

Codman[®]

CODMAN MICROSENSOR[®] Basic Kit REF 626631US



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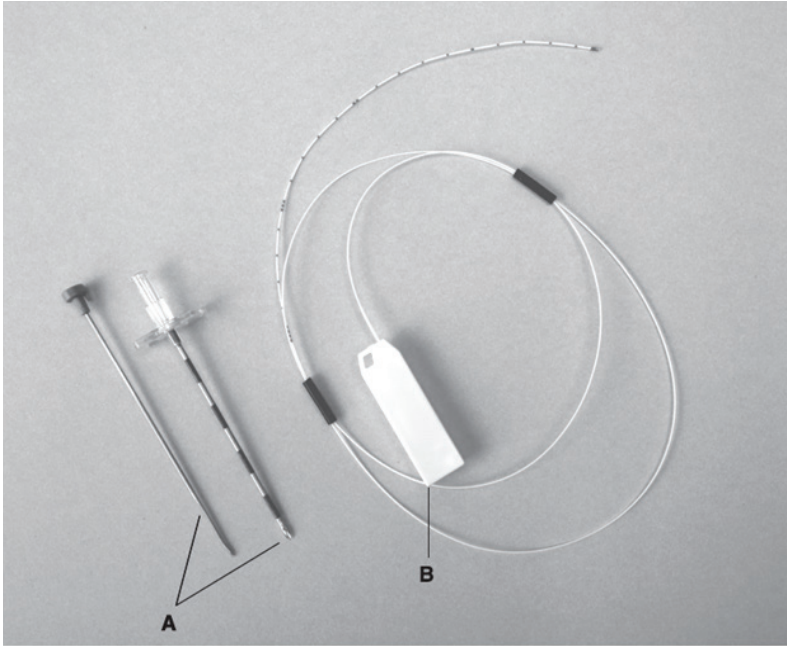
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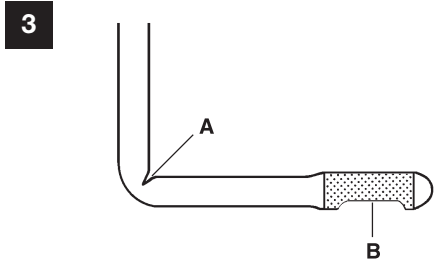
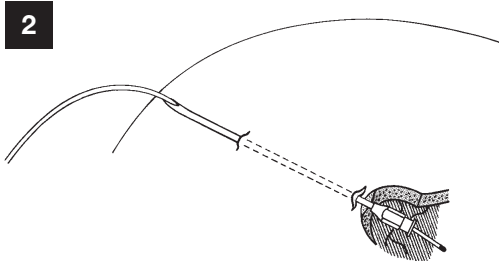
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1

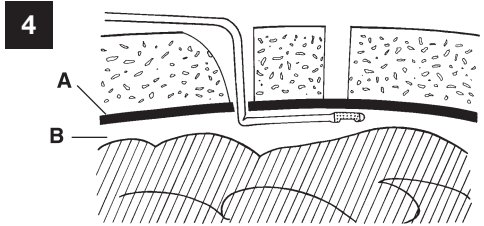


- A. 14 Gauge Tuohy Needle with Stylet
- B. MICROSENSOR ICP Transducer with cm depth markings



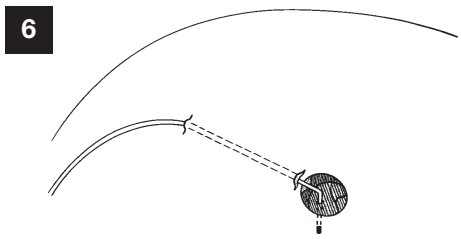
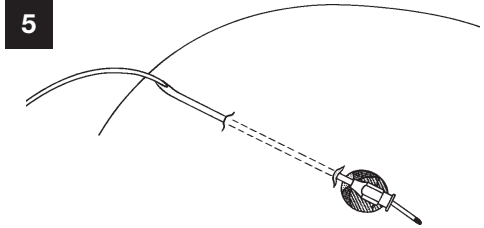
CAUTION: Avoid direct contact with the sensing element of the transducer.

- A. Kink
- B. Sensing Element

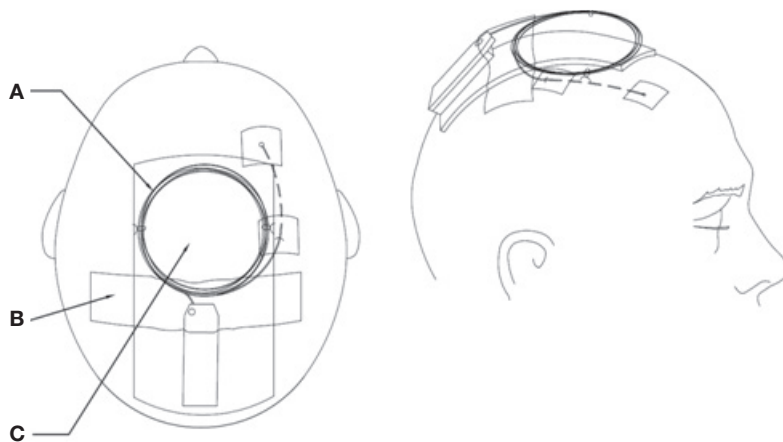


Subdural Placement under Intact Skull

- A. Dura
- B. Subdural Space



7



CODMAN MICROSENSOR configuration to ensure patient safety during MRI

A. 6 cm Loops

B. Tape

C. Dry Gauze Pad

Image Not to Scale

ENGLISH

IMPORTANT INFORMATION

Please Read Before Use

CODMAN MICROSENSOR® Basic Kit

REF 626631US

STERILE EO

Rx Only

Description

The CODMAN MICROSENSOR® Basic Kit, catalog no. 626631US, consists of the CODMAN MICROSENSOR ICP Transducer and a 14-gauge Tuohy needle with stylet (see Figure 1).

The CODMAN MICROSENSOR ICP Transducer is a catheter with a microminiature strain gauge pressure sensor mounted at one end and an electrical connector at the other end. It is designed for use with the ICP EXPRESS® Monitor, catalog no. 82-6634 (117 VAC) and 82-6635 (230 VAC) or any other suitable Codman pressure monitoring interface or device.

The CODMAN MICROSENSOR Basic Kit is designed for use with the CODMAN® Cranial Hand Drill, catalog no. 82-6607. The drill facilitates access to the intraparenchymal area. The drill is also available as a component of the CODMAN Cranial Access Kit, catalog nos. 82-6612, 82-6614, and 82-6616.

Indications

Use of the CODMAN MICROSENSOR Basic Kit is indicated when direct ICP monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only.

Contraindications

This kit is not designed, sold, or intended for any use except as indicated.

This kit is not designed, sold, or intended for use as a therapeutic device.

WARNINGS

Take extreme care to avoid damage to the dura and underlying cerebrum.

The use of electrosurgical equipment, e.g., monopolar, bipolar, diathermy, can cause damage to the CODMAN MICROSENSOR Transducer and/or the ICP EXPRESS

Monitor. This could lead to permanent or temporary disabling of either device.

Before conducting an MRI procedure on a patient with an implanted CODMAN MICROSENSOR Transducer, read the *MRI Information* section. Failure to read and strictly adhere to these guidelines can result in serious injury to the patient.

Precautions

Inspect the sterile package carefully. Do not use if:

- the package or seal appears damaged,
- contents appear damaged, or
- the expiry date has passed.

Avoid direct contact with the sensing element at the transducer tip. Care must be taken at all times during handling of the transducer to protect the tip from impact. Damage could result.

Do not hit the transducer tip with the stylet. Damage could result.

It is essential to maintain strict sterile technique during transducer placement.

Exposure to electrostatic discharge (ESD) energy could damage this device. High levels of ESD could damage the electronic components and cause the transducer to be rendered inaccurate or inoperable. Take all precautions to reduce the buildup of electrostatic charge during the use of this product and avoid touching the transducer connector pins, which are identified with the ESD symbol. (Refer to *Electrostatic Discharge (ESD) Information* section.)

The use of a defibrillator or any electrosurgical equipment, e.g., monopolar, bipolar, diathermy, can cause damage to the MICROSENSOR™ ICP Transducer. This could lead to permanent or temporary disabling of the transducer.

Take care when tying sutures onto the sensor. Tying sutures too tightly can collapse the wall of the sensor body, causing damage to internal wires.

The transducer must be zeroed at atmospheric pressure prior to implantation.

The transducer tip must remain wet during the zeroing process.

Do not submerge the tip of the transducer or catheter vertically in a deep pool or cup of sterile water/sterile saline. Doing so will impose a hydrostatic pressure on the transducer diaphragm that is higher than atmospheric zero, resulting in an inaccurate zero reference.

The transducer can be damaged if exposed to pressures over 1250 mmHg (166,650 Pa).

Do not forcibly pull or jerk the transducer catheter.

Do not expose the transducer to solvents or cleaning agents, including alcohol; these may cause damage leading to inaccurate ICP measurements.

Read all instructions included with the monitoring display device prior to use.

Adverse Events

The following Adverse Events may occur with the use of the CODMAN MICROSENSOR:

- Hemorrhage*
- Infection
- Subcutaneous CSF leakage
- Neurological sequelae

*Subarachnoid, intracerebral, or extracerebral hemorrhage may occur at the site of transducer placement (either skull, cortical, or dural areas). Testing of the blood clotting factor should be conducted on patients before insertion.

MRI Information



Read and understand this document 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.

The **CODMAN MICROSENSOR** is MR Conditional.

MRI SAFETY INFORMATION:

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).
- Special positioning of the CODMAN MICROSENSOR is required to ensure patient safety during the MRI procedure (see “PREPARATION FOR THE MRI PROCEDURE” below for specific instructions).
- **WARNING:** Do not bring the ICP EXPRESS monitor, cables or other accessories such as Tuohy needles, trocar or stylet into the MRI suite.
- **WARNING:** 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.
- **WARNING:** Do not scan a patient with an elevated body temperature.

MRI-Related Heating

Under the scanning conditions defined above, the CODMAN MICROSENSOR is expected to produce a maximum temperature rise of less than 2°C after 15 minutes of continuous scanning. The effects of scanning beyond 15 minutes are undetermined.

Artifact Information

In non-clinical testing, the maximum artifact size was seen on the gradient echo pulse sequence at 3T and extends to a zone approximately 2 mm relative to the size and shape of the CODMAN MICROSENSOR.

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 ICP EXPRESS Monitor, 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 Figure 7). 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 Figure 7). Use care when removing the tape to prevent damage to the CODMAN MICROSENSOR.
5. Do not exceed the following MRI parameters during imaging:
 - a. Maximum spatial gradient magnetic field of 1,000 G/cm (10 T/m). The highest SG magnetic field is commonly located off-axis, at a side wall, and near the opening of the bore of the scanner. Please refer to MRI manufacturer's published value and location of the peak SG that is accessible to the patient.
 - b. Maximum gradient field slew rate of 170 T/m/s.
 - c. 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).

Electrostatic Discharge (ESD) Information



CAUTION: Exposure to electrostatic discharge (ESD) energy could damage this device. High levels of ESD could damage the electronic components and cause the transducer to be rendered inaccurate or inoperable. Take all precautions to reduce the buildup of electrostatic charge during the use of this product.

- Provide patient grounding, e.g., grounding straps on gurneys
- Avoid the use of materials that could generate ESD during patient movement and transport, e.g., nylon transfer boards with bedding
- Before touching the patient, caretakers should discharge ESD buildup by touching a grounded metal surface, such as a bed rail

It is recommended that all hospital personnel in contact with these devices receive an explanation of the ESD symbol and training in ESD precautionary procedures. Training should include, at a minimum, an introduction to electrostatic discharge, when and why it occurs, precautionary measure, and the damage that can be done to electronic components if touched by a user who is electrostatically charged.

Avoid touching the connector pins, which are identified with the ESD symbol, before following ESD precautionary procedures. Avoid touching the transducer tip (sensing element) at all times.

How Supplied



This device is intended for SINGLE USE ONLY; DO NOT RESTERILIZE.

Integra single-use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or resterilization, after a single patient use. These devices are intended to come into contact with the central nervous system and the ability does not currently exist to destroy possible contaminants such as Creutzfeldt-Jakob Disease. Reuse can also compromise device performance and any usage beyond the design intent of this single-use device can result in unpredictable use hazards or loss of functionality.

Integra will not be responsible for any product that is resterilized, nor accept for credit or exchange any product that has been opened but not used.

As long as the individual package is not damaged or opened, the product is sterile.

All components have been tested and were determined to be nonpyrogenic, **except** for the electrical connector of the sensor and the silicone tubing used for packaging, which are not tested.

The device is packaged using a combination of recyclable and non-recyclable materials. Recycle or dispose of all packaging waste in accordance with hospital procedures and regulations.

Connecting and Zeroing the MICROSENSOR Transducer

CAUTION: The transducer must be zeroed at atmospheric pressure before implantation.

1. Connect the transducer to a compatible CODMAN ICP Monitor using an appropriate CODMAN interface cable. Refer to instructions for use provided with the cable for sterilization information.
2. If applicable, connect the CODMAN ICP Monitor to an available pressure channel on an external patient monitor using a CODMAN Patient Monitor Interface Cable.

CAUTION: Use CODMAN Patient Monitor Interface Cables only with the patient monitors for which they are specifically designed and designated.

3. Zero and calibrate the external patient monitor according to the instructions provided with the CODMAN ICP Monitor, as well as the external patient monitor manufacturer's instructions.
4. Prepare to zero the catheter by laying the tip of the catheter flat in a shallow pool of sterile water or sterile saline. The accompanying sterile blister package has a marked well that is suitable for this procedure. Pour sufficient sterile water or sterile saline into the well, then lay at least a 5 cm section of the catheter horizontally just under the surface of the sterile water or sterile saline.

CAUTION: Do not submerge the tip of the catheter vertically in a deep pool or cup of sterile water or sterile saline. Doing so will impose a hydrostatic pressure on the sensor diaphragm that is higher than atmospheric pressure, resulting in an inaccurate zero reference.

5. While keeping the tip of the catheter flat and still in the sterile water or sterile saline, zero the catheter according to the instructions provided with the ICP Monitor.

CAUTION: The sensor tip must remain wet during the zeroing process.

CAUTION: The sensor tip must remain still during the zeroing process. Motion of the sensor may be interpreted by the CODMAN ICP Monitor as a fluctuating ICP signal which will prevent the sensor zeroing process from successfully completing.

6. If available, record the three-digit zero reference number provided by the ICP Monitor. Mark this number on the catheter connector housing and the patient's chart for future reference.

General Surgical Procedure

The following is a general guide for informational purposes only. The surgeon may wish to alter details in accordance with his or her own clinical experience and medical judgment. The CODMAN Cranial Access Kit is recommended for this procedure. This device is not designed, sold, or intended for use as a therapeutic device.

Measuring Subdural Pressure

1. Following craniotomy and bone flap removal, connect and zero the transducer. Refer to *Connecting and Zeroing the MICROSENSOR Transducer*.
2. Choose the burr hole through which the transducer will be placed and bevel the edge on the side the transducer will exit to facilitate removal.
3. Use the Tuohy needle to tunnel under the scalp from the craniotomy site to the desired transducer exit site.
4. Remove the Tuohy needle stylet and thread the transducer from the tip of the needle until the approximate length for desired placement exits from the hub (see Figure 2).

CAUTION: The inner edges of the Tuohy needle are sharp; exercise caution when threading the catheter.

5. Gently remove the needle and estimate the length of the transducer from the tip to the first bend.
6. Fold back the transducer once completed at the desired bend site to leave a kink in the catheter. Verify that the kink is on the opposite side of the transducer from the transducer sensing element, as shown in Figure 3.
7. Place the tip of the transducer on the brain tissue under the dura opposite the beveled burr hole. The kink must be placed at the bottom of the burr hole so that the transducer sensing element faces the cortex, as shown in Figure 4.

CAUTION: To ensure accurate ICP measurements, position the sensing element of the transducer tip towards the cortex during subdural pressure monitoring.

CAUTION: To minimize movement artifacts of the bone flap, place the transducer under the intact skull.

8. Close and suture down the dura following standard neurosurgical procedure.

9. Replace the bone flap and close the scalp incision.
10. Secure the catheter to the scalp. To provide additional strain relief, make a small loop with the catheter and tie the loop down.
11. Close and dress the incision site.

Measuring Intraparenchymal Pressure

NOTE: The CODMAN Cranial Hand Drill, catalog no. 82-6607, is recommended for this procedure.

1. Connect and zero the transducer. Refer to *Connecting and Zeroing the MICROSENSOR Transducer*.
2. Perform craniotomy and retraction procedures required to expose the skull. Put the 2.7 mm drill bit into the drill chuck and make a drill hole through the outer table.
CAUTION: Proceed gently through the inner table with care to avoid injury to the dura or parenchyma.
3. Carefully bevel the bone at the incision site towards the side from which the catheter will exit.
4. Use the Tuohy needle to make a cruciate puncture in the dura.
5. Use the Tuohy needle with stylet in place to tunnel under the scalp from the incision site to the exit site.
6. Remove the stylet and thread the transducer from the tip of the needle until approximately twice the placement length exits from the hub (see Figure 5).
CAUTION: The inner edges of the Tuohy needle are sharp; exercise caution when threading the transducer.
7. Gently remove the needle and estimate the length of the transducer from the tip to where it will bend upon exiting the skull.
8. Fold the transducer once completely at the desired bend site to leave a kink in the transducer.
9. Place the tip of the transducer into the parenchyma through the puncture in the dura until the kink is at the edge of the hole, as shown in Figure 6.
10. Carefully pull back the excess transducer.
11. Remove the retractor, verify hemostasis in the insertion area, and then suture the incision site closed.
12. Secure the catheter to the scalp. For additional strain relief, make a small loop with the catheter and tie the loop down.
13. Close and dress the incision site.

Specifications

Probe Specifications

Note: All performance specifications based on 5 VDC excitation voltage

Sensing element	Strain gauge silicon microchip
Probe usable length	100 cm nominal
Probe material	Nylon, titanium, silicone, epoxy
Probe tip diameter	1.3 mm maximum
Probe tubing diameter	0.8 mm maximum
Functional pressure range	-50 mmHg to +250 mmHg
Functional overpressure range without damage	-700 mmHg to +1250 mmHg
Input/output impedance	1000 ohms nominal
Zero drift	No greater than 5 mmHg over 30 days
Output signal (sensitivity)	5 μ V/V/mmHg nominal
Frequency response	Greater than 200 Hz

Environmental Specifications

(for non-implantable portion of device)

Operating temperature range	5°C to 45°C
Operating humidity range	30% to 90% relative humidity (non-condensing)
Operating atmospheric pressure range	700 millibar to 1060 millibar

PRODUCT INFORMATION DISCLOSURE

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Do not use if package is damaged



Prescription device only (USA)



Manufacturer



Made In



Nonpyrogenic; see instructions for use



Attention, consult accompanying document



MR Conditional



Quantity



Radiopaque



Consult instructions for use



Refer to instruction manual/booklet



Electrostatic sensitive device; see instructions for use