



Health innovation that matters

## **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.