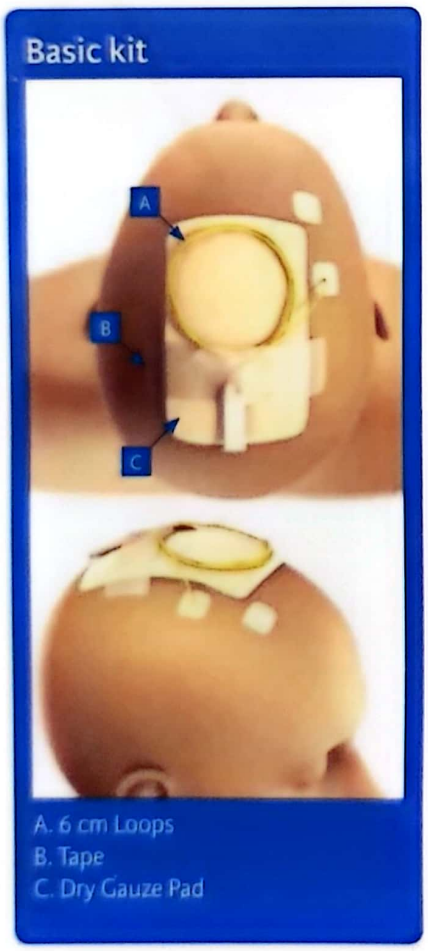
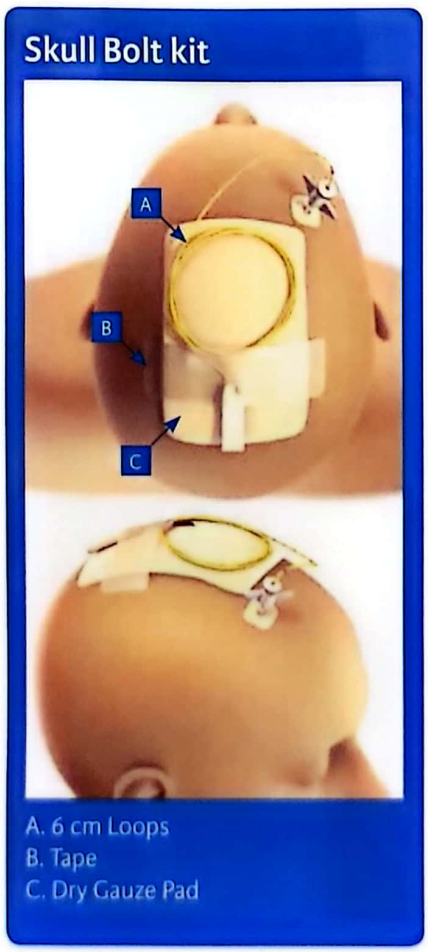
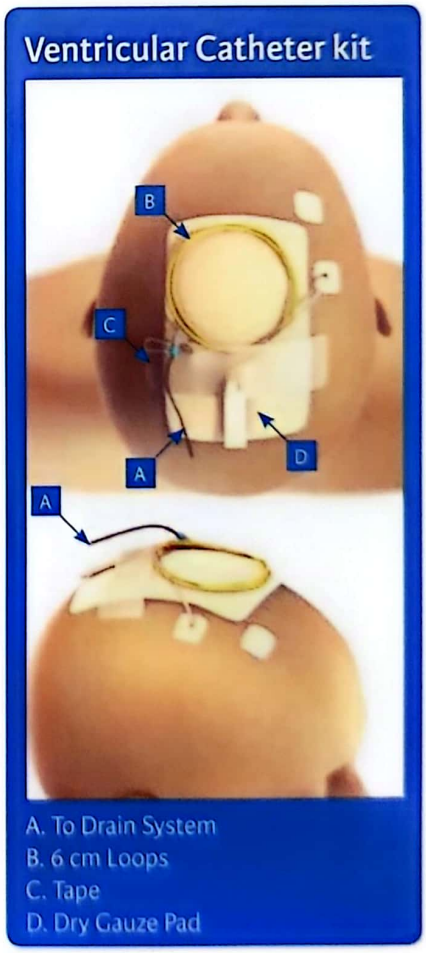
See Instructions for Use for complete product information and specific MRI Safety Information. Read and understand the IFU in its entirety prior to performing a Magnetic Resonance Imaging Procedure on a patient with an implanted CereLink® ICP Sensor. The ICP Monitor is contraindicated for use in a Magnetic Resonance (MR) environment. Failure to adhere to the Conditions for Safe Use may result in serious injury to the patient.

PREPARATION FOR THE MRI PROCEDURE:

1. Immediately prior to entering the MRI suite, verify that the CereLink ICP Sensor is functioning properly. DO NOT perform an MRI procedure if the CereLink ICP Sensor is damaged or otherwise not functioning properly.
2. Disconnect all cables and patient monitoring devices attached to the CereLink ICP Sensor 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 CereLink ICP Sensor is required to ensure patient safety during the MRI procedure. The CereLink ICP Sensor must be placed in a specific geometry to minimize the potential for excessive heating of the sensor tip. Coil the tubing of the CereLink ICP Sensor 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 CereLink ICP Sensor 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 CereLink ICP Sensor 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 CereLink ICP Sensor.







All images not to scale

Codman
SPECIALTY SURGICAL

MR Technician Notice

CereLINK®
ICP monitoring system
Discover the Unseen

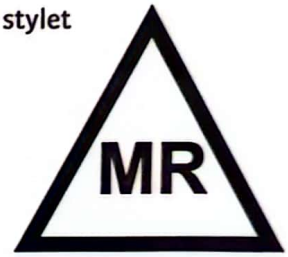
Non-clinical testing has demonstrated that the CereLink ICP Sensor is MR Conditional.

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 200 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).
- MRI scan duration shall not exceed 15 minutes of continuous scanning.

WARNINGS

- **Do not bring the ICP 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 CereLink ICP Sensor is required to ensure patient safety during the MRI procedure (see "PREPARATION FOR THE MRI PROCEDURE").**



MR CONDITIONAL

CereLink ICP Monitor

Consult the Instructions for Use for complete list of indications, contraindications, warnings, precautions, and adverse events.

Contraindications • The ICP Monitor is contraindicated for use in a Magnetic Resonance (MR) environment. Refer to the ICP Sensor IFU for MR environment use.

CereLink ICP Sensor Kit

826850, 826851, 826852, 826854 Indications for Use • (826850, 826851, 826852) Use of the CereLink ICP Sensor Basic Kit and CereLink ICP Bolt Kit are indicated when direct intracranial pressure (ICP) monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only. • (826854) Use of the ICP Sensor Ventricular Catheter Kit is indicated when direct intraventricular pressure monitoring is required. The kit is indicated for use in ICP monitoring and cerebrospinal fluid (CSF) drainage applications.

Warnings • Take extreme care to avoid damage to the dura and underlying cerebrum. • Before conducting an MRI procedure on a patient with an implanted ICP Sensor, read the MRI Information section. Failure to read and strictly adhere to these guidelines can result in serious injury to the patient.

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.
- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.
- Consult product labels and inserts for any indication, contraindications, hazards, warnings, precautions, and instructions for use.

For more information or to place an order, please contact:

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