

Abbott  
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To Whom It May Concern:

Thank you for your inquiry regarding magnetic resonance imaging (MRI) examination of patients implanted with the Abbott MitraClip™ family of products.

Non-clinical testing has demonstrated that Clip Implants are Magnetic Resonance Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T)
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode)

Under the scan conditions defined above, Clip Implants are expected to produce a maximum temperature rise of less than or equal to 3.1°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by a pair of Clip Implants extends approximately 40 mm beyond the Clip Implant(s) when imaged with a spin echo or gradient echo pulse sequence and a 3 T magnetic resonance imaging system. The presence of additional implants in a patient's valve may increase the image artifact size when imaged in an MRI system.

Based on non-clinical testing and clinical experience, performing an MRI scan under the scanning conditions listed is considered safe immediately after Clip implantation [1] as well as at later timeframes [2,3].

If you require additional assistance or information, please contact Abbott Customer Service at 1-800-227-9902.

1 Hamilton-Craig et al., Annals of Cardiothoracic Surgery 2015;4(4):341-351

2 Krumm et al., Clinical Research in Cardiology 2014;103:397-404.

3 Radunski et al., Journal of Cardiovascular Magnetic Resonance 2012, 14(Supplement 1):P101

**CAUTION:** This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at [eifu.abbottvascular.com](http://eifu.abbottvascular.com) or at [medical.abbott/manuals](http://medical.abbott/manuals) for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**. Always check the regulatory status of the device in your region.

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