



Patient and MR Safety Information

FlexForm™ Annuloplasty Ring and FlexForm™ Annuloplasty Band

The FlexForm™ Annuloplasty Ring and FlexForm™ Annuloplasty Band are implantable flexible rings and bands intended for surgical repair of heart valves. The ring or band provides support for the mitral or tricuspid annulus.

Non-clinical testing has demonstrated that the FlexForm™ Annuloplasty Ring and Band are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

Static magnetic field of 3.0 Tesla or less Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m) or less Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Mode)
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Under the scan conditions defined above, the FlexForm™ Annuloplasty Ring and Band are expected to produce a maximum temperature rise of 2.7°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 2 mm from the FlexForm Annuloplasty Ring and Band when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.