Magnetic Resonance Imaging (MRI)

The following section applies to the SYNCHRONY cochlear implant only. It does not apply to the SYNCHRONY ABI auditory brainstem implant

MRI CAUTION

Evidence has been provided for this implant type to pose no known hazard in specified MRI environments (without surgical removal of the internal magnet) when adhering to the conditions and Safety Guidelines listed below. The implant has a specially designed magnet which allows safe MRI scanning with the magnet in place, and there is no need to remove the implant magnet regardless of the scanner field strength. The implant magnet can be surgically removed if needed to avoid imaging artefacts. The physician/MRI operator should always be informed that a patient is a cochlear implant user and that special safety guidelines have to be followed.

MRI scanning is possible in consideration of the Safety Guidelines if the following conditions are fulfilled:

- MRI scanners with static magnetic fields of 0.2T, 1.0T, 1.5T or 3.0T only. No other field strengths are allowed. When using other field strengths, injury to the patient and/or damage to the implant are possible.
- In case of additional implants, e.g. a hearing implant in the other ear: MRI safety guidelines for this additional implant need to be met as well.

Safety Guidelines:

- Before patients enter any MRI room all external components of the implant system (audio processor and accessories) must be removed from the head. For field strengths of 1.0T, 1.5T and 3.0T, a supportive head bandage must be placed over the implant. A supportive head bandage may be an elastic bandage wrapped tightly around the head at least three times (refer to Fig. A). The bandage shall fit tightly but should not cause pain. Performing an MRI without head bandage could result in pain in the implant area and in worst case can lead to migration of the implant and/or dislocation of the implant magnet.
- Head orientation: In case of 1.0T, 1.5T and 3.0T MRI systems, straight head orientation is required. The patient should not incline his/her head to the side; otherwise torque is exerted onto the implant magnet which could cause pain. In case of 0.2T scanners, no specific head orientation is required.
- For 0.2T, 1.0T and 1.5T scans sequences in Normal Operating Mode shall be used only. For 3.0T scans the SAR limit must not exceed 1.6 W/kg to avoid any potentially dangerous heating at the electrode contacts. For the same reason head transmit coils or multi-channel transmit coils must not be used in case of a 3.0T MRI.
- During the scan patients might perceive auditory sensations such as clicking or beeping. Adequate counselling of the patient is advised prior to performing the MRI. The likelihood

and intensity of auditory sensations can be reduced by selecting sequences with lower specific absorption rate (SAR) and slower gradient slew rates.

- The magnet can be removed by pushing on the top side of the magnet so that it comes out at the bottom side of the implant to reduce image artefacts. If the magnet is not removed, image artefacts are to be expected (refer to Fig. B and Fig. C).
- The exchange of the magnets with the Non-Magnetic Spacer and vice versa has been tested for at least five repetitions.
- The above instructions should also be followed if areas of the body other than the head are to be examined (e.g. knee, etc.). When lower extremities are to be examined, it is recommended that the patient's legs are positioned in the scanner first.

If the conditions for MRI safety and the Safety Guidelines are not followed, injury to the patient and/or damage to the implant may result!

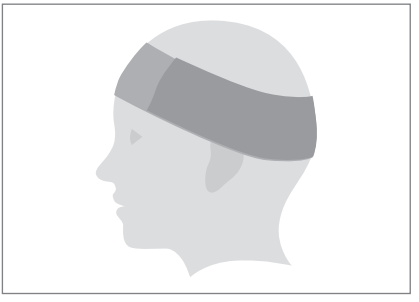

Fig. A Head bandage to support fixation of the implant

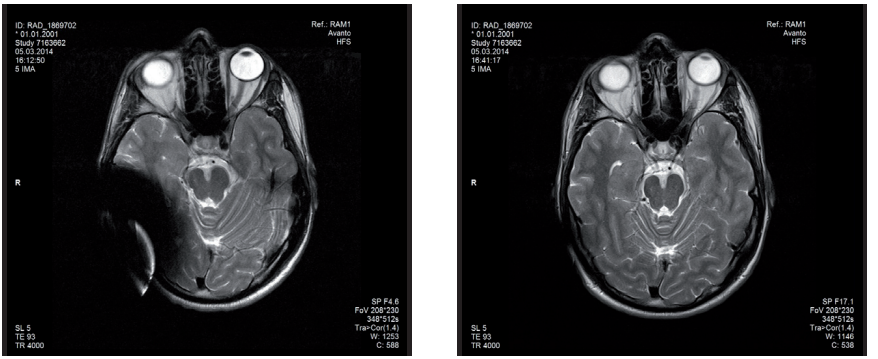

Fig. B Image artefacts arising in a 1.5T scanner. The left picture shows the artefacts obtained with the implant magnet in place whereas the right picture illustrates the image artefacts when the implant magnet is replaced with the Non-Magnetic Spacer.

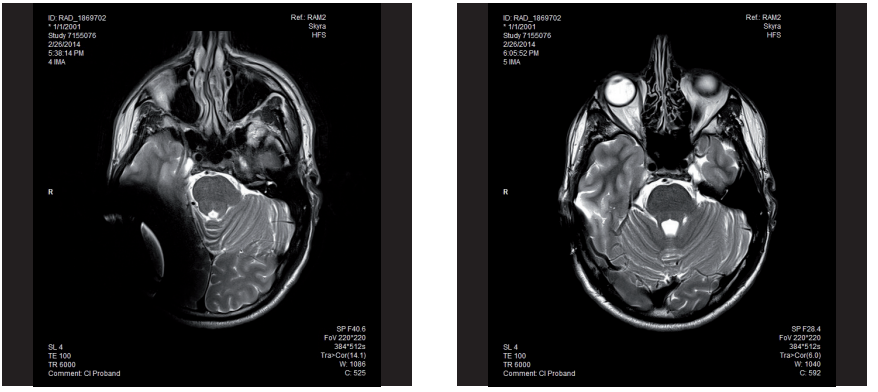

Fig. C Image artefacts arising in a 3.0T scanner. The left picture shows the artefacts obtained with the implant magnet in place whereas the right picture illustrates the image artefacts when the implant magnet is replaced with the Non-Magnetic Spacer.

The following section applies to the SYNCHRONY ABI auditory brainstem implant only

MRI CAUTION

Evidence has been provided for this implant type to pose no known hazard in specified MRI environments (without surgical removal of the internal magnet) when adhering to the conditions and Safety Guidelines listed below. The implant has a specially designed magnet which allows safe MRI scanning with the magnet in place, and there is no need to remove the implant magnet regardless of the scanner field strength. The implant magnet can be surgically removed if needed to avoid imaging artefacts. The physician/MRI operator should always be informed that a patient is an auditory brainstem implant user and that special safety guidelines have to be followed.

MRI scanning is possible in consideration of the Safety Guidelines if the following conditions are fulfilled:

- MRI scanners with static magnetic fields of 0.2T, 1.0T, or 1.5T only. No other field strengths are allowed. When using other field strengths, injury to the patient and/or damage to the implant are possible.
- In case of additional implants, e.g. a hearing implant in the other ear: MRI safety guidelines for this additional implant need to be met as well.

Safety Guidelines:

- Before patients enter any MRI room all external components of the implant system (audio processor and accessories) must be removed from the head. For field strengths of 1.0T and 1.5T, a supportive head bandage must be placed over the implant. A supportive head bandage may be an elastic bandage wrapped tightly around the head at least three times (refer to Fig. A). The bandage shall fit tightly but should not cause pain. Performing an MRI without head bandage could result in pain in the implant area and in worst case can lead to migration of the implant and/or dislocation of the implant magnet.
- Head orientation: In case of 1.0T and 1.5T MRI systems, straight head orientation is required. The patient should not incline his/her head to the side; otherwise torque is exerted onto the implant magnet which could cause pain. In case of 0.2T scanners, no specific head orientation is required.
- Sequences in Normal Operating Mode shall be used only.
- During the scan patients might perceive auditory sensations such as clicking or beeping. Adequate counselling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory sensations can be reduced by selecting sequences with lower specific absorption rate (SAR) and slower gradient slew rates.
- The magnet can be removed to reduce image artefacts. If the magnet is not removed, image artefacts are to be expected (refer to Fig. B).

- The exchange of the magnets with the Non-Magnetic Spacer and vice versa has been tested for at least five repetitions.
- The above instructions should also be followed if areas of the body other than the head are to be examined (e.g. knee, etc.). When lower extremities are to be examined, it is recommended that the patient's legs are positioned in the scanner first.

If the conditions for MRI safety and the Safety Guidelines are not followed, injury to the patient and/or damage to the implant may result!

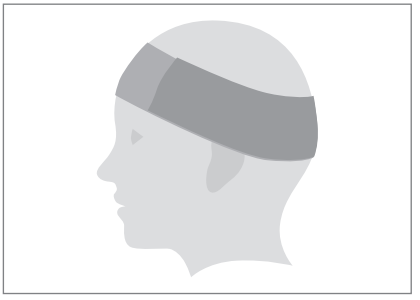

Fig. A Head bandage to support fixation of the implant

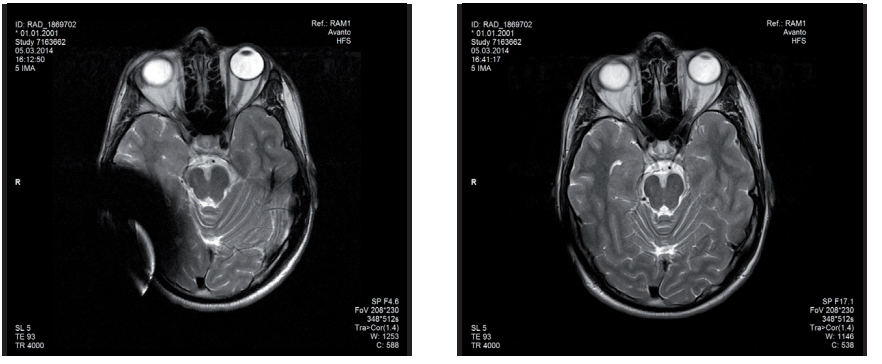

Fig. B Image artefacts arising in a 1.5T scanner. The left picture shows the artefacts obtained with the implant magnet in place whereas the right picture illustrates the image artefacts when the implant magnet is replaced with the Non-Magnetic Spacer.

The following section applies to all other types of implants (CONCERTO, SONATA TI100, PULSAR CI100, C40+, C40)

MRI CAUTION

MRI is possible in patients with cochlear or auditory brainstem implants only with specified models of MRI machines.

Evidence has been provided for these implants to pose no known hazard in magnetic field strengths of 0.2T, 1.0T and 1.5T (without surgical removal of the internal magnet) when the following safety recommendations and guidelines are adhered to. The physician/MRI operator should always be informed that a patient is a cochlear implant or an auditory brainstem implant user and that special safety recommendations and guidelines have to be followed.

Safety recommendations and guidelines for MRI scanning:

- MRI scanner with static magnetic field strength of 0.2T, 1.0T or 1.5T only. No other field strengths are allowed. (When using other field strengths, injury to the patient and/or damage to the implant are possible.)
- MRI scan not earlier than 6 months post implantation. (Performing an MRI at an earlier stage may result in implant displacement and/or damage to the implant).
- A minimum thickness of the bone underneath the implant magnet of 0.4 mm is required in order to withstand forces of 5 N (equals a gravitational force of about 0.5 kg) or up to 9 N for the C40 cochlear implant. (In an MRI scanner torque forces act on the implant magnet, exerting rotational pressure: the device will try to turn to line up with force lines. The resulting forces on the edges of the implant are counterbalanced by the cranial bone and the skin flap. Bone underneath the implant magnet should be thick enough to withstand these exerting forces.)
- Patients with mechanically damaged implants must not undergo MRI. (Ignoring this guideline could result in injury to the patient.)

Safety Guidelines:

- Before patients enter any MRI room all external components of the implant system (audio processor and accessories) must be removed. For field strengths of 1.0T or 1.5T a supportive head bandage must be placed over the implant. A supportive head bandage may be an elastic bandage wrapped tightly around the head at least three times (refer to Fig. A). The bandage shall fit tightly but should not cause pain.
- Head orientation: In case of 1.0T and 1.5T systems, the longitudinal axis of the head must be parallel to the main magnetic field of the scanner. For example this is the case when the patient is in a supine position with the head kept straight. (The patient should not turn or bend his/her head to the side; otherwise partial demagnetization of the implant magnet is possible.) In case of 0.2T scanners, no specific head orientation is required.

- Sequences in Normal Operating Mode shall be used only! During the scan patients might perceive auditory sensations such as clicking or beeping. Adequate counselling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory sensations can be reduced by selecting sequences with lower specific absorption rate (SAR) and slower gradient slew rates.
- Image artefacts are to be expected (refer to Fig. B).
- The above instructions should also be followed if areas of the body other than the head are to be examined (e.g. knee, etc.). When lower extremities are to be examined, it is recommended that the patient's legs are positioned in the scanner first to minimize any risk of weakening the implant magnet.
- The above instructions also apply for patients with bilateral cochlear implants or bilateral auditory brainstem implants.

If the conditions for MR safety and the Safety Guidelines are not followed, injury to the patient and/or damage to the implant may result!

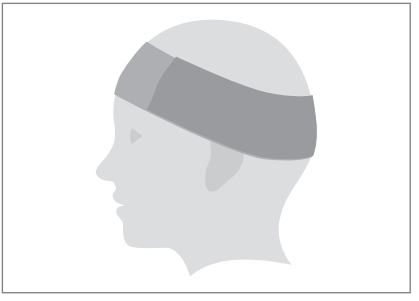

Fig. A Head bandage to support fixation of the implant

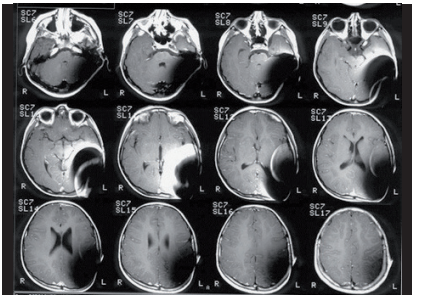

Fig. B MR images obtained with a 1.5T scanner (8 year old child)