



## **MEMO Platform – Important Safety Information**

### **INTENDED USE/INDICATIONS**

The Memo platform is a family of annuloplasty rings intended to restore the proper mitral/tricuspid valve leaflet coaptation and valve function by reshaping the annulus. The Memo family is indicated for use in patients suffering from congenital or acquired mitral/tricuspid insufficiencies or steno-insufficiencies with dilatation and/or deformation of the annulus. The decision to undertake a 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. For TriMemo: greatly dilated annulus (not reducible by standard techniques).

### **KEY WARNINGS**

The annuloplasty ring is a single-use device and is intended for single patient use only. Do not sterilize the accessory instrumentation by ethylene oxide (EtO) or radiation methods. 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. For Memo 3D ReChord/Memo 4D: 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. The device is not suitable for tricuspid valve repair.

### **TOP POTENTIAL SIDE EFFECTS**

The use of prosthetic annuloplasty rings is associated with serious potential complications, which include: death, reoperation and explant, Endocarditis, Sepsis, Anaphylactic shock, Fever, Skin rushes, Epatic impairment, Renal impairment, Anemia, Cardiogenic shock, Myocardial infarction, Tissue damage, Necrosis, Arrythmia, Stroke/TIA, Multiple organ dysfunction syndrome, Teratogenic effect, Cancer, Decompensated Haemolitic anemia, Heart failure.

### **MRI CONDITIONAL**

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