

MEMO 4D – Important Safety Information

INDICATIONS:

EUROPE and US: The MEMO 4D annuloplasty ring is intended for correction of mitral insufficiencies, steno-insufficiencies or acquired mitral insufficiencies (type I, type II, type III) with dilatation and deformation of the mitral annulus. The decision to undertake a mitral valve repair must remain with the surgeon after having evaluated short- and long-terms risks and benefits towards alternative procedures and on the visual inspection of the lesion in the individual case.

TOP POTENTIAL SIDE EFFECTS:

The use of prosthetic annuloplasty rings is associated with serious potential complications, which include: death, reoperation and explants, residual or recurrent regurgitation, stenosis, thromboembolism, hemolysis, atrio-ventricular block, endocarditis, low cardiac output, failure or degeneration of the natural valvular apparatus due to progression of disease, partial/total ring dehiscence, partial dislodgment of the ring from its site of Attachment, malfunction of the ring due to distortion or fracture at implant or physical or chemical deterioration of ring components; fabric tearing due to the use of cutting needles or serrated forceps, systolic anterior motion (SAM) and left ventricular outflow tract obstruction (LVOTO), prosthesis thrombosis, infection.

CONTRAINDICATIONS:

The annuloplasty rings should not be used in the case of:

- Severe organic lesions with retraction of chordae tendinae.
- Congenital malformations with limited valvular tissue.
- Extensive calcification of valve leaflets.
- Evolving bacterial endocarditis.

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.