Rx Only

Important safety information

Epic™ Elite and Epic™ Supra G3 valves

Indications for Use

The Epic™ Elite valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic and/or mitral heart valve. It may also be used as a replacement for a previously implanted aortic and/or mitral prosthetic heart valve.

The Epic™ Supra G3 valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic heart valve. It may also be used as a replacement for a previously implanted aortic prosthetic heart valve.

Contraindications

There are no known contraindications.

Potential Adverse Events

Adverse events potentially associated with the use of bioprosthetic heart valves (in alphabetical order) include: angina; annular/aortic injury; cardiac arrhythmias/conduction disturbances; coronary obstruction; endocarditis; heart failure; hemolysis; hemolytic anemia; hemorrhage, leak, transvalvular or paravalvular; myocardial infarction; nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other); prosthesis regurgitation; stroke; structural deterioration (calcification, leaflet tear, or other); thromboembolism; valve thrombosis.

It is possible that these complications could lead to: reoperation; explantation; permanent disability; death.