

# Magnetic Resonance Imaging with the SOUNDBRIDGE VORP 503<sup>1</sup>



The VORP 503 is MR Conditional at 1.5 Tesla. This means that the VIBRANT SOUNDBRIDGE has been tested and is approved for MRI examinations in 1.5 Tesla closed-bore scanners. All MRI testing (including tests regarding force, torque, heating, device malfunction, image artifacts and unintended output) has successfully been passed under certain conditions. The implant magnet does not have to be removed before the MR imaging is carried out. This is possible due to the patented VORP 503 holding magnet and a redesigned FMT which are basically force- and torque-neutral in the MRI.

## The following conditions shall be observed:

- MRI examination with the VORP 503 is only permissible in 1.5 Tesla (T) closed-bore MRI scanners.
- The MRI scanner has to be limited to "Normal Operating Mode"; "First Level Operating Mode" has to be avoided.
- Local transmitting RF coils must not be used in the head and neck region. Local receiver coils are not restricted in use.
- Before patients enter any MRI room, the audio processor must be removed from the head. Audible interference can occur during the scan. Patients shall be advised to indicate any possible discomfort that may arise and to request that the MRI be discontinued if needed. After the MRI examination, the patient shall put on the audio processor only after leaving the MRI room.
- During MRI examination straight head orientation is required.
- An image artifact of approximately 14 cm around the implant will be present on the images. Metal Artifact Reducing Sequences (MARS) may be used to reduce image artifacts.
- If an MRI examination is needed prior to the first activation of the SOUNDBRIDGE, safety measures shall be taken into account to prevent wound healing complications due to the possible movement of the implant in the strong MR field.
- When lower extremities are to be examined, it is recommended, but not required, that the patient's legs are positioned in the scanner first.
- The patient may experience pain or a loud noise within an MR environment. If this happens, immediate removal of the patient from the MR environment and subsequent testing of the device may be required. Details of the event should be reported to MED-EL.

**MRI examination with > 1.5 T will damage the implant and must be avoided.**

- MR imaging at 1.5 Tesla
- Force/torque-free, patented magnet technology
- No magnet removal necessary

## Specific Data

- Non-clinical testing has demonstrated the VORP 503 is MR 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, with
  - » maximum static magnetic field
  - » maximum spatial field gradient product of 469 T<sup>2</sup>/m
  - » maximum whole body averaged (WBA) specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode) at 1.5 Tesla for 15 minutes of continuous MR scanning. A maximum body temperature rise of 0.8 °C may occur.
  - » maximum gradient slew rate of 80 T/m/s
- In clinically relevant worst-case testing the VORP 503 produced a temperature rise of ≤ 0.8 °C (with a background temperature increase of ≈ 0.1 °C) for 15 min. of continuous MR scanning with a body coil in a 1.5 Tesla Intera, Philips Medical System (PMS) (Software: Release 12.6.1.4, 2012-05-22) MR Scanner at a maximum whole body averaged specific absorption rate (SAR) of ≈ 2.3 W/kg assessed by calorimetry.
- Gradient magnetic fields: stimulation level parameter PNS = 42 % (1.5 T Intera, Philips Medical Systems (PMS)) was used during RF heating tests. No tests have been performed regarding possible nerve or other tissue stimulation.
- The VORP 503 has not been tested in simultaneous combination with other devices.
- MR image quality is compromised. Worst-case image artifacts are expected to affect the image in a surrounding area with a radius of 14 cm measured from the geometrical center of the implant. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.

<sup>1</sup> Please note that this material is for information only. For further clarification the "Instructions For Use" for the respective VORP 503 device should be consulted.

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