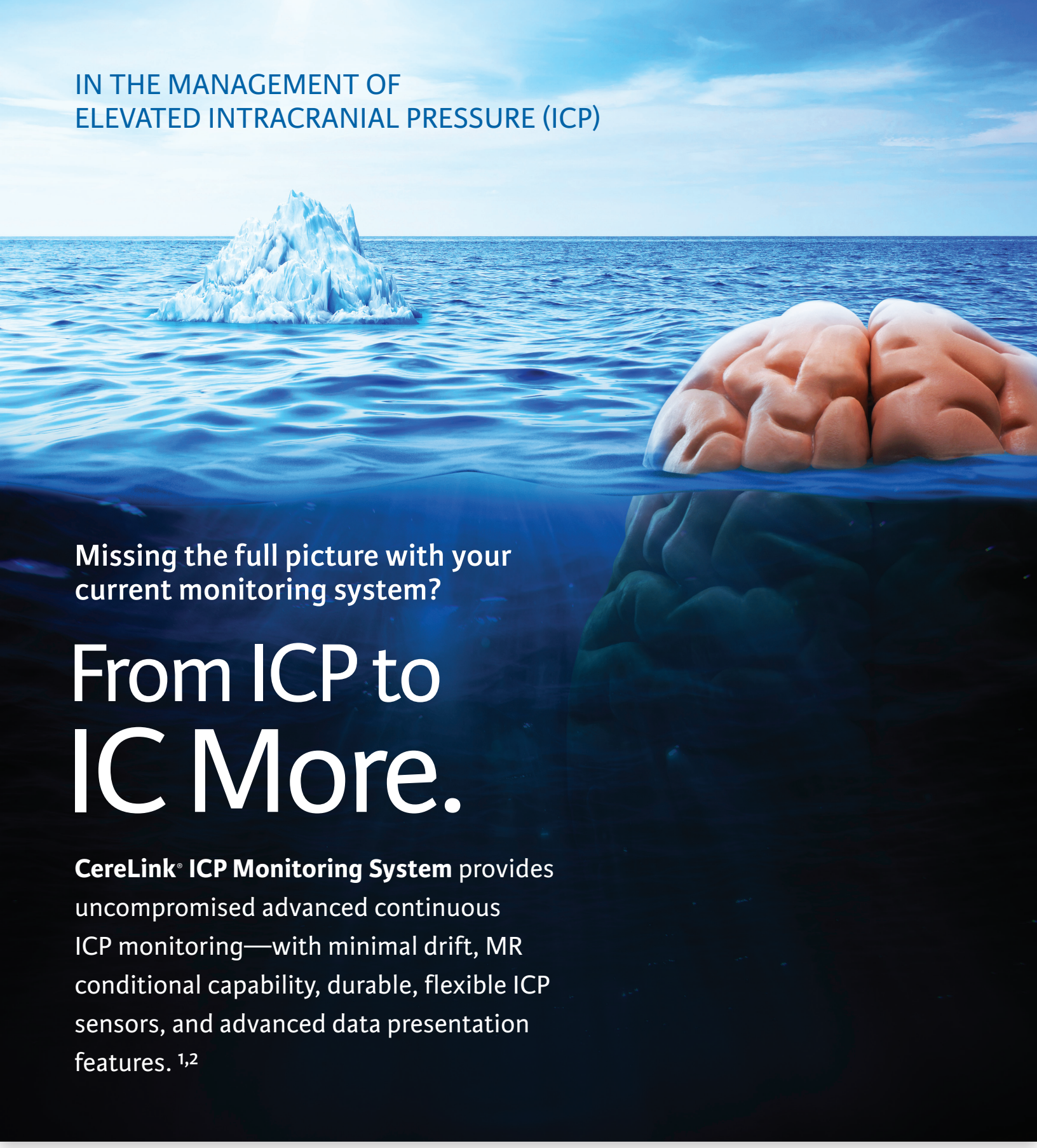
IN THE MANAGEMENT OF
ELEVATED INTRACRANIAL PRESSURE (ICP)



Missing the full picture with your current monitoring system?

From ICP to IC More.

CereLink® ICP Monitoring System provides uncompromised advanced continuous ICP monitoring—with minimal drift, MR conditional capability, durable, flexible ICP sensors, and advanced data presentation features. [1,2]

Codman SPECIALTY SURGICAL

CereLINK®
ICP monitoring system
Discover the Unseen

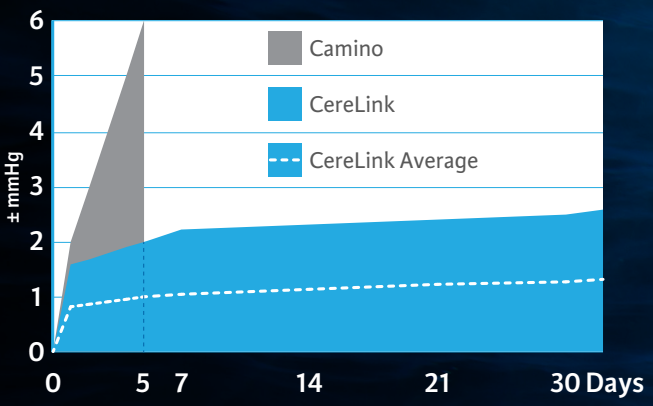
Uncompromised ICP Monitoring.

See More...

More Accuracy
Due To Less Drift [1-3]

The CereLink ICP Monitoring System is more accurate than the leading competitor in terms of less drift over time[1-3]

CereLink vs Camino® Drift Over Time



Camino Data not available after 5 days. Camino average drift not available.

More Protection
MR Conditional Capability

Features 1.5 and 3T MR conditional [2] capability for all sensor configurations

Codman SPECIALTY SURGICAL

A DIVISION OF INTEGRA LIFESCIENCES

CereLINK®

ICP monitoring system

More Choice

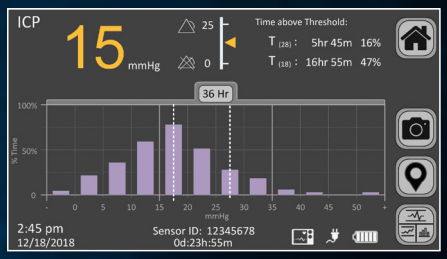
Durable, Flexible ICP Sensors

Sensor flexibility allows for physician choice in implantation and fixation methods with greater durability

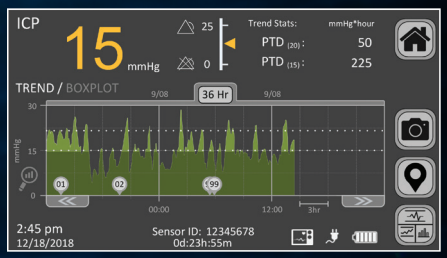
More Information

Advanced Data Presentation

Time Above Threshold and Histograms



Pressure Time Dosage



CereLINK®

ICP monitoring system

Discover the Unseen

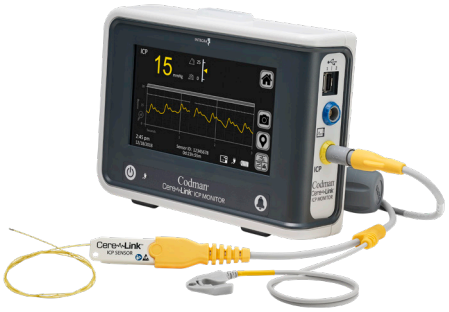
From ICP to IC More.

CereLink® ICP Monitoring System provides:

- The CereLink ICP Monitoring System is more accurate than the leading competitor in terms of less drift over time[1-3]
- MR conditional capability[2]
- Durable, flexible ICP sensors
- Advanced data presentation features

Ordering Information

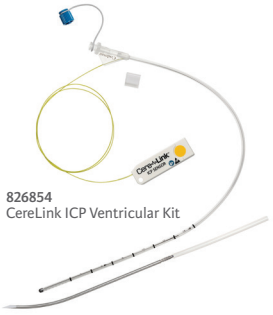
	SKU	Description
Box	826820	CereLink ICP Monitor
	826845	CereLink ICP Extension Cable
CereLink ICP Sensors	826850	CereLink ICP Sensor Basic Kit
	826851	CereLink ICP Metal Bolt Kit
	826852	CereLink ICP Plastic Bolt Kit
	826854	CereLink ICP Ventricular Kit
Patient Monitor Cables	826880	DRAGER / SIEMENS Infinity®
	826881	PHILIPS Intellivue
	826882	GE Dash™
	826883	SPACELABS 6-pin
	826884	GE Datex™ Ohmeda™
	826887	NIHON KODEN 5-pin
	826889	FUKUDA DENSHI DS-7000
Accessories	826822	CereLink ICP Monitor Replacement Power Supply
	826824	CereLink ICP Monitor Replacement Battery
	EXPORTCAB	CereLink USB to RS232 Adapter



826820
CereLink ICP Monitor

826850
CereLink ICP Sensor Basic Kit

826851
CereLink ICP Metal Bolt Kit



826854
CereLink ICP Ventricular Kit

See more at
www.nocompromiseICP.com

Scan me

References: 1. CereLink bench test shows (2 stdev) of ±2.2 mmHg over 7 days and 3.8mmHg (4 stdev) over 7 days. 2. CereLink system IFUs 3. Camino System IFU (A40256 Rev H)

Consult the Instructions for Use for complete indications, warnings and precautions.

826820 Indications for Use • The ICP Monitor is intended for use as an interface between compatible strain gauge type pressure transducers and standard physiological pressure monitoring systems. The ICP Monitor is also intended for use as an independent pressure monitor for displaying the mean, systolic and diastolic values of a physiologic pressure waveform in the absence of an external patient monitor. **Contraindications** • The ICP Monitor is contraindicated for use in a Magnetic Resonance (MR) environment. Refer to the ICP Sensor IFU for MR environment use. **WARNINGS** • Read the entire instruction manual before attempting to operate the ICP Monitor. • Always zero the ICP Sensor prior to implantation. Never attempt to re-zero a sensor while implanted inside the patient. • Always verify physiological alarm limits are set appropriately for each patient prior to treatment. The physiological alarm can be disabled by manually turning it off or by selecting extreme limits. • Use of the ICP Monitor is restricted to one patient at a time. • Maintain strict sterile technique when connecting the ICP Sensor to the ICP Extension Cable. The ICP Extension Cable can be sterilized before use if desired, and has been tested to withstand 100 autoclave cycles. Cable performance beyond 100 autoclave cycles has not been evaluated. Refer to the ICP Sensor IFU and to the ICP Extension Cable IFU for more information. • Do not cover the ICP Monitor's vents because it will increase internal temperature and cause overheating and possible device failure. • Keep device away from fluid sources. • Modification or disassembly of the ICP Monitor (including power supply, cables and sensors) is not permitted. Unauthorized modifications to the ICP Monitor can cause a malfunction resulting in serious patient injury, damage to internal circuitry or electric shock. • Explosion Hazard: Do not use in the presence of flammable materials (e.g., anesthetics, solvents, cleaning agents and endogenous gases). • Electrical Shock Hazard: • Use only Codman approved power supplies listed in Recommended Accessories and Reordering Information section. Use of another power supply may not provide electrical isolation from supply mains and protection against electrical hazards. • Do not remove side, front or rear panels. Contact Technical Support for service and repair. • The ICP Monitor contains a lithium ion battery: • Do not open the battery compartment or attempt to replace the battery while monitoring a patient or while the device is connected to the AC Power Supply. • Use in extreme conditions (e.g., extreme temperature, high humidity, deep discharge) may decrease battery performance. • Do not puncture the battery. • Do not dispose of in fire. • Do not short circuit battery contacts as battery may get hot, leak, ignite or explode. • Use only Codman approved batteries listed in Recommended Accessories and Reordering Information section. Use of another battery may present a risk of fire or explosion. • The device may become warm during normal operation and surface temperatures may reach up to 50°C. Avoid prolonged skin contact with the device (less than 5 minutes) to reduce heat-related concerns. The device complies with user-accessible surface temperature limits defined by the International Standards for Safety (IEC 60601-1). **Precautions** • When using the CereLink ICP Monitor, always handle with care. • Routinely inspect all electrical plugs and connections; do not use if damaged. • Use only Codman approved accessories with the ICP Monitor, including Extension Cable, Interface Cables, ICP Sensors, Power Supply and Battery, listed in the Recommended Accessories and Reordering Information section. • To prevent injury to the patient, user or other persons, make sure that the battery cover is closed securely during use of the ICP Monitor. • When clamping the ICP Monitor to the IV pole, always verify that it is secure to prevent injury to the patient, user, or other persons, or damage to the ICP Monitor. • Ensure the CereLink Power Supply is grounded (See Figure 14 in Initial Setup): • Use only the CereLink Power Supply, which provides three or more electrical pins/contacts depending on the geographical region. • Connect the CereLink to only "hospital grade" or "hospital only" receptacles. • Do not attempt to bypass the grounding contact on the CereLink Power Supply by using an adapter. • NOTE: Failure to properly connect the CereLink ICP Monitor to a grounded power supply can affect the accuracy and performance of the pressure readings. • Ensure patient monitor is connected to a properly grounded power supply. • The connectors for both the Interface Cable and the Extension Cable must be properly aligned with the receptacles on the ICP Monitor before pushing these parts together. DO NOT twist the connectors. Twisting the connector in this manner will damage the pins and can lead to product malfunction. • The Patient Lead of the Extension Cable MUST always be attached to the patient via an ECG electrode to ensure reliable performance of the sensor. • When cables or cords cross paths, contact each other, or are tangled together, interfering electrical signals may transfer into the CereLink ICP Monitor and affect the pressure sensor reading. • To avoid this, any excess cables or cords connected to the CereLink ICP Monitor should be coiled and secured. • The power cord should be disconnected from the CereLink ICP Monitor during patient transport. • The cable that connects to the patient monitor should not be connected to the CereLink ICP Monitor when a patient monitor is not being used. • If your power cord comes in two pieces, the piece of the power cord that connects to the wall outlet should NOT be coiled together with the piece of the power cord that connects to the CereLink ICP Monitor. • The signal processing algorithms used to detect and display physiological pressure data may vary among patient bedside monitors of different make and model. Therefore, pressure data displayed by the ICP Monitor may not always be consistent with the data displayed on an externally connected patient bedside monitor. Refer to the patient bedside monitor manufacturer's instruction manual for specific details regarding signal processing, calibration and accuracy. • The ICP Sensor must be zeroed at atmospheric pressure prior to implantation. • This device should be used in environments that meet the electromagnetic environment – guidance in Appendix A of this manual. • Exposure to electrostatic discharge (ESD) energy could damage the ICP Sensor connected to this device. Please refer to the ICP Sensor IFU for more information. • The ICP Sensor is susceptible to damage from defibrillation. The sensor may need to be replaced before ICP monitoring can resume. • Disconnect the ICP Monitor from the ICP Sensor before utilizing any electrosurgery equipment. The use of electrosurgical equipment (e.g., Monopolar, Bipolar, Diathermy) can cause damage to both the ICP Monitor and ICP Sensor if left connected. • Only use the USB port to download or stream data. The only devices that can be connected to the USB port are: • USB memory stick or USB flash drive. • USB to serial adapter (refer to Recommended Accessories section) connected to a computer that is properly grounded. • Always disconnect the ICP Monitor from the power supply before wiping external surfaces. • Do not sterilize the ICP Monitor..

826850, 826851, 826852, 826854 Indications for Use • (826850, 826851, 826852) Use of the CereLink ICP Sensor Basic Kit and CereLink ICP Bolt Kit are indicated when direct intracranial pressure (ICP) monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only. •(826854) 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. Pressure monitoring is required. The kit is indicated for use in ICP monitoring and cerebrospinal fluid (CSF) drainage applications. **Contraindications** • This kit is not designed, sold or intended for use as a therapeutic device (826850-826852 only) • Ventriculostomy is contraindicated in patients with coagulopathy or active infection in the area of the catheter (826854 only) • Use of the Ventricular Catheter Kit is contraindicated in children less than one year of age. • Insertion of the skull bolt is contraindicated in children less than one year of age. (826850-826852 only) **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. • 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 (826851and 826852 only). Excessive torque applied to the skull bolt during insertion can cause breakage. (826851and 826852 only). • Do not remove the thrust washer or the sealing washer that are preassembled on the skull bolt, as this can result in an inadequate seal between the washer and the skull. (826852 only) • This device is designed to break off at the area between the hexagonals if excessive torque is applied. (826852 only) • The lower portion of the screw can still be removed using the screw handle. (826852 only) **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 device 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 device. 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 device'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 ventricularcatheter from coming in contact with towels, drapes, talc, or any other linty or granular surface, as well as airborne particles.(826854 only) • 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. (826854 only)• 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 (826850 826854 only) • Finger-tighten all luer fitting connections on the Tuohy-Borst adapter prior to use. Connections could loosen during shipping and handling. (826852) • Bolt fit can be compromised if used with drills other than those sold by Codman separately or as part of the Codman Cranial Access Kit. (826851 and 826852 only) • 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 CereLink ICP Sensor: • 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.

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.
- Consult product labels and inserts for any indication, contraindications, hazards, warnings, precautions, and instructions for use.

For more information or to place an order, please contact:

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