

MRI Safety Information for the CG (Colvin-Galloway) Future Annuloplasty Ring and Band

The MRI information in this document pertains to all models of the CG (Colvin-Galloway) Future Annuloplasty Ring and Band, which includes the model numbers listed below, as well as earlier model numbers which may be different from those listed below. The “xx” in the model numbers denotes the different sizes.

CG (Colvin-Galloway) Future Annuloplasty Ring and Band		
Model Numbers		
638RLxx	638Bxx	638BLxx
MRI Safety Information		
<p>Nonclinical testing has demonstrated the CG Future annuloplasty ring and band are MR Conditional. A patient with this device can be safely scanned immediately after implantation in an MR system meeting the following conditions:</p> <ul style="list-style-type: none"> • Static magnetic field of 1.5 T or 3 T • Maximum spatial field gradient of 2500 gauss/cm (25 T/m) • Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 4 W/Kg (First Level Operating Mode) <p>Under the scan conditions defined above, the CG Future ring and band is expected to produce a maximum temperature rise of less than 2°C after 15 minutes of continuous scanning.</p> <p>In nonclinical testing, the image artifact caused by the device extends approximately 20 mm from the CG Future ring and band when imaged with a gradient echo pulse sequence and a 3 T MRI system.</p>		

Source Document:

- [CG Future Annuloplasty Ring and Band IFU \(Document #M059951T001 Rev. 1A\)](#)