MEMO 3D RECHORD – Important Safety Information

INTENDED USE/INDICATIONS
Europe: Memo 3 D ReChord device is intended to reshape and support the mitral annulus after the surgical repair. The use of the Memo 3D ReChord device is indicated for use in patients suffering from congenital or acquired mitral insufficiencies or steno-insufficient with dilatation and deformation of the mitral annulus.
US, Canada, Australia: Memo 3D ReChord device is intended for correction of mitral insufficiencies or steno-insufficiencies. The use of the Memo 3D ReChord device is indicated for correction of congenital or acquired mitral insufficiencies with dilatation and deformation of the mitral annulus.

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 annuloplasty ring or accessory instrumentation by ethylene oxide (EtO) or radiation methods. The device is not suitable for tricuspid valve repair. Use only appropriate accessories supplied by Sorin Group Italia. 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; residual or recurrent regurgitation; stenosis; thromboembolism; hemolysis; atrio-ventricular block; endocarditis; low cardiac output; right heart failure; failure or degeneration of the natural valvular apparatus due to progression of disease, endocarditis, incomplete/inadequate repair of the valvular and subvalvular structures; obliteration of the circumflex coronary artery due to surgical suturing; partial/total ring dehiscence; complications related to prolonged bypass, aortic cross-clamping, and inadequate myocardial protection; 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; bleeding complications related to the use of anticoagulant therapy; systolic anterior motion (SAM) and left ventricular outflow tract obstruction (LVOTO); prosthesis thrombosis; infection.
MRI conditional

For professional use. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Not approved in all geographies. Consult your labeling.