CODMAN NEURO

DePuy Synthes

CODMAN MICROSENSOR® Basic Kit (catalog number 82-6631)

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ENGLISH

IMPORTANT INFORMATION
Please Read Before Use

CODMAN MICROSENSOR® Basic Kit

STERILE	EO

℞ Only

Description
The CODMAN MICROSENSOR Basic Kit, catalog number 82-6631, consists of the CODMAN MICROSENSOR ICP Transducer and a 14-gauge Tuohy needle, as shown in Figure 1.

The CODMAN MICROSENSOR ICP Transducer is a catheter with a microminiature silicon strain gauge type sensor mounted at one end and an electrical connector at the other end. It is designed for use with the CODMAN ICP EXPRESS® Monitor, catalog numbers 82-6634 (117 VAC) and 82-6635 (230 VAC). In conjunction with the ICP EXPRESS Monitor, the MICROSENSOR may be interfaced to a wide variety of patient monitoring systems for ICP waveform display, or for consolidation of ICP data with other vital signs information.

The CODMAN MICROSENSOR Basic Kit is designed for use with the CODMAN Cranial Hand Drill, catalog number 82-6607. The drill facilitates access to the intraparenchymal area.

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

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

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

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

WARNINGS
The use of electrosurgical equipment (e.g., Monopolar, Bipolar, Diathermy) can cause damage to the ICP MICROSENSOR and/or ICP EXPRESS Monitor. This could lead to permanent or temporary disabling of either device.

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.

It is essential to maintain strict sterile technique during transducer placement. All procedures should be performed by a qualified neurosurgeon using standard surgical procedure. The neurosurgeon is responsible for taking appropriate steps and procedures to avoid infections and complications.

The transducer can break if exposed to pressures over 1250 mm Hg (166650 Pa).

Do not strongly pull or jerk the catheter.

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

The transducer element is light sensitive and should be shielded from direct light sources during zeroing and usage.

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.

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

Avoid direct contact with the sensing element of the transducer.

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

Read all instructions included with the ICP EXPRESS Monitor prior to use.

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

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 MICROSENSOR transducer tip must remain wet during the zeroing process.

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. 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 sensor.

Adverse Events

Hemorrhage may occur at the site of transducer placement from either the skull, cortical or dural areas. Testing of the blood clotting factor should be conducted on patients before insertion.

Decisions regarding the possibility of subarachnoid, intracerebral or extracerebral hemorrhage at the site of placement are the sole responsibility of the attending neurosurgeon.

Infection, subcutaneous CSF leakage, and neurological sequelae are potential complications of this procedure.

Connecting and Zeroing the Transducer

CAUTION: Read all instructions included with the ICP EXPRESS Monitor prior to use.

CAUTION: The MICROSENSOR must be zeroed at atmospheric pressure prior to implantation.

1. Connect the MICROSENSOR to the ICP EXPRESS Monitor using the appropriate sterile transducer interface cable. Use cable model 82-6636. The cable must be sterilized prior to use. Refer to product insert provided with the cable for sterilization information.

2. If applicable, connect the ICP EXPRESS 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.** Secure the two locking screws on the cable to prevent inadvertent disconnection during use.

3. Proceed to zero and calibrate the external patient monitor according to the instructions provided with the ICP EXPRESS Monitor, as well as the external patient monitor manufacturer's instructions.

4. Prepare to zero the MICROSENSOR by laying the tip of the transducer (or ventricular catheter) 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/sterile saline into the well then lay at least a 5 cm section of the transducer (or ventricular catheter) horizontally just under the surface of the sterile water/sterile saline. **CAUTION: 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.**

5. While keeping the tip of the MICROSENSOR (or ventricular catheter) flat in the sterile water/ sterile saline, proceed to zero the MICROSENSOR according to the instructions provided with the ICP EXPRESS Monitor. **CAUTION: The MICROSENSOR transducer tip must remain wet during the zeroing process.**

6. Record the three-digit zero reference number provided by the ICP EXPRESS Monitor. Mark the number on the MICROSENSOR connector housing or 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. 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 the Connecting and Zeroing the Transducer section.

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 transducer 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 through.

5. Gently remove the needle, and estimate the length of the transducer catheter from the tip to the first bend.

6. Fold back the transducer once, completely, at the desired bend site to leave a kink in the catheter. Verify that the kink is on the opposite side of the catheter 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 number 82-6607 is recommended for this procedure.

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

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 incision site towards the side from which the transducer 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 catheter through.

7. Gently remove the needle, and estimate the length of the transducer catheter 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 catheter.

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 catheter.

11. Remove the retractor, verify hemostasis in the insertion area, and 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.

Electrostatic Discharge (ESD) Information

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 ESD and training in ESD precautionary procedures. Training should include, at a minimum, an introduction to electrostatic discharge, when and why it occurs, precautionary measures, and the damage that can be done to electronic components if touched by a user who is electrostatically charged.

Avoid touching the connector pins before following ESD precautionary procedures. Avoid touching the transducer tip (sensing element) at all times.

Sterilization

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The CODMAN MICROSENSOR Basic Kit is intended for SINGLE USE ONLY; DO NOT RESTERILIZE. 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 contaminates 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.

Codman & Shurtleff 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.

All components have been tested and were determined to be nonpyrogenic, except the electrical sensor, the barcode label, the string catheter, and if present, the disposable ICP handle and the hexagonal key, which are not tested.

MICROSENSOR Specifications

Sensing Element	Strain gauge silicon micro chip
Diameter of tip	3.6 Fr (1.2 mm), nominal
Usable length	100 cm nominal
Catheter outside diameter	0.7 mm nominal
Catheter material	Nylon
Functional pressure range	–50 mm Hg to +250 mm Hg (–6666 Pa to +33330 Pa)
Functional overpressure range without damage	–700 mm Hg to +1250 mm Hg (–93324 Pa to +166650 Pa)
Input impedance	1000 ohms nominal
Excitation range	2.5 V to 7.5 VDC or VAC RMS (performance based on 5 VDC)
Zero drift	no greater than 5 mm Hg (667 Pa)/7 days
Zero offset	±50 mm Hg (±6666 Pa) maximum
Output impedance	1000 ohms nominal
Leakage current	less than 10 μA at 120 VAC
Output signal (sensitivity)	5 μV/V/mm Hg (5 μV/V/133 Pa) nominal

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.**