

Carbomedics Annuloplasty Rings – Important Safety Information

INDICATIONS:

The Carbomedics Annuloplasty Rings are indicated as reinforcement for repair of the human cardiac mitral valves damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring.

The Carbomedics AnnuloFlex Annuloplasty Rings are also indicated as reinforcement for repair of the human cardiac tricuspid valve damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring.

The annuloplasty rings should be used only in cases where visual inspection confirms that the valve is repairable and does not require replacement.

TOP POTENTIAL SIDE EFFECTS:

Adverse events potentially associated with the use of mechanical prosthetic annuloplasty rings include: Death; failure or degeneration of the patient's natural valvular apparatus due to progression of disease, endocarditis, or inadequate/incomplete repair of the valvular and subvalvular structures; Reoperation and explant; Suture obliteration of the circumflex coronary artery; Residual or recurrent regurgitation; complications related to prolonged bypass, aortic cross-clamping, and inadequate myocardial protection; stenosis; partial dislodgment of the ring from its site of attachment; thromboembolism; malfunction of the ring due to distortion at implant or physical or chemical deterioration of ring components; hemolysis; tearing of the cloth covering with the use of cutting needles or serrated forceps; A-V block; bleeding diatheses related to the use of anticoagulant therapy; low cardiac output; systolic anterior motion and left ventricular outflow tract obstruction whenever a large anterior and/or posterior leaflet is present; right heart failure; prosthesis thrombosis; infection.

CONTRAINDICATIONS:

The annuloplasty devices are contraindicated for the following:

- severe organic lesions with retracted chordæ;
- congenital malformations with lack of valvular tissue;
- evolving bacterial endocarditis;
- extensive calcification, which upon removal, does not result in pliable leaflets.

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.