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MRI SAFETY OF THE CODMAN® MICROSENSOR ICP TRANSDUCER AT 1,5 Tesla

WARNING

It is important to read and understand this document in its entirety before conducting an MRI (magnetic resonance imaging) procedure on a patient with an implanted CODMAN MicroSensor. Failure to strictly adhere to these guidelines may result in serious injury to the patient.

This information applies to the following Codman products that contain the CODMAN MicroSensor:

82-6631 CODMAN MicroSensor basic kit
82-6632 CODMAN MicroSensor bolt kit
82-6638 CODMAN MicroSensor skull bolt kit (each)
82-6639 CODMAN MicroSensor skull bolt kit (5 per case)

WARNINGS

- These guidelines apply to MRI procedures conducted in a 1,5 tesla MR system, **ONLY**.
- Disconnect all cables and patient monitoring devices from the CODMAN MicroSensor prior to entering the MR environment. It is not possible to monitor intracranial pressure during MRI procedures using this device.
- The CODMAN MicroSensor must be placed in the recommended coiled configuration (see figure 1) to minimize the potential for device heating. Do not perform MRI with the CODMAN MicroSensor in a "straight line" configuration. Failure to follow this guideline may result in serious injury to the patient.
- MRI must not be performed on a damaged CODMAN MicroSensor. Verify the functionality of the CODMAN MicroSensor prior to placing the patient in the MR environment.
- DO NOT EXCEED AN RF (RADIO FREQUENCY) WHOLE BODY AVERAGED SAR (SPECIFIC ABSORPTION RATE) OF 1,0 W/KG IN THE HEAD OR EXCEED GRADIENT MAGNETIC FIELDS GREATER THAN 20 TESLA/SEC DURING THE MRI PROCEDURE.
- An individual with expert knowledge, such as an MRI-trained radiologist or MRI physicist, must insure that all recommendations in this guideline are followed and that the MRI scan parameters recommended in this document are adhered to in order to ensure safe examination of a patient with an implanted CODMAN MicroSensor.

OVERVIEW

The CODMAN MicroSensor has undergone extensive laboratory testing to demonstrate that, by following specific guidelines, it is safe to perform an MRI procedure on a patient with an implanted sensor in a 1,5 tesla MR system, ONLY. However, variability among MR systems, differences in how they compute various MR scan parameters (e.g. SAR), and the individual characteristics of each MR system's installation cannot be simulated comprehensively in the laboratory environment. This document outlines recommended guidelines and specific conditions under which the CODMAN MicroSensor has been shown to pose minimal risk to a patient undergoing an MRI procedure. Deviation from these guidelines may increase the potential for serious harm to the patient. MRI conditions utilizing MR systems with higher or lower static magnetic fields have not been assessed for the CODMAN MicroSensor and, as such, must be avoided to ensure patient safety.

MRI – CODMAN MicroSensor INTERACTIONS

INDUCED HEATING – Under certain conditions, RF fields generated by MR imaging sequences can induce currents in the sensor wires contained within the catheter body. This may rapidly produce significant heating at the tip of the sensor or at any location where sensor lead wires are broken. Failure to follow the recommendations for preparing the MicroSensor prior to MR imaging, or performing an MRI procedure on a damaged sensor may result in the generation of thermal lesions and serious patient harm.

MAGNETIC FIELD INTERACTION – Magnetic materials contained within an implanted device may experience translational or rotational forces when brought into the static magnetic field of an MR system. The CODMAN MicroSensor contains minimal quantities of magnetic material and has been shown in safety testing to not be substantially affected by translational attraction and torque related to exposure to a 1,5 tesla static magnetic field of an MR system. The CODMAN MicroSensor skull bolt kits, 82-6638 and 82-6639, have been shown to experience negligible translational forces and minor torque in the 1,5 tesla MR environment. These magnetic field interactions are much smaller than the mechanical fixation forces holding the bolt into the skull and, therefore, are not of concern. The skull bolt kit, 82-6632, contains only nonmagnetic polymeric materials and is not subject to substantial magnetic field interactions.

INDUCED STIMULATION – Voltages induced by the gradient magnetic fields present during the MRI procedure may theoretically induce painful neurostimulation. When intact and functioning properly, the CODMAN MicroSensor is electrically isolated from the patient and represents an insignificant risk for induced stimulation.

IMAGE ARTIFACT – The tip of the CODMAN MicroSensor will cause minor image artifact. It is up to the discretion of the interpreting physician to determine if the location of the sensor is in the area of imaging interest and whether it will adversely affect the quality of the diagnostic information required from the MRI procedure. The CODMAN MicroSensor connector will cause substantial image artifact and distortion on the MR image. As such, position the connector away from the anatomy of interest during the MRI procedure. All skull bolts used with the CODMAN MicroSensor will cause some artifact near the implantation site.

PROCEDURE

In addition to standard safety procedures for MRI, the following precautions must be followed specific to the CODMAN MicroSensor:

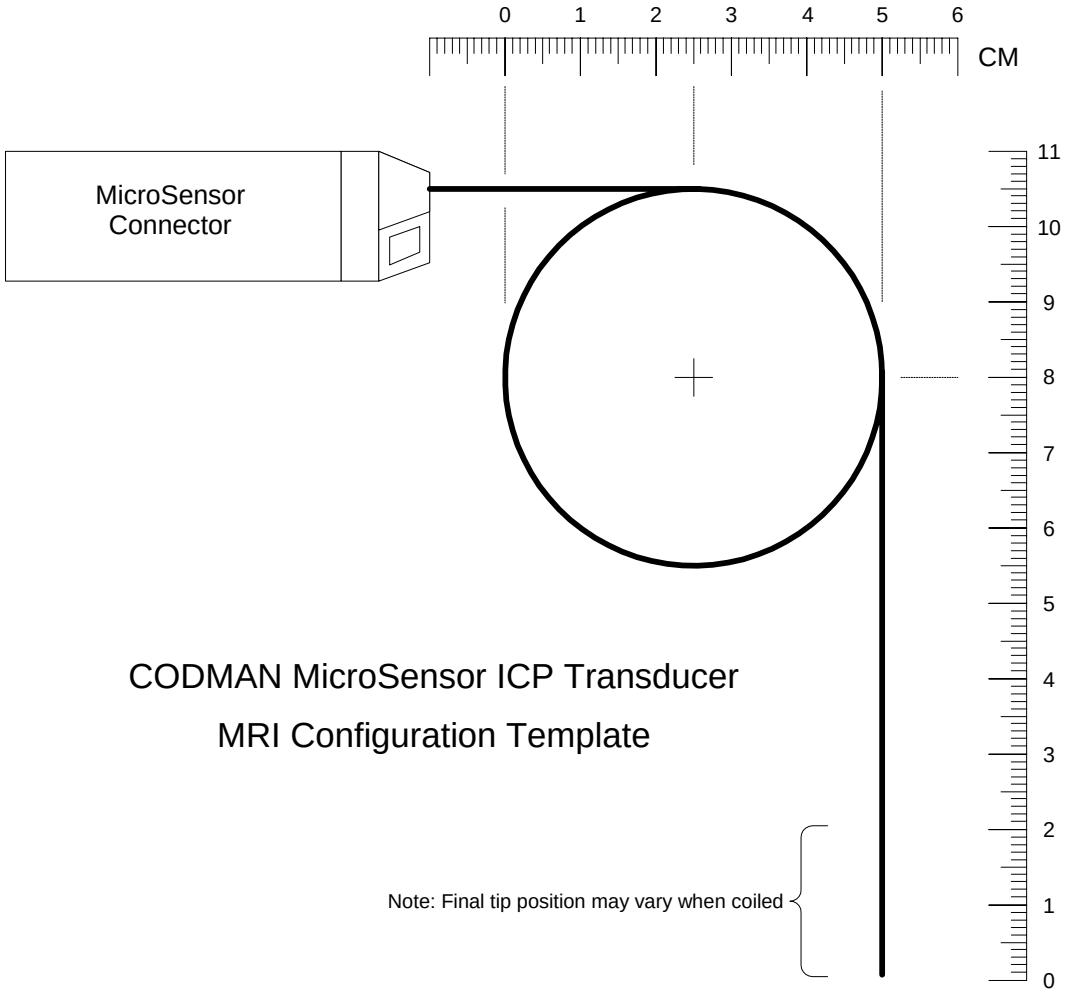
1. Inform the patient of the potential risks of undergoing an MRI procedure with this device.
2. Immediately prior to entering the MR environment, check that the CODMAN MicroSensor is functioning properly. Verify that valid ICP readings are displayed on a connected monitoring device. DO NOT perform an MRI procedure if you suspect the CODMAN MicroSensor is damaged or otherwise not functioning properly.
3. Disconnect all cables and patient monitoring devices attached to the CODMAN MicroSensor prior to transporting the patient into the MR environment.
4. It is important to configure the CODMAN MicroSensor in a specific geometry to minimize the potential for excessive heating of the sensor tip. Leave a straight segment approximately 8 cm in length, as measured from the tip of the implanted sensor. Coil the remaining CODMAN MicroSensor near the base of the connector into 5 or 6 loops approximately 5 cm in diameter. See figure 1. The CODMAN MicroSensor must not be imaged in a "straight line" configuration as testing has shown that this can result in rapid heating at the sensor tip under certain conditions.

Figure 1: CODMAN MicroSensor ICP transducer configuration for MR imaging

5. Insulate the patient's tissue from the coiled CODMAN MicroSensor and connector using a dry gauze pad at least 1 cm in thickness. If using tape to secure the sensor to the insulating pad, use care when removing the tape to prevent damage to the CODMAN MicroSensor.
6. Use only the following types of radio frequency coils for the MRI procedure:
    a. Transmit / receive RF body coil
    b. Transmit body coil / receive-only head coil
    c. Transmit / receive head coil
7. Set MRI parameters to the lowest usable whole body averaged SAR level. THIS MUST NOT EXCEED 1,0 WATTS / KG IN THE HEAD OR

BODY to minimize the risk of excessive heating of device components. Verify that the MR system has appropriately calculated and updated the SAR value after all parameter changes have been made.

8. Verify that unconventional or nonstandard MR techniques that exceed gradient magnetic fields of 20 tesla/sec are not being utilized.
9. A knowledgeable MRI expert must verify that all set-up steps and settings have been properly implemented and checked prior to performing the MRI procedure.
10. If conscious and alert, provide the patient with a means of alerting the MR system operator of unusual sensations. Instruct the patient to watch for sensations such as overheating or shock. Terminate the MRI procedure immediately if so notified by the patient.
11. Monitor the patient continuously during the MRI examination and be prepared to stop and respond in the event of an emergency.



CODMAN MicroSensor ICP Transducer

MRI Configuration Template