reoperation and explant.

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.