Bicarbon – Important Safety Information

INDICATIONS

Bicarbon prostheses are indicated for the replacement of damaged natural heart valves or malfunctioning prosthetic devices.

KEY CONTRAINDICATIONS

The Bicarbon prostheses are contraindicated in patients at risk for complications associated with long-term anticoagulant treatment that clinical experience has shown to be indispensable for patients with mechanical heart valves.

KEY WARNINGS

For single use only. The use of Bicarbon prostheses must be judiciously evaluated in cases where residual calcium is present in the patient’s annulus and in patients with an excessively fragile or irregularly shaped annulus that does not fit prosthesis geometry. The use of the Bicarbon prostheses is not recommended in patients with hypersensitivity to Titanium alloys and to Cobalt Chromium alloys (Stellite). Do not manipulate the Bicarbon prosthesis with instruments other than those supplied by the manufacturer.

TOP POTENTIAL SIDE EFFECTS

The risks or potential adverse events associated with cardiac valve replacement with a prosthetic mechanical heart valve include, but may not be limited to: cardiac arrhythmias, death, endocarditis, hemolysis, anti-coagulation related hemorrhage, leaflet entrapment by tissue ingrowth or impingement on anatomic structures, intravalvular and/or paravalvular leak, prosthetic thrombosis, thromboembolism, 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.