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

MR Conditional

Risk Assessment: *Experience shows that MRI scanning of patients with Finetech-Brindley (Vocare) sacral anterior root bladder stimulator implant is possible using a 1.5 Tesla cylindrical-bore magnet, horizontal field orientation MRI system.*
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 and should be considered reasonable guidelines in all cases.

Potential Adverse Events
The Finetech-Brindley SARS has been designed to minimize potential events that may cause patient harm. The following potential events may occur in the MRI environment:

- Lead electrode heating resulting in tissue damage or serious patient injury.
- Receiver heating resulting in tissue damage or patient discomfort or both.
- Induced currents on leads resulting in unpleasant sensations or motor disturbances.
- Damage to the functionality or mechanical integrity of the system resulting in the inability to function as required.
- Movement or vibration of the receiver or leads.

Preparation for Scanning:

- Patients shall determine with the clinician that the implant is functioning normally to confirm that the implant is complete and without breaks to the leads. Providing that the implant is functioning normally, scanning can be performed in accordance with the conditions below.
- Patients who have any portion of their system exposed due to skin erosion are not suitable for MRI scanning. The MRI scan may cause heating of the system, which could result in serious patient injury.
- Patients should be advised to empty their bladder prior to MRI scanning.
- The patient's external equipment (Controller, Transmitter Block or Transmitter Lead) must not enter a room where an MRI scanner is located. The implant only functions when coupled with the external equipment.
- The potential risk of scanning a patient with an abandoned or non-functional implant should be considered on a case-by-case basis against the benefits of scanning. Imaging a patient with a non-functional implant lead may result in excessive heating around any potential break in the leads.

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

- Following confirmation that the implant is functioning normally to confirm that the implant is complete and without breaks in the leads.
- This device has been tested using a 1.5 Tesla MR System with a maximum Spatial Field Gradient (SFG) of 450 gauss/cm (General Electric Co., Signa System). All other scanner configurations should be assessed by the clinical team for risk / benefit prior to scanning.
- 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.
- All proposed MRI sequences should be assessed by the clinical team for risk / benefit prior to scanning.
- Consideration to differences in SAR calculation between vendors may be required.
- The use of coils other than the scanner's Body Coil or a Head Coil is untested and must be assessed by the clinician team for risk / benefit. The use of local transmit or transmit-receive coils on the patient's trunk 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 124 mm^2 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 255 mm^2 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, outside of the scanning area.

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Document History				
Date	**Issue**	**Revisions made**	**IMR**	**Author**
14 July 2008	001	New MRI Guidance Instruction Document	n/a	J Spensley
10th 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 www.MRIsafety.com	IMR785	John Spensley
25th July 2019	6.0	Clarification of MRI scanning parameters and inclusion of Potential Adverse Events.	IMR967	John Spensley, Tara Noone
20th August 2019	7.0	Clarification of acceptable coil types and remove reference to maximum slew rate	IMR977	Tara Noone
11th January 2021	7.1	Update to acceptable coil types description and inclusion of note regarding vendor SAR calculation differences	IMR1161	Tara Noone