

## Finetech-Brindley Sacral Anterior Root Stimulator (SARS) MRI Guidance Information

# MRI guidance information for Finetech-Brindley Sacral Anterior Root Stimulator (SARS)



**Risk Assessment:** Experience shows that MRI scanning of patients with Finetech-Brindley (Vocare) sacral anterior root bladder stimulator implants is harmless if a 1.0 or 1.5 Tesla scanner is used. A 0.5 Tesla scanner is very probably harmless. Scanners of 0.2 Tesla are known by experience to be slightly unsafe. Several Stoke Mandeville (UK) spinal centre patients have been scanned in such a scanner, and toe movements and mild autonomic dysreflexia were reported. This was not surprising, as the radio frequency of a 0.2 Tesla scanner is 8.4MHz, very close to the frequency to which the Finetech-Brindley receivers are most sensitive. The frequency of the pulsed radio field in a MRI scanner in MHz is 42 times the magnetic field in Tesla. The greater action of low-magnetic field scanners than high-magnetic field ones is to be expected from theory.

In addition to the information given above, FDA approval has been granted to allow MRI scanning of Finetech-Brindley Bladder Stimulator System recipients in the USA. The testing has shown that, within indicated limits of scanning hardware and exposure, patients and implanted hardware can be safely scanned using MRI. The following summarises the key points of the MRI precautionary technical information associated with approval in the USA and should be considered sensible guidelines in all cases.

### Preparation for Scanning:

- The function of each electrode should be tested prior to MRI scanning. Imaging a patient with a broken implanted lead may result in excessive heating around the break in the lead. This potential risk of scanning a patient with a broken implanted lead would have to be considered on a case-by-case basis against the benefits of scanning.
- Patients should be advised to empty their bladders prior to MRI scanning by testing the stimulated response of each channel.
- The patient's external equipment must not enter a room where an MRI scanner is located. The implant only operates when coupled with the external equipment.

### MRI Scanning Conditions – MRI scanning can be performed on individuals implanted with the Finetech-Brindley SARS only under the following conditions:

- A 1.5T (Tesla) scanner with a spatial gradient of 450 gauss/cm or less can be used (this covers the majority of MRI scanners used today).
- Scanners between 1.0T and 1.5T (Tesla) level can be used.
- The imaging mode used must not load the patient with an average Specific Absorption Rate (SAR) of more than 1.1 W/kg for a scan of 30 minutes duration and gradient magnetic fields no greater than 20 T/sec.
- Unconventional or non-standard MRI modes must not be used.
- The use of Transmit Coils other than the scanner's Body Coil or a Head Coil is prohibited.

### During Scanning:

- Patients must be closely monitored during scanning and asked to report any unusual sensations or muscle activity.

### Image Quality:

- If the location to be scanned is in the same area or relatively close to the position of the implanted receiver, artefacts may compromise the quality of the image.
- In non-clinical testing, the worst case image artefact caused by the device extends approximately 124mm<sup>2</sup> from the implantable receiver when managed with a gradient echo pulse sequence and a 1.5T MRI system.
- In non-clinical testing, the worst case image artefact caused by the device extends approximately 255mm<sup>2</sup> from the implantable receiver when managed with a spin echo pulse sequence and a 1.5T MRI system.

### After Scanning:

- The implant should be checked for correct function with the external equipment, outside of the scanning area.

<b>Approved By:</b>	<b>Date:</b>
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<b>Document History</b>				
<b>Date</b>	<b>Issue</b>	<b>Revisions made</b>	<b>IMR</b>	<b>Author</b>
14 July 2008	001	New MRI Guidance Instruction Document	n/a	J Spensley
10 <sup>th</sup> April 2012	002	Update to new template	n/a	A Cruickshank
29 July 2013	00C	Clarify device name. Limit scanner to 1.5Tesla	n/a	J Spensley
21/04/2016	0.4	Updated information consistent with BS400, BS401 and BS403	ECR19	Jack Spensley
28/03/2018	5.0	Add reference to gradient magnetic fields from <a href="http://www.MRIsafety.com">www.MRIsafety.com</a>	IMR785	John Spensley