BICARBON - IMPORTANT SAFETY INFORMATION

INTENDED USE/INDICATIONS
The Bicarbon prosthesis is intended for use as a replacement valve in patients with diseased, damaged, or malfunctioning mitral or aortic heart valve. This device may also be used to replace a previously implanted mitral or aortic prosthetic heart valve. Bicarbon Aortic/Mitral prostheses, respectively, are indicated for use in patients suffering from aortic/mitral valvular heart disease, that is a condition involving obstruction of the aortic/mitral heart valve or stenosis; leakage of the aortic/mitral valve, known as regurgitation, incompetence, or insufficiency; and combinations of the two; or patients with a previously implanted aortic/mitral valve prosthesis that is no longer functioning adequately and requires replacement.

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 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 Sorin Group Italia.

TOP POTENTIAL SIDE EFFECTS
The complications associated with heart valve prosthesis implantation include: hemolysis, infections, thrombosis or thromboembolic events, dehiscence, unacceptable hemodynamic performance, hemorrhagic events due to anticoagulant therapy, prosthesis malfunction, heart failure, myocardial infarction due to coronary obstruction, allergic reaction and death. Any one of these complications may require re-operation or removal of the prosthesis.

MRI conditional

For professional use. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Not approved in all geographies. Consult your labeling.