

MRI Conditional Safety Information

The implanted components of the Esteem System, which includes a Model 2001 Sound Processor with the 7002/7004/7010 sensors and 7502/7504/7510 drivers, are MR Conditional and are safe for MRI scans under certain conditions.

Approved Conditions Non-clinical testing has demonstrated that the Esteem System, which includes a Model 2001 Sound Processor with the 7002/7004/7010 Sensors and 7502/7504/7510 Drivers, is MR Conditional. An Esteem patient can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) and 3-Tesla (3 T).
- Maximum spatial static magnetic field gradient:
 - At 1.5 T: Maximum spatial field gradient of 1900 G/cm (19.0 T/m) with sound processor present.
 - At 1.5 T: Maximum spatial field gradient of 1900 G/cm (19.0 T/m) with sound processor removed.
 - At 3.0T: Maximum spatial field gradient of 1100 G/cm (11 T/m) with the sound processor present. ○ At 3.0T: Maximum spatial field gradient of 1900 G/cm (19 T/m) with the sound processor removed.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2 W/kg and head SAR of 3.2 W/kg using body coil transmission.
- Gradients having a maximum slew rate of 200 T/m/s and amplitude of 40 mT/m.
- Scan duration should be limited to 30 minutes.

Under the scan conditions defined above, the Esteem System is expected to produce a maximum temperature rise of less than 4.7°C after 30 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the Esteem System extends approximately 5.7 cm from the device when imaged with a spin-echo pulse sequence in a 3 T MRI system. If necessary, the Sound Processor can be removed by an appropriately trained

surgeon. With the sound processor removed, the image artifact extends approximately 3.3 cm from the device.

All external components of the Esteem System (e.g. Personal Programmer, Intraoperative System Analyzer, Commander Programmer, and related accessories) are MR Unsafe. These devices must not enter a room where an MRI scanner is located.

Sound Processor Removal (only if prescribed) Due to image artifact interference directly around the Esteem Sound Processor, it may be prescribed that the Sound Processor should be removed for image quality and diagnostic ability of the scan in the immediate vicinity of the Sound Processor. This should be determined well in advance of the MRI scan. Care should be taken to order the removal of the Sound Processor only if medically necessary. Only a qualified and trained surgeon experienced with the Esteem System can remove the Sound Processor surgically prior to MRI Scan. While the Sound Processor is removed, the patient will be unable to hear out of the ear implanted with the Esteem System. A subsequent appointment will need to be made to re-implant a new and sterile Sound Processor.

Prior to MRI Scan Ensure the Esteem Sound Processor has been turned off. Leaving the Esteem Sound Processor on can cause discomfort, additional or total hearing loss, or damage to the device. The Esteem Sound Processor is turned off by using the Esteem Personal Programmer (patient external handheld remote) for the Esteem System. The patient will be unable to hear out of the ear implanted with the Esteem System while the Sound Processor is turned off, but the patient may perceive sounds from the MR Scan. The Personal Programmer is MR Unsafe and should not be brought in the MR room.

During MRI Scan In addition to the normal risks of undergoing an MRI, there are some additional potential risks specific to having an MRI scan with the Esteem System:

- **Reset to Factory Default Settings.** In some cases exposure to MR scanning can reset the Sound Processor to factory default settings (i.e., basic baseline settings that are not customized).
- **Sound Processor Movement.** The Esteem Sound Processor may move out of position during a MRI scan due to vibration, force, or torque. If the Esteem Sound Processor

does move, this may cause some soreness and/or skin or tissue trauma around the implant.

- **Perceived Sound or Uncomfortable Sensation.** Even when the implant is off, MRI exposure may result in uncomfortable sensations such as loud sounds, noise, and/or pain.
- **Implant Heating.** The implant's materials may heat up slightly and feel warm.
- **Image Artifact.** The implant itself will cause shadowing or the appearance of a reflection on the MRI scan in the vicinity of the implanted components. This is often called "image artifact." This will result in reduced image quality in that area and potential loss of diagnostic information in that immediate area.
- **MRI Scans Beyond Tested Conditions.** MRI scans performed under different conditions have not been deemed safe and may result in irreversible device damage or serious and permanent injury including, additional or total loss of hearing, head trauma, coma, paralysis, or death.

After MRI Scan After exiting the MRI room, the Sound Processor can be turned back on using the Esteem Personal Programmer. Once on, confirm that (a) the Esteem is working and sound is being delivered and (b) that the sound being delivered is as it was prior to the MRI scan. If the perceived sound quality from the Esteem System has changed, a hearing evaluation and Esteem fitting appointment should be scheduled with an Esteem audiologist. If necessary, contact Envoy Medical at (651) 361-8000 for assistance in locating an Esteem audiologist.