REF 826851

Codman® CereLink™

ICP Sensor

Metal Skull Bolt Kit

Codman®
SPECIALTY SURGICAL

INTEGRA®

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CereLink™ ICP Sensor Metal Skull Bolt Kit

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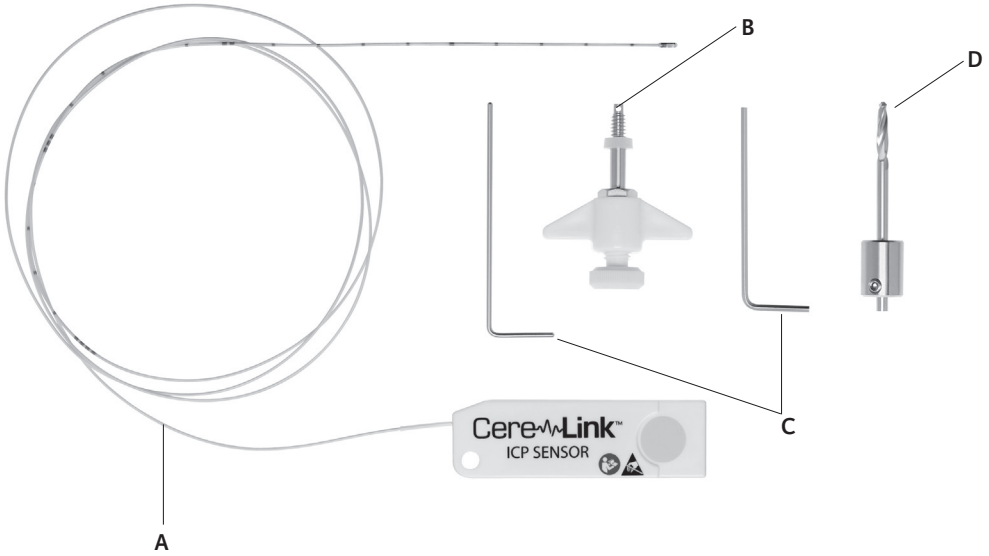


EN – ENGLISH
A. CereLink ICP Sensor
B. Skull Bolt
C. Obturator
D. Drill with depth guide and hex wrench

FR – FRANÇAIS
A. Capteur ICP CereLink
B. Boulon crânien
C. Obturateur
D. Foret avec guide de profondeur et clé hexagonale

DE – DEUTSCH
A. CereLink ICP-Sensor
B. Schädelschraube
C. Obturator
D. Bohrer mit Tiefenführung und Sechskantschlüssel

IT – ITALIANO
A. Sensore ICP CereLink
B. Bullone per cranio
C. Otturatore
D. Trapano con guida di profondità e chiave esagonale

ES – ESPAÑOL
A. Sensor ICP CereLink
B. Perno craneal
C. Obturador
D. Perforador con guía de profundidad y llave hexagonal

DA – DANSK
A. CereLink ICP-sensor
B. Kraniebolt
C. Obturator
D. Bor med dybdevisning og unbrakonøgle

FI – SUOMI
A. Cerelink ICP-anturi
B. Kalloruuvi
C. Obturaattori
D. Pora, syvyysmittari ja kuusioavain

JA – 日本語
A. CereLink ICPセンサー
B. 頭蓋骨用ボルト
C. オブチュレータ
D. 深さガイドと六角レンチ付きのドリル

NO – NORSK
A. CereLink ICP-sensor
B. Skallebolt
C. Obturator
D. Bor med dybdeveiledning og sekskantnøkkel

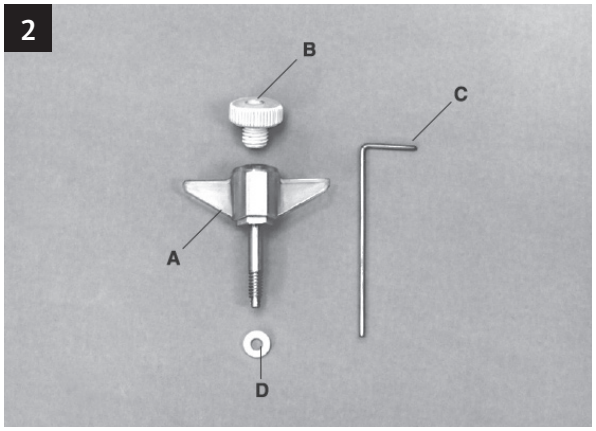
PT (EU) – PORTUGUÊS
A. Sensor de ICP CereLink
B. Parafuso craniano
C. Obturador
D. Broca com guia de profundidade e chave sextavada

RU – Русский
A. Датчик ВЧД CereLink
B. Болт для черепа
C. Обтуратор
D. Трепан с ограничителем глубины и шестигранным ключом

ZH-CN – 中文（简体）
A. CereLink ICP 传感器
B. 颅骨螺栓
C. 充填器
D. 配有测深尺和六角扳手的颅骨钻

SV – SVENSKA
A. CereLink ICP-sensor
B. Skallbult
C. Obturator
D. Borra med djupguide och insexnyckel

2



EN – ENGLISH
A. Skull Bolt
B. Compression Cap
C. Obturator
D. Washer

FR – FRANÇAIS
A. Boulon crânien
B. Capuchon de compression
C. Obturateur
D. Laveuse

DE – DEUTSCH
A. Schädelschraube
B. Kompressionskappe
C. Obturator
D. Unterlegscheibe

IT – ITALIANO
A. Bullone per cranio
B. Cappuccio di compressione
C. Otturatore
D. Rondella

ES – ESPAÑOL
A. Perno craneal
B. Tapa de compresión
C. Obturador
D. Arandela

DA – DANSK
A. Kraniebolt
B. Kompressionsdæksel
C. Obturator
D. Afstandsskive

FI – SUOMI
A. Kalloruuvi
B. Kompressiokorkki
C. Obturaattori
D. Aluslevy

JA – 日本語
A. 頭蓋骨用ボルト
B. 圧縮キャップ
C. オブチュレータ
D. ワッシャ

NO – NORSK
A. Skallebolt
B. Kompresjonshette
C. Obturator
D. Trykkskive

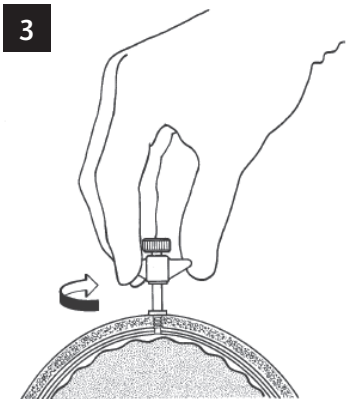
PT (EU) – PORTUGUÊS
A. Parafuso craniano
B. Tampa de compressão
C. Obturador
D. Anilha

RU – Русский
A. Болт для черепа
B. Компрессионный колпачок
C. Обтуратор
D. Шайба

ZH-CN – 中文 (简体)
A. 颅骨螺栓
B. 压缩盖
C. 充填器
D. 垫圈

SV – SVENSKA
A. Skallbult
B. Kompressionshatt
C. Obturator
D. BRICKA

3



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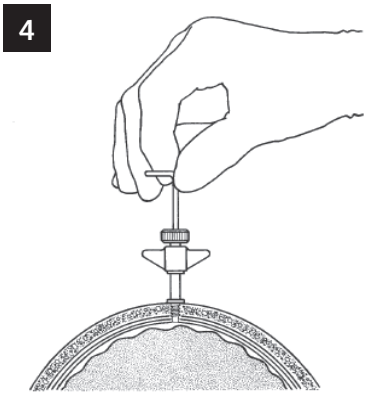

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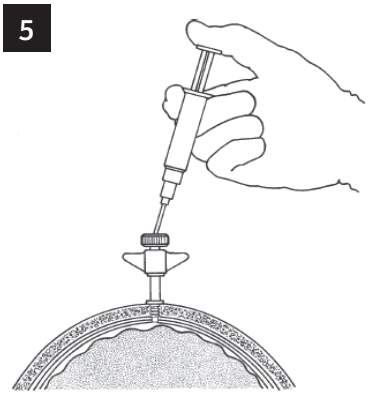

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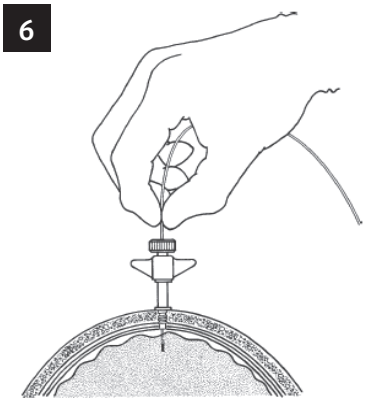

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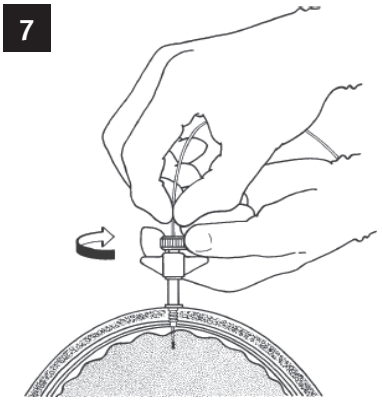

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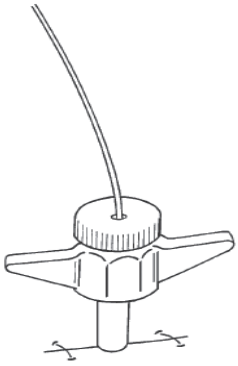

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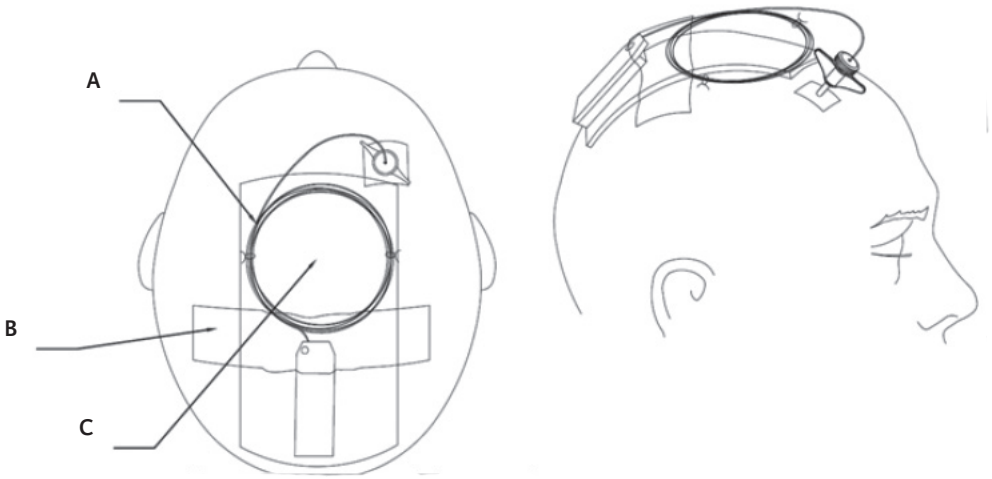

EN – ENGLISH
A. 6cm Loops
B. Tape
C. Dry Gauze Pad
Image Not to Scale

FR – FRANÇAIS
A. Boucles de 6cm
B. Ruban adhésif
C. Tampons de gaze sèche
Image non à l'échelle

DE – DEUTSCH
A. 6-cm-Schlaufen
B. Klebeband
C. Trockene Gazeauflage
Bild nicht maßstabsgerecht

IT – ITALIANO
A. Avvolgimento da 6 cm di diametro
B. Nastro
C. Compressa di garza asciutta
Immagine non in scala

ES – ESPAÑOL
A. Bucles de 6 cm
B. Cinta
C. Almohadilla de gasa seca
Imagen no a escala

DA – DANSK
A. 6 cm løkker
B. Tape
C. Tør gazepude
Billedet kan ikke skaleres

FI – SUOMI
A. 6cm:n silmukat
B. Teippi
C. Kuiva sideharso
Kuva ei mittakaavassa

JA – 日本語
A. 6cmループ
B. テープ
C. ドライガーゼパッド
図は正確な寸法ではありません

NO – NORSK
A. 6 cm sløyfer
B. Tape
C. Tørr gasbindpute
Bildet avviker fra ekte størrelse

PT (EU) – PORTUGUÊS
A. Círculos de 6 cm
B. Fita
C. Compressa de gaze seca
A imagem não se encontra à escala real

RU – Русский
A. Петли 6 см
B. Пластырь
C. Сухая марлевая салфетка
Изображение не в масштабе

ZH-CN – 中文 (简体)
A. 6cm 环
B. 胶布
C. 干纱布垫
图片非按比例呈现

SV – SVENSKA
A. 6cm öglor
B. Tejp
C. Torr kompress
Bilden ska inte skalas

Codman® CereLink™

ICP Sensor

Metal Skull Bolt Kit

IMPORTANT INFORMATION
Please Read Before Use

Pozicija Nr 5

Rx ONLY

Description

The Codman® CereLink™ ICP Sensor Metal Skull Bolt Kit consists of an intracranial pressure (ICP) sensor, skull bolt with integrated compression cap and optional washer, obturator/dura pierce, and drill bit with depth guide and hex wrench (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.

The ICP Sensor Metal Skull Bolt Kit is designed for use with the Codman® Cranial Hand Drill. The drill facilitates access to the intraparenchymal area. The drill and bits are sold separately and are also available as components of the Codman Cranial Access Kit.

The skull bolt is preassembled with a washer for optional use in adjusting the depth of the bolt and a compression cap for securing the ICP Sensor in place. An obturator/dura pierce is also provided for clearing the passage for the ICP Sensor and piercing the dura (see Figure 2).

Indications

Use of the ICP Sensor Metal Skull Bolt 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

Use of the skull bolt is contraindicated in children less than one year of age.

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.

Installation of the skull bolt must be performed with the bolt held within 10 degrees of the perpendicular to the incision site. Installing at an angle can result in fracture of the device or in an inadequate seal between the washer and the skull.

Excessive torque applied to the skull bolt during insertion can cause breakage.

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 bolt insertion and ICP Sensor 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 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).

Bolt fit can be compromised if used with drills other than those provided in this kit or the Codman Cranial Access Kit.

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. Excessive force can result in fracture of the ICP Sensor or unintended withdrawal from the skull bolt.

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 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 and Metal Skull Bolt are MR Conditional.

MRI SAFETY INFORMATION:

Non-clinical testing has demonstrated that the ICP Sensor and Metal Skull Bolt are MR Conditional. A patient implanted with these devices 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 and 25 mm relative to the size and shape of the Metal Skull Bolt.

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 bedside monitoring devices attached to the ICP Sensor prior to transporting the patient into the MRI suite. DO NOT bring the ICP monitor, 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 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 9). 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 9). 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, prior to 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 hex wrench, the dura pierce, the bolt assembly, and the silicone tubing used for packaging, which have not been 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.

Installing the Skull Bolt

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. Using the provided 2.7 mm drill bit, drill a 2.7 mm hole through the outer table of the skull. **CAUTION: Bolt fit can be compromised if used with other drills.**
3. Open the dura with a sharp instrument, such as an 18-gauge spinal needle, or similar.
4. If desired, adjust the seating depth of the bolt using the washer provided.
5. Condition the compression cap and sensor locking mechanism before installation of the bolt. First, hand-tighten the compression cap by turning it clockwise. Then loosen the cap by turning it counterclockwise the same or a lesser amount.
6. Put the skull bolt in position and screw manually in a clockwise direction until properly seated (see Figure 3). **CAUTION: Do not loosen the cap during installation of the bolt. WARNING: Excessive torque applied to the skull bolt during insertion can cause breakage. Installation of the skull bolt must be performed with the bolt held within 10° of perpendicular to the incision site. Installing at an angle may result in fracture of the ICP Sensor.**
7. Use the obturator/dura pierce to clear the pathway through the bolt and to further open the dura (see Figure 4). **CAUTION: Do not plunge the obturator. Carefully push the obturator until the dura has been pierced.**
8. Irrigate the channel with non-bacteriostatic sterile saline (see Figure 5).
9. Guide the ICP Sensor through the bolt until the ICP Sensor tip is in the subdural or parenchymal space (see Figure 6).
10. Turn the compression cap firmly in a clockwise direction to secure the ICP Sensor (see Figure 7). **WARNING: If the skull bolt compression cap is not initially tightened properly, ICP Sensor movement and/or leakage can occur. If during the implantation period the patient is moved or becomes active, check the security of the ICP Sensor in the skull bolt compression cap and tighten, if necessary.**
11. Remove retractor and close the skin incision in one layer using interrupted sutures (see Figure 8). Apply appropriate dressing to wound site.

Removing the Skull Bolt

1. Loosen the compression cap by turning in a counterclockwise direction.
2. Carefully withdraw the ICP Sensor from the bolt assembly.
3. Manually unscrew the bolt in a counterclockwise direction until the bolt is free. **CAUTION: Make certain that the depth washer, if used, has been removed from the incision area before closing.**
4. Apply pressure with sterile gauze until hemostasis is achieved. Close the incision again in one layer, with uninterrupted sutures. Apply a dry sterile dressing.

Specifications

Pozicija Nr 5

Device 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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