



Health innovation that matters

## **CARBOMEDICS – Important Safety Information**

### **INDICATIONS**

The Carbomedics Prosthetic Heart Valves are indicated as a replacement for human cardiac valves that are malfunctioning as a result of acquired or congenital disease, or as a replacement of a previously implanted prosthesis.

### **KEY CONTRAINDICATIONS**

There are no absolute contraindications to the use of the Carbomedics Prosthetic Heart Valve. The mechanical heart valves are contraindicated or difficult to apply in patients unable to tolerate long term anticoagulation therapy or for whom this type of therapy is difficult to carry out.

### **KEY WARNINGS**

For single use only. Safety and effectiveness of the Carbomedics valve has not been demonstrated for valve replacement in the pulmonic and tricuspid positions. Handle the valve only with accessories provided by the manufacturer specifically for the Carbomedics valve. Only use sizers provided by the manufacturer specifically for the Carbomedics valve. Do not rotate the valve with the valve holder; use only the rotator provided by the manufacturer specifically for the Carbomedics valve.

### **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.