CODMAN MICROSENSOR® Ventricular Catheter Kit with Tuohy-Borst Adapter

REF 626633US
ENGLISH

IMPORTANT INFORMATION
Please Read Before Use

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Tuohy-Borst Adapter

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Description
The CODMAN MICROSENSOR Ventricular Catheter Kit, catalog no. 626633US, consists of the CODMAN MICROSENSOR ICP Transducer, a 35 cm ventricular catheter with female LUER-LOK™ connector, a Tuohy-Borst adapter with drainage port, a split trocar, a 10-gauge ventricular needle and a 15 cm stylet (see Figure 1).

The CODMAN MICROSENSOR ICP Transducer is a catheter with a microminiature strain gauge 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.

Indications
Use of the Kit is indicated when direct intracranial pressure monitoring is required. The kit is indicated for use in intraventricular pressure monitoring and cerebrospinal fluid (CSF) drainage applications.

Contraindications
Ventriculostomy is contraindicated in patients with coagulopathy or active infection in the area of the catheter. Use of the Ventricular Catheter Kit is contraindicated in children less than one year of age.

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

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 ventriculostomy, and subsequent 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. This could lead to permanent or temporary disabling of the transducer.

Silicone is highly electrostatic and, as a result, attracts airborne particles and surface contaminants that could produce tissue reaction. Use extreme care to prevent the ventricular catheter from coming in contact with towels, drapes, talc, or any other linty or granular surface, as well as airborne particles.

Silicone has a low cut and tear resistance; therefore, care should be exercised when placing ligatures so as not to tie them too tightly. The use of stainless steel ligatures on silicone is not advised. In addition, 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 Ventricular Catheter is MR Conditional.

MRI SAFETY INFORMATION:

Non-clinical testing has demonstrated that the CODMAN MICROSENSOR Ventricular Catheter 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 1000 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 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 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 and Ventricular Catheter 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 and Ventricular Catheter 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 10). 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 10). 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
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.

Connecting and Zeroing the MICROSSENSOR 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 CODMAN ICP Monitor.

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

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

6. If available, record the three-digit zero reference number provided by the CODMAN 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.

1. Connect and zero the transducer. Refer to Connecting and Zeroing the MICROSENSOR Transducer.

2. Incise the scalp to expose the skull and then make a twist drill hole using a 5.8 mm drill bit.

3. Gently bevel the burr hole on one side to allow the catheter to exit without a sharp angulation.

4. Puncture the dura using a needle or cautery.

5. Use the split trocar to tunnel the ventricular catheter under the scalp from the craniotomy site to any other convenient site located at least 3 cm from the burr hole.

6. Remove the stylet from the split trocar.

7. Insert the ventricular catheter through the split trocar from the exit site to the burr hole wound, as shown in Figure 2.

8. Remove the split trocar from under the scalp.

9. Verify that the transducer tip is located at the first large hole at the distal end of the ventricular catheter, as shown in Figure 8. If necessary, loosen the Tuohy-Borst adapter cap (turn counterclockwise) and adjust transducer position as required.

10. Firmly tighten the Tuohy-Borst adapter cap (turn clockwise) and LUER-LOK connections. Verify that the transducer tip remains in position as shown in Figure 8. Readjust if necessary.

11. Insert the tip of the 15 cm stylet through the middle large hole at the distal end of the ventricular catheter (see Figure 3).

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

Accidental contact with the transducer can be detected by a simultaneous transient waveform response on the monitor trace and/or an increase in the numeric display. In such cases, do not use the transducer.

12. Advance the stylet and catheter at a right angle to the skull into the lateral ventricle at a depth of approximately 7 cm (see Figure 4). Note: Some surgeons may prefer to first use the 10-gauge ventricular needle to locate the ventricle, as shown in Figure 5, and then pass the stylet and catheter through the tract thus created.

13. To verify ventricular placement, remove the cap from the side drain port of the Tuohy-Borst adapter to allow CSF to flow through the catheter.

14. Hold the catheter in place and gently withdraw the stylet.

15. Press down on the ventricular catheter and pull any excess catheter away from the incision site.

16. Secure the catheter to the scalp with sutures at the exit site. Additional sutures may be placed through the holes in the female LUER-LOK connector flange.

17. Close and dress the incision site.

18. If desired, attach the drainage port of the ventricular catheter to a ventricular drainage system.

Alternate Tunneling Technique

The following is an alternate technique for tunneling the ventricular catheter under the scalp without the transducer preloaded. The surgeon may wish to alter details in accordance with his or her clinical experience and medical judgment.

1. Carefully detach the ventricular catheter from the white female LUER-LOK connector and Tuohy-Borst adapter.

2. Gently pull the Tuohy-Borst adapter and transducer assembly completely out of the catheter.

3. Connect and zero the transducer as described in Connecting and Zeroing the MICROSENSOR Transducer.

4. Use either a split trocar (included) or a standard tunneling trocar (not included), see Figure 6 to tunnel the ventricular catheter under the scalp from the craniotomy site to any other convenient site located at least 3 cm from the burr hole.

5. At this point, the catheter can be cut to the desired length. Leave enough excess catheter at the incision site to permit cannulation.

6. Thread the tip of the transducer back through the proximal end of the catheter as shown in Figure 7. Sterile saline may be used to irrigate the inner channel of the catheter to facilitate transducer advancement. Continue to advance the transducer until the tip can be seen through the first hole at the distal end of the catheter, as shown in Figure 8.
7. Reattach the white female LUER-LOK connector and Tuohy-Borst adapter to the ventricular catheter as shown in Figure 9. Finger-tighten all LUER-LOK connections.

8. Firmly tighten the Tuohy-Borst adapter cap (turn clockwise), verifying that the transducer tip remains in position as shown in Figure 8. Readjust if necessary.

9. Introduce the ventricular catheter into the ventricle as described in General Surgical Procedure.

Specifications

Ventricular Catheter Specifications

Catheter outside diameter . . 3.5 mm maximum
Catheter usable length ...... 35 cm nominal
Catheter material ........... Silicone

Transducer 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 µV/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

Warranty

Codman & Shurtleff, Inc. warrants that this medical device is free from defects in both materials and workmanship. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer’s instructions for use. There are no warranties that extend beyond the description on the face hereof.

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™ LUER-LOK is a trademark of Becton, Dickinson, and Company
A. Ventricular Needle  
B. Split Trocar  
C. Stylet  
D. Tuohy Borst Adapter with Drainage Port  
E. Ventricular Catheter  
F. CODMAN MICROSENSOR ICP Transducer
Threading Catheter through Split Trocar
A. Tuohy Borst Adapter

Inserting Stylet into Distal Tip of Catheter

Using Stylet to Advance the Catheter into the Ventricle

Locating Ventricle with Ventricular Needle

Tunneling with Standard Barbed Trocar

Advancing Transducer Through Catheter
CODMAN MICROSENSOR® Ventricular Catheter Kit
with Tuohy-Borst Adapter  REF 626633US

8

A. End of Transducer

9

Reattaching Luer-Lok and Tuohy Borst Adapter to Catheter

10

CODMAN MICROSENSOR configuration to ensure patient safety during MRI
A. 6 cm Loops
B. Tape
C. Dry Gauze Pad
D. To Drain System

Image Not to Scale
Do not resterilize

Do not use if package is damaged

Prescription device only (USA)

Manufacturer

Distributed in the USA by

Made In

Nonpyrogenic; see instructions for use

Attention, consult accompanying document

Electrical and electronic equipment. Return waste to collection system or treatment and recycling facilities. Applicable in the EU. Follow decontamination instructions before return.

MR Conditional

Quantity

Radiopaque

Consult instructions for use

Refer to instruction manual/booklet

Electrostatic sensitive device; see instructions for use
* For recognized manufacturer, refer to product label.