

A DIVISION OF INTEGRA LIFESCIENCES



Integra®
NeuroCritical Care
Product Catalog



# Codman<sup>®</sup> Specare a complete solution for your





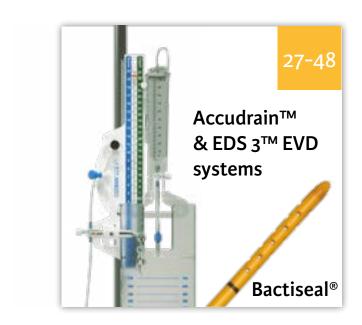
Access



**Diagnosis** 



# ciality Surgical NeuroCritical Care patients





# **Table of Content**



Customer Service and Warranty Information	5
Cranial access	7
Cranial Access kits	8
Drills & Accessories	11
Diagnosis - Neuromonitoring	13
CereLink™ ICP Monitor	14
DirectLink™ ICP Module	15
CereLink™ ICP Sensors & Kits	16
CereLink™ & DirectLink™ Patient Monitor Interface Cables	19
Licox® P <sub>t</sub> O <sub>2</sub> Monitor	19
Licox® Probes & Kits	20
Licox® - Patient Monitor Interface Cables	25
Therapy & Infection Prevention - External Drainage	27
Codman® EDS3™ External Drainage System	28
Accudrain™ External CSF Drainage System	30
Hermetic™ Plus External CSF Drainage System	32
Pole Mount External CSF Drainage Systems	33
Basic External Drainage Systems	34
Infection Prevention - Bactiseal™ EVD Catheter	38
Ventricular Drainage Catheters	39
Lumbar Drainage Catheters	43
Subdural catheter & kit	44
Replacement Drainage Bags	44
Luer Connectors	45
Indications and Contraindications	47
Product References	49



### **Customer Services:**

### International

+33 (0)4 37 47 59 50 +33 (0)4 37 47 59 25 (Fax) csemea@integralife.com

### Germany

+49 (0) 2102 5535 6200 +49 (0) 2102 553 6636 (Fax) custsvcgermany@integralife.com

### **United Kingdom**

+44 (0)1264 312 725 +44 (0)1264 312 821 (Fax) custsvcs.uk@integralife.com

### Switzerland

+41 (0)22 721 23 00 +41 (0)22 721 23 99 (Fax) custsvcsuisse@Integralife.com

### Belgium/Luxembourg

+32 (0) 2 257 4130 +32 (0) 2 253 2466 (Fax) custsvcbenelux@Integralife.com

### Ireland

+353 1800 901567 +353 1822 5952 (Fax) custsvcire@integralife.com

### Austria

+43(0)720816067 +43(0)19287201 (Fax) CustSvcAustria@integralife.com

### Netherlands

+31(0)852083167 +31(0)207093627 (Fax) custsvcnetherlands@integralife.com

### Italy

+39 (0) 2 577 89 21 +39 (0) 2 575 11 371 (Fax) custsvcitaly@Integralife.com

### France

+33 (0)4 37 47 59 10 +33 (0)4 37 47 59 29 (Fax) custservfrance@integralife.com

### Integra Limited Warranty

INTEGRA LIFESCIENCES CORPORATION and its wholly owned subsidiaries («INTEGRA») warrant to INTEGRA authorized distributors and the original purchaser only that each new INTEGRA or CODMAN product is free from manufacturing defects in material and workmanship under normal use and service from the date of delivery by INTEGRA (or its authorized distributor) to the original purchaser, but in no event beyond the expiration date stated on any product labeling. For purposes of products sold by INTEGRA through an authorized distributor of INTEGRA, «original purchaser» shall include the purchaser of INTEGRA products to whom the distributor first sells the product.

- Surgical instruments are guaranteed to be free from defects in material and workmanship when maintained and cleaned properly and used normally for their intended purpose.
- Any covered product that is placed by INTEGRA under a lease, rental or
  installment purchase agreement and that requires repair service during the
  term of such placement agreement shall be repaired in accordance with the
  terms of such agreement.

If any covered defect occurs during the warranty period or term of such placement agreement, the purchaser or distributor should communicate directly with INTEGRA. If purchaser or distributor seeks to invoke the terms of this warranty, the product must be returned to INTEGRA. The defective product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to INTEGRA shall be at sender's risk. INTEGRA's sole responsibility under this warranty shall be repair or replacement, at INTEGRA's sole discretion at INTEGRA's expense, subject to the terms of this warranty and applicable agreements.

IN NO EVENT SHALL INTEGRA BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY INTEGRA PRODUCT. Further, this warranty shall not apply to, and INTEGRA shall not be responsible for, any loss arising in connection with the purchase or use of any INTEGRA product that has been repaired by anyone other than an authorized INTEGRA service representative or altered in any way so as, in INTEGRA's judgment, to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used otherwise than in accordance with the instructions furnished by INTEGRA.

THIS INTEGRA LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON INTEGRA'S PART OR THE PART OF ITS DISTRIBUTORS, AND INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY REPRESENTATIVE OR OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH INTEGRA'S PRODUCTS.

INTEGRA DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OR WARRANTY OF QUALITY AS WELL AS ANY EXPRESS OR IMPLIED WARRANTY TO PATIENTS. No warranty or guarantee may be created by any act or statement nor may this Standard Warranty be modified in any way, except as a result of a writing signed by an officer of INTEGRA. These limitations on the creation or modification of this warranty may not be waived or modified orally or by any conduct.

INNO EVENT SHALL INTEGRA AUTHORIZED DISTRIBUTORS BE LIABLE TOWARDS THE ORIGINAL PURCHASER FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY INTEGRA PRODUCT. Further, this warranty shall not apply to, and INTEGRA authorized distributors shall not be responsible towards the original purchaser for, any loss, arising in connection with the purchase or use of any INTEGRA product that has been repaired by anyone other than an authorized INTEGRA service representative or altered in any way so as to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used otherwise than in accordance with the instructions furnished by INTEGRA. THIS INTEGRA DISTRIBUTOR LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES TOWARDS THE ORIGINAL PURCHASER, EXPRESS OR IMPLIED, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES TOWARDS THE ORIGINAL PURCHASER ON INTEGRA AUTHORIZED DISTRIBUTOR'S PART.

INTEGRA AUTHORISED DISTRIBUTORS DISCLAIM ALL OTHER WARRANTIES TOWARDS THE ORIGINAL PURCHASER, EXPRESS OR IMPLIED INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OR WARRANTY OF QUALITY AS WELL AS ANY EXPRESS OR IMPLIED WARRANTY TO PATIENTS.



**Cranial Access** 



# **Cranial Access Kit**

### **CODMAN Cranial Access Kit**

Catalog No. 826617

The CODMAN Cranial Access Kit is a disposable intracranial procedural kit, which contains all the basic items used during each step of the cranial access procedure. The kit contains the following items:

# **Preparation Components**

	Description
Α	Double Edge Razor (1)
D	Gauze Sponges, 4" x 4", 10 x 10 cm 12 ply (10)
Е	Medicine Cup, 2 oz., 60 cc (2)

### **Cranial Access Preparation**

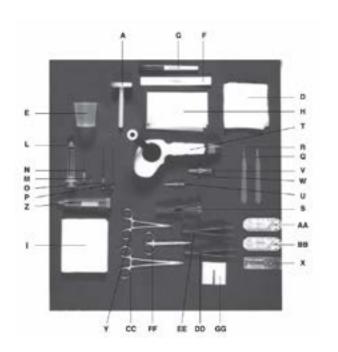
	•
	Description
F	Ruler, 6", 15 cm (1)
G	Marking Pen (1)
Н	Fenestrated Drape w/Barrier, 24" x 26", 61 x 66 cm (1)
ı	Absorbent Towel, 15" x 21", 38 x 53,3 cm (3)

### **Cranial Access**

	Description
L	Syringe, 12 cc (2)
М	Needle, 18 G x 1 1/2", 3,8 cm (2)
N	Needle, 25 G x 5/8", 1,6 cm (1)
0	Spinal Needle, 18 G x 3 1/2", 8,9 cm (1)
Р	Ventricular Needle, 12 G x 3 1/2", 8,9 cm (1)
Q	Scalpel, #15 (1)
R	Scalpel, #11 (1)
S	Retractor, Blunt (1)
Т	Hand Crank Drill (1)
U	2.7 mm Drill Bit w/stop (1)
V	5.8 mm Drill Bit w/stop (1)
W	Allen Wrench (1)
Х	Bone Wax (1)
Υ	Mosquito Forceps, curved (2)
Z	Culture Tube w/screw cap (1)

# **Preparation Components**

	Description
AA	2.0 Silk Suture (1)
ВВ	3.0 Nylon Suture (1)
СС	Needle Holder, Serrated (1)
DD	Adson Forceps (1)
EE	Adson Forceps w/teeth (1)
FF	Suture Scissors (1)





# **Cranial Access Kit**

# **CRANIAL ACCESS KIT (WITHOUT PREP SOLUTIONS)**

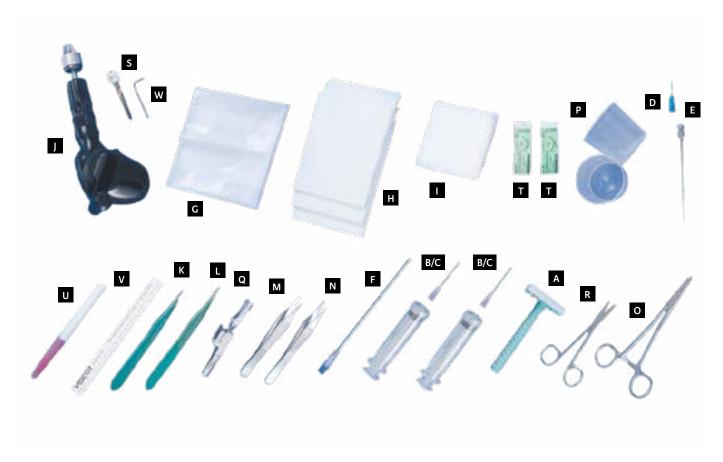
Catalog No. INS5HND

The Cranial Access Kit is a convenient pre-packaged sterile set containing all necessary components for burr-hole entry into the cranium. This kit does not include prep solutions.

### **Preparation Components**

· · · · · · · · · · · · · · · · · · ·		
	Description	
Α	Disposable razor	
В	12 ml safety syringes (2)	
С	18 G x 1-1/2", 3,8 cm needles (2)	
D	25 G x 5/8", 1,6 cm needle	
Ε	18 G x 3-1/2", 8,9 cm spinal needle	
F	12 G x 5-1/2", 12,7 cm ventricular needle	
G	15" x 15", 38 x 38 cm fenestrated drape with barrier	
Н	18" x 26", 45,7 x 66 cm white absorbent towels (3)	
I	4" x 4", 10 cm x 10 cm gauze sponges (10)	
J	Hand drill	
K	#11 scalpel with handle	
L	#15 scalpel with handle	

	Description
М	Adson forcep-serrated
N	Adson forceps, 1 x 2 teeth
0	Needle holder
Р	2 oz, 60 ml medicine cup (2)
Q	Self-retaining retractor
R	Scissors
S	5.31 mm drill bit with depth guard
Т	3-0 nylon suture (packaged outside kit) (2)
U	Marker
V	Flexible ruler
W	Hex wrench for depth guard adjustment





# **Cranial Access: Drills & Accessories**

### **DISPOSABLE DRILLS**

Reference	Description
826607	MicroSensor Hand Drill Disposable



# **DRILL BITS**

Drill bits intended for single-use in neurosurgical procedures.

Reference	Description
SP0075	Single drill bit with collar, 5/32" (3.97 mm)
SPoo87	Single drill bit with collar, 13/64" (5.31 mm)
SPoo88	Single drill bit with collar, 1/4" (6.35 mm)

Reference	Description
826608	MicroSensor Drill Bit O 5.8mm Disposable

Reference	Description
826609	MicroSensor Drill Bit O 2.7mm Disposable



Note: When using the Licox  $^{\circ}$  Monitoring Kits, please use the drill bit provided with that kit.









Diagnosis - Neuromonitoring



### **CERELINK™ ICP MONITOR**

### **Technical specifications:**

- Flat size (depth 59mm without pole clamp x H165mm x W222mm)
- Weight less than 2 Kg
- Screen: 18 cm diagonale TFT LCD
- Battery autonomy: 3 h

### **Functions:**

- High Fidelity ICP waveform (100 samples per second for a 25 Hz ICP waveform bandwidth)
- Advanced Trend Functions:
  - > ICP trends for up to 14 days
  - > Programmable user specific thresholds enabling calculation of pressure time dose & time above threshold
  - > histogram, boxplot
- Event Markers facilitate visualization of the impact of therapeutic interventions on ICP
- Screenshots
- Touchscreen interface
- Real-time streaming of ICP waveform or mean ICP through USB
- Data storage and export of 24 hours of ICP Waveform or up to 14 days of mean ICP
- Visual & audible alarms
- Free-standing positioning or attachable to an IV pole



Reference	Description
826820	CereLink™ ICP Monitor

### System includes:

Reference	Description
826845	CereLink ICP Extension Cable
826822	CereLink ICP Monitor Replacement Power Supply
826824	CereLink ICP Monitor Replacement Battery
EXPORTCAB	CereLink USB to RS232 Adapter



### **DIRECTLINK™ 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.



### 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 CereLink<sup>™</sup> ICP Sensor 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.



Actual size



# ICP Monitoring: CereLink™ ICP Sensor

### **CERELINK™ ICP SENSOR**

The CERELINK™ ICP Transducer consists of a miniature strain gauge pressure sensor mounted in a titanium case at the tip of a 100cm flexible nylon tube. The CERELINK™ monitors intracranial pressure directly at the source – subdural, parenchymal or intraventricular. Information is relayed electronically rather than through a hydrostatic column or fiberoptics.

The low profile (tip diameter of 1.3 mm) & the high mechanical resistance of the CereLink $^{\text{TM}}$  sensor allow for minimal invasive insertion & explantation without breakage of the transducer.

The CERELINK<sup>TM</sup> sensor is available in four different kit configurations and is designed for the use with CereLink<sup>TM</sup> ICP monitor, ICP Express and DirectLink<sup>TM</sup>.

### **CERELINK™ ICP SENSOR BASIC KIT**

Reference D	escription
826850 C	erelink™ ICP Sensor Basic Kit — The kit can be used in both ubdural and intraparenchymal pressure monitoring oplications.  ontains the following components:  CereLink™ ICP Sensor  14 Gauge Touhy Needle with stylet



# CERELINK™ ICP SENSOR PLASTIC SKULL BOLT KIT

Reference	Description
826852	CERELINK™ ICP SENSOR Plastic Skull Bolt Kit - The kit can be used in both subdural and intraparenchymal pressure monitoring applications. Contains the following components: • CERELINK™ ICP SENSOR • Adult and Pediatric Skull Bolt with Luer • Spacing Washers • Touhy-Borst Adapter (mounted on the catheter portion of the transducer) • Disposable ICP Handle





# ICP Monitoring: CERELINK™ ICP SENSOR

### CERELINK™ ICP SENSOR METAL SKULL BOLT KIT

The kit can be used in both subdural and intraparenchymal pressure monitoring applications.



Reference	Description
826851	CERELINK™ ICP SENSOR Metal Skull Bolt Kit Contains the following components:  • CereLink™ ICP sensor  • Winged skull bolt with compression cap  • Spacing washer  • Obturator  • 2.7mm Drill Bit  • Hex wrench

### CERELINK™ ICP SENSOR VENTRICULAR CATHETER KIT

• Catheter anchoring clip



Reference Description

CERELINK™ ICP SENSOR Ventricular Catheter Kit
Contains the following components:

• 38 cm ventricular catheter with an integrated stylet
• Intracranial pressure (ICP) sensor
• 7-gauge tunneling trocar for placement

CERELINK™ ICP SENSOR Ventricular Catheter Kit with ICP transducer.



# CereLink™ & DirectLink™ Patient Monitor Interface Cables

Reference	Description	Picture
826881	PHILIPS	
826882	GE Dash	Box 100
826884	GE Datex-Ohmeda	
826880	DRAGER / SIEMENS Infinity	
826883	SPACELABS 6-pin	
826887	NIHON KODEN 5-pin	
826888	FUKUDA DENSHI DS-800	
826889	FUKUDA DENSHI DS-7000	
826880	Dräger/Siemens (7 pin) using adaptater IBO ADAPTATER CALBLE 10-07-PIN (REF 3368383) from Dräger	
826887	Nihon koden(12 pin) using adaptater JP-910P from Nihon Koden	



# LICOX® P,O, MONITOR

The Integra Licox® P.O. Monitor provides functionality for continuously monitoring oxygen partial pressure (P.O.) in brain tissue. Tissue temperature compensation, which is required for the calculation of P.O. measurements, may also be continuously measured with an accuracy of ± 0.1°C. To measure P.O. and temperature tissue compensation continuously, the Integra Licox° P.O. Monitor supports a series of minimally invasive probes that are inserted directly into the patient:

Licox

INTEGRA

All Miller Miller L. Land

- The P<sub>2</sub>O<sub>2</sub> probe uses an electrochemical micro-cell for oxygen measurements.
- The temperature probe uses a thermocouple for temperature measurements.

### **Key Functions of Monitor**

Touch screen interface for evaluating patient data and setting patient parameters

- Physiological alarm that activates if the patient's P.O. value falls below a user-specified limit
  - Storage of patient's trend data for up to 5 days
  - Outputs for transferring patient data to a patient bedside monitor
- Rechargeable battery that supplies power to monitor during patient transport
- Outputs for extracting patient data to remote media types via USB drive

### Catalog No. LCXo2

System includes:

• Integra Licox® P.O. Monitor

• Probe cables:

> BC10PA cable: Blue P.O. probe cable

> BC10PV cable: Blue P.O. probe extension cable

> BC10TA cable: Green Temperature probe cable > BC10TV cable: Green Temperature probe extension cable

> PMOCAB cable: Blue combined P.O./Temperature probe cable

> BC10PMO cable: Y-adapter cable for Blue combined P.O. /Temperature probe cable

> BC10R: Test set (Test smard card, test probe)

PMIOMPM1 cable: Main cable for connecting Licox® P.O. monitor to patient bedside monitor

• EXPORTCAB cable: USB-to-RS232 adapter cable

• MONPWR cable: Power cable

• BAT1001: Rechargeable Battery

Interface cable is to be ordered separately depending on the bedside monitor manufacturer model\*:

• ICPXX: Oxygen pressure adapter cable

ICTXX: Temperature adapter cable

<sup>\*</sup>Please contact Integra for the correct adapter cable product code



# **Probes only**

# LICOX® OXYGEN PROBE

Probe's tube Diameter at tip	o.8 mm
Probe's tube Length	150 mm
Oxygen sensitive area	13 mm2
Introducer kit compatibility	IM1/ IM2EU/IM3EU
Storage condition	Between 2° and 10°C

# Catalog No. CC1SB

Supplied sterile

# LICOX®TEMPERATURE PROBE

Probe's tube Diameter at tip	o.8 mm
Probe's tube Length	126 mm
Probe Type	Thermocouple Type K
Introducer kit compatibility	IM <sub>3</sub> EU

# Catalog No. C8B

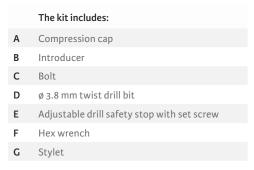
Supplied sterile

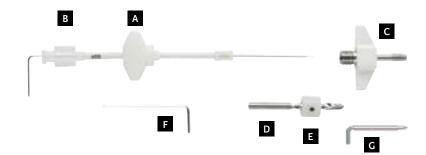




# **Introducer Kits only**

# LICOX® INTRODUCER KIT, SINGLE LUMEN

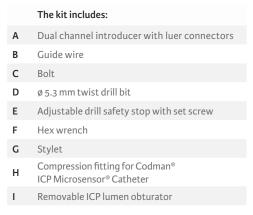




Supplied sterile

Catalog No. IM1

# LICOX® INTRODUCER KIT, DOUBLE LUMEN



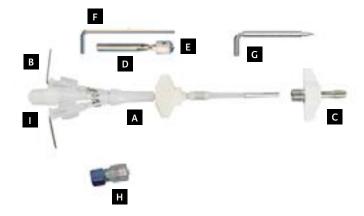
B

Supplied sterile

Catalog No. IM2EU

# LICOX® INTRODUCER KIT, TRIPLE LUMEN

	The kit includes:
Α	Triple channel introducer with luer connectors
В	Guide wires (x2)
С	Bolt
D	ø 5.3 mm twist drill bit
E	Adjustable drill safety stop with set screw
F	Hex wrench
G	Stylet
Н	Compression fitting for Codman® ICP Microsensor® Catheter
1	Removable ICP lumen obturator



Supplied sterile

Catalog No. IM3EU



### **Introducer Kits only**

### LICOX® COMPLETE BRAIN PROBE KIT, SINGLE LUMEN

The kit includes:

Oxygen probe

CC1SB

Single Lumen Introducer

IM1

Storage condition: between 2° and 10°C

Supplied sterile

Catalog No. IM1S



### LICOX® COMPLETE BRAIN PROBE KIT, DOUBLE LUMEN

The kit includes:

Oxygen probe

CC1SB

Double Lumen Introducer

IM2EU

Storage condition: between 2° and 10°C

Supplied sterile

Catalog No. IM2SEU



## LICOX® COMPLETE BRAIN PROBE KIT, TRIPLE LUMEN

The kit includes:

Oxygen probe
CC1SB
Triple Lumen Introducer
IM3EU

Storage condition: between 2° and 10°C Supplied sterile

Catalog No. IM3SEU



## LICOX® COMPLETE BRAIN PROBE KIT WITH TEMPERATURE PROBE, TRIPLE LUMEN

The kit includes:

Oxygen probe
CC1SB

Temperature probe
C8B

Triple Lumen Introducer
IM3EU

Storage condition: between 2° and 10°C Supplied sterile

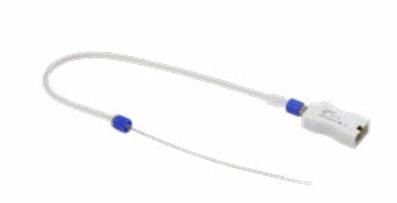
Catalog No. IM3STEU





# **Combined Probe only and Introducer kits**

### LICOX® COMBINED OXYGEN AND TEMPERATURE PROBE

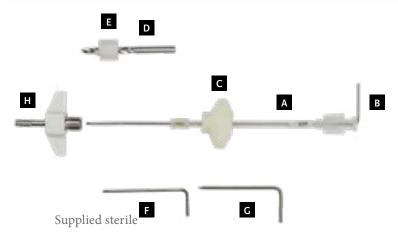


The kit includes:		
Probe's tube Diameter at probe tip	0.65mm	
Probe's tube Length	460 mm	
Oxygen sensitive area	18 mm²	
Compatibility with	IP1/IP2/VK52	

Storage condition: between  $2^{\circ}$  and  $10^{\circ}$ C Supplied sterile

Catalog No. CC1P1

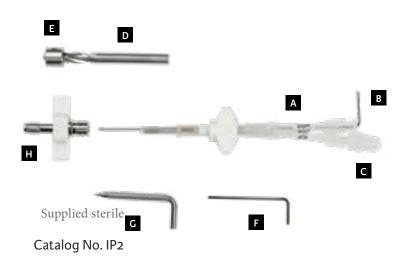
### LICOX® SINGLE LUMEN INTRODUCER KIT



	The kit includes:
Α	Bolt with single lumen introducer
В	Guide wire
С	Compression cap
D	Drill bit diam. 3.8 mm
Ε	Adjustable drill stop with set screw
F	Hex wrench for adjustment of drill stop
G	Stylet
Н	Bolt

Catalog No. IP1

## LICOX® DOUBLE LUMEN INTRODUCER KIT

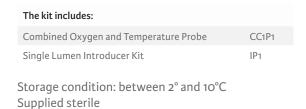


	The kit includes:
Α	Bolt with double lumen introducer for Licox® combined oxygen and temperature probe
В	Guide wire
С	Compression cap fitting for ICP catheter
D	Drill bit diam. 6.3 mm
E	Adjustable drill stop with set screw
F	Hex wrench for adjustment of drill stop
G	Stylet
Н	Bolt



# **Combined Probe with Bolted and Tunneling Introducer kits**

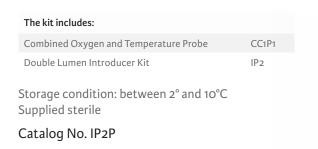
# LICOX® COMPLETE BRAIN PROBE KIT, SINGLE LUMEN



Catalog No. IP1P



# LICOX® COMPLETE BRAIN PROBE KIT, DOUBLE LUMEN





### LICOX® COMPLETE BRAIN TUNNELING PROBE KIT

The kit includes:	
Combined Oxygen and Temperature Probe	CC1P1
Parenchymal Probe Guide	VK52

Storage condition: between 2° and 10°C Supplied sterile

Catalog No. IT2EU





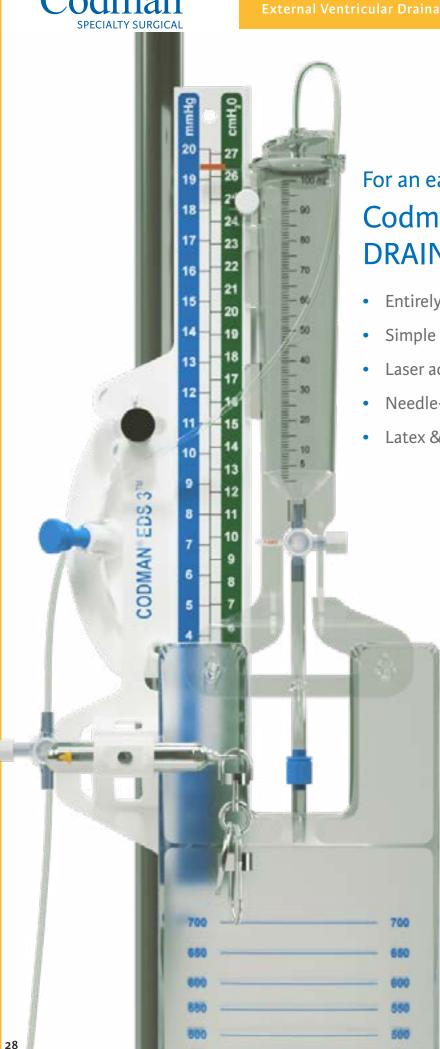
# **LICOX® - PATIENT MONITOR INTERFACE CABLES**

Adapter Cable	Picture
ICP16	
ICP17	
ICP18	
ICP19	
ICP22	
ICP33	
ICP39	
ICP46	
ICP60	BESSESS
ICP80	
ICP81	
ICP90	BOOKERS .
ICTo <sub>1</sub>	0
ICT39	6





Therapy & Infection Prevention -External Drainage



# For an easy-to-use solution, choose the Codman<sup>®</sup> EDS 3<sup>™</sup> EXTERNAL **DRAINAGE SYSTEM**

- Entirely disposable, complete system
- Simple set up
- Laser accuracy
- Needle-free access
- Latex & PVC free



The Codman® EDS 3<sup>™</sup> External Drainage System was developed with input from more than 200 nurses and physicians.

- High-visibility pressure scales in mmHg (-3 to 20) and cmH2O (-5 to 27)
- Drip Chamber with hydrophobic & haemorepellent filter marked for O-100ml capacity, funnel bottom, and sampling site (outlet)
- Improved, larger tubing connecting the drip chamber and the drainage bag
- Reusable Leveling Device incorporates bubble level with laser lamp
- Pressure-resistant striped CSF tubing line
- Redesigned drainage bag with needle-free access port

Reference	Description
821730C	Codman® External Drainage System EDS 3™ with ventricular catheter
821731C	CODMAN® External Drainage System EDS 3™ No Ventricular Catheter
821732C	EDS 3™ Collection Bag Kit - 5 Bags
821733	EDS 3™ Leveling Device



# PANEL MOUNT EXTERNAL DRAINAGE SYSTEMS

# ACCUDRAIN™ EXTERNAL CSF DRAINAGE SYSTEM

- Green striped patient line
- Two needleless sampling sites
- Anti-microbial hydrophobic vent
- Funnel-shaped 75 ml graduated burette
- Patient-line stopcock
- Four-way high flow burette stopcock
- One-hand Squeeze-Lok™ tabs for easy and secure burette height adjustment
- · Line level device
- 700 ml drainage bag
- MR Compatibility Status: Please refer to the Directions for Use of this product for further information.

Reference	Description
INS8400	Without anti-reflux valve
INS8401	With anti-reflux valve

Latex free Sterile, packaged individually



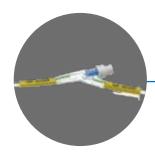
Squeeze-Lok™ tabs for adjusting burette level



Antimicrobial hydrophobic filter

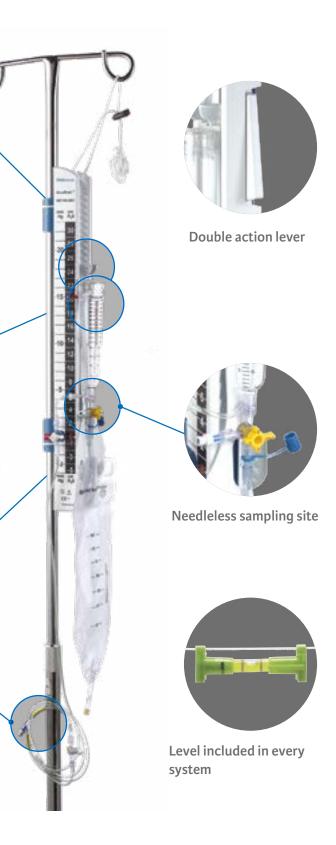


Burette has funnel-shaped bottom with large bore outlet and stopcock



Yellow label on access site







 $\label{eq:def:Drainage} \textit{Drainage Bag compatible with AccuDrain}^{\text{\tiny{TM}}} \; \textit{External CSF Drainage System:}$ 

Reference	Description
INS8700	<ul><li>700 ml Replacement Drainage Bag</li><li>Anti-Reflux valve</li></ul>

Latex free Sterile, 5 units per box



# PANEL MOUNT EXTERNAL DRAINAGE SYSTEMS

### HERMETIC™ PLUS EXTERNAL CSF DRAINAGE SYSTEM

- Green striped pressure monitoring tubing patient line
- Two SmartSite® needleless sampling site
- Anti-microbial hydrophobic vent
- 50 ml graduated burette
- Patient-line stopcock
- Four-way high flow burette stopcock
- Velcro® straps & large suspension cord locking mechanism
- · Line level device
- 700 ml drainage bag
- MR Compatibility Status: Please refer to the Directions for Use of this product for further information.

Reference	Description
INS8301	With anti-reflux valve in patient line

Sterile, packaged individually

Drainage Bag compatible with Hermetic™ Plus External CSF Drainage System:

	Reference	Description
	INICOZOO	• 700 ml Replacement Drainage Bag
INS8700	Anti-Reflux valve	

Latex Free Sterile, 5 units per box







# POLE MOUNT EXTERNAL CSF DRAINAGE SYSTEMS



### **EXTERNAL CSF DRAINAGE SYSTEM**

- Two SmartSite® needleless sampling site
- Anti-Microbial hydrophobic vent
- 50 ml graduated burette
- Patient and burette stopcocks
- 700 ml drainage bag
- Product not tested in MR environment
- · Sterile, packaged individually
- Anti-reflux valve bonded distal to patient stopcock

Reference	Description
INS8600	<ul><li> Large-bore blue striped tubing patient line</li><li> In-line anti-reflux valve</li></ul>
INS8601	<ul> <li>Green-striped pressure tubing patient line</li> <li>Removable anti-reflux valve distal to panel mount stopcock</li> </ul>

Sterile, packaged individually

Drainage Bag compatible with AccuDrain™ External CSF Drainage System:

Reference	Description
INS8700	<ul><li>700 ml Replacement Drainage Bag</li><li>Anti-Reflux valve</li></ul>

Latex free Sterile, 5 units per box



### MONITORR ICP™ POLE MOUNT ASSEMBLY

- Graduated rail measurements in cmH2O and mmHg scales
- Extendable antenna

Reference	Description
INS305	<ul> <li>Compatible with Hermetic<sup>™</sup> External CSF</li> </ul>
1143305	Drainage System INS8600 & INS8601

Latex free Packaged individually





# **BASIC CSF DRAINAGE SYSTEM - EXTERNAL DRAINAGE SET (EDS)**

			Reference	
		EDS	EVDS*	LDS**
Standard System	Package content	910110a	910112a	910120a
	Unit(s) per box	6	1	1
A TES	<ul> <li>150 cm patient line</li> <li>4-way stopcock</li> <li>Anti-reflux valve and sampling port</li> <li>75 ml graduated cylinder</li> <li>T-connectors / stopcock assembly</li> <li>500 ml drainage bag and ruler</li> <li>Hydrophobic filter</li> </ul>	*	*	*
	<ul> <li>Straight ventricular catheter (35cm, 8 Fr)</li> <li>20 cm and 35 cm introducing rods</li> <li>Suturable tubing clamp (8 Fr)</li> <li>Subcutaneous passer</li> </ul>	-	*	-
(4==0)	<ul> <li>Closed tip lumbar catheter (80 cm, 5 Fr)</li> <li>Suturable tubing clamp (5 Fr)</li> <li>Luer lock connector</li> <li>14 G Tuohy needle</li> <li>Guide wire in dispenser</li> </ul>	-	-	*

Latex Free Sterile, packaged individually

<sup>\*</sup>External Ventricular Drainage Set \*\* Lumbar Drainage Set

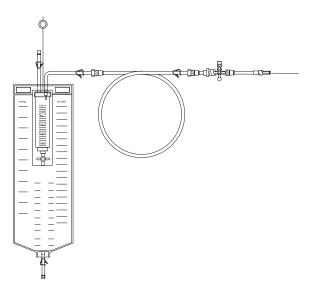


# **BASIC CSF DRAINAGE SYSTEM - INTEGRAL DRAINAGE SET (IDS)**

			Reference	
		IDS	IVDS***	ILDS****
Standard IDS	Package content	910410	910412	910420
	Unit(s) per box	6	1	1
	One-piece assembly Patient line with attached clamp, check valve 700 ml graduated bag Hydrophobic vent filter Drip chamber Suspension string with adjustable clip 360° 3-way stopcock with 2 female luer-lock connectors with cap  10 cm piece of tubing with 1 male luer-lock connector with cap	*	*	*
	<ul> <li>Straight ventricular catheter (35cm, 8 Fr)</li> <li>20 cm and 35 cm introducing rods</li> <li>Suturable tubing clamp (8 Fr)</li> <li>Subcutaneous passer</li> </ul>	-	*	-
(X).	<ul> <li>Closed tip lumbar catheter (80 cm, 5 Fr)</li> <li>Suturable tubing clamp (5 Fr)</li> <li>Luer lock connector</li> <li>14 G Tuohy needle</li> <li>Guide wire in dispenser</li> </ul>	-	-	*

Latex Free Sterile, packaged individually

### **BASIC CSF DRAINAGE SYSTEM - VENTRICULAR DRAINAGE SYSTEM**



- Patient line with clamp and self-sealing injection/sampling port
- Four-way stopcock
- 50 ml rigid drip chamber
- 30 cmH2O and 20mmHg height scales
- Removable one-way check valve

Reference NL850500V

Sterile, packaged individually

\*\*\*Integral Ventricular Drainage Set \*\*\*\*Integral Lumbar Drainage Set



# INFECTION PREVENTION

# BACTISEAL® EVD prevents colonisation by

For the NCC specialist who wants to control infection rates¹ in their unit, BACTISEAL° is an impregnated anti-microbial catheter:



- that provides constant dual-drug protection from Rifampicin & Clindamycin
- that prevents catheter colonization up to 28 days<sup>2</sup>

BACTISEAL® EVD kills 100% of target organisms and delivers reduced EVD infection rates.<sup>3</sup>

 $<sup>1.\,</sup>Harrop,\,J.S.,\,et\,al.,\,Impact\,of\,a\,standardized\,protocol\,and\,antibiotic-impregnated\,catheters\,on\,ventriculostomy\,infection\,rates\,in\,cerebrovascular\,patients.\,Neurosurgery,\,2010.\,67(1):\,p.\,187-91.$ 

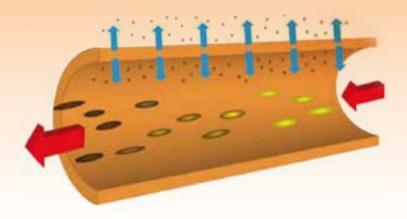
<sup>2.</sup> Bayston, R. and E. Lambert, Duration of protective activity of cerebrospinal fluid shunt catheters impregnated with antimicrobial agents to prevent bacterial catheter-related infection. J Neurosurg, 1997. 87(2): p. 247-51.

2. Bayston R. Ashraf W. Bhundia C. Mode of action of an antimicrobial highest relationships.

<sup>3.</sup> Bayston R. Ashraf W, Bhundia C. Mode of action of an antimicrobial biomaterial for use in hydrocephalus shunts. J. Antimicrobial Chemotherapy vol. 53, 778-782, March 2004



# positive bacteria.





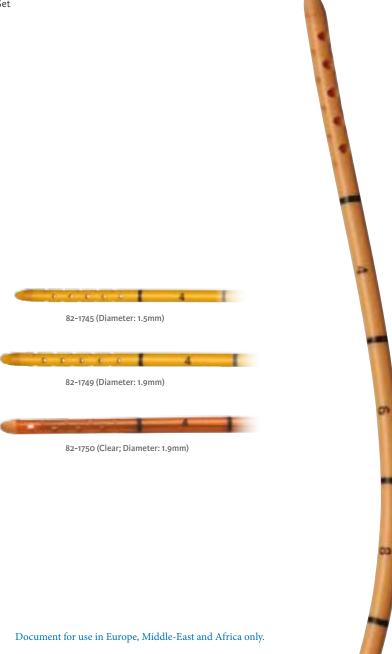


# **CODMAN BACTISEAL™ EVD CATHETER**

The Anti-microbial Technology Demanded for CSF Drainage. A technically innovative anti-microbial impregnated catheter for external CSF drainage which reduces gram positive bacteria on catheter tube surfaces. Treated with the patented BACTISEAL Advanced Impregnation Process

- Reducing the potential for bacterial colonization on inner lumen and exterior catheter wall
- Soft, flexible, pliable silicone catheters
- Depth markings for accurate placement
- Requires no technique change
- Available with either normal or large drainage lumen
- Available 'clear' or opaque'.

Description
BACTISEAL EVD Catheter Set Depth Markings 3cm to 15cm Inner Lumen Diameter 1.5mm
BACTISEAL EVD Catheter Set Depth Markings 3cm to 15cm Inner Lumen Diameter 1.9mm
CLEAR BACTISAL EVD Catheter Set Depth Markings 3cm to 15cm Inner Lumen Diameter 1.9mm





# **Ventricular Drainage Catheters**

# HERMETIC™ VENTRICULAR CATHETER SET

Reference	Description
INS8220	<ul> <li>One (1) 35 cm barium impregnated ventricular catheter OD: 2.7 mm x ID: 1.3 mm</li> <li>One (1) 38 cm stainless steel stylet</li> <li>One (1) luer connector</li> <li>One (1) suture collar</li> <li>One (1) 15 cm 10 Fr. trocar</li> <li>One (1) yellow male end cap</li> </ul>

Latex Free Sterile, packaged individually



# HERMETIC™ VENTRICULAR SMALL CATHETER SET

Reference	Description
INCARR	<ul> <li>One (1) 20 cm barium striped ventricular catheter OD: 2.5 mm x ID: 1.3 mm</li> <li>One (1) 26 cm stainless steel stylet</li> <li>One (1) luer connector</li> </ul>
INS4000	One (1) suture collar
	<ul> <li>One (1) 15 cm 10 Fr. trocar</li> <li>One (1) yellow male end cap</li> </ul>

Latex Free Sterile, packaged individually





# **Ventricular Drainage Catheters**

# HERMETIC™ LARGE STYLE VENTRICULAR CATHETER SET

Reference	Description
INS4500	<ul> <li>One (1) 35 cm barium striped ventricular catheter OD: 3 mm x ID: 1.6 mm</li> <li>One (1) 38 cm stainless steel stylet</li> <li>One (1) luer connector</li> <li>One (1) suture collar</li> <li>One (1) 15 cm 10 Fr. trocar</li> <li>One (1) yellow male end cap</li> </ul>

Latex Free Sterile, packaged individually



## TRAUMACATH™ VENTRICULAR CATHETER SET

Reference	Description
	• One (1) 35 cm barium striped ventricular catheter OD
INS8420	3.3 mm x ID: 1.9 mm
	<ul> <li>One (1) 38 cm stainless steel stylet</li> </ul>
	One (1) luer connector
	One (1) suture collar
	<ul> <li>One (1) 15 cm 10 Fr. trocar</li> </ul>
	<ul> <li>One (1) yellow male end cap</li> </ul>
	Large holes (1.8mm)
Latex Free	
Sterile, pa	ckaged individually
	m -

# **EXTERNAL DRAINAGE VENTRICULAR SET**

Reference	Description	
821735	clear CSF ventricular catheter (1.5mm inner Lumen diameter)	



# **Ventricular Drainage Catheters**

# **VENTRICULAR CATHETER ACCESSORY KIT (VCAK)**



Reference	Description	
951303	<ul> <li>35 cm 8 Fr radiopaque silicone elastomer straight ventricular catheter with large side holes and graphite length dots at 5, 10 and 15 cm from catheter tip</li> <li>OD: 2.7 mm; ID: 1.4 mm</li> <li>20 cm and 35 cm introducing rods</li> <li>Luer lock connector and watertight cap</li> <li>Suturable tubing clamp (8 Fr)</li> <li>Subcutaneous passer</li> </ul>	

Latex Free Sterile, packaged individually

# STRAIGHT VENTRICULAR DRAINAGE CATHETER



Reference	Description
	20 cm 8 Fr radiopaque silicone elastomer straight ventricular catheter with large side holes and graphite length dots at 5, 10 and 15 cm from catheter tip     OD: 2.7 mm; ID: 1.4 mm
901302	• 22 cm introducing rod
	Luer lock connector and watertight cap
	Suturable tubing clamp (8 Fr)

Latex Free Sterile, packaged individually

# INTRAVENTRICULAR MONITORING CATHETER SET (IVMCS)



Reference	Description
	<ul> <li>35 cm 8 Fr radiopaque silicone elastomer straight ventricular catheter with large side holes and graphite length dots at 5, 10 and 15 cm from catheter tip</li> <li>OD: 2.7 mm; ID: 1.4 mm</li> </ul>
910130a	• 20 cm and 35 cm introducing rods
	<ul> <li>Luer lock connector and watertight cap</li> </ul>
	Suturable tubing clamp (8 Fr)
	<ul> <li>T-connector/stopcock assembly with 3-way</li> </ul>
	stopcock and self-sealing sampling port

Latex Free Sterile, packaged individually



# **Lumbar Drainage Catheters**

# **LUMBAR DRAINAGE CATETERS**

# HERMETIC™ LUMBAR CATHETER CLOSED TIP

Reference	Description
INS5010	<ul> <li>One (1) 80 cm closed-tip lumbar catheter OD: 1.5 mm x ID: 0.7 mm</li> <li>One (1) 14-gauge x 8.8 cm Tuohy needle</li> <li>One (1) flexible luer adapter</li> <li>Two (2) suture collars</li> <li>One (1) Veni-Gard® Dressing</li> <li>One (1) strain relief tubing</li> <li>One (1) PTFE coated guide wire</li> <li>One (1) 22-gauge blunt needle</li> <li>One (1) yellow male end cap</li> </ul>

Latex Free Sterile, packaged individually



## HERMETIC™ LUMBAR CATHETER OPEN TIP

Reference	Description
INS8330	<ul> <li>One (1) 80 cm open-tip lumbar catheter OD: 1.5 mm x ID: 0.7 mm</li> <li>One (1) 14-gauge x 8.8 cm Tuohy needle</li> <li>One (1) flexible luer adapter</li> <li>Two (2) suture collars</li> <li>One (1) Veni-Guard® Dressing</li> <li>One (1) strain relief tubing</li> <li>One (1) 22-gauge blunt needle</li> </ul>
	One (1) yellow male end cap
Latev Free	

Sterile, packaged individually



# **LUMBAR CATHETER ACCESSORY KIT (LCAK)**

Reference	Description
910121	<ul> <li>Radiopaque silicone elastomer catheter with closed tip and depth markers every 2 cm (80 cm, 5 Fr)</li> <li>OD: 1.6 mm; ID: 0.8 mm</li> <li>Suturable tubing clamp (5 Fr)</li> <li>Luer lock connector</li> </ul>
	<ul><li>14 G Tuohy needle</li><li>Guide wire in dispenser</li></ul>

Latex Free Sterile, packaged individually





# **Speciality drainage products**



- Radiopaque silicone elastomer catheter with extendable, cage-shaped tip, and internal, polypropylene cup (20 cm, 8 Fr) OD: 2.7 mm; ID: 1.2 mm
- Introducing rod
- Right angle guide
- Luer lock connector
- Suturable tubing clamp (8 Fr)



Reference	Description
951315	Subdural catheter
951310 (Additional components in kit)	Subdural catheter kit; procedure-ready kit Subdural catheter, disposable drill Bit (5 mm) with adjustable stop, allen wrench and subcutaneous passer

Latex Free Sterile, 1 unit per box



## **Accessories**

# REPLACEMENT DRAINAGE

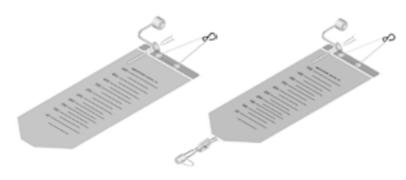
Reference	Description
821732C	• EDS 3 <sup>™</sup> Collection Bag Kit 700 ml - 5 Bags
Reference	Description

Latex Free Sterile, 5 units per box



Reference	Description
910116a	• 500 ml Closed drainage bag
910116d	• 500 ml Drainable Collection bag

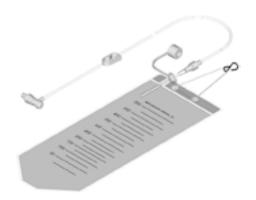
Sterile, 6 units per box



# **DRAINAGE ACCESSORY KIT**

Reference	Description
910122	500 ml Closed drainage bag with 150 cm patient line for intra-operative drainage of CSF

Sterile, 5 units per box









• OD: 2.0 mm; ID: 1.4 mm for use with 8 Fr. catheters

Reference	Description
999108	Sterile, 5 units per box

# **LUER LOCK CONNECTORS**

- Polycarbonate luer lock connectors.
- $\bullet~$  OD: 1.2 mm; ID: 0.7 mm for use with 5 Fr. and 7 Fr. catheters

Reference	Description
999105	Sterile, 5 units per box











# Indications and Contraindications



# Drill Bits (Spoo75, Spoo87, Spoo88)

#### Indications

The Cranial Access Kit allows for access to the subarachnoid space or the lateral ventricles of the brain. The kit is intended to be used with an external drainage and monitoring system in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF, and to monitor ICP.

#### Contraindications

This product is not designed, sold, or intended for use except as indicated.

# **CODMAN® Cranial Hand Drill and Cranial Drill Bits**

#### Indications

The CODMAN Cranial Hand Drill and Cranial Drill Bits are indicated when a craniotomy is required for placement of an intracranial pressure (ICP) monitoring device and/or cerebrospinal fluid drainage device.

#### Contraindications

This device is not designed, sold, or intended for any use except as indicated.

#### DirectLink™ ICP Module

#### Indications

The intended use of the DirectLink 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.

#### Contraindications

This device is not designed, sold or intended for use except as indicated

#### Cerelink™ ICP Monitor

#### Indications

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 numeric 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. Use of the kit is indicated when direct intracranial pressure (ICP) monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications.

#### Cerelink™ ICP Sensors

#### Indications

Use of the kit is indicated when direct intracranial pressure (ICP) monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications. 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.

#### 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. Ventriculostomy is contraindicated in patients with coagulopathy, or active infection in the area of the catheter. Use of the Ventricular Catheter is contraindicated in children less than one year of age. This kit is not designed, sold, or intended for any use except as indicated.

#### **CODMAN®** Double Lumen Bolt

#### Indications

The CODMAN Double Lumen Bolt is designed to introduce and secure in place sensors for intracranial monitoring applications.

#### Contraindications

Insertion of the bolt is contraindicated in children less than one year of age. This device is not designed, sold, or intended for use as a therapeutic device.

#### **Patient Monitor Interface Cables**

#### Indications

The Patient Monitor Interface Cable is intended for use as a connecting cable between DirectLink  $^{\text{TM}}$  ICP Module or CereLink  $^{\text{TM}}$ , and selected patient monitors available from third party suppliers

#### Contraindications

This device is not designed, sold or intended for use except as indicated.



# Licox® P<sub>+</sub>O<sub>2</sub> Monitor LCX02 & Accessories

#### **Indications**

The Integra® Licox®  $P_tO_2$  Monitor measures oxygen partial pressure ( $P_tO_2$ ) and temperature in brain tissue and these parameters are used together as an aid in the determination of the perfusion status of cerebral tissue local to sensor placement. Monitor values are relative within an individual, and should not be used as the sole basis for determining a diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.

#### Contraindications

The Integra Licox P<sub>t</sub>O<sub>2</sub> Monitor and its accessories are contraindicated for use in a Magnetic Resonance (MR) environment.

# Licox® IM1S, IM2SEU, IM3STEU, IP1P, IP2P, IT2EU (included CC1SB, C8B, CC1P1, IM1, IM2EU, IM3EU, IM3SEU, IP1, IP2 and VK52)

#### Indications

The Licox Brain Oxygen Monitoring System measures intracranial oxygen and temperature and is intended as an adjunct monitor of trends of these parameters, indicating the perfusion status of cerebral tissue local to sensor placement. Licox System values are relative within an individual, and should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.

#### Contraindications

Licox products are not intended for any use other than that indicated. Contraindications for device insertion into the body apply, e.g. coagulopathy and/or susceptibility to infections or infected tissue. A platelet count of less than 50 000 per  $\mu l$  is considered a contraindication. This value may differ according to different hospital protocols.

### **Licox® Probe Cables**

#### Indications

The Licox probe cables and probe extension cables are accessories for the Integra Licox Monitor range. The test set (BC10R) is intended to be used when testing and maintaining the Licox monitor. The procedures are intended to be performed by the hospital's biomedical engineering staff.

#### Contraindications

The Integra Licox monitor and its accessories are contraindicated for use in a Magnetic Resonance (MR) environment.

#### EDS<sub>3</sub>

#### **Indications**

Use of the Codman® EDS 3<sup>™</sup> CSF External Drainage System (EDS 3) is indicated for draining cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing intracranial pressure and CSF volume.

#### Contraindications

Codman® EDS 3™: Use of this device is contraindicated if scalp infection is present. Use of this device is contraindicated for patients receiving anticoagulants or for patients who are known to have a bleeding diathesis. Use of this device is contraindicated where 24-hour supervision from trained personnel is not available.

#### AccuDrain®

#### Indications

Draining and monitoring of Cerebrospinal Fluid (CSF) flow from the ventricles of the brain or lumbar subarachnoid space is indicated in selected patients to: • Reduce Intracranial Pressure (ICP) • Monitor Intracranial Pressure (ICP) • Monitor Cerebrospinal Fluid (CSF) • Provide temporary CSF drainage.

#### Contraindications

This device is not designed, sold, or intended for use except as indicated. The External Drainage System is contraindicated in the following: Anticoagulation therapy, Coagulation disorders, Untreated scalp infections. System use is contraindicated where trained personnel are not available to supervise drainage and monitoring on a 24-hour a day basis.

# Hermetic Plus™ External CSF Drainage Systems

#### Indications

Draining and monitoring of Cerebrospinal Fluid (CSF) flow from the lateral ventricles of the brain or lumbar subarachnoid space is indicated in selected patients to: • Reduce Intracranial Pressure (ICP) • Monitor Intracranial Pressure (ICP) • Monitor Cerebrospinal Fluid (CSF) • Provide temporary CSF drainage for patients with infected hydrocephalic shunts.

Monitoring of Intracranial Pressure (ICP) is usually performed in selected patients with: • Severe head injury • Subarachnoid hemorrhage • Reyes syndrome or similar encephalopathies • Hydrocephalus • Intracranial hemorrhage • Under physician supervision and discretion when drainage is to be used as a therapeutic maneuver.

Monitoring can also be used to evaluate the status pre-and postoperatively for space-occupying lesions.



#### Contraindications

This device is not designed, sold, or intended for use except as indicated. Lumbar drainage and/or lumbar pressure monitoring should not be used in the presence of: non-communicating hydrocephalus; a large intracranial mass, tumor or hematoma; and in patients who have demonstrated a blockage of cerebrospinal fluid pathways due to trauma, tumor, hematoma or other large intracranial mass. Lumbar catheters are contraindicated in cases of spinal abnormalities that would prevent free insertion of the lumbar catheter. Lumbar catheters are contraindicated in infants where the lower end of the spinal cord has not yet migrated to its cephalad L1-2 position. In view of the marked narrowing of the lumbosacral canal in achondroplastic patients, a lumbar catheter in the subarachnoid space is contraindicated.

# **Pole Mount Assembly and Accessories**

#### Indications

The Pole Mount Assembly provides support and alignment for External Ventricular Drainage (EVD) Systems. Draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space is indicated in selected patients to: • Reduce Intracranial Pressure (ICP) • Monitor Intracranial Pressure (ICP) • Monitor Cerebral Spinal Fluid (CSF) • Provide temporary CSF drainage for patients with infected hydrocephalic shunts. Monitoring of Intracranial Pressure (ICP) is usually performed in selected patients with: • Severe head injury • Subarachnoid hemorrhage • Reyes syndrome or similar encephalopathies • Hydrocephalus • Intracranial hemorrhage • Under physician supervision and discretion when drainage is to be used as a therapeutic maneuver.

Monitoring can also be used to evaluate the status pre-and postoperatively for space-occupying lesions.

#### Contraindications

This device is not designed, sold, or intended for use except as indicated.

## **EDS, IDS & Luer Lock Connectors**

#### Indications

The drainage sets are intended for cerebrospinal fluid (CSF) drainage, sampling and collection.

#### Contraindications

External ventricular drainage and integral ventricular and lumbar drainage sets are contraindicated for patients with a history of blood-clotting abnormalities, receiving anticoagulants or with scalp or skin infections.

# **Ventricular Drainage System**

#### **Indications**

The major indication for external drainage is the management of hydrocephalic shunt infections. If an internal shunt is not indicated, treatment of other cerebral conditions such as preoperative or post-operative pressure monitoring may also require external drainage of CSF to control increased intracranial pressure.

#### Contraindications

This device is not designed, sold, or intended for use except as indicated

#### **Bactiseal®**

#### Indications

The Codman® BACTISEAL® EVD Catheter and Codman® BACTISEAL® Clear EVD Catheter Sets (BACTISEAL® EVD Catheters), are indicated for gaining access to the ventricles of the brain and can be used with dimensionally compatible devices for draining cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing intracranial pressure and CSF volume.

#### Contraindications

Bactiseal®: Do not implant this device in patients with active infections, such as ventriculitis meningitis, or skin infections at or near the implantation site. Treat the infection before implanting this device. Do not implant this device in patients with known hypersensitivity to rifampin or clindamycin hydrochloride. Use of this device is contraindicated in patients receiving anticoagulants or known to have a bleeding diasthesis.

# **HERMETIC™** External Drainage Catheters

#### **Indications**

External ventricular drainage catheters are indicated for drainage and monitoring of CSF from the lateral ventricles of the brain. The catheters may be used to reduce intracranial pressure (ICP), to monitor ICP, to monitor CSF and in the management of hydrocephalic shunt infections. External lumbar drainage catheters are indicated for drainage and monitoring of CSF from the lumbar subarachnoid space.

#### Contraindications

These devices are not designed, sold or intended for use except as indicated. Lumbar drainage and/or lumbar pressure monitoring should not be used in the presence of: non-communicating hydrocephalus; a large intracranial mass, tumor or hematoma; or in patients who have demonstrated a blockage of cerebrospinal fluid path ways due to trauma, tumor, hematoma or other large intracranial mass. Lumbar catheters are contraindicated in cases



of spinal abnormalities that would prevent free insertion of the lumbar catheter. Lumbar catheters are contraindicated in infants where the lower end of the spinal cord has not yet migrated to its cephalad L1-2 position. In view of the marked narrowing of the lumbosacral canal in achondroplastic patients, a lumbar catheter in the subarachnoid space is contraindicated.

# CODMAN® EDS 3™ Clear Ventricular CSF Catheter

#### **Indications**

Use of the CODMAN EDS 3 Clear Ventricular CSF Catheter (EDS 3 Ventricular Catheter) is indicated for gaining access to the ventricles of the brain. It is designed for use with dimensionally compatible devices for draining cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing intracranial pressure and CSF volume.

#### Contraindications

This device is not designed, sold, or intended for use except as indicated. Use of this device is contraindicated if scalp infection is present. It is contraindicated in patients receiving anticoagulants or who are known to have a bleeding diathesis.

# **Ventricular Catheter Accessory Kit**

#### Indications

The Ventricular Catheter is intended for use with Integra external cerebrospinal fluid (CSF) drainage, sampling, and collection systems.

#### Contraindications

External ventricular drainage is contraindicated for patients: with a history of blood-clotting abnormalities, receiving anticoagulants, with scalp or skin infections.

# Intraventricular Monitoring Catheter Set (IVMCS)

#### **Indications**

The IVMCS is intended for intraventricular pressure monitoring, external drainage and sampling of cerebrospinal fluid (CSF).

#### Contraindications

ICP monitoring and external CSF drainage systems are contraindicated in patients: with a history of blood-clotting abnormalities, receiving anticoagulants, with scalp or skin infections.

# **Lumbar Catheter Accessory Kit**

#### Indications

The LCAK is designed for CSF drainage from the lumbar intrathecal space.

#### Contraindications

External lumbar drainage is contraindicated in patients: with a history of blood-clotting abnormalities, receiving anticoagulants, with skin infections.

# Subdural Drainage Catheter Kit Subdural Catheter

#### Indications

The Subdural Drainage Catheter is intended for drainage of extraventricular fluid collections, such as hygromas and chronic hematomas, into an external drainage system (such as the Suction Reservoir or the EDS or IDS Systems from Integra NeuroSciences) or an implanted catheter communicating with an appropriate drainage site. The patient clinical pathology dictates whether the Subdural Drainage Catheter is connected to an internal or external drainage system.

#### Contraindications

The use of the Subdural Catheter is contraindicated in patients with acute or subacute subdural hematoma and in patients undergoing anticoagulant therapy.

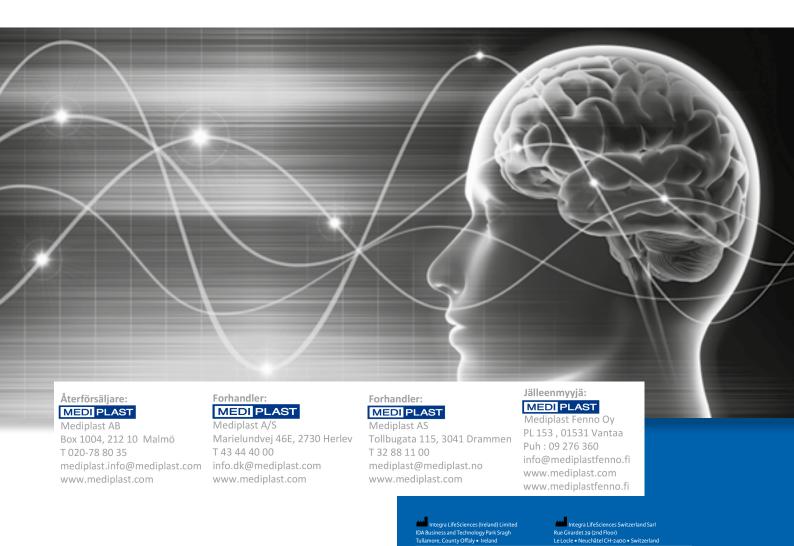


	Index			I	
92_6617		8	ICP16		21
. ,		,			
		-			
		-,	•		
		_			
			•		
		,			
					-
					-
			_		
-			-		
					, -
826884		18	INS4500		4C
826887		18	INS5010		42
826888		18	INS8220		33, 39
826889		18	INS8301		32
901302		41	INS8330		42
910110A		34	INS8400		30
910112A		34	INS8401		30
910116A		44	INS8420		40
910116D		44	INS8600		33
910120A		34	INS8601		
910121		42	INS8700		31, 32, 33, 44
•					
•					
				M	
999100		45			
			MONPWR		19
	Α.				
	Α				
				N	
AC31 EII		10		IN	
AC3.1_E0		19			
			NL850500V		35
	_				
	В				
				D	
				Р	
BAT1001		19			
BC10PA		19	DMIOMDM1		16
BC10PMO		19			
BC10PV		19	PIVIOCAB		
BC10R		19			
BC10TA		19			
				C	
		, and the second		S	
			SPOOZE		
	C				
Can			JPUU88		1
				11	
CC1SB		20, 22		V	
	-		VKE2		22.24
	E		v I/JZ		23, 24





#### A DIVISION OF INTEGRA LIFESCIENCES



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

Integra LifeSciences Services (France) SAS
Sales & Marketing EMEA
Immeuble Séquoia z \* 97 allée Alexandre Borodine
Part Cethonlogique de la Porte des Alpes
69800 Saint Priest \* FRANCE +33 (0)4 37 47 59 00 phone = +33 (0)4 37 47 59 99 fax integralife.eu

#### Customer Services

Customer Services
International: +33 (o)4 37 47 59 50 \* +33 (o)4 37 47 59 25 (Fax) \* csemea@integralife.com
Belgium/Luxembourg: +32 (o)2 257 4130 \* +32 (o)2 253 2466 (Fax) \* custsvcbenelux@integralife.com
Itally: +39 (o) 2 577 89 21 \* +39 (o) 2 575 1137 (Fax) \* custsvctlaly@integralife.com
Cermany: +49 (o) 20102 5535 6500 \* +49 (o)2102 553 6636 (Fax) \* custsvcgermany@integralife.com
Switzerland: +41 (o)2 27 21 23 00 \* +41 (o)2 27 21 23 99 (Fax) \* custsvcsuisse@integralife.com Switzerland: -41 (0)2 77 21 23 00 + -41 (0)2 72 71 23 90 (rax) \*\* CUSTSVCSUSSEQIENTEGRAITEC.COM
Prance: +32 (0)3 74 75 910 \*\* -33 (0)4 37 47 59 10 \*\* 33 (0)4 37 47 59 10 \*\* 33 (0)4 37 47 59 10 \*\* 33 (0)4 37 47 59 10 \*\* 31 62 31



silability of these products might vary from a given country or region to another, as a result of specific local regulatory proval or clearance requirements for sale in such country or region. on-contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to

11 Enterprise Drive Hainsboro New Jersey 08536 • USA

EC REP \*Integra LifeSciences Services (France) SAS

Integra NeuroSciences Implants (France) S.A.S. 2905 route des dolines 06921 Sophia Antipolis Cedex • France Integra LifeSciences Production Corporation

11 Cabot Boulevard Mansfield • MA 02048 • USA

formation on devices classification. All the medical devices mentioned on this document are CE marked according European council directive 93/42/EEC on medical devices mentioned on this document are CE marked according European council directive 93/42/EEC on medical devices and its relatives, unless specifically identified as "NOT CE ARKEO". Directink, CereLink, Accurdain, Squeeze-Lok, Traumacath, MoniTor ICP and EDS3 are trademarks of Integra resciences Corporation or its subsidiaries. Codman Microsensor, Bactiseal, Codman, Licox, Integra and the Integra logo, er egistered trademarks of Integra LifeSciences Corporation or its subsidiaries in the United States and/or other countries lcro, Veni-gard and Smartsite are trademarks of their respective owners.

©2020 Integra LifeSciences Corporation. All rights reserved. 1148092-5-EN DOCUMENT FOR USE IN EUROPE, MIDDLE-EAST and AFRICA ONLY. Last revision date: 07/2020.