

When Simplicity and Accuracy Matter

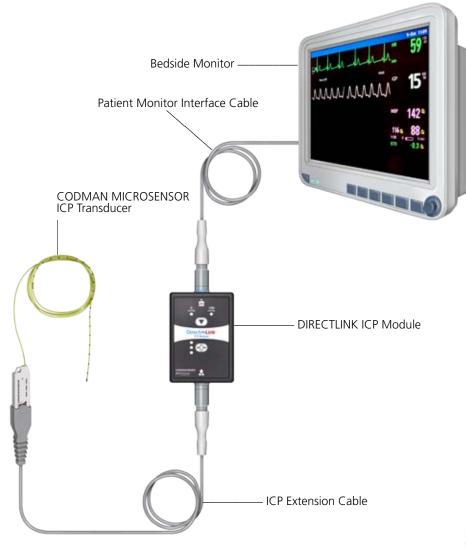
DIRECTLINK[™] ICP Module and CODMAN MICROSENSOR[®] ICP Transducer

> CODMAN MICROSENSOR[®] ICP Transducer is MR Conditional at 1.5T and 3T



DirectmLink

Direct-MLink ICP Module



The DIRECTLINK[™] ICP Module is an easy to use, cost-effective solution to monitor Intracranial Pressure (ICP) without the need for a stand-alone ICP monitor.

Features Include:

- Ability to connect and calibrate an ICP sensor directly to a patient bedside monitor to display a patient's ICP value.
- Enable ICP data to be stored in an Electronic Medical Record (EMR) system.
- Allows for the patient to be disconnected and reconnected to the patient bedside monitor during routine clinical care events such as transport for imaging.

Easy to Use

- The simple to use two button interface offers quick equipment setup for monitoring ICP.
- Single button zeroing of the patient monitor and ICP transducer.
- Allows the CODMAN MICROSENSOR ICP Transducer to interface with a variety of patient monitors, enabling movement of patients throughout the hospital.

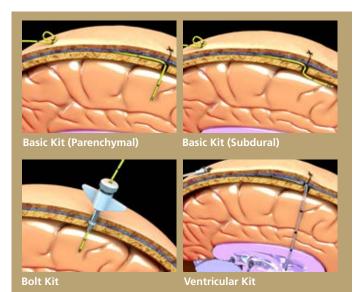
Compact and Durable

- Measuring approximately 2.5" X
 3.5" X 1" (6.4 cm X 8.9 cm X 2.5 cm) and weighing under 3.5 oz (100 g), the DIRECTLINK ICP Module is lightweight and easy to transport.
- Little to no maintenance costs as a result of no internal battery or moving parts.



Direct Pressure Monitoring at the Source in Multiple Procedural Kit Configurations

The CODMAN MICROSENSOR ICP Transducer consists of a miniature strain gauge pressure sensor mounted in a titanium case at the tip of a 100 cm 3F flexible nylon tube. The CODMAN MICROSENSOR ICP Transducer monitors intracranial pressure directly at the source – parenchymal, subdural, or intraventricular.



Small, Flexible and Low-Profile

The small size and flexibility allows for low-profile tunneling under the scalp and kinking of the transducer without breakage or monitoring interruption.

MR conditional

The CODMAN MICROSENSOR ICP Transducer is MRI conditional and may be imaged in the MR environment when used in accordance with the manufacturer's instructions for use.¹

Critically ill neurosurgical patients may benefit from the additional information gained through MR imaging for planning therapy and predicting outcomes.²

Elimination of Maintenance Requirements Associated with Fluid Coupled Systems

The CODMAN MICROSENSOR ICP Transducer eliminates the need for constant alignment of the transducer to the patient's head and periodic re-zeroing. False readings associated with obstructions, air bubbles or movement of the patient fluid lines are no longer a concern.

Minimal Drift and Accuracy

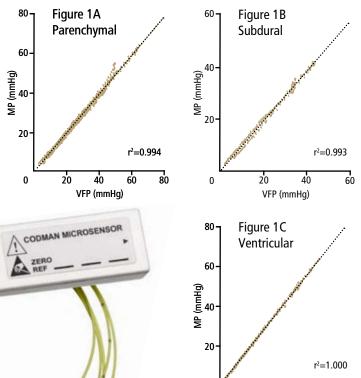
Studies performed on the CODMAN MICROSENSOR ICP Transducer^{3,4,5} demonstrate a high degree of accuracy and stability in ICP monitoring.

One study showed a mean drift of 0.9 mm Hg over an average 7.2 days of monitoring, with 25 percent of the sensors exhibiting no drift during the entire monitoring period³.

| TIME (Days) | DRIFT (Mean) |
|-------------|---------------|
| 7.2 ±.04 | 0.9 ±0.2 mmHg |

Figure 1:

Comparison of CODMAN MICROSENSOR ICP Transducer versus standard ventricular pressure as measured with an external fluid transducer (a) parenchymal, (b) subdural space and (c) ventricular fluid pressure.



0 20 40 60 80 VFP (mmHg)

ORDERING INFORMATION

| DIRECTLINK ICP System | | CODMAN MICROSENSOR ICP Transducer | |
|-----------------------|---|-----------------------------------|---|
| Part No. | Description | Part No. | Description |
| 826828 | DIRECTLINK ICP Module (includes ICP Extension Cable) | 626631US | CODMAN MICROSENSOR Basic Kit |
| 826840 | Replacement ICP Extension Cable | 626638US | CODMAN MICROSENSOR Metal Bolt Kit |
| DIRECTLII Part No. | NK Patient Monitor Interface Cables Description | 626632US | CODMAN MICROSENSOR Plastic Bolt Kit |
| 826880 826881 | Dräger [™] / Siemens INFINITY [™] 10 pin input Philips Intellivue [™] / HP Merlin [™] 12 pin input | 626653US | CODMAN MICROSENSOR Ventricular Catheter Kit |
| 826882 | GE / Marquette™ 11 pin input | 626633US | CODMAN MICROSENSOR Ventricular Catheter Kit with Tuohy-Borst Adaptor |

References

- 1. CODMAN MICROSENSOR Instructions for Use, 2015.
- 2. Heidenreich JO, Stendel R, Brock M, Wolf KJ, Schilling AM. Evaluation of MR imaging compatibility of a new intracranial pressure monitoring device. AJNR Am J Neuroradiol. 2005;26(2):360-2.
- Koskinen L, Olivecrona M: Clinical Experience with the Intraparenchymal Intracranial Pressure Monitoring Codman Microsensor System. Neurosurgery 56: 693-698, 2005.
 Gopinath S, Robertson C, Contant C, Narayan R, Grossman R: Clinical Evaluation of a Miniature Strain-Gauge Transducer for Monitoring Intracranial Pressure. Neurosurgery 36: 1137-1141, 1995.
- 5. Marmarou A, Tsuji O, Dunbar JG: Experimental Evaluation of a New Solid State ICP Monitor. Intracranial Pressure IX: 15-17, 1994.

Products may be manufactured at one of the following:

Codman & Shurtleff, Inc. 325 Paramount Drive Raynham, MA 02767-0350 USA www.depuysynthes.com

Medos International SÀRL

Chemin-Blanc 38 CH-2400 Le Locle Switzerland

CODMAN NEURO

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Indications

The intended use of the DIRECTLINK ICP Module is to enable the connection of Codman intracranial pressure sensors to an available invasive blood pressure input channel on select commercially available third party patient bedside monitor systems.

Use of the CODMAN MICROSENSOR Basic Kit and CODMAN MICROSENSOR Skull Bolt 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.

Use of the CODMAN MICROSENSOR Catheter Kit is indicated when direct intracranial pressure (ICP) monitoring is required. The kit is indicated for use in intraventricular pressure monitoring and cerebral spinal fluid (CSF) drainage applications.

See Instructions for Use for complete product information and specific MRI Safety Information.

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