LivaNova

Health innovation that matters

Carbomedics Ascending Aortic Prostheses – Important Safety Information

INDICATIONS

The Carbomedics Ascending Aortic Prostheses are intended for use in open heart surgery for simultaneous replacement of the ascending aorta and the aortic valve in cases of aneurysm, dissection, or other disease conditions of the aorta combined with disease or degeneration of the aortic valve.

KEY CONTRAINDICATIONS

The Carbomedics Ascending Aortic Prostheses are contraindicated in patients unable to tolerate long term anticoagulation therapy or for whom this type of therapy is difficult to maintain. In general, a valve/graft replacement procedure should not be carried out if superior results may be achieved through surgical reconstructive methods or medical management.

KEY WARNINGS

For single use only. The long term durability of the Ascending Aortic Prostheses containing Pyrolite® carbon components and sealed grafts has not been established. The sterile cautery is for single use only.
This product should not be implanted in patients who exhibit sensitivity to polyester or material of bovine origin. Use only instrumentation provided by the manufacturer. Do not preclot. Manipulation and handling of the gelatin-impregnated graft material should be minimized to avoid compromising the sealed properties of the device. The use of sizers made by other manufacturers or the use of the sizing technique employed for other manufacturers' valve prostheses may result in misleading sizing information. Do not rotate the valve with the pre-attached Valve Handle – use only the appropriate sized Carbomedics Aortic Valve Rotator. Clamping may damage the Carbomedics Ascending Aortic Prosthesis. Extreme care must be taken to evacuate all air from the device. Incomplete air removal may cause gaseous embolization and secondary stroke.

TOP POTENTIAL SIDE EFFECTS

The risks or potential adverse events associated with the use of prosthetic aortic heart valves include, but may not be limited to: cardiac arrhythmias, death, endocarditis, hemolysis, hemorrhage anti-coagulation related, leaflet entrapment by tissue ingrowth or impingement on anatomic structures, intravalvular and/or paravalvular leak, prosthetic thrombosis, thromboembolism, structural valve deterioration, reoperation and explant.
Adverse events potentially associated with the use of vascular grafts: collagen has been shown to be a weak immunogen (clinical reactions to collagen implantation generally have been described as infrequent, mild, localized, and self limiting), aneurysm, embolism, hemorrhage, infection, occlusion (including thrombosis and anastomotic intimal hyperplasia), pseudoaneurysm, seroma, death, 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.