REF 826854

Codman® CereLink™

ICP Sensor

Ventricular Catheter Kit

Codman® SPECIALTY SURGICAL

INTEGRA®

A DIVISION OF INTEGRA LIFESCIENCES

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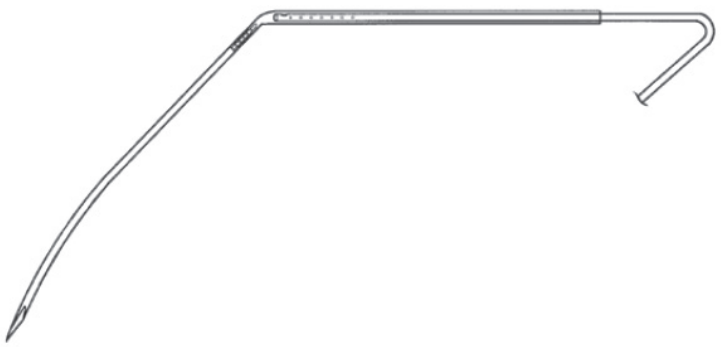

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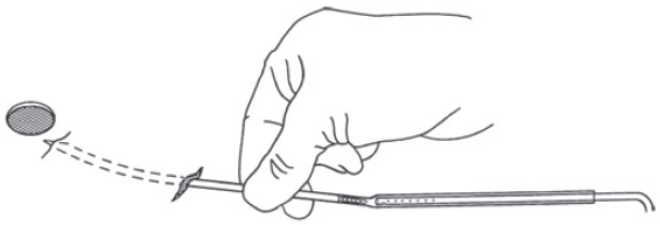

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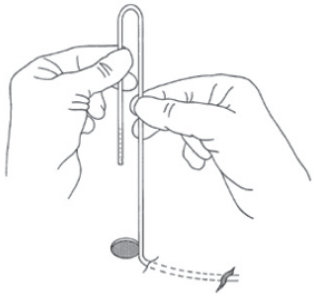

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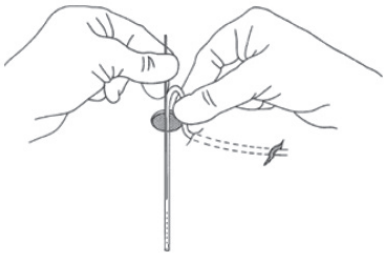

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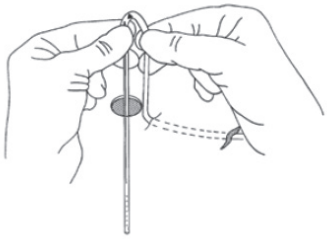

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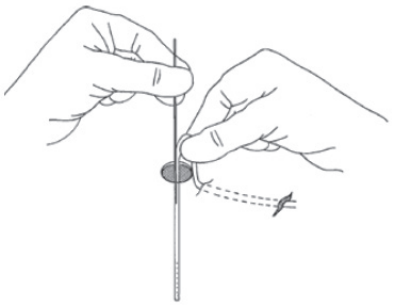

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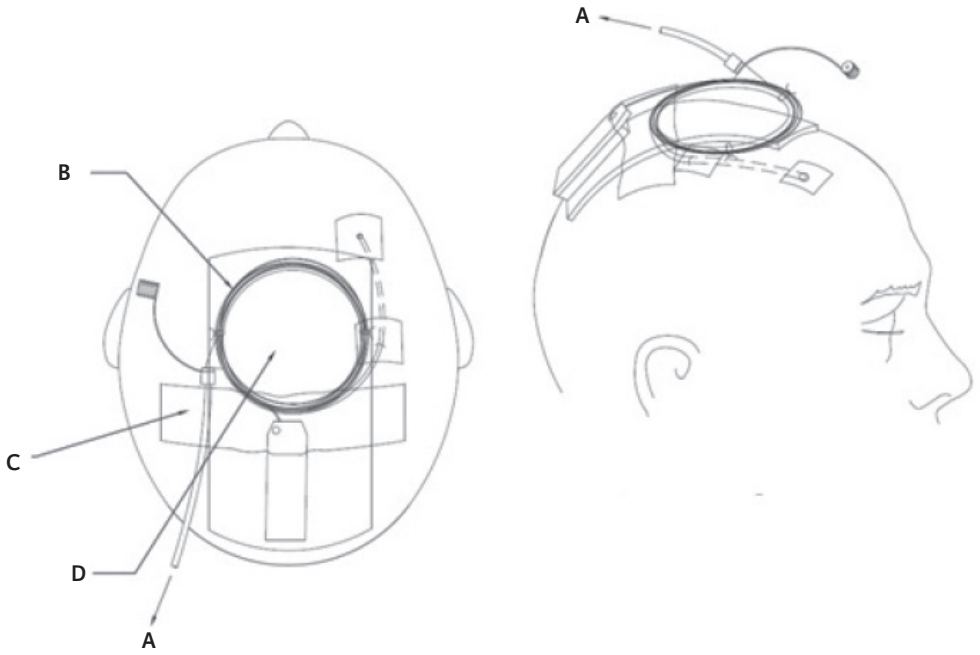

EN – ENGLISH
A. To Drain System
B. 6 cm Loops
C. Tape
D. Gauze

FR – FRANÇAIS
A. Vers le système de drainage
B. Boucles de 6 cm
C. Ruban adhésif
D. Gaze

DE – DEUTSCH
A. Zum Drainagesystem
B. 6-cm-Schlaufen
C. Klebeband
D. Gaze

IT – ITALIANO
A. Sistema di drenaggio
B. Avvolgimento da 6 cm di diametro
C. Nastro
D. Garza

ES – ESPAÑOL
A. Para drenar el sistema
B. Bucles de 6 cm
C. Cinta
D. Gasa

DA – DANSK
A. Til dræning af systemet
B. 6 cm løkker
C. Tape
D. Gaze

FI – SUOMI
A. Dreenijärjestelmään
B. 6 cm:n silmukat
C. Teippi
D. Sideharso

JA – 日本語
A. ドレーンシステムへ
B. 6 cmループ
C. テープ
D. ガーゼ

NO – NORSK
A. For å drenere systemet
B. 6 cm sløyfer
C. Teip
D. Gasbind

PT (EU) – PORTUGUÊS
A. Sistema de drenagem
B. Círculos de 6 cm
C. Fita
D. Gaze

RU – Русский
A. В систему слива
B. Петли 6 см
C. Пластырь
D. Марля

ZH-CN – 中文（简体）
A. 至引流系统
B. 6 cm 环
C. 胶带
D. 纱布

SV – SVENSKA
A. Dränera systemet
B. 6 cm öglor
C. Tejp
D. Gasväv

Codman® CereLink™

ICP Sensor

Ventricular Catheter Kit

IMPORTANT INFORMATION
Please Read Before Use

Rx ONLY

Pozicija Nr 6

Description

The Codman® CereLink™ ICP Sensor Ventricular Catheter Kit consists of a 38 cm ventricular catheter with an integrated stylet and intracranial pressure (ICP) sensor, a catheter anchoring clip, and a 7-gauge tunneling trocar (see Figure 1).

The Codman CereLink ICP Sensor (ICP Sensor) is a nylon tube with a microminiature strain gauge pressure transducer (sensing element) mounted at one end and an electrical connector at the other end. It is designed for use with a Codman intracranial pressure monitoring device.

Indications

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.

Contraindications

Ventriculostomy is contraindicated in patients with coagulopathy, or active infection in the area of the catheter. Use of the Ventricular Catheter 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.

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.

Precautions

Inspect the sterile package carefully. Do not use if:

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

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

Do not hit the ICP Sensor tip with the stylet. Damage could result.

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

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

Exposure to electrostatic discharge (ESD) energy could damage this ICP Sensor. High levels of ESD could damage the electronic components and cause the ICP Sensor 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 ICP Sensor's electrical connector pins, which are identified with the ESD symbol. (Refer to Electrostatic Discharge (ESD) Information section).

Silicone is highly electrostatic and, as a result, attracts airborne particles and surface contaminants that could produce tissue reaction. Use 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.

Take care when tying sutures around the ICP Sensor. Tying sutures too tightly can collapse the wall of the ICP Sensor tubing, causing damage to internal wires.

The ICP Sensor must be zeroed at atmospheric pressure prior to implantation.

The ICP Sensor tip must remain wet during the zeroing process.

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

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

Do not forcibly pull or jerk the ICP Sensor.

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

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

Adverse Events

The following Adverse Events may occur with the use of the ICP Sensor:

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

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

MRI Information

MR

MR Conditional

Read and understand this document in its entirety prior to performing a Magnetic Resonance Imaging Procedure on a patient with an implanted ICP Sensor. Failure to adhere to the Conditions for Safe Use may result in serious injury to the patient.

The **ICP Sensor Ventricular Catheter** is MR Conditional.

MRI SAFETY INFORMATION:
Non-clinical testing has demonstrated that the ICP Sensor Ventricular Catheter is MR Conditional. A patient implanted with this ICP Sensor can be safely scanned in an MR system which meets or is operated under the following conditions:

- Static magnetic field of 1.5 T and 3 T 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
- MRI scan duration shall not exceed 15 minutes of continuous scanning
- Special positioning of the ICP Sensor 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 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 ICP Sensor 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 ICP Sensor.

Preparation for the MRI Procedure:

1. Immediately prior to entering the MRI suite, verify that the ICP Sensor is functioning properly. DO NOT perform an MRI procedure if the ICP Sensor is damaged or otherwise not functioning properly.
2. Disconnect all cables and patient monitoring devices attached to the ICP Sensor prior to transporting the patient into the MRI suite. DO NOT bring the monitors, cables or other accessories into the MRI suite.
3. Special positioning of the ICP Sensor is required to ensure patient safety during the MRI procedure. The ICP Sensor must be placed in a specific geometry to minimize the potential for excessive heating of the ICP Sensor tip. Coil the tubing of the 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 Figure 7). Do not perform MRI with the 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 ICP Sensor 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 ICP Sensor.
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 manufacturers published value and location of the peak SG that is accessible to the patient.
    b. Maximum gradient field slew rate of 200 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.

Electrostatic Discharge (ESD) Information

CAUTION: Exposure to electrostatic discharge (ESD) energy could damage this ICP Sensor. High levels of ESD could damage the electronic components and cause the ICP Sensor 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, the damage that can be done to electronic components if touched by a user who is electrostatically charged, and precautionary measures.

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

How Supplied
This ICP Sensor 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 contaminates such as those causing 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 ICP Sensor, the disposable ICP handle, and the silicone tubing used for packaging, which are not tested.

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

1. Connect the ICP Sensor to the ICP monitor using an appropriate Codman Extension Cable. Refer to instructions for use provided with the Extension Cable for sterilization information.
2. If applicable, connect the ICP monitor to an available pressure channel on an external patient bedside monitor using a Patient Monitor Interface Cable. CAUTION: Use Codman Patient Monitor Interface Cables only with the patient bedside monitors for which they are specifically designed and designated.
3. If applicable, zero and calibrate the external patient bedside monitor according to the instructions provided with the ICP monitor, as well as the external patient bedside monitor manufacturer's instructions.

4. Prepare to zero the ICP Sensor by laying the tip of the ICP Sensor 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 ICP Sensor horizontally just under the surface of the sterile water or sterile saline.
   CAUTION: Do not submerge the tip of the ICP Sensor vertically in a deep pool or cup of sterile water or sterile saline. Doing so will impose a hydrostatic pressure on the ICP Sensor diaphragm that is higher than atmospheric pressure, resulting in an inaccurate zero reference.
5. While keeping the tip of the ICP Sensor flat and still in the sterile water or sterile saline, zero the ICP Sensor according to the instructions provided with the ICP Monitor.

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

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 ICP Sensor. Refer to Connecting and Zeroing the ICP Sensor.
2. Perform craniotomy and retraction procedures required to expose the skull. Drill a 5.8 mm hole through the outer table of the skull.
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. Insert the tip of the catheter into the end of the clear tubing of the tunneling trocar until the tubing is filled (see Figure 2).
6. Use the tunneling trocar to tunnel the ventricular catheter under the scalp to the craniotomy site. The point of entry can be any convenient location at least 3 cm from the burr hole (see Figure 3). Due to the rigidity of the integrated stylet, it is advisable to limit tunneling to 7 cm in order to have sufficient catheter length for insertion into the ventricle.
7. Continue to advance the trocar until the trocar and the clear tubing exit the scalp at the burr hole. Remove the tunneling trocar and tubing from the catheter.
8. Pull the tunneled catheter toward the craniotomy site until the Y-connector almost touches the initial tunneling entrance. This will provide adequate catheter length for insertion.
9. Holding the catheter at a right angle to the skull, advance the catheter into the lateral ventricle to the desired depth (see Figure 4).
10. To verify ventricular placement, observe CSF flowing through the catheter.
11. Holding the catheter (see Figure 5A), bend the catheter to the side opposite the two black arrows to expose approximately 3 cm of the catheter stylet (see Figure 5B). The black arrows indicate the portion of the catheter that has been slit for stylet removal.
12. Holding the catheter firmly in place, gently withdraw the stylet (see Figure 6).
13. Remove any excess catheter from the burr hole by gently pulling back on the catheter when it exits the scalp incision.
14. Place the catheter clip over the catheter at the exit site; suture the clip to the scalp. Additional sutures may be placed through the holes in the catheter Y-connector.
15. Close and dress the incision.
16. If desired, attach the drainage port of the ventricular catheter to an appropriate external drainage system such as the Codman EDS 3.

Specifications

Ventricular Catheter Specifications

Catheter outside diameter	3.4 mm maximum
Catheter usable length	38 cm nominal
Catheter material	Silicone

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ICP Sensor Specifications

Note: All performance specifications based on 5 VDC excitation voltage

Sensing element	Strain gauge silicon microchip
Device usable length	100 cm nominal
Sensor material	Nylon, titanium, silicone, epoxy
Sensor tip diameter	1.3 mm maximum
Device 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

PRODUCT INFORMATION DISCLOSURE

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