Innovation Spotlight: Codman Microsensor® ICP Transducer

TRAUMATIC BRAIN INJURY (TBI)

Intracranial pressure (ICP) monitoring has become a valuable tool in managing traumatic brain injury (TBI), cerebral edema and subarachnoid hemorrhage. When ICP monitoring was first introduced in the 1960s, it was considered a controversial approach as complication risks were unknown. Between 1995 and 2005, the use of ICP monitoring in the management of TBI more than doubled in the U.S.[1] In 2007, the Brain Trauma Foundation updated its guidelines to recommend ICP monitoring in severe TBI patients with a Glasgow Coma Score between 3 and 8 after resuscitation to reduce in-hospital and 2-week post-injury mortality.[2]

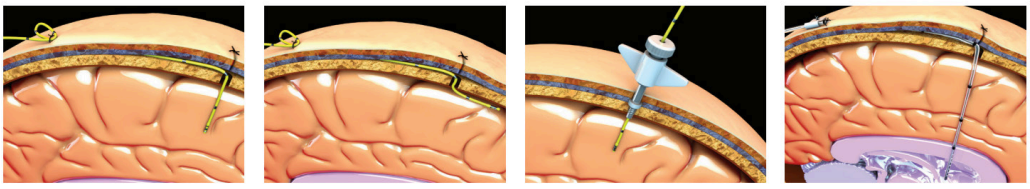
According to the CDC, an estimated 1.5 million Americans sustain a TBI every year.[3] The major causes of TBI are motor vehicle crashes, violence, falls and sports related injuries. The sooner a patient gets medical attention for the TBI, the more quickly they can be stabilized to prevent further injury.

CODMAN MICROSENSOR® ICP TRANSDUCER

Codman, now part of Integra LifeSciences - a world leader in medical technology with an innovative portfolio of surgical instruments, neurosurgical products and advanced wound care products, reached out to Millar in 1990 to develop a better method for measuring intracranial pressure (ICP) in patients with traumatic brain injury (TBI).

In 1994, after more than 3 years of feasibility studies, prototyping and research and development, Codman launched the Microsensor® ICP Transducer. The Microsensor is now a part of the Codman CereLink™ System which provides uncompromised advanced continuous ICP monitoring with MR conditional capability, durable, flexible ICP sensors, and advanced data presentation features and minimal drift.[5]

Millar's patented strain-gauge technology in the Codman Microsensor® ICP Transducer gives medical practitioners the precise, reliable information they need to intervene quickly and relieve brain-damaging pressure. The Microsensor consists of a MEMS pressure sensor that is mounted in a sensor housing at the tip of a 100cm 3F flexible nylon catheter and has the ability to measure intracranial pressure directly at the source – parenchymal, subdural, or intraventricular. Additionally, with the MR conditional capability, patients can be safely scanned in 1.5T and 3T MR environments, with the ICP sensor implanted, for all sensor configurations when following the MRI conditions as listed in the IFU.



Basic Kit (Parenchymal) | Basic Kit (Subdural) | Bolt Kit | Ventricular Kit

Source image from Codman Microsensor Brochure[6]

The partnership between Millar and Codman was essential in determining optimal sensor integration possibilities. Throughout the years, there have been some major milestones in the relationship, including:

- The development of Millar's 4-pin connector sensor, created for the Codman Microsensor® ICP Transducer and still in use today.
- The addition of markings to the catheter body, acting as a ruler for the doctor to understand sensor placement.
- Updated catheters to be in line with new RoHS Compliance.
- Revised coloring of the catheter tubing to yellow, versus white, allowing for potentially better visibility during procedures.
- The addition of a memory board in the connector lid of the Microsensor® ICP Transducer as part of the CereLink™ System. This update allows a Microsensor to be seamlessly moved between monitors without requiring recalibration as a patient is moved, potentially saving time and reducing the potential for errors.

Contact us to learn more about the Millar OEM Advantage:
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MEMS PIEZO-RESISTIVE VS. OTHER SENSORS

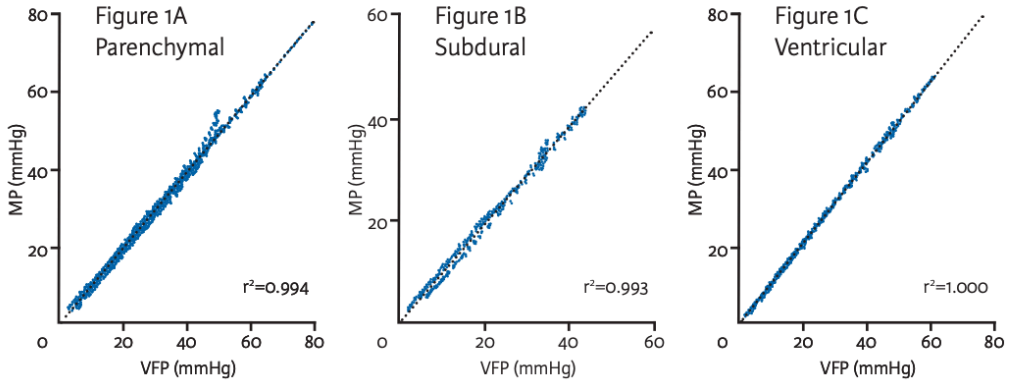
When choosing the appropriate sensor for the Codman Microsensor® ICP Transducer – there were three options to consider: Fluid-filled, Fiber Optic or MEMS piezo-resistive. Each sensor technology presented different trade-offs that were necessary to understand, high frequency response and accuracy during movement being key requirements. Additionally, the design of the catheter body needed to allow the physician the flexibility to choose implantation and fixation methods with greater durability, including tunneling, bolting and ventricular placement.

While fiber optic catheters offered an improvement over traditional fluid-filled pressure measurement, these devices did not meet the customers bending requirements to take readings at the cranial site. The small size and flexibility of the Millar MEMS piezo-resistive pressure sensor in the Codman Microsensor® ICP Transducer allows for low-profile tunneling under the scalp and kinking of the transducer with resistance to breakage and monitoring interruption. The Codman Microsensor® ICP Transducer eliminates the need for constant alignment of the transducer to the patient's head and periodic re-zeroing. As such, false readings associated with obstructions or movement of the patient fluid lines are no longer a concern.

	MEMS	Fiber Optics	Fluid-Filled
High frequency response	YES	YES	NO
Measures pressure at source	YES	YES	NO
Robust design	YES	NO	YES
Accuracy during movement or bend	YES	NO	NO
No overshoot, true signal	YES	YES	NO

RESULTS

A study performed on the Codman Microsensor ICP Transducer showed a mean drift of 0.9mmHg over an average of 7.2 days of monitoring, with 25 percent of the sensors exhibiting no drift during the entire monitoring period.[4]



Source image from Codman Microsensor Brochure[6]

In a study by "The world's northernmost neurosurgeons", Koskinen and Olivercrona evaluated the Codman intraparenchymal ICP monitoring system in 128 patients. They showed that there is almost 0 drift of the sensor during the monitoring period. The study quotes "This strongly enforces the amazing accuracy that the Codman engineers have been able to provide in this instrument".[4]

THE FUTURE OF CODMAN AND MILLAR

With the global market for Intracranial Pressure (ICP) Monitoring Devices projected to grow due to the increasing prevalence of traumatic accidents and neurological disorders across the globe, Millar plans to stay ahead of the curve by continually pushing the limits of medical device understanding and innovation across the ICP market and beyond. One thing that makes Millar unique among contract manufacturers is that we also produce our own products, which ensures that we remain compliant with rapidly changing regulatory rules. With 100% inspection, accuracy and drift testing of each device, Millar has manufactured more than 1.1M units for Codman to date. In 2023, Millar is planning to move into a new 56,000 sq.ft. headquarters facility, providing expanded manufacturing space and room for significant growth opportunity for this partnership.

Many device companies are interested in adding pressure sensing capabilities to their new or next generation devices. As the medical device community's only dedicated pressure sensor integrator, Millar is the natural partner for excellence. Leveraging more than 50 years of manufacturing experience, Millar has led improvements that continue to smooth the development process and improve placement accuracy.

References:

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