Continuous ICP monitoring is essential in the standard management of patients with a wide range of intracranial conditions, including severe head injury. As MRI often provides important clinical information in the acute stage of brain injury, ICP monitoring in patients undergoing MRI examination is growing increasingly common. However, given that there have been a substantial number of thermal injuries caused by the effect of the RF radiation used in MRI on monitoring devices, special care must be taken to ensure the safety and accuracy of ICP monitoring devices in the MRI setting.

Two types of systems are used to monitor ICP: fluid-coupled systems, which use an intraventricular catheter, and non–fluid-coupled systems, which use one of the variety of intracranial miniature transducers that have been developed over the past 25 years. Although use of

Overheated and melted intracranial pressure transducer as cause of thermal brain injury during magnetic resonance imaging

Case report

Reiichi Tanaka, M.D.,1 Tetsuya Yumoto, M.D.,2 Naoki Shiba, M.D.,1 Motohisa Okawa, M.D., Ph.D.,3 Takao Yasuhara, M.D., Ph.D.,4 Tomotsugu Ichikawa, M.D., Ph.D.,2 Koji Tokunaga, M.D., Ph.D.,5 Isao Date, M.D., Ph.D.,5 and Yoshihito Uike, M.D., Ph.D.1

1Department of Critical Care and Emergency Medicine, Okayama University Hospital; 3Department of Health Science, College of Life Science, Kurashiki University of Science and The Arts; 4Department of Neurological Surgery, Okayama University Graduate School of Medicine, Okayama; 2Department of Surgery, National Hospital Organization Mito Medical Center, Ibaraki; and 5Department of Neurological Surgery, Okayama University Graduate School of Medicine, Okayama, Japan

Magnetic resonance imaging is used with increasing frequency to provide accurate clinical information in cases of acute brain injury, and it is important to ensure that intracranial pressure (ICP) monitoring devices are both safe and accurate inside the MRI suite. A rare case of thermal brain injury during MRI associated with an overheated ICP transducer is reported.

This 20-year-old man had sustained a severe contusion of the right temporal and parietal lobes during a motor vehicle accident. An MR-compatible ICP transducer was placed in the left frontal lobe. The patient was treated with therapeutic hypothermia, barbiturate therapy, partial right temporal lobectomy, and decompressive craniectomy. Immediately after MRI examination on hospital Day 6, the ICP monitor was found to have stopped working, and the transducer was subsequently removed. The patient developed meningitis after this event, and repeat MRI revealed additional brain injury deep in the white matter on the left side, at the location of the ICP transducer. It is suspected that this new injury was caused by heating due to the radiofrequency radiation used in MRI because it was ascertained that the tip of the transducer had been melted and scorched. Scanning conditions—including configuration of the transducer, MRI parameters such as the type of radiofrequency coil, and the specific absorption rate limit—deviated from the manufacturer’s recommendations. In cooperation with the manufacturer, the authors developed a precautionary tag describing guidelines for safe MR scanning to attach to the display unit of the product.

Strict adherence to the manufacturer’s guidelines is very important for preventing serious complications in patients with ICP monitors undergoing MRI examinations.

(http://thejns.org/doi/abs/10.3171/2012.9.JNS12738)

Key Words • antenna effect • electromagnetic induction heating • intracranial pressure monitor • magnetic resonance imaging • meningitis • thermal brain injury

Abbreviations used in this paper: DBS = deep brain stimulation; FDA = US Food and Drug Administration; GCS = Glasgow Coma Scale; ICP = intracranial pressure; RF = radiofrequency; SAR = specific absorption rate; WBC = white blood cell.
an intraventricular catheter was once the gold standard, commercially available intracranial transducers offer advantages in terms of ease of insertion and reduced risk of infection and are now used more commonly.7,14,16,19,28,30

The FDA has provided useful definitions regarding the safety of clinical equipment in the MR environment. A device is defined as “MR safe” when its use in MRI has been demonstrated to present no additional risk to the patient but the MR environment may affect the quality of the diagnostic information. A device is defined as “MR compatible” when it is MR safe and has also been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR environment. The Codman MicroSensor (Johnson & Johnson, Codman & Shurtleff, Inc.) is considered an MR-compatible device in many countries of the European Union and also in Japan (although not in the US). It is not well known, however, that the manufacturer’s guidelines must be strictly followed, including configuration of the transducer in a specific geometry and adherence to the recommended parameters, such as using a 1.5-T MR system with a transmit/receive RF body coil, transmit body coil/receive-only head coil, or transmit/receive head coil; and limiting the SAR to 1.0 W/kg. The aim of this article is to present an unusual case of severe brain injury sustained in a traffic accident followed by a thermal brain injury, which we believe was caused by an overheated and melted Codman MicroSensor ICP transducer during MRI scanning, as a result of not strictly following the manufacturer’s guidelines.

Case Report

History and Presentation. This 20-year-old man was involved in a motor vehicle accident in October 2008 and was found unresponsive at the scene. He was transported by ambulance directly to the emergency room of the Critical Care and Emergency Medicine Department at Okayama University Hospital. On arrival, he had a blood pressure of 150/100 mm Hg, heart rate of 112 beats per minute, and GCS score of 7. Both pupils were 7.0 mm, round, and unreactive to light. Tracheal intubation was performed immediately after arrival in the emergency room. Radiography of the patient’s chest revealed bilateral pulmonary contusions and a fractured right clavicle. A subsequent CT scan of the chest revealed bilateral pulmonary contusions and fractured right transverse processes and vertebral arches of T5–7. A CT scan of the head demonstrated a right parietal fracture, no skull base fracture, contusion of the right temporoparietal lobe, right subdural hematoma, subarachnoid hemorrhage, and a slight shift of the midline to the left.

Initial Treatment, Lobectomy, and Decompressive Craniectomy. We inserted an ICP transducer (Codman MicroSensor; Johnson & Johnson, Codman & Shurtleff, Inc.) and obtained an initial ICP reading of 63 mm Hg and a cerebral perfusion pressure reading of 40 mm Hg. Therapeutic hypothermia at 32°C was started immediately after admission. However, in spite of intensive intervention, including barbiturate therapy, the patient’s ICP remained higher than 40 mm Hg and a second head CT scan revealed a deterioration of brain swelling. A partial right temporal lobectomy and decompressive craniectomy were performed 8 hours after admission. The patient’s ICP decreased to 10–20 mm Hg postoperatively and a third head CT scan performed immediately after surgery showed decreased brain swelling.

Postoperative Course and Imaging Findings. A CT scan of the patient’s head on hospital Day 5 demonstrated improvement of brain swelling and showed that the tip of the ICP transducer was located in the parenchyma of the left frontal lobe near the frontal angle of the left lateral ventricle (Fig. 1A and B).

When therapeutic hypothermia was discontinued on Day 6, MRI was performed to evaluate the presence of intracranial lesions, including diffuse axonal injury, and any cervical spinal cord injury. The scans revealed contusions of the right temporoparietal lobe only, and no diffuse axonal injury or cervical spinal cord injury (Fig. 1C–E). No contusions were demonstrated in the left cerebral hemisphere.

After the scan, the patient was returned to the intensive care unit, where it became evident that the ICP monitoring system was no longer functioning. The transducer was removed and submitted to Johnson & Johnson without careful inspection.

Three days afterward (that is, on hospital Day 9), the patient developed neck stiffness and fever up to 40°C. Blood tests revealed a WBC count of 12,000/mm³, an increased proportion of immature leukocytes (band neutrophils), and a C-reactive protein level of 12.21 mg/dl.

On Day 10, blood tests revealed a WBC count of 20,950 cells/mm³ and a blood sugar level of 145 mg/dl. Cerebrospinal fluid examination revealed a WBC count of 5730 cells/mm³ with 80% polymorphonuclear neutrophils and 20% lymphocytes, an elevated protein content (312 mg/dl), and a decreased glucose concentration (33 mg/dl). Another head CT scan was performed (on Day 10), and the radiology report indicated that the low-density area in the left frontal lobe near the frontal angle of the left lateral ventricle, was slightly more conspicuous than in the head CT scan from Day 5 (Fig. 2A).

The patient’s condition was diagnosed as bacterial meningitis, and the relevance of the ICP transducer malfunction was not recognized at that time. Although the examination of a Gram-stained CSF smear showed no bacteria, antibiotic treatment was started immediately after the diagnosis of meningitis, on Day 10. Repeated culture of the CSF did not reveal any bacteria. The patient was treated with intravenously administered meropenem trihydrate 2 g/day for 9 days and intraspinal injection of gentamicin sulfate 10 mg/day for 5 days. The patient became afebrile and CSF findings showed a marked improvement on Day 17. His level of consciousness improved markedly (GCS score E4VTM6), although it became evident on Day 26 that he had total left hemiplegia.

A follow-up CT scan of the head was performed on Day 26 because blood testing revealed a WBC count of 38,890/mm³ (Fig. 2B). The ICP transducer was present in the right temporal lobe area (Fig. 2C). The diffusely high-intensity area was consistent with brain swelling. The patient was extubated on Day 27, and on Day 30, he was transferred to the rehabilitation hospital with improvement of the left hemiplegia.
R. Tanaka et al.

13,660 cells/mm and left shift, although the patient was afebrile. The CT scan revealed that the low-density area in the left frontal lobe near the frontal angle of the left lateral ventricle, where the ICP transducer had been located, remained almost unchanged.

This finding led to the suspicion of thermal brain injury caused by the overheated and melted ICP transducer during the MRI procedure. Contrast-enhanced CT scans on Day 27 and Gd-enhanced T1-weighted MRI scans on Day 28 revealed a ring-enhancing lesion (Fig. 2B and D). Diffusion-weighted and T2-weighted MRI on Day 28 revealed a well-circumscribed, ovoid, high-intensity lesion with a low-intensity center, approximately 26.5 mm in a diameter, in the left frontal lobe near the frontal angle of the left lateral ventricle, in the previous location of the ICP transducer (Fig. 2C and E). Furthermore, T2-weighted imaging revealed a high-intensity tract in a low-intensity center with a high-intensity small surrounding area, which did not have findings compatible with a brain abscess, such as a large high-intensity circumference indicating edema of the surrounding parenchyma (Fig. 2E). We diagnosed the lesion as a healing thermal brain injury, because the combination of a small high-intensity area surrounding the lesion and a low-intensity central area on T2-weighted MR images, which corresponded to the ring-enhancing lesion evident on Gd-enhanced T1-weighted scans, was compatible with coagulative necrosis.

It was decided to continue conservative treatment without antibiotic therapy, because both physical examination findings and blood testing indicated that the inflammation had decreased, and the CT scan obtained on Day 27 demonstrated a reduction in the low-density area compared with Day 10 (Fig. 2A and B). An MRI study of the head on Day 41 revealed a further reduction in the size of the lesion. Cranial osteoplasty was performed on Day 47 and there were no postoperative complications. The patient made an excellent cognitive recovery and was discharged to a rehabilitation unit on Day 59.

**Investigation of the Cause of the Incident.** When we removed the ICP transducer from the patient on Day 6, we submitted it to Johnson & Johnson and asked them to investigate why it had stopped working. The Medical Accident Investigation Board at Okayama University Hospital discussed the cause of the incident several times and asked Johnson & Johnson to undertake an in-depth analysis. Four months after the incident, they reported that the transducer was melted and scorched 4–13 mm from the tip, with the most melted portion being 7–12 mm from the tip (Fig. 3 left). Radiophotography showed that the 3 copper conducting wires in the nylon-coated transducer had snapped at 9 mm from the tip (Fig. 3 right). Johnson & Johnson also indicated that the conductor of the ICP transducer...
Thermal brain injury and ICP transducer

might form a closed loop if configured in parallel with the RF coil, or if it was touching the patient on another part of his body other than where it was inserted. They concluded that under these conditions, the RF energy of the MR scanner might induce an electrical current of sufficient magnitude to increase the temperature of the tip of the transducer, melt the nylon coating, and snap the conducting wires. Furthermore, the Medical Device Reporting document prepared by the Quality Assurance Department of Johnson & Johnson K.K. Vigilance and Safety Group provided information about 6 other cases similar to the current case that had been reported as of December 2008 worldwide, but not published (Table 1).

It was ascertained that the multiple scan sequence of the MRI on Day 6 in the current case used a standard transmit/receive circular polarization head coil for the head scan, and a standard transmit body coil and receive neck array coil for the cervical spinal cord scan, with a 1.5-T unit (Magnetom Vision, Siemens AG). All the MR images were reviewed, and the examination protocols are summarized (with sequence parameters) in Table 2. A total of 430 images were obtained during this examination, with various pulse sequences used in both the axial and sagittal planes (Table 2). The actual whole-body-averaged SAR values were calculated based on the imaging parameters used and the weight of the patient by Siemens Japan K.K., and they ranged from 0.001 to 1.2938 W/kg. Only the highest value of 1.2938 W/kg, during cervical spinal cord imaging, exceeded the limit of 1.0 W/kg recom-

Fig. 2. A: Axial CT image obtained on Day 10 demonstrating that the low-density area in the left frontal lobe parenchyma (white arrow), in the previous location of the ICP transducer, is slightly more conspicuous than on Day 5. B: Contrast-enhanced CT image obtained on Day 27 demonstrating a reduction in the low-density area (white arrow) compared with Day 10. C–E: Axial MR images obtained on Day 28, including diffusion-weighted (C), Gd-enhanced T1-weighted (D), and T2-weighted (E) sequences. The diffusion-weighted and T2-weighted images demonstrate a high-intensity lesion with a low-intensity center approximately 26.5 mm in diameter (white arrow), which is a well-circumscribed ovoid mass deep in the white matter of the left frontal lobe near the frontal angle of the left lateral ventricle, in the previous location of the ICP transducer. The T2-weighted image also demonstrates a high-intensity tract inside a low-intensity center surrounded by a small high-intensity area. The high-intensity tract corresponds to the shape and location of the tip of the ICP transducer. The Gd-enhanced T1-weighted MR image reveals a ring-enhancing lesion (white arrow). The ring enhancement in the Gd-enhanced T1-weighted image (D) corresponds to the small area of high signal intensity surrounding the lesion in the T2-weighted image (E).

Fig. 3. Photographs of the Codman MicroSensor ICP transducer. Left: Enlargement of the photograph of the strain gauge transducer of the Codman MicroSensor used in the current case. (Each scale interval represents 1 mm.) Although the copper wire in the transducer is not exposed, the transducer is melted and scorched at 7–12 mm from the tip. A black substance can be seen on the surface of the transducer tip. The appearance of this coating was consistent with charred blood. Right: Enlargement of a portion of a radiophotograph of the Codman MicroSensor ICP transducer removed from our patient demonstrating that the 3 copper conducting wires within the nylon coating were completely broken at 9 mm from the tip. Original magnification ×150.
The total examination time was 48 minutes.

Although it became evident that the instruction manual that came with the ICP monitoring system used in the current case was the old version, which did not include any information about the correct configuration of the transducer or the recommended parameters for MRI, we concluded that the incident happened due to failure by medical doctors to follow the safety recommendations published by the manufacturer. After the report from Johnson & Johnson, Codman Shurtleff, Inc., we developed a precautionary tag in cooperation with them, which clearly illustrates the correct configuration of the transducer and the important parameters for safe MR scanning. The manufacturer attached the tag to all display units in hospitals using this product in Japan immediately after it was produced.

### Discussion

In the current case, an ICP transducer stopped functioning after MRI of the head and cervical spine on the

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Country</th>
<th>Date of Event</th>
<th>MR Strength</th>
<th>MDR Description of Event or Problem</th>
<th>Device Evaluated</th>
<th>MDR Investigation Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sweden</td>
<td>12/23/2002</td>
<td>1.5 T</td>
<td>Following placement, the patient was exposed to MRI and the magnetic field caused damage to the tip of the sensor. The tip of the sensor burned and broke. The heat around the tip of the sensor caused damage to the brain and further surgery was required to remove the broken sensor tip from the brain.</td>
<td>yes</td>
<td>The outer sheath of the sensor was burned and melted, apparently resulting from exposure to a high heat source. The heat source cannot be determined, although some form of electrical damage might be the root of the problem. The device could not be fully evaluated due to the extensive damage incurred.</td>
</tr>
<tr>
<td>2</td>
<td>Sweden</td>
<td>1/22/2003</td>
<td>1.5 T</td>
<td>The patient had a sensor implanted on 1/16/03. The sensor was not functioning on 1/22/03 when the patient was exposed to MRI. The sensor was burned and stuck in the patient’s brain. The nylon catheter broke when the doctor tried to remove the sensor from the patient. A piece of the catheter remained in the patient’s brain. The remaining piece had to be surgically removed on 1/23/03.</td>
<td>yes</td>
<td>The pressure sensor, case, and distal section of the catheter were returned for evaluation. The first 1.3 cm of the catheter appeared melted and the wires were broken. Several damaged areas of the catheter containing bends, kinks, and indentations were visible. Due to the damaged condition, no testing of the device was possible.</td>
</tr>
<tr>
<td>3</td>
<td>US</td>
<td>5/3/2004</td>
<td>unk</td>
<td>The sensor was placed following a craniotomy. The device functioned for 2 days &amp; then the patient underwent MRI. Following MRI, the sensor did not work and examination found that the sensor wire had melted onto the patient’s scalp. The sensor was discarded by the hospital following removal.</td>
<td>no</td>
<td>The sensor is not available for evaluation.</td>
</tr>
<tr>
<td>4</td>
<td>US</td>
<td>11/2003</td>
<td>unk</td>
<td>During MRI the patient became uncomfortable. When the MRI was completed, the patient’s skin had blisters associated with burns where the ICP sensor had contacted the skin. It was observed that the sensor had melted and that this was the source of the burn on the patient’s skin. Preliminary information indicated that the patient’s neurological status appeared to be intact after the procedure.</td>
<td>no</td>
<td>The sensor is not available for evaluation.</td>
</tr>
<tr>
<td>5</td>
<td>US</td>
<td>3/2008</td>
<td>unk</td>
<td>The sensor stopped working after the patient underwent MRI. The sensor was removed and the portion of the catheter near the sensor was black and burned. The patient died due to a condition unrelated to the device.</td>
<td>yes</td>
<td>A portion of the sensor catheter was returned with the pressure sensor still attached to the end of the catheter. The portion of the catheter was covered with black matter, which was consistent in appearance with charred blood.</td>
</tr>
<tr>
<td>6</td>
<td>US</td>
<td>7/2008</td>
<td>unk</td>
<td>The sensor broke during MRI. A 1-cm burn was noted at the trocar exit site. The sensor was discarded by the hospital.</td>
<td>no</td>
<td>The sensor is not available for evaluation.</td>
</tr>
</tbody>
</table>

* These data were prepared by Johnson & Johnson K.K. Vigilance and Safety Group, Quality Assurance Department. Abbreviations: MDR = Medical Device Reporting; unk = unknown.
6th day of hospitalization (Day 6). The ICP transducer was melted and scorched when it was removed from the patient’s brain, and the wires had snapped. The patient developed a high fever and leukocytosis 3 days after the patient’s brain, and the wires had snapped. The patient was melted and scorched when it was removed from the 6th day of hospitalization (Day 6). The ICP transducer had overheated and melted during the

lead, electrodes, pulse oximeters, thermodilution Swan-Ganz catheters, intravascular guidewires, DBS electrodes, and other devices that use conductive leads, wires, and cables have been reported to be associated with thermal injuries. Unfortunately, inappropriate use of monitoring devices during MRI is often the cause of thermal injuries. However, to our knowledge, no serious thermal brain injuries associated with ICP transducers have previously been reported after MRI.

According to Maxwell’s theory of electromagnetism, heating can be caused by the RF radiation used in MRI by 3 mechanisms. The first mechanism is electromagnetic induction heating, whereby a change in the flux of the magnetic induction through a conducting medium gives rise to an electromotive force that lasts as long as the flux is changing. The second mechanism is heating of conductors by resonance heating occurs when the circuit is in the resonant condition, resulting in induction of the maximum current. The third mechanism is heating of conductors by resonant RF waves, known as the “antenna effect.” The monitoring cable can be considered as an RF wire antenna that is sensitive to the electrical component, rather than the magnetic component, of the RF radiation used for MRI. The incident RF wave enters the antenna and is bounced back at the open ends of the wire, causing reflected RF waves to travel back and forth along the longi-
The transducer was composed of a carbon film resistor inserted by the International Electrotechnical Commission, the SAR limit is an unreliable indicator of implant safety and may be the cause of the high SAR (Table 2). Third, the whole-body SAR limit in our 1.5-T unit (Magnetom Vision, Siemens AG) was 1.5 W/kg at that time. Although this value was in accord with the MRI safety guidelines determined by the International Electrotechnical Commission, the FDA, and the Ministry of Health, Labor, and Welfare in Japan, it was higher than the maximum of 1.0 W/kg recommended in the manufacturer's safety guidelines (Appendix). Evidence has accumulated that the whole-body SAR limit is an unreliable indicator of implant safety and that using this limit alone as a safety recommendation is potentially dangerous. However, the highest SAR value of 1.2938 W/kg in one series of spinal cord scans, which was more than the recommended 1.0 W/kg, may have

R. Tanaka et al.
been one of the causes of overheating of the transducer tip in the current case. The SAR limit recommended by the FDA and the International Electrotechnical Commission has recently been deregulated. Therefore, the whole-body-averaged SAR limit of 1.0 W/kg in the manufacturer’s guidelines for the Codman MicroSensor seems to be slightly too strict. If this SAR limit is adhered to, it will be necessary to consider alternative scan sequences, which decrease the whole-body-averaged SAR, to maintain the quality of MR images.

Conclusions

Many factors should be taken into consideration when performing MRI in a patient with an implanted device. Moreover, we should not be influenced by preconceptions that loop formation must be avoided at all times during MRI. Any deviations from the manufacturer’s safety guidelines may result in serious injury to the patient. We emphasize the crucial importance of strictly and carefully adhering to safety guidelines when performing MRI on a patient with an implanted ICP monitoring device, to prevent catastrophic incidents, including the possibility of meningeal, transient dystonia, paralysis, coma, or even death following thermal brain injury.

Appendix

The Appendix follows the last page of this article.

Acknowledgments

The authors thank Mr. Seiichiro Ohno of Central Division of Radiology, Okayama University Hospital, for his technical support; Mr. Ryuji Sakai of Siemens Japan K.K., for his helpful comments; and Ms. Maiko Toyama of Johnson & Johnson, Inc., for her assistance.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author contributions to the study and manuscript preparation include the following. Conception and design: Tanaka, Yamoto, Shiba, Okawa, Ichikawa, Tokunaga. Acquisition of data: Tanaka, Yamoto, Shiba. Analysis and interpretation of data: Tanaka, Okawa, Yasuhara, Tokunaga, Ujike. Drafting of the article: Tanaka. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Tanaka. Study supervision: Date, Ujike.

References

8. Hall SC, Stevenson GW, Suresh S: Burn associated with temperature monitoring during magnetic resonance imaging. Anesthesiology 76:152, 1992 (Letter)


Manuscript submitted April 11, 2012.
Accepted September 4, 2012.
Portions of this work were presented orally at the 37th Annual Meeting of the Japanese Association of Acute Medicine, Iwate, Japan, October 30, 2009.
Please include this information when citing this paper: published online October 12, 2012; DOI: 10.3171/2012.9.JNS12738.
Address correspondence to: Reiichiro Tanaka, M.D., Department of Critical Care and Emergency Medicine, Okayama University Hospital, 2-5-1 Shikata-Cho, Kita-ku, Okayama 700-8558, Japan. email: Rtanaka17@aol.com.
Thermal brain injury and ICP transducer

Appendix

ADDENDUM SHEET
CODMAN® MicroSensor Products
Catalog no. 82-6631, 82-6632, 82-6633, 82-6636, 82-6639 and 82-6653

The following information pertains to Instructions for Use #171976-001, 171977-001, 171978-001, 197138-001 and 197605-001.

Addition to WARNINGS section:
Before conducting an MRI procedure on a patient with an implanted CODMAN MicroSensor, read the MRI Safety section. Failure to read and strictly adhere to these guidelines can result in serious injury to the patient.

Remove the following CONTRAINDICATION:
Compatibility of implantable catheter-tipped pressure transducers with magnetic resonance imaging (MRI) has not been determined.

Add the following section:
MRI Safety
CAUTION: These guidelines apply to MRI (magnetic resonance imaging) procedures conducted in a 1.5 tesla MR system, ONLY. Higher magnetic field systems have not been tested and may cause burn or serious injury.

IMPORTANT: 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. The CODMAN MicroSensor Skull Bolt is a steel bolt included with catalog no. 82-6638 and 82-6639. It will cause substantial image artifact and distortion on the MR image in the proximity of the bolt. Optimize MR imaging parameters for the presence of the metallic device.

The ability to safely perform an MRI procedure on a patient with an implanted CODMAN MicroSensor has been demonstrated when the following guidelines are followed:

1. Immediately prior to entering the MRI environment, 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 before transporting the patient into the MRI environment.
3. The CODMAN MicroSensor must be placed 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. Center the coil on the top of the patient’s head. See Figure 1. Do not perform MRI with the CODMAN MicroSensor in a “straight line” configuration. Failure to follow this guideline can result in serious injury to the patient.
4. Use a dry gauze pad at least 1 cm thick to insulate the patient’s tissue from the coiled CODMAN MicroSensor and connector. If using tape to secure the sensor to the insulating pad, use care when removing the tape to prevent damage to the CODMAN MicroSensor.
5. 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
6. Set MRI parameters to the lowest usable whole body averaged SAR level. CAUTION: Do not exceed an RF (radio frequency) WHOLE BODY AVERAGED SAR (specific absorption rate) or RF HEAD AVERAGED SAR of 1.0 W/kg.

Figure 1: CODMAN MicroSensor ICP transducer configuration for MR imaging

Disclaimer

Codman distributes this addendum to the Instructions for Use only outside of the United States. This addendum has not been cleared by the US Food and Drug Administration for use in the US. This addendum to the Instructions for Use is current as of the date that permission was granted to use this material in this publication [September 24, 2012].