



## **MEMO 4D – Important Safety Information**

### **INTENDED USE/INDICATIONS**

Europe, US, Canada and Australia:

Memo 4D is a mitral annuloplasty ring intended to restore the proper mitral valve leaflet coaptation and valve function by reshaping the mitral annulus.

The Memo 4D is indicated for use in patients suffering from congenital or acquired mitral insufficiencies or steno-insufficiencies with dilatation and/or deformation of the mitral annulus. The decision to undertake a mitral valve repair must remain with the surgeon after having evaluated short- and long-term risks and benefits towards alternative procedures and on the visual inspection of the lesion in the individual case.

### **KEY 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.

### **KEY WARNINGS**

The annuloplasty ring is a single-use device and is intended for single patient use only. Do not attempt to clean, resterilize, or reuse any prosthesis. Do not sterilize the accessory instrumentation by ethylene oxide (EtO) or radiation methods. The device is not suitable for tricuspid valve repair. Use only appropriate accessories supplied by Corcym. The use of sizers provided by other manufacturers or the use of the sizing technique employed for another manufacturer's annuloplasty ring may result in misleading sizing information. Do not cut the yellow loops of the RCS. Do not pull the blue and yellow knots of the RCS threads contemporarily. Do not attempt to remove the yellow thread loops by pulling the yellow knot without having completely removed the blue thread first.

### **TOP POTENTIAL SIDE EFFECTS**

The use of mechanical prosthetic annuloplasty rings is associated with serious potential complications, which

include: death, reoperation and explant, Endocarditis, Sepsis, Anaphylactic shock, Fever, Skin rashes, Epatic impairment, Renal impairment, Anemia, Cardiogenic shock, Myocardial infarction, Tissue damage, Necrosis, Arrhythmia, Stroke/TIA, Multiple organ dysfunction syndrome, Teratogenic effect, Cancer, Decompensated Haemolytic anemia, Heart failure.

### **MRI conditional**

For professional use. Instructions for Use are available upon request through the manufacturer's website. Not approved in all geographies. Follow your labeling.