... until recently.

ProMRI®, a new innovation from BIOTRONIK, allows patients with our cardiac devices to safely undergo MRI scans under specific conditions.

ProMRI®
More access. More options.

BIOTRONIK SE & Co. KG As one of the world's leading cardiovascular medical device companies, with several million devices implanted, BIOTRONIK is represented in over 100 countries by its global workforce of more than 5 600 employees. Quality, innovation and reliability define BIOTRONIK and its growing success – and deliver confidence and peace of mind to physicians and their patients worldwide.

CE 0123
0681

383 358/A/1112

BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin · Germany
Tel +49 (0) 30 68905-0
Fax +49 (0) 30 6852804
sales@biotronik.com
www.biotronik.com

BIOTRONIK
excellence for life

ProMRI®
Radiologist information

BIOTRONIK
excellence for life

ProMRI®

Cardiac device patients were denied MRI access ...

ProMRI®

MR Conditional[1] portfolio

Until recently, 50–75 % of the patients with a cardiac device were denied access to MRI scanning procedures.[2]

Now with the new ProMRI® technology, BIOTRONIK offers a broad range of MR Conditional cardiac devices and leads that are tested and approved for the MRI environment.

Pacemaker with reduced ferromagnetic components, designed to withstand the strong electromagnetic fields of the 1.5 T MRI scanner.

1 MR Conditional is a standard of ASTM International. (previously known as the Amercian Society for Testing and Materials)
2 Kalin R., Stanton M.S., Pacing Clin Electrophysiol, 2005, 28: 326–8.

Tested and approved

The approval for conditional MRI use is granted when the system consists of a BIOTRONIK ProMRI® cardiac device in combination with BIOTRONIK ProMRI® leads.[3]

ProMRI® device **ProMRI® leads** **ProMRI® system**

Cardiac systems with ProMRI® have been tested extensively in various configurations and under the realistic conditions of an MRI environment. The TÜV, a globally recognized certification organization, has examined the product design and strictly evaluated the MRI tests before giving the approval. The approval guarantees the patient will undergo a safe MRI procedure when the devices are used in accordance with the manufacturer's instructions for use.

3 For more information, please read the ProMRI® manual (order number 371712 or download from www.biotronik.com/manuals/home).

Device programming

To ensure a safe MRI scan for a patient with an MR Conditional system, the following measures must be taken before, during and after the scan.

Cardiologist

Prior to the scan, the cardiac device needs to be programmed to a specific MRI setting with limited therapy functionality. Shortly after the scan has been performed, a reprogramming of the device to its prescan settings is required and a regular follow-up has to be performed.

Radiologist

Please be aware of the ProMRI® conditions related to the MRI scanner, the patient status and the scanning procedure.

The patient's pacemaker ID card indicates whether the cardiac device and leads are ProMRI® labeled.

Specific conditions

The ProMRI® conditions include, among others, the following requirements and restrictions.

MRI scanner requirements

- MRI scanner of 1.5 Tesla
- The slew rate must not exceed 216 T/m/s
- No additional local transmitting coils are used

Restrictions during the procedure

- The overall MRI scanning time must not exceed 30 minutes
- The scanner is programmed to Normal Operating Mode (SAR[4] ≤ 2 W/kg for the body, 3.2 W/kg for the head)
- The permissible scan zone must be adhered to.

4 SAR = specific absorption rate.

More information about ProMRI®

For detailed information about ProMRI®, including the complete set of conditions and prerequisites, visit www.biotronik.com/promri