

CODMAN MICROSENSOR® ICP Transducer MR Technician Notice

See Instructions for Use for complete product information and specific MRI Safety Information. Read and understand the IFU in its entirety prior to performing a Magnetic Resonance Imaging Procedure on a patient with an implanted CODMAN MICROSENSOR[®]. Failure to adhere to the Conditions for Safe Use may result in serious injury to the patient.

Non-clinical testing has demonstrated that the CODMAN MICROSENSOR is MR Conditional.

A patient implanted with this device can be safely scanned in an MR system which meets or is operated under the following conditions:

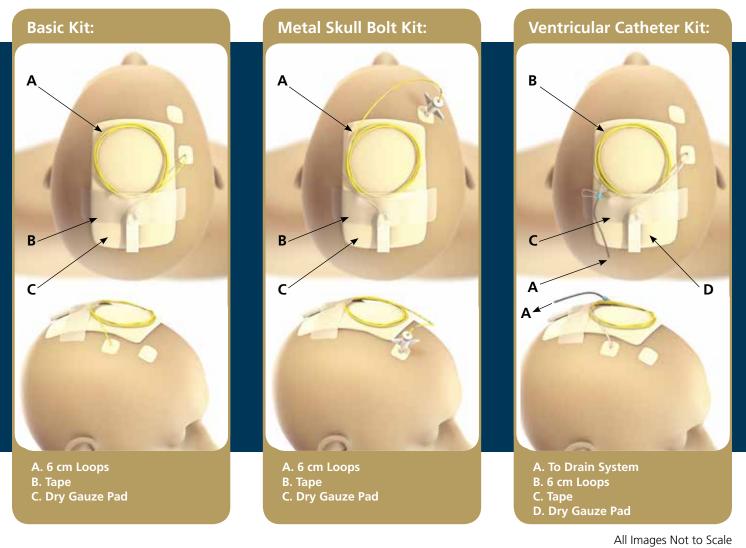
- Static magnetic field of 1.5 and 3 tesla only.
- Maximum spatial gradient magnetic field of 1,000 G/cm (10 T/m).
- Maximum gradient field slew rate of 170 T/m/s.
- Horizontal cylindrical bore MRI scanner.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg or Head-SAR of 3.2 W/kg (Normal Operating Mode).

WARNINGS

- Do not bring the ICP EXPRESS monitor, cables or other accessories such as Tuohy needles, trocar or stylet into the MRI suite.
- Do not use Transmit / Receive or Transmit-only RF Head coils. Only use Transmit / Receive RF Body coil or Transmit RF Body coil / Receive-only RF Head coil.
- Do not scan a patient with an elevated body temperature.
- Special positioning of the CODMAN MICROSENSOR is required to ensure patient safety during the MRI procedure (see "PREPARATION FOR THE MRI PROCEDURE" on back for specific instructions).

PREPARATION FOR THE MRI PROCEDURE:

- 1. Immediately prior to entering the MRI suite, verify that the CODMAN MICROSENSOR is functioning properly. DO NOT perform an MRI procedure if the CODMAN MICROSENSOR is damaged or otherwise not functioning properly.
- 2. Disconnect all cables and patient monitoring devices attached to the CODMAN MICROSENSOR prior to transporting the patient into the MRI suite. DO NOT bring the patient monitoring devices, cables or other accessories into the MRI Suite.
- **3.** Special positioning of the CODMAN MICROSENSOR is required to ensure patient safety during the MRI procedure. The CODMAN MICROSENSOR must be placed in a specific geometry to minimize the potential for excessive heating of the sensor tip. Coil the tubing of the CODMAN MICROSENSOR near the base of the electrical connector into 5 or 6 loops approximately 6 cm in diameter and center on top of the patient's head (see graphics below). Do not perform MRI with the CODMAN MICROSENSOR in a "straight line" configuration (i.e., uncoiled). Failure to follow this guideline can result in serious injury to the patient.
- **4.** Insert a dry gauze pad at least 1 cm thick between the CODMAN MICROSENSOR electrical connector with coiled tubing and the patient's scalp. Secure in place using tape (see graphics below). Use care when removing the tape to prevent damage to the CODMAN MICROSENSOR.



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