



A DIVISION OF INTEGRA LIFESCIENCES

ICP EXPRESS® MONITORING SYSTEM AND CODMAN MICROSENSOR® ICP TRANSDUCER

POCKET REFERENCE GUIDE



Our Commitment to Developing Neuro Critical Care Solutions:

At **Integra**, we are committed to the physicians and nurses we serve and the patients they treat. We strive to make this commitment apparent in our dedicated service, the clinical education and resources we provide our clinicians, and in our full line of Neuro Critical Care Solutions (NCC) products. Our portfolio of Neuro Critical Care Solutions facilitates neurosurgery and neurointensive care, from the access and monitoring phase through post-op and therapy. Just as care has been inherent in the CODMAN® name for more than a century, so it is today – and we will strive to continue this commitment into the next century.

Table of Contents






| | |
|--------------------------|----|
| ICP EXPRESS® | 3 |
| CRANIAL ACCESS KIT | 7 |
| BASIC KIT | 10 |
| SKULL BOLT KIT | 15 |
| VENTRICULAR CATHETER KIT | 19 |
| NEURO ESSENTIALS | 26 |
| CRANIAL NERVES | 27 |
| ORDERING INFORMATION | 28 |

This instructional program has been prepared to assist you with the proper operation and maintenance of the ICP Monitoring System. This guide is not intended to replace the product inserts. Rather it is to be used along with the product inserts as a training aid. Please refer to the product inserts and read the sections on contraindications, warnings and cautions.

ICP EXPRESS®

- 1 To operate the ICP EXPRESS® Transducer, first make sure that all cables are connected. The power cable and the CODMAN MICROSENSOR® Transducer cables are supplied with the unit. Ensure that the white center line on the cable is aligned with the corresponding mark on the ICP EXPRESS® System connector and snapped into place.
- 2 If you are connecting to a bedside monitor, the monitor cable you use will depend on the type of patient monitors used in the hospital. They will have to be ordered separately through your *CODMAN® Neuro Sales Consultant*.



- 3 Begin by using the  key to turn the unit on, and wait for the screen to prompt you with instructions.
- 4 If the ICP EXPRESS® System is connected to a patient monitor, the screen will prompt you to zero the monitor. Proceed to zero the monitor according to the manufacturer's instructions. Verify that the patient monitor displays a numeric mean ICP of zero and press the  key.
- 5 Next you must calibrate the patient monitor by pressing the  or  key labeled Calibrate Patient Monitor. Press the  key when calibration is complete.




- 6 Connect the CODMAN MICROSENSOR® and wait for the message "Press Zero to Zero Transducer". NOTE: If the screen display prompts you to accept a zero reference number prior to zeroing, turn off the monitor and return to step 3.



- 7 Place the CODMAN MICROSENSOR® tip in sterile water and press the blue key labeled "Zero Transducer." The CODMAN MICROSENSOR® zero offset number will be displayed on the ICP EXPRESS® System screen.



8 This offset number is frequently called the reference number and is specific to the transducer that you have just zeroed. It is also recorded electronically onto the E-Prom memory chip in-line with the transducer cable.

9 Care must be taken to record this zero offset reference number in the patient chart and on the CODMAN MICROSENSOR® connector. Press the  key. The CODMAN MICROSENSOR® ICP Transducer is now ready for implantation.



CRANIAL ACCESS KIT

The CODMAN® Cranial Access Kits contain medical devices with sharp injury prevention features to help minimize occupational exposure to blood borne pathogens.

- 1 The CODMAN® Cranial Access Kit includes all the necessary components to create the initial access hole for ICP monitoring and CSF drainage procedures.
- 2 When making the initial access hole, begin by shaving, prepping, and draping the patient.



- 3 Make the necessary incision and retract the scalp to expose the skull.
- 4 Now select the appropriate drill bit. The 5.8 mm bit should be used for ventriculostomy procedures or with the Plastic Skull Bolt Kit, 826632. The 2.7 mm bit should be used for subdural and intraparenchymal procedures or with the Metal Skull Bolt Kit, 826638.
- 5 Place the bit into the chuck, then hold the drill handle in place and turn the chuck counterclockwise to tighten the bit.

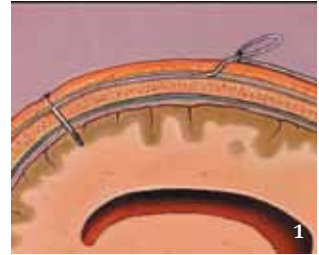


- 6 Next, loosen the drill guide with the appropriate hex wrench, and carefully slide the drill guide towards the tip of the bit until the desired skull depth is reached. It is important to note that the drill guide will not stop the drill. It is designed only to provide the neurosurgeon with a marker for drilling depth.
- 7 Finally, tighten the drill guide in place with a hex wrench, and begin drilling.

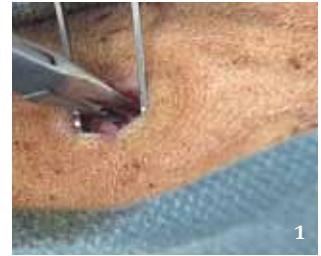


BASIC KIT

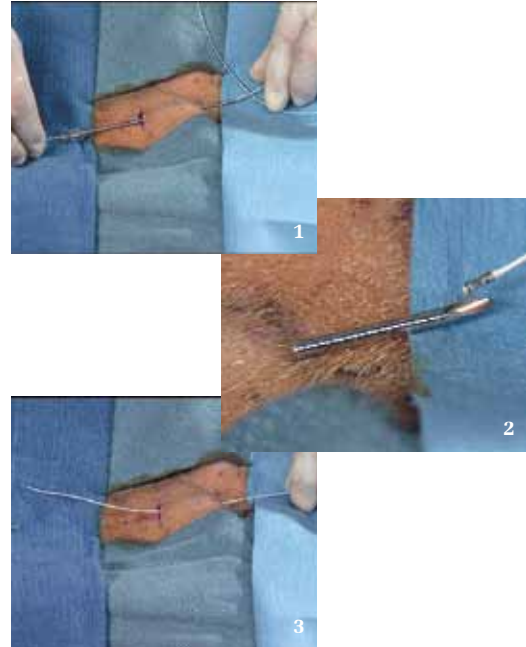
- 1 To measure ICP via the Intraparenchymal approach, begin with the CODMAN MICROSENSOR® already zeroed and connected to the required cables and monitor.
- 2 Create the Burr Hole through which the CODMAN MICROSENSOR® ICP Transducer will be placed, with the 2.7 mm drill bit which is included in the drill kit.



- 3 Bevel the Burr Hole edge on the side where the CODMAN MICROSENSOR® ICP Transducer will exit. This will facilitate removal of the CODMAN MICROSENSOR®
- 4 Use the Touhy needle to tunnel under the scalp from the Burr Hole site to the desired CODMAN MICROSENSOR® exit site



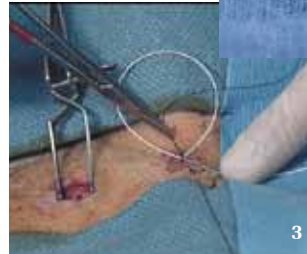
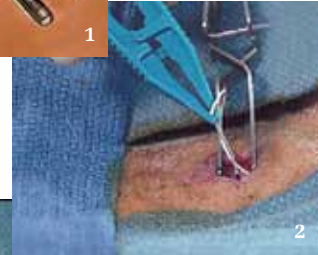
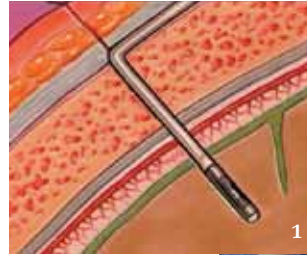
- 5 Remove the Touhy needle stylet and thread the CODMAN MICROSENSOR® ICP Transducer from the tip of the needle until the appropriate length for placement exits from the hub. The inner edges of the Touhy needle are sharp, so exercise caution while threading the CODMAN MICROSENSOR® through.
- 6 Gently remove the needle and estimate the length of the CODMAN MICROSENSOR® ICP Transducer from the tip to the first kink.



- 7 Once again, retract the Burr Hole site.
- 8 Fold the CODMAN MICROSENSOR® ICP Transducer forward once at the desired bend site to leave a kink in it. Avoid touching the sensor diaphragm.



- 9 Place the tip of the CODMAN MICROSENSOR® ICP Transducer in the Parenchyma through the puncture in the Dura until the kink is at the top edge of the hole.
- 10 Carefully pull back the excess slack and secure the CODMAN MICROSENSOR® ICP Transducer to the scalp. For additional strain relief, make a small loop with the line and suture it down.



SKULL BOLT KIT

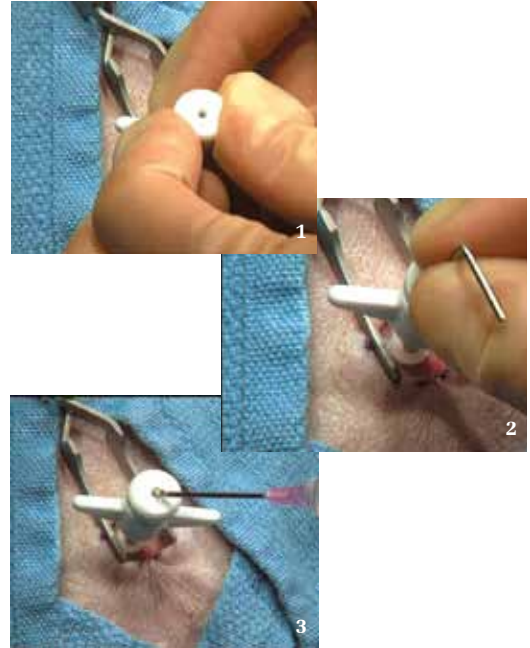
- 1 To measure ICP utilizing the Intraparenchymal approach, begin with the CODMAN MICROSENSOR® ICP Transducer already zeroed and connected to the required cables and monitor.
- 2 Use the drill bit included in the CODMAN MICROSENSOR® Skull Bolt Kit to perform a craniotomy. Remember that the CODMAN MICROSENSOR® Skull Bolt Kit is contraindicated for children of one year or less.



- 3 The CODMAN MICROSENSOR® Skull Bolt comes pre-assembled with a spacing washer which may be discarded if not required.
- 4 Put the Skull Bolt in position, and turn it clockwise until the spacing washer rests against the outer table of the skull.

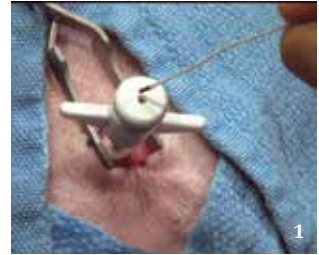


- 5 Loosen the cap adapter on top of the Bolt by turning it counterclockwise.
- 6 Make a puncture in the Dura to establish an assured path between the bolt and the intraparenchymal area. Irrigate the channel with non-bacteriostatic, preservative-free, sterile saline.



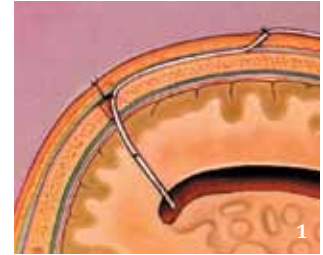
- 7 Insert the CODMAN MICROSENSOR® ICP Transducer through the Bolt to the desired depth. Secure the CODMAN MICROSENSOR® ICP Transducer to the Bolt by turning the adapter clockwise.

- 8 Close the incision and dress the wound site.



VENTRICULAR CATHETER KIT

- 1 To measure intraventricular pressure, begin with the CODMAN MICROSENSOR® ICP Transducer already zeroed and connected to the required cables and monitor.
- 2 Perform the craniotomy using the 5.8 mm drill bit which is included in the CODMAN® Cranial Access Kit.

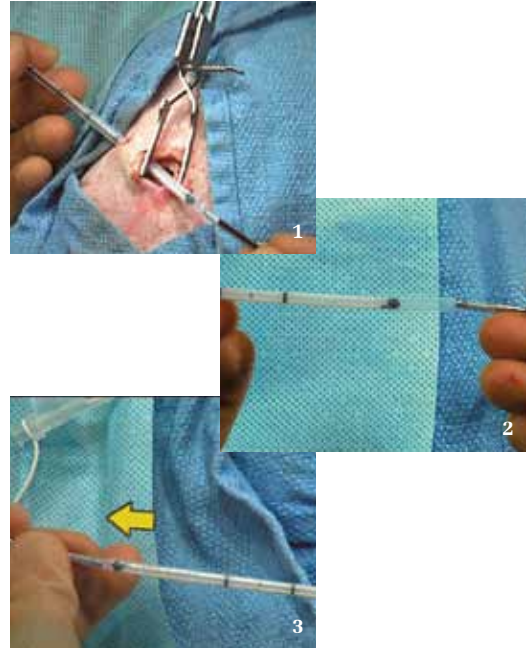


3 Gently bevel the Burr Hole on the side where the catheter exit site will be.

4 Make a cruciate puncture in the Dura.



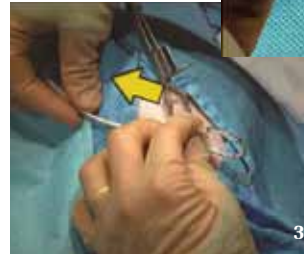
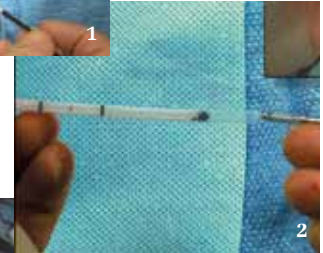
- 5 Place the Ventricular Catheter in the trocar tube and tunnel it under the scalp from the desired exit site towards the Burr Hole.
- 6 Remove the trocar.



- 7 Depending on surgeon preference, the 10 gauge ventricular needle may first be used to locate the ventricle. Advance the catheter into the lateral ventricle, making sure to enter the skull at a right angle.
- 8 Verify that the tip of the ventricular catheter is situated in the ventricle by removing the cap on the drain port and allowing CSF to flow out and then recap the drain port.



- 9 Bend the catheter in place and gently withdraw the preloaded stylet.
- 10 Hold the ventricular catheter in place, securely, and pull any slack on the catheter away from the incision site.



- 11 Secure the catheter to the scalp at the exit site. A removable suture clip is provided. Close and dress the incision site.
- 12 If you so choose, you may attach the drain port of the ventricular catheter to a ventricular drain system such as the EDS 3[®] CSF External Drainage System. This configuration will allow you to drain CSF and monitor ICP through a single catheter.



CONTACT INFORMATION

For any questions, please contact your local *sales representative*

Contact Details:

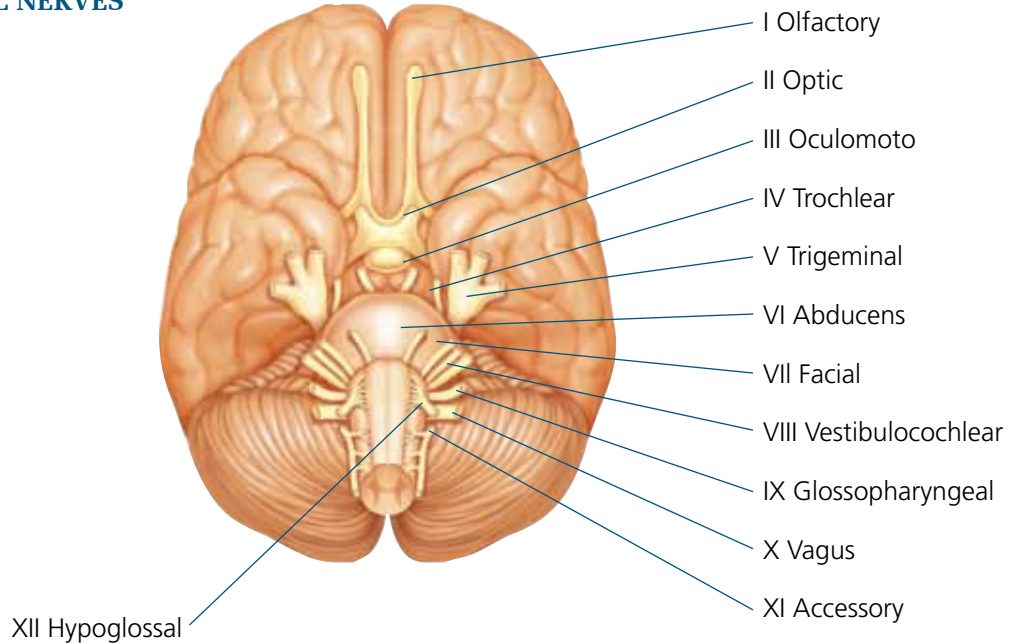
NEURO ESSENTIALS

Glasgow Coma Scale¹

| | 1 | 2 | 3 | 4 | 5 | 6 |
|---------------|--------------------|---|-------------------------------------|---------------------------------------|------------------------------|----------------|
| EYES | Does not open eyes | Opens eyes in response to painful stimuli | Opens eyes in response to voice | Opens eyes spontaneously | N/A | N/A |
| VERBAL | Makes no sounds | Incomprehensible sounds | Utters inappropriate words | Confused, disoriented | Oriented, converses normally | N/A |
| MOTOR | Makes no movements | Extension to painful stimuli | Abnormal flexion to painful stimuli | Flexion/Withdrawal to painful stimuli | Localizes painful stimuli | Obeys commands |

1. <http://www.bt.cdc.gov/masscasualties/pdf/glasgow-coma-scale.pdf>

CRANIAL NERVES



ORDERING INFORMATION

ICP EXPRESS® SYSTEM

| | |
|--------|--|
| 826635 | ICP EXPRESS® – includes one ICP EXPRESS® with pole clamp and one ICP EXPRESS® Transducer Cable |
|--------|--|

| | |
|--------|-------------------------------|
| 826636 | ICP EXPRESS® Transducer Cable |
|--------|-------------------------------|

Cranial Access Kit

| | |
|--------|------------------------------------|
| 826617 | Cranial Access Kit (without drugs) |
|--------|------------------------------------|

CODMAN MICROSENSOR® ICP TRANSDUCER

| | |
|--------|-------------------------------|
| 826631 | CODMAN MICROSENSOR® Basic Kit |
|--------|-------------------------------|

| | |
|--------|--|
| 826632 | CODMAN MICROSENSOR® Skull Bolt Kit (plastic) |
|--------|--|

| | |
|--------|--|
| 826638 | CODMAN MICROSENSOR® Skull Bolt Kit (metal) |
|--------|--|

| | |
|--------|--|
| 826653 | CODMAN MICROSENSOR® Ventricular Catheter Kit |
|--------|--|

CSF Drainage

| | |
|--------|--|
| 821730 | EDS 3® CSF Drainage System With Catheter |
| 821731 | EDS 3® CSF Drainage System Without Catheter |
| 821732 | CODMAN® CSF Drainage System Replacement Collection Bags |
| 821738 | CODMAN® EDS 3® with CODMAN® Lumbar Catheter Kit II |
| 821733 | EDS 3® Laser Leveling Device |
| 821745 | Bactiseal® EVD Catheter Inner Lumen Diameter 1.5mm |
| 821749 | Bactiseal® EVD Catheter Inner Lumen Diameter 1.9mm |
| 821750 | Bactiseal® EVD (Clear) Catheter Inner Lumen Diameter 1.9mm |

INDICATIONS:

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

Use of the **CODMAN MICROSENSOR® Basic** and **CODMAN MICROSENSOR® Skull Bolt Kits** 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.

The **CODMAN® Cranial Access Kit** is indicated when a craniotomy is required for placement of an intracranial pressure (ICP) monitoring device and/or cerebrospinal fluid drainage procedures.

The **ICP EXPRESS® Monitor** is intended to serve as an interface between the CODMAN MICROSENSOR® ICP Transducer and compatible patient monitoring systems. When connected to a MICROSENSOR, the ICP EXPRESS® Monitor provides a continuous numeric display of the mean, systolic and diastolic intracranial pressure. For detailed waveform analysis the ICP EXPRESS® Monitor generates an output signal that may be interfaced directly to the pressure channel input on most patient monitoring systems.

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.

Manufacturer:



Codman & Shurtleff, Inc
325 Paramount Drive
Raynham, MA 02767-0350, USA



Johnson & Johnson Medical, Ltd.
Pinewood Campus, Nine Mile Ride
Wokingham, RG40 3EW
United Kingdom

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

Integra Neurosciences

Unit 3, 24-30 Winterton Road, Clayton,
VIC 3168 Australia
1300 550 599 office ■ 1300 550 699 fax
ordersau@integralife.com

integralife.com

Integra New Zealand

0800 400 660 office
0800 400 770 fax
ordersnz@integralife.com
integralife.com

