Codman®

# CODMAN® EDS 3™ CSF External Drainage System with Ventricular Catheter

# CODMAN® EDS 3™ CSF External Drainage System without Ventricular Catheter

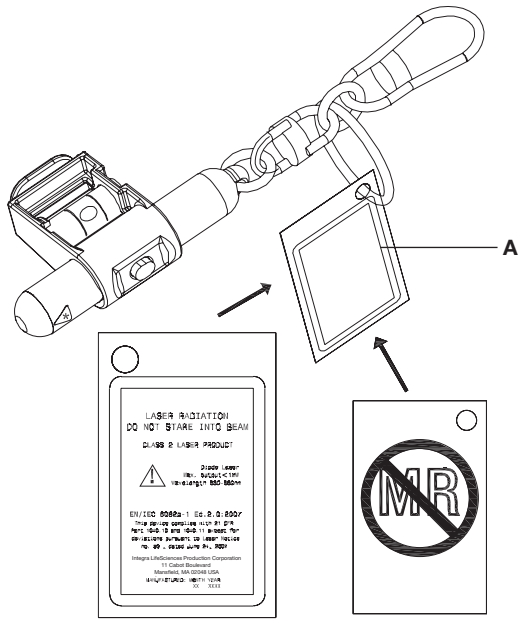
Integra LifeSciences Production Corporation
11 Cabot Boulevard
Mansfield, MA 02048 USA

EC REP
Integra LifeSciences Services (France)
Immeuble Séquoïa 2
97 Allée Alexandre Borodine
Parc Technologique de la Porte des Alpes
69800 Saint Priest – France

CE
2797

**LCN 208650-001 Rev E 06/19 1145988-3**

**1a**




**EN - ENGLISH**
**A.** WARNING LABEL

**FR - FRANÇAIS**
**A.** ETIQUETTE D'AVERTISSEMENT

**DE - DEUTSCH**
**A.** WARNAUFKLEBER

**NL - NEDERLANDS**
**A.** WAARSCHUWINGSETIKET

**IT - ITALIANO**
**A.** ETICHETTA di AVVERTENZE

**ES - ESPAÑOL**
**A.** ETIQUETA DE ADVERTENCIA

**PT (EU) - PORTUGUÊS**
**A.** ETIQUETA DE ADVERTÊNCIA

**DA - DANSK**
**A.** ADVARSELSETIKET

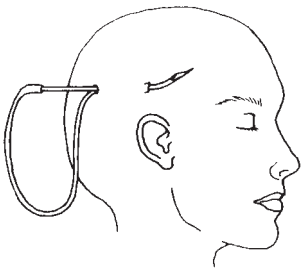
**SV - SVENSKA**
**A.** VARNINGSETIKETT

**FI - SUOMI**
**A.** VAROITUSTARRA

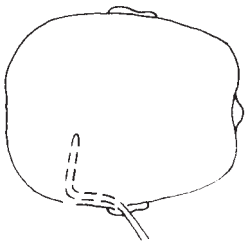
**EL - ΕΛΛΗΝΙΚΑ**
**A.** ΕΤΙΚΕΤΑ ΠΡΟΕΙΔΟΠΟΙΗΣΗΣ

**HU - MAGYAR**
**A.** FIGYELMEZTETŐ CÍMKE

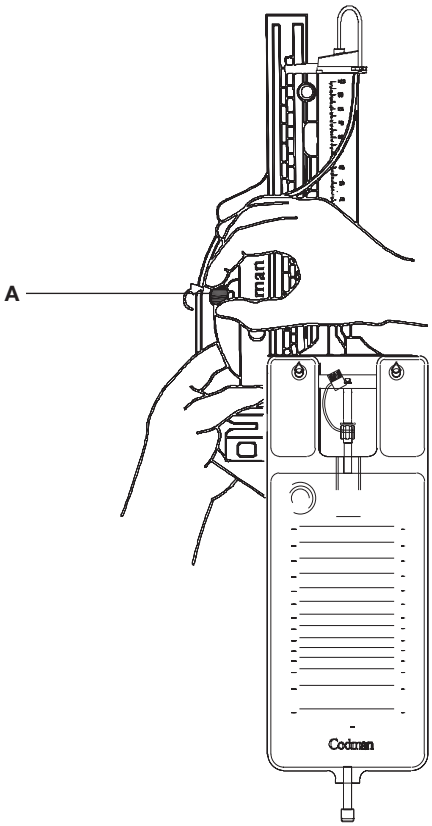
**2**



**3**



**4**




**EN - ENGLISH**
**A.** Blue screw

**FR - FRANÇAIS**
**A.** Vis bleue

**DE - DEUTSCH**
**A.** Blaue Schraube

**NL - NEDERLANDS**
**A.** Blauwe schroef

**IT - ITALIANO**
**A.** Vite blu

**ES - ESPAÑOL**
**A.** Tornillo azul

**PT (EU) - PORTUGUÊS**
**A.** Parafuso azul

**DA - DANSK**
**A.** Blå skrue

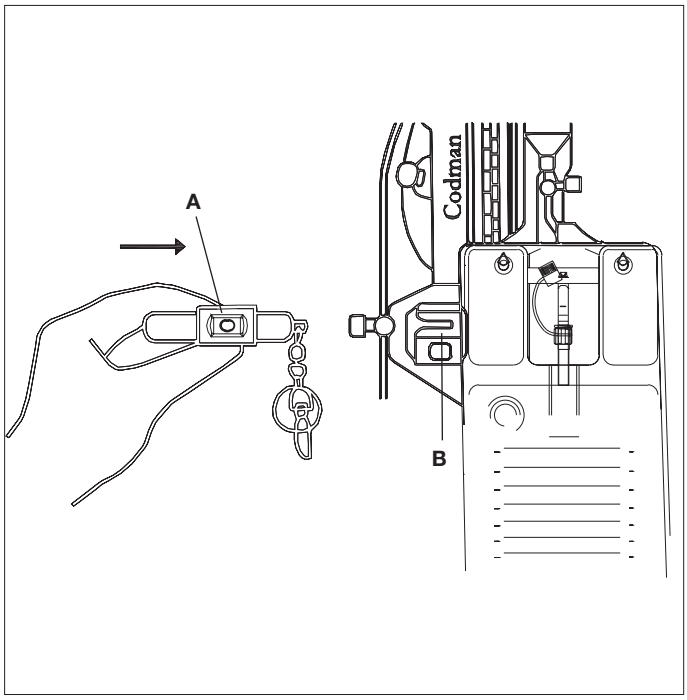
**SV - SVENSKA**
**A.** Blå skruv

**FI - SUOMI**
**A.** Sininen ruuvi

**EL - ΕΛΛΗΝΙΚΑ**
**A.** Μπλε βίδα

**HU - MAGYAR**
**A.** Kék csavar

**5**




**EN - ENGLISH**
- **A.** Leveling device
- **B.** Slot for leveling device

**FR - FRANÇAIS**
- **A.** Dispositif de nivellement
- **B.** Fente pour dispositif de nivellement

**DE - DEUTSCH**
- **A.** Nivelliergerät
- **B.** Schlitz für Nivelliergerät

**NL - NEDERLANDS**
- **A.** Waterpasinstrument
- **B.** Sleuf voor waterpasinstrument

**IT - ITALIANO**
- **A.** Dispositivo di livellamento
- **B.** Fessura per il dispositivo di livellamento

**ES - ESPAÑOL**
- **A.** Dispositivo de nivelación
- **B.** Ranura para dispositivo de nivelación

**PT (EU) - PORTUGUÊS**
- **A.** Dispositivo de nivelamento
- **B.** Ranhura para dispositivo de nivelamento

**DA - DANSK**
- **A.** Nivelleringsanordning
- **B.** Rille til nivelleringsanordning

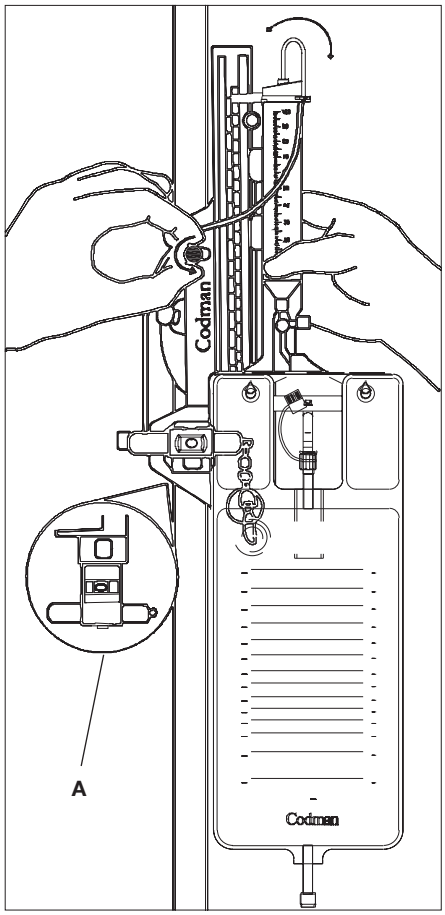
**SV - SVENSKA**
- **A.** Nivåjusteringsanordning
- **B.** Plats för nivåjusteringsanordning

**FI - SUOMI**
- **A.** Tasain
- **B.** Aukko tasaimelle

**EL - ΕΛΛΗΝΙΚΑ**
- **A.** Συσκευή ευθυγράμμισης
- **B.** Σχισμή για τη συσκευή ευθυγράμμισης

**HU - MAGYAR**
- **A.** Szintező készülék
- **B.** Szintező készülék nyílása

**6**




**EN - ENGLISH**
- **A.** Viewed from above: Bubble in center indicates level

**FR - FRANÇAIS**
- **A.** Vue du dessus : lorsque la bulle est au milieu, le système est de niveau

**DE - DEUTSCH**
- **A.** Draufsicht: Die Blase in der Mitte zeigt an, dass das Gerät ausgerichtet ist

**NL - NEDERLANDS**
- **A.** Van boven af gezien: Luchtbel in het midden duidt op waterpaspositie

**IT - ITALIANO**
- **A.** Visualizzazione dall'alto: la bolla al centro indica il livello

**ES - ESPAÑOL**
- **A.** Vista superior: la burbuja en el centro indica la nivelación

**PT (EU) - PORTUGUÊS**
- **A.** Observado de cima: A bolha no centro indica o nível

**DA - DANSK**
- **A.** Set fra oven: Boblen i centrum angiver vandret position

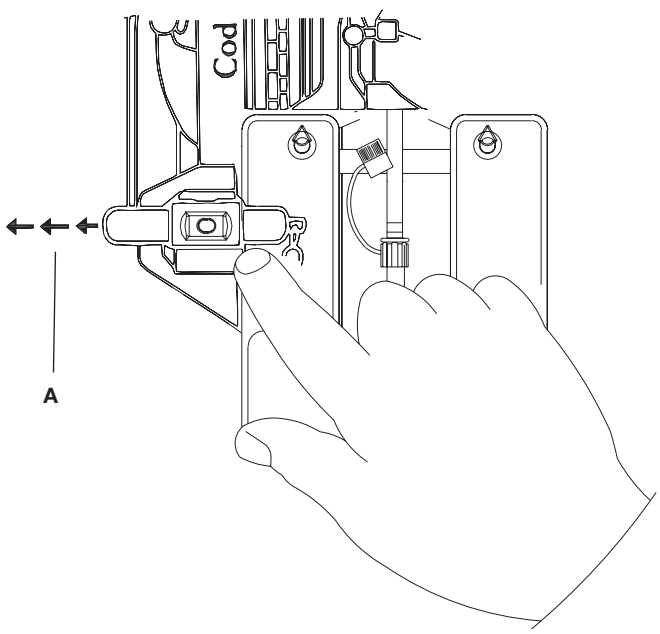
**SV - SVENSKA**
- **A.** Från ovan: Bubblan i mitten indikerar nivån

**FI - SUOMI**
- **A.** Kuva yläpuolelta: Keskellä oleva kupla osoittaa tasausta

**EL - ΕΛΛΗΝΙΚΑ**
- **A.** Κάτοψη: Η φυσαλίδα στο κέντρο υποδεικνύει οριζόντια θέση

**HU - MAGYAR**
- **A.** Felülnézet: a buborék középen történő elhelyezkedése jelzi a megfelelő helyzetet

**7**




**EN - ENGLISH**
**A.** Beam of laser light

**FR - FRANÇAIS**
**A.** Rayon de la lumière du laser

**DE - DEUTSCH**
**A.** Laserstrahl

**NL - NEDERLANDS**
**A.** Laserlichtstraal

**IT - ITALIANO**
**A.** Fascio di luce del laser

**ES - ESPAÑOL**
**A.** Haz de luz láser

**PT (EU) - PORTUGUÊS**
**A.** Raio de luz laser

**DA - DANSK**
**A.** Laserens lysstråle

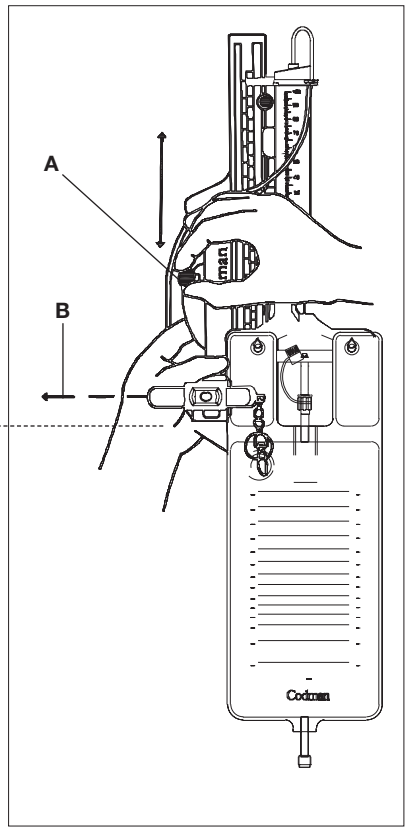
**SV - SVENSKA**
**A.** Laserljusstråle

**FI - SUOMI**
**A.** Lasersäde

**EL - ΕΛΛΗΝΙΚΑ**
**A.** Δέσμη φωτός λέιζερ

**HU - MAGYAR**
**A.** Lézersugár

**8a**




**EN - ENGLISH**
**A.** Blue screw
**B.** Beam of laser light

**FR - FRANÇAIS**
**A.** Vis bleue
**B.** Rayon de la lumière du laser

**DE - DEUTSCH**
**A.** Blaue Schraube
**B.** Laserstrahl

**NL - NEDERLANDS**
**A.** Blauwe schroef
**B.** Laserlichtstraal

**IT - ITALIANO**
**A.** Vite blu
**B.** Fascio di luce del laser

**ES - ESPAÑOL**
**A.** Tornillo azul
**B.** Haz de luz láser

**PT (EU) - PORTUGUÊS**
**A.** Parafuso azul
**B.** Raio de luz laser

**DA - DANSK**
**A.** Blå skrue
**B.** Laserens lysstråle

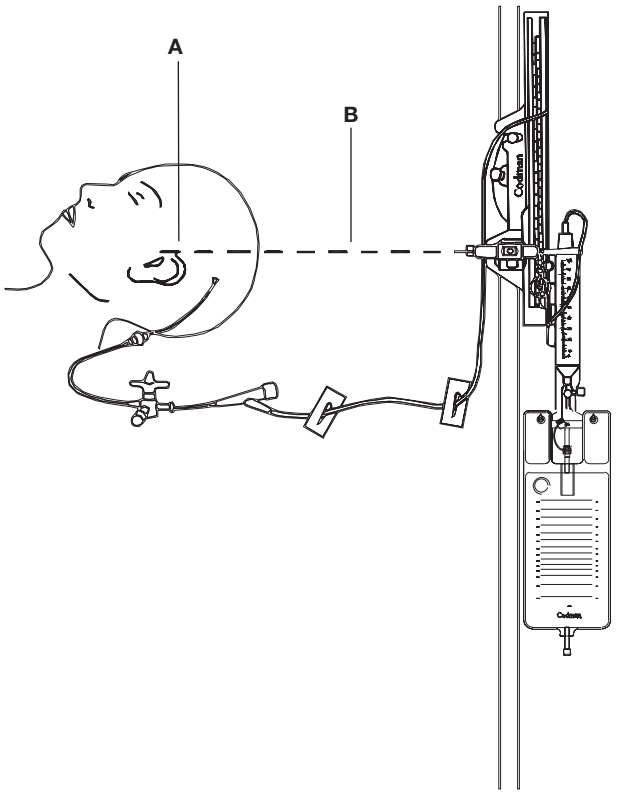
**SV - SVENSKA**
**A.** Blå skruv
**B.** Laserljusstråle

**FI - SUOMI**
**A.** Sininen ruuvi
**B.** Lasersäde

**EL - ΕΛΛΗΝΙΚΑ**
**A.** Μπλε βίδα
**B.** Δέσμη φωτός λέιζερ

**HU - MAGYAR**
**A.** Kék csavar
**B.** Lézersugár

**8b**




**EN - ENGLISH**
- **A.** External auditory meatus
- **B.** Beam of laser light

**FR - FRANÇAIS**
- **A.** Conduit auditif externe
- **B.** Rayon de la lumière du laser

**DE - DEUTSCH**
- **A.** Äußerer Gehörgang
- **B.** Laserstrahl

**NL - NEDERLANDS**
- **A.** Uitwendige gehoorgang
- **B.** Laserlichtstraal

**IT - ITALIANO**
- **A.** Meato uditorio esterno
- **B.** Fascio di luce del laser

**ES - ESPAÑOL**
- **A.** Meato auditivo externo
- **B.** Haz de luz láser

**PT (EU) - PORTUGUÊS**
- **A.** Meato auditivo externo
- **B.** Raio de luz laser

**DA - DANSK**
- **A.** Ydre øregang
- **B.** Laserens lysstråle

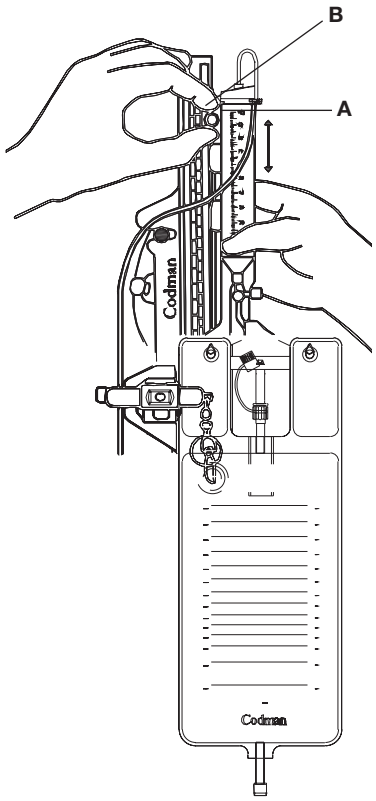
**SV - SVENSKA**
- **A.** Yttre hörselgång
- **B.** Laserljusstråle

**FI - SUOMI**
- **A.** Ulompi korvakäytävä
- **B.** Lasersäde

**EL - ΕΛΛΗΝΙΚΑ**
- **A.** Έξω ακουστικός πόρος
- **B.** Δέσμη φωτός λέιζερ

**HU - MAGYAR**
- **A.** Külső hallónyílás
- **B.** Lézersugár

**9**




**EN - ENGLISH**
- **A.** White screw
- **B.** Drip chamber pressure reference line

**FR - FRANÇAIS**
- **A.** Vis blanche
- **B.** La ligne de référence de pression de la chambre compte-gouttes

**DE - DEUTSCH**
- **A.** Weiße Schraube
- **B.** Druckeinstellungsmarkierstab der Tropfkammer

**NL - NEDERLANDS**
- **A.** Witte schroef
- **B.** Drukreferentielijn van de druppelkamer

**IT - ITALIANO**
- **A.** Vite bianca
- **B.** Linea di riferimento di pressione della camera di gocciolamento

**ES - ESPAÑOL**
- **A.** Tornillo blanco
- **B.** Línea de referencia de presión de la cámara de goteo

**PT (EU) - PORTUGUÊS**
- **A.** Parafuso branco
- **B.** Linha de referência de pressão da câmara conta-gotas

**DA - DANSK**
- **A.** Hvid skrue
- **B.** Trykreferencelinie på dråbekammeret

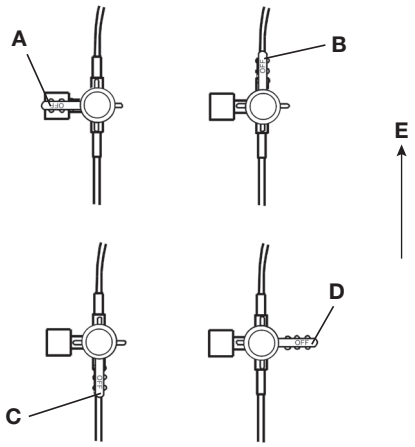
**SV - SVENSKA**
- **A.** Vit skruv
- **B.** Droppkammartryckets referenslinje

**FI - SUOMI**
- **A.** Valkoinen ruuvi
- **B.** Tiputussäiliön paineraja

**EL - ΕΛΛΗΝΙΚΑ**
- **A.** Άσπρη βίδα
- **B.** Γραμμή αναφοράς πίεσης του θαλάμου ροής

**HU - MAGYAR**
- **A.** Fehér csavar
- **B.** A cseppgyűjtő tartály nyomás-referenciavonala

**10**




### EN - ENGLISH
**Using the patient line stopcock**
- **A.** Drainage only
- **B.** Monitoring only
- **C.** Closed position
- **D.** Null position
- **E.** Direction of drainage

### FR - FRANÇAIS
**Utilisation du robinet d'arrêt de la ligne de patient**
- **A.** Drainage uniquement
- **B.** Monitoring uniquement
- **C.** Fermée
- **D.** Zéro
- **E.** Sens de drainage

### DE - DEUTSCH
**Verwenden des Verschlusshahns der Patientenleitung**
- **A.** Nur Drainage
- **B.** Nur Überwachung
- **C.** Geschlossen
- **D.** Null
- **E.** Drainage-Richtung

### NL - NEDERLANDS
**Het gebruik van de patiënt-infuuslijnafsluiter**
- **A.** Uitsluitend draineren
- **B.** Uitsluitend monitoring
- **C.** Gesloten
- **D.** Geen functie
- **E.** Drainagerichting

### IT - ITALIANO
**Utilizzo del rubinetto della linea paziente**
- **A.** Solo drenaggio
- **B.** Solo monitoraggio
- **C.** Chiuso
- **D.** Zero
- **E.** Direzione del drenaggio

### ES - ESPAÑOL
**Uso de la llave de paso de la línea del paciente**
- **A.** Sólo drenaje
- **B.** Sólo monitorización
- **C.** Cerrada
- **D.** Nula
- **E.** Dirección de drenaje

### PT (EU) - PORTUGUÊS
**Utilização da válvula de segurança da linha do paciente**
- **A.** Apenas drenagem
- **B.** Apenas monitorização
- **C.** Fechada
- **D.** Zero
- **E.** Direcção da drenagem

### DA - DANSK
**Sådan anvendes stophanen på patientslangen**
- **A.** Kun drænage
- **B.** Kun overvågning
- **C.** Lukket
- **D.** Nul
- **E.** Drænageretning

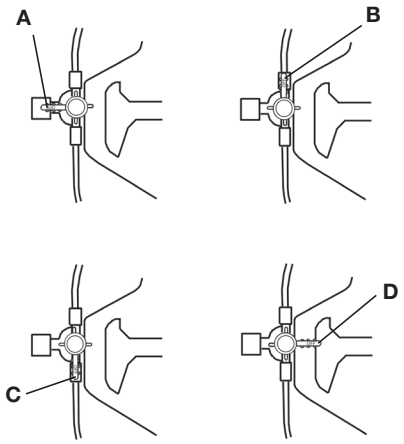
### SV - SVENSKA
**Användning av patientslangens kran**
- **A.** Endast dränering
- **B.** Endast övervakning
- **C.** Stängd
- **D.** Noll
- **E.** Dräneringsriktning

### FI - SUOMI
**Potilasletkun sulkuventtiilin käyttö**
- **A.** Ainoastaan dreenaus
- **B.** Ainoastaan tarkkailu
- **C.** Suljettu
- **D.** Nolla
- **E.** Dreenauksen suunta

### EL - ΕΛΛΗΝΙΚΑ
**Χρήση της στρόφιγγας της γραμμής ασθενούς**
- **A.** Μόνον παροχέτευση
- **B.** Μόνον παρακολούθηση
- **C.** Κλειστή
- **D.** Μηδενική
- **E.** Κατεύθυνση αποστράγγισης

### HU - MAGYAR
**A betegvezeték zárócsapjának használata**
- **A.** Csak drenázs
- **B.** Csak monitorozás
- **C.** Zárt pozíció
- **D.** Nulla pozíció
- **E.** A folyás iránya

**11**




### EN - ENGLISH
**Using the system stopcock**
- **A.** Drainage only
- **B.** Monitoring only
- **C.** Closed
- **D.** Null

### FR - FRANÇAIS
**Utilisation du robinet d'arrêt du système**
- **A.** Drainage uniquement
- **B.** Monitoring uniquement
- **C.** Fermée
- **D.** Zéro

### DE - DEUTSCH
**Verwenden des Verschlusshahns des Systems**
- **A.** Nur Drainage
- **B.** Nur Überwachung
- **C.** Geschlossen
- **D.** Null

### NL - NEDERLANDS
**Het gebruik van de systeemafsluiter**
- **A.** Uitsluitend draineren
- **B.** Uitsluitend monitoring
- **C.** Gesloten
- **D.** Geen functie

### IT - ITALIANO
**Utilizzo del rubinetto del sistema**
- **A.** Solo drenaggio
- **B.** Solo monitoraggio
- **C.** Chiuso
- **D.** Zero

### ES - ESPAÑOL
**Uso de la llave de paso del sistema**
- **A.** Sólo drenaje
- **B.** Sólo monitorización
- **C.** Cerrada
- **D.** Nula

### PT (EU) - PORTUGUÊS
**Utilização da válvula de segurança do sistema**
- **A.** Apenas drenagem
- **B.** Apenas monitorização
- **C.** Fechada
- **D.** Zero

### DA - DANSK
**Sådan anvendes systemets stophane**
- **A.** Kun drænage
- **B.** Kun overvågning
- **C.** Lukket
- **D.** Nul

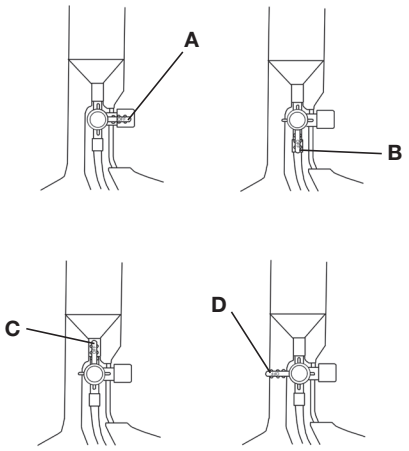
### SV - SVENSKA
**Användning av systemkranen**
- **A.** Endast dränering
- **B.** Endast övervakning
- **C.** Stängd
- **D.** Noll

### FI - SUOMI
**Järjestelmän sulkuventtiilin käyttö**
- **A.** Ainoastaan dreenaus
- **B.** Ainoastaan tarkkailu
- **C.** Suljettu
- **D.** Nolla

### EL - ΕΛΛΗΝΙΚΑ
**Χρήση της στρόφιγγας του συστήματος**
- **A.** Μόνον παροχέτευση
- **B.** Μόνον παρακολούθηση
- **C.** Κλειστή
- **D.** Μηδενική

### HU - MAGYAR
**A rendszer zárócsapjának működtetése**
- **A.** Csak drenázs
- **B.** Csak monitorozás
- **C.** Zárva
- **D.** Nulla

**12**




**EN - ENGLISH**

**Using the drip chamber stopcock**

**A.** Drainage only
**B.** Sampling only
**C.** Drip chamber
**D.** Null

**FR - FRANÇAIS**

**Utilisation du robinet d'arrêt de la chambre d'écoulement**

**A.** Drainage uniquement
**B.** Prélèvement uniquement
**C.** Chambre compte-gouttes
**D.** Zéro

**DE - DEUTSCH**

**Verwenden des Verschlusshahns der Tropfkammer**

**A.** Nur Drainage
**B.** Nur Probenentnahme
**C.** Tropfkammer
**D.** Null

**NL - NEDERLANDS**

**Het gebruik van de druppelkamerafsluiter**

**A.** Uitsluitend draineren
**B.** Uitsluitend vochtafname
**C.** Druppelkamer
**D.** Geen functie

**IT - ITALIANO**

**Utilizzo del rubinetto della camera di gocciolamento**

**A.** Solo drenaggio
**B.** Solo campionamento
**C.** Camera di gocciolamento
**D.** Zero

**ES - ESPAÑOL**

**Uso de la llave de paso de la cámara de goteo**

**A.** Sólo drenaje
**B.** Sólo toma de muestras
**C.** Cámara de goteo
**D.** Nula

**PT (EU) - PORTUGUÊS**

**Utilização da válvula de segurança da câmara conta-gotas**

**A.** Apenas drenagem
**B.** Apenas amostra
**C.** Câmara conta-gotas
**D.** Zero

**DA - DANSK**

**Sådan anvendes stophanen på dråbekammeret**

**A.** Kun drænage
**B.** Kun prøvetagning
**C.** Dråbekammer
**D.** Nul

**SV - SVENSKA**

**Användning av droppkammarens kran**

**A.** Endast dränering
**B.** Endast provtagning
**C.** Droppkammare
**D.** Noll

**FI - SUOMI**

**Tiputussäiliön sulkuventtiilin käyttö**

**A.** Ainoastaan dreenaus
**B.** Ainoastaan näytteenotto
**C.** Tiputussäiliö
**D.** Nolla

**EL - ΕΛΛΗΝΙΚΑ**

**Χρήση της στρόφιγγας του θαλάμου ροής**

**A.** Μόνον παροχέτευση
**B.** Μόνον δειγματοληψία
**C.** Θάλαμος ροής
**D.** Μηδενική

**HU - MAGYAR**

**A cseppgyűjtő tartály zárócsapjának használata**

**A.** Csak drenázs
**B.** Csak mintavétel
**C.** Cseppgyűjtő tartály
**D.** Nulla

# ENGLISH

## Table of Contents



**IMPORTANT INFORMATION**
Please Read Before Use

# CODMAN® EDS 3™ CSF External Drainage System with Ventricular Catheter

# CODMAN® EDS 3™ CSF External Drainage System without Ventricular Catheter

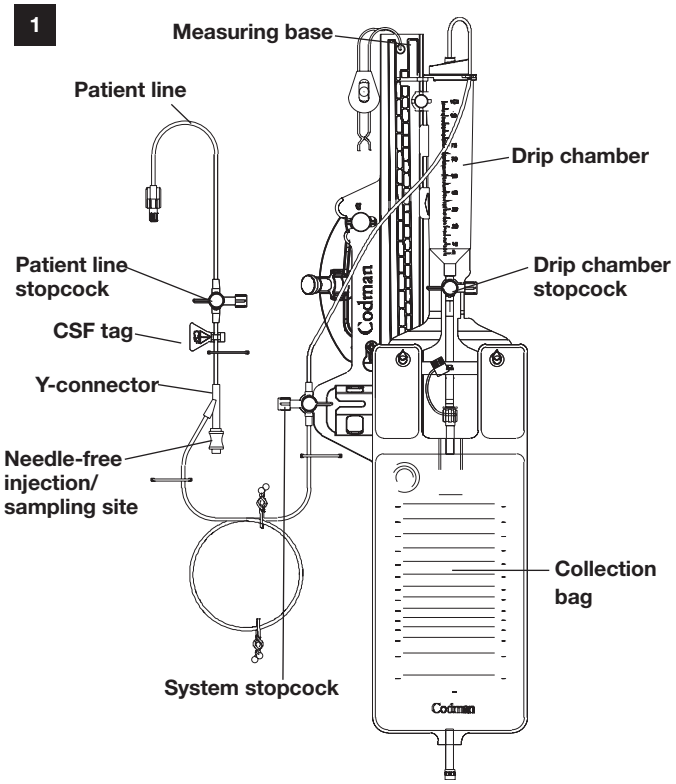
| STERILE | EO |
|---|---|

℞ Only

## Indications

Use of the CODMAN® EDS™ 3 CSF External Drainage System (EDS 3) is indicated for draining cerebrospinal fluid (CSF) from the cerebral ventricles or the lumbar subarachnoid space as a means of reducing intracranial pressure and CSF volume when the insertion of a permanent, internal shunt is not indicated.

## Description




The EDS 3 system, Figure 1, consists of:

- A 35 cm (13.8 in.) clear silicone ventricular catheter (1.5 mm I.D., 3.1 mm O.D.) with radiopaque stripe and depth markings (not shown)
- A 36 cm straight stainless steel stylet for catheter placement (not shown)
- A curved stainless steel trocar with a barbed end for drawing the catheter subcutaneously (not shown)
- A female LUER-LOK® connector and LUER-LOK cap to connect the distal end of the catheter (not shown)
- A doubled 76.2 cm (30 in.) cord with locking mechanism
- A 33 cm measuring base for regulating intracranial pressure (ICP) with mm Hg conversion
- A 100 mL drip chamber equipped with a microbial retentive atmospheric vent
- A 162 cm (64 in.) patient line equipped with:
  - 1 male LUER-LOK connector with vented cap
  - 1 four-way stopcock with a female LUER-LOK port
  - 1 Y-connector with needle-free sampling/injection site
  - 3 clamps
- Two four-way stopcocks with female LUER-LOK ports
- A sterile, vented, 700 mL capacity collection bag, graduated in 50 mL increments.

Pozicija Nr 1 ir 2 →

The EDS 3 system without Catheter comprises the external component only for replacement purposes. A male LUER-LOK connector with cap is provided for connection with a 1.5 mm inner-diameter silicone ventricular drainage catheter. The above products are provided sterile.

The EDS 3 system is not made with natural rubber latex.

**Note:** Collection bag volume measurement ±20 mL, or ±10% of actual liquid volume. Drip Chamber volume measurement ±1%.

The CODMAN EDS 3 Leveling Device is a nonsterile accessory designed for use with the CODMAN EDS 3 CSF External Drainage System. The EDS 3 Leveling Device consists of a laser-pointing device permanently encased in a mounting bracket that allows for attachment to and use with the CODMAN EDS 3 System.

Please see the label affixed to the leveling device (Figure 1a), which reads:

LASER RADIATION
DO NOT STARE INTO BEAM
CLASS 2 LASER PRODUCT
Diode Laser
Maximum Output <1mW
Wavelength 630-680 nm
EN/IEC 60825-1 Ed.2.0:2007
EN/IEC 60825-1 Ed.3.0:2014
This device complies with 21 CFR
Part 1040.10 and 1040.11 except for
deviations pursuant to Laser Notice
no. 50, dated June 24, 2007
Integra LifeSciences Production Corporation
11 Cabot Boulevard
Mansfield, MA 02048 USA
MANUFACTURED: MONTH YEAR

Pozicijos Nr 1, 2 ir 4

## Contraindications

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.

## WARNINGS

Intracranial pressure is controlled by the height of the Drip Chamber relative to the patient. It is important that neither the Drip Chamber nor the patient be raised or lowered accidentally. If either is raised or lowered, it is imperative to re-level the drainage system.

Turn the drip chamber stopcock closed to the bag to prevent liquid from refluxing to the drip chamber.

Close the Patient Line stopcock before transporting the patient to reduce the risk of liquid refluxing to the patient.

The height of the Drip Chamber or the position of the patient should only be changed by qualified personnel on the orders of a physician.

Movement by the patient after positioning of the Drip Chamber may affect the patient's ICP.

The EDS 3 System provides direct access to the ventricular drainage catheter via the patient line stopcock and the needle-free injection site. Care must be taken when administering medication through these locations to minimize the chance of intravascular medications being injected into the cerebrospinal fluid.

When using a lumbar catheter, take care not to withdraw the catheter after insertion into the Tuohy needle. If the catheter must be removed, to minimize the risk of damage to the catheter, withdraw the Tuohy needle and catheter simultaneously.

Finger-tighten all stopcock caps before using the system. Connections may loosen during shipping and handling. (Do not attempt to tighten or remove the needle-free injection port. This component is glued in place.)

Do not leave the EDS 3 system in the *Monitoring Only* position if shunting (draining) is the primary function. Always return the EDS 3 stopcocks to the *Drainage Only* position to resume draining.

Monitoring ICP with a stopcock in the *Null* position may result in false ICP readings. Simultaneous drainage and transducer monitoring may result in waveform artifacts and artificially low ICP readings. Alternate drainage and ICP monitoring can be achieved by adjusting the stopcocks to either the *Drainage Only* position for drainage or the *Monitoring Only* position for ICP monitoring.

If the system or drip-chamber stopcock is turned to the *Monitoring Only* position or *Off* position during ICP monitoring or flushing of the system, it must be returned to the *Drainage Only* position in order to resume draining.

Care should be taken not to raise or lower the Drip Chamber when calculating the drainage rate.

### Magnetic Resonance Imaging (MRI) Information

**CAUTION: Remove the Laser Leveling Device from the EDS 3 System before entering the MRI suite. This component is MR unsafe.**

MR

**EDS 3 Drainage System:**

#### MR SAFETY INFORMATION

Non-clinical testing has demonstrated that the EDS 3 Drainage System is MR Conditional. A patient connected to this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 or 3 T
- Maximum spatial gradient of 3,400 gauss/cm (34 T/m) (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
- A horizontal, cylindrical, closed-bore scanner
- WARNING: Do not use Transmit/Receive or Transmit-only RF Head coils. Only use Transmit/Receive RF Body coil or Transmit RF Body coil/Receive-only RF Head coil.
- WARNING: Do not bring any system components that are not marked MR Safe or MR Conditional into the MR suite.

***MRI-Related Heating***

Under the scan conditions defined above, the EDS 3 Drainage System is expected to produce a maximum temperature rise of less than 0.6°C after 15 minutes of continuous scanning.

***Artifact Information***

In non-clinical testing, the image artifact caused by the device extends less than 57 mm from the CODMAN EDS 3 Drainage System when imaged with a gradient echo pulse sequence and a 3 T MRI system.

**EDS 3 Ventricular Catheter (Included in 82-1730C):**

#### MR SAFETY INFORMATION

Non-clinical testing has demonstrated that the EDS 3 Ventricular Catheter is MR Conditional. A patient implanted with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 or 3 T
- Maximum spatial gradient of 5,800 gauss/cm (58 T/m) (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
- A horizontal, cylindrical, closed-bore scanner
- WARNING: Do not use Transmit/Receive or Transmit-only RF Head coils. Only use Transmit/Receive RF Body coil or Transmit RF Body coil/Receive-only RF Head coil.
- WARNING: Do not bring any system components that are not marked MR Safe or MR Conditional into the MR suite.

***MRI-Related Heating***

Under the scan conditions defined above, the EDS 3 Ventricular Catheter is expected to produce a maximum temperature rise of less than 2.8°C after 15 minutes of continuous scanning.

***Artifact Information***

In non-clinical testing, the image artifact caused by the device extends approximately 40 mm from the EDS 3 Ventricular Catheter when imaged with a gradient echo pulse sequence and a 3 T MRI system.

**EDS 3 Lumbar Catheter (Included in 82-1738C):**

#### MR SAFETY INFORMATION

Non-clinical testing has demonstrated that the EDS 3 Lumbar Catheter is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 or 3 T
- Maximum spatial field gradient of 4,000-gauss/cm (40 T/m) (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
- A horizontal, cylindrical, closed-bore scanner

- WARNING: Do not use Transmit/Receive or Transmit-only RF Head coils. Only use Transmit/Receive RF Body coil or Transmit RF Body coil/Receive-only RF Head coil.
- WARNING: Do not bring any system components that are not marked MR Safe or MR Conditional into the MR suite.

***MRI-Related Heating***
Under the scan conditions defined above, the EDS 3 Lumbar Catheter is expected to produce a maximum temperature rise of less than 1.6°C after 15 minutes of continuous scanning.

***Artifact Information***
In non-clinical testing, the image artifact caused by the device extends approximately 4 mm from the EDS 3 Lumbar Catheter when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system.

## Precautions
Refer to manufacturer's instructions when using components other than Integra LifeSciences Corporation's.

Inspect the sterile package carefully. Do not use if:
- the package or seal appears damaged,
- contents appear damaged, or
- the expiry date has passed.

Aseptic technique is necessary in all phases of the use of this product.

Exercise extreme care to prevent the ventricular catheter from coming in contact with bare fingers, towels, drapes, talc, or any linty or granular surfaces. Silicone rubber is highly electrostatic and therefore attracts airborne particles and surface contaminants that could produce tissue reaction.

Silicone rubber cuts and tears easily. Use rubber shod forceps when handling the catheter.

It is recommended that the catheter be sutured to the LUER-LOK hub to prevent possible separation of the components when the catheter is removed.

Exercise care when placing ligatures to avoid cutting or occluding the tubing. The use of stainless steel ligatures on silicone products is not recommended.

To prevent contamination, do not touch the inside threads or surface of the LUER-LOK cap with bare fingers. Do not set the LUER-LOK cap on a non-sterile surface.

**Do not** attempt to access the silicone seal of the needle-free injection/sampling site using a needle or blunt cannula. To prevent damage to the seal, access using standard Luer connection devices only.

Do not allow residue from disinfectants to remain on the inner surfaces of the LUER-LOK connectors. Such residue might cause the components to stick together. Contact the manufacturer of the disinfectant for further information.

To reduce the likelihood of infection, it is recommended that care of the catheter exit site and the connection to the external drain be carried out in accordance with principles established for the care of long-term hyperalimentation catheters.

Always attach the EDS 3 Device to the I.V. pole by fitting the clamp over the pole. Tighten the blue screw to secure the system in place. The locking mechanism is available as a secondary safety feature and must not be the primary method of attaching the system to the pole.

### Precautions for EDS 3 Leveling Device
Do not stare into the laser beam.

Laser light, when reflected from a mirror-like surface, can be dangerous.

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

## Sterility
②

The CODMAN EDS 3 CSF External Drainage System is intended for SINGLE USE ONLY; DO NOT RESTERILIZE. Use aseptic technique in all phases of handling. Integra LifeSciences Corporation's Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. These devices are intended to come into contact with the central nervous system and the ability does not currently exist to destroy possible contaminates such as Creutzfeldt-Jakob Disease. Reuse can also compromise device performance and any usage beyond the design intent of this single-use device can result in unpredictable use hazards or loss of functionality.

Integra LifeSciences Corporation will not be responsible for any product that is resterilized, nor accept for credit or exchange any product that has been opened but not used.

As long as the inner unit is not opened or damaged, the product is sterile.

The following components have been tested and were determined to be nonpyrogenic:

- Drainage Tubing fluid pathway from injection site to male LUER-LOK Connector
- Catheter
- Catheter LUER-LOK

## INSTRUCTIONS FOR USE
### General Surgical Technique: Ventricular Catheter
Since the sites of insertion of the ventricular catheter vary, decisions regarding the technique of insertion and verification of proper placement must be made by the surgeon on a case-by-case basis.

1. Aseptically prepare and drape the operative site.
2. Perform the craniotomy.
3. Perform the catheterization with the stylet inserted in the catheter.
4. Remove the stylet, and check for free flow of fluid. If using the CODMAN EDS 3 Clear Ventricular CSF Catheter the depth of insertion can be verified using the scale printed on the catheter.
5. Insert the barbed end of the trocar into the distal end of the catheter. Insert the sharp end of the trocar into the skin and tunnel subcutaneously for a short distance. See Figure 2.
6. Bring the trocar out through the scalp. Taking care not to dislodge the implanted portion of the catheter, draw the catheter through the subcutaneous tunnel until the loop of the catheter no longer protrudes from the incision. See Figure 3.
7. Occlude the catheter with rubber shod forceps and remove the trocar from the catheter.
8. **Caution:** Silicone tears and cuts easily. Use rubber shod forceps when handling silicone catheters.
9. Insert the barbed end of the female LUER-LOK connector (with cap attached) into the end of the catheter. Suture the components together. Do not remove the LUER-LOK cap until ready to attach the catheter to the patient line of the drainage system.
10. Caution: It is recommended that the catheter be sutured to the LUER-LOK connector to prevent possible separation of the components when the catheter is removed.
11. Exercise care when placing ligatures to avoid cutting or occluding the tubing. The use of stainless steel ligatures on silicone products is not recommended.
12. Secure the catheter to the skin at the exit site. Suture the incision site. Cover the area with a sterile dressing.

### General Surgical Technique: Lumbar Catheter
Refer to the instructions packaged with the lumbar catheter for placement procedures.

### Installing the EDS 3 CSF External Drainage system
Installing the EDS 3 system comprises the following:
- Mounting the EDS 3 device to an I.V. pole.
- Leveling the EDS 3 device in relationship to the floor.
- Leveling the EDS 3 device in relationship to the patient.
- Positioning the Drip Chamber.
- Priming the EDS 3 unit.
- Connecting the EDS 3 device to the patient catheter.

### Mounting the EDS 3 device to an I.V. pole
1. Remove the product from its packaging.
2. Secure the EDS 3 device to an I.V. pole by fitting the clamp over the pole and securing it in place by tightening the *blue* screw (see Figure 4).
3. Place the cord that is attached to the EDS 3 device over the I.V. pole and secure it in place by pressing the button on the locking mechanism and sliding the mechanism until it is tight against the pole. Knot the cord above the locking mechanism after placement.

### Leveling the EDS 3 device in Relationship to the Floor

1. Attach the CODMAN EDS 3 Leveling Device to the unit by sliding the securing tab over the slot on the EDS 3 (see Figure 5).
   **Note: Point the laser on the leveling device toward the patient.**

2. Level the CODMAN EDS 3 System on the I.V. pole as follows (see Figure 6):

   a. Loosen the *black* screw and rotate the assembly to the point where it is level to the floor (bubble is centered in glass tube).

   b. Once it is level, secure the EDS 3 system into position by tightening the *black* screw.

3. Proceed to *Leveling the EDS 3 device in Relationship to the Patient*.

### Leveling the EDS 3 device in Relationship to the Patient

1. Secure the CODMAN EDS 3 Leveling Device to the EDS 3 system, pointing the laser on the leveling device toward the patient.

2. Level the unit on the I.V. pole as follows:

   a. Press the button on the laser pointer once to turn on. The laser beam emits from the pointer.

   b. Direct the laser towards the patient.

   c. Loosen the *blue* screw and adjust the height of the EDS 3 System (see Figure 8a) centering the laser pointer to the patient's external auditory meatus for ventricular drainage or to the lumbar catheter exit site for lumbar drainage. This represents the "zero" reference point (see Figure 8b).

3. The laser beam will automatically turn off after 30 seconds. To reactivate, press the button again.

4. Remove the leveling device from the EDS 3 unit.

### Positioning the Drip Chamber

**WARNING: Intracranial pressure is controlled by the height of the Drip Chamber relative to the patient. It is imperative that neither the Drip Chamber nor the patient be raised or lowered accidentally.**

**Movement by the patient after positioning of the Drip Chamber may affect the patient's ICP.**

Turn the drip chamber stopcock closed to the bag to prevent liquid from refluxing to the drip chamber.

1. Loosen the *white* screw and slide the black Drip Chamber pressure reference line to the appropriate pressure setting in mm Hg or cm $H_2O$. Turn the *white screw clockwise* to secure. DO NOT OVERTIGHTEN THE SCREW (see Figure 9).

   **Note:** The Drip Chamber pressure reference line corresponds to the fluid outlet within the Drip Chamber. The inlet tubing has no effect on the pressure setting because both sides of the tubing are equidistant to its peak from the pressure setting arrow.

2. Refer to *Operating the EDS 3 CSF External Drainage System* to set the stopcocks to perform the appropriate procedure.

3. If you are using intracranial pressure monitoring lines (not supplied), attach them to the system stopcock or to the patient line stopcock. Refer to *Monitoring ICP* for instructions on setting the respective stopcock to the *Monitoring Only* position. **Note:** The design of the CODMAN EDS 3 system permits air to enter at the Drip Chamber microbial retentive atmospheric vent. This allows setting of the drainage pressure by means of the Drip Chamber height and prevents suction or backpressure from the downstream line or collection bag from affecting the setting. It is normal to have air in the tubing downstream from the Drip Chamber.

### Operating the EDS 3 CSF External Drainage System

The EDS 3 system allows you to perform several patient drainage and monitoring procedures. These are:

- Draining CSF into the Drip Chamber;
- Draining CSF into the collection bag from the Drip Chamber;
- Monitoring ICP with a fluid coupled transducer (FC transducer);
- Injecting medication into the system;
- Sampling CSF.

Operating the three stopcocks enable each of these procedures. This section describes the correct operation of the stopcocks.

**Note:** The following procedures assume the EDS 3 system has been properly installed, and leveled.

**Note:** The EDS 3 system is shipped with the stopcocks in the *Null* position.

### Using the Patient Line Stopcock

**(Refer to Figure 10)**

The Patient Line stopcock controls the flow of CSF from the patient line to the other components of the EDS 3 system. The following describes how you can set the patient line stopcock. Since the patient line is flexible and is sometimes looped, the patient line stopcock should always be positioned relative to the monitoring port.

- **Drainage Only Position** – This allows the patient line to communicate with the system stopcock. This position disables the monitoring port. This is the position for drainage of CSF.
- **Monitoring Only Position** – This allows the patient line to communicate with the monitoring port. This position stops the flow of CSF to the system stopcock. This is the position for monitoring ICP with an FC transducer.
- **Closed Position** – This stops the flow of CSF to the system stopcock and disables the monitoring port.
- **Null Position** – This position may result in inaccurate ICP readings and therefore it is not recommended.

### Using the System Stopcock

**(Refer to Figure 11)**

The System stopcock controls the flow of CSF to the Drip Chamber. It also provides a port that can be used to connect an ICP monitor (FC transducer). The following describes how you can set the system stopcock.

- **Drainage Only Position** – The system stopcock communicates with the Drip Chamber. This position disables the monitoring port. This is the position for drainage of CSF.
- **Monitoring Only Position** – This allows the patient line to communicate with the monitoring port. This position stops the flow of CSF to the Drip Chamber. This is the position for monitoring ICP with a FC transducer.
- **Closed Position** – This stops the flow of CSF to the Drip Chamber and disables the monitoring port.
- **Null Position** – This position may result in inaccurate ICP readings when using an FC transducer and therefore it is not recommended.

### Using the Drip Chamber Stopcock

**(Refer to Figure 12)**

The Drip Chamber stopcock controls whether CSF flows into the collection bag or accumulates in the Drip Chamber. It also provides a port for sampling. The following describes how you can set the Drip Chamber stopcock.

- **Drainage Only Position** – This allows fluid from the Drip Chamber to empty into the collection bag. In this position, the sampling port is disabled. This is the position for draining CSF into the collection bag.

**WARNING: Monitoring ICP with an FC transducer at the Drip Chamber stopcock gives you readings that are clinically irrelevant. Do not monitor ICP at the Drip Chamber stopcock.**

- **Sampling Only Position** – This allows the Drip Chamber to communicate with the sampling port, but does not allow fluid to drain into the collection bag. This is the position for sampling collected CSF.
- **Drip Chamber Position** – This stops the flow of CSF to the collection bag and disables the sampling port. In this position, CSF accumulates in the Drip Chamber, but cannot be sampled.
- **Null Position** – This position is not recommended.

### Priming the EDS 3 System

**Note:** The stopcocks are shipped in the *Nul* position.

**Note:** It is important to use aseptic technique while priming the EDS 3 system.

1. Fill a LUER-LOK syringe with sterile physiological saline solution. It is recommended that a 10 mL syringe be used.

2. Place the Patient Line stopcock in the *Monitoring Only* position (see *Using the Patient Line Stopcock*).

3. Remove the LUER-LOK cap from the catheter connector (proximal end) of the Patient Line.

4. Remove the cap from the monitoring port of the patient line stopcock.

5. Connect the syringe to the monitoring port of the patient line stopcock.

6. Depress the syringe slightly and flush the small length of line from the patient line stopcock to the catheter connector.
7. Place the patient line stopcock into the *Closed* position. Depress the syringe and flush the system through to Drip Chamber. Verify absence of leaks. Verify there is a free flow of fluid to the Drip Chamber.
8. Verify that fluid drains from the Drip Chamber into the collection bag.
9. Place the patient line stopcock into the *Drainage Only* position and remove the syringe. Replace the cap on the monitoring port of the Patient Line stopcock.

### Connecting the EDS 3 Unit to the Patient Catheter
Remove the caps from the ventricular or lumbar catheter and from the patient line. Attach the female connector of the catheter to the patient line.

**CAUTION: Take care when removing and replacing the LUER-LOK cap to prevent contamination.**

### Draining CSF into the Drip Chamber
1. Loosen the white screw by turning it *counter-clockwise*. Slide the Drip Chamber arrow to the appropriate pressure setting in mm Hg or cm $H_2O$. Turn the white screw *clockwise* to secure. DO NOT OVERTIGHTEN THE SCREW.
2. Rotate the patient line stopcock until it is in the *Drainage Only* position.
3. Rotate the system stopcock until it is in the *Drainage Only* position.
4. Rotate the Drip Chamber stopcock until it is in the *Drip Chamber* position.
5. Verify that CSF drains from the patient to the Drip Chamber, and that the Drip Chamber fills with CSF. Monitor the Drip Chamber and record collected volumes as required.

### Draining CSF into the Collection Bag from the Drip Chamber
1. To ensure an accurate measure of the fluid contained in the Drip Chamber, rotate the system stopcock until it is in the *Closed* position.
2. Rotate the Drip Chamber stopcock until it is in the *Drainage Only* position.
3. Verify that CSF drains from the Drip Chamber to the collection bag and that the collection bag fills with CSF.
4. Rotate the system stopcock until it is the *Drainage Only* position.
5. Monitor the collection bag as required.

### Monitoring ICP
**WARNING:** MONITORING ICP WITH A STOPCOCK IN THE *NULL* POSITION MAY RESULT IN FALSE ICP READINGS. SIMULTANEOUS DRAINAGE AND TRANSDUCER MONITORING MAY RESULT IN WAVEFORM ARTIFACTS AND ARTIFICIALLY LOW ICP READINGS. ALTERNATE DRAINAGE AND ICP MONITORING CAN BE ACHIEVED BY ADJUSTING THE STOPCOCKS TO EITHER THE *DRAINAGE ONLY* POSITION FOR DRAINAGE OR THE *MONITORING ONLY* POSITION FOR ICP MONITORING.

Monitor ICP from either the patient line stopcock or the system stopcock. ICP monitoring is accomplished by connecting the ICP monitoring equipment (i.e., fluid coupled transducer), to the desired stopcock and placing the stopcock in the *Monitoring Only* position.

**Note:** Always refer to the manufacturer's instructions for proper leveling and operation of an ICP monitoring transducers and equipment.

### Using the Needle-Free Sampling/Injection Site
**WARNING:** The EDS 3 System provides direct access to the ventricular drainage catheter via the patient line stopcock and the needle-free injection site. Care must be taken when administering medication through these locations to minimize the chance of intravascular medications being injected into the cerebrospinal fluid.

**CAUTION:** Do not attempt to access the silicone seal of the needle-free injection/sampling site using a needle or blunt cannula. To prevent damage to the seal, access using standard Luer connection devices only.

A. Injecting Medication into the System
B. Sampling Fluid from the Needle-Free Sampling/Injection Site
C. Flushing the system

### A. Injecting Medication into the System
Medication can be administered to the patient via the needle-free sampling/injection site on the Y-connector, which is part of the patient line. Follow this procedure to administer medication via this site:

1. Rotate the patient line stopcock until it is in the *Drainage Only* position and close the slide clamp immediately distal to the Y-connector. (**Note:** Slide clamps are provided if a double-clamping technique is utilized.)
2. Swab the silicone seal of the injection site with 70% isopropyl alcohol prior to use. Allow to dry for 1 minute.
3. Use a male slip luer syringe or a male luer lock syringe. Grasp the injection site and firmLy push and twist the syringe clockwise onto the injection site until tight. Administer the medication. (**Note:** The capacity of the patient line and ventricular catheter, from the injection site to the proximal tip of the catheter, is approximately 1.5 cc.)
4. To disconnect, twist the syringe counterclockwise until loose. When the syringe is removed, the injection site is closed; do not cap.
5. Flush the site in accordance with the facility's protocol.
6. Reopen the clamp(s) after injection to resume drainage.

### B. Sampling Fluid From the Needle-Free Sampling/Injection Site
1. Swab the silicone seal of the injection site with 70% isopropyl alcohol prior to use. Allow to dry for 1 minute.
2. Use a male slip luer syringe or a male luer lock syringe. Grasp the injection site and firmLy push and twist the syringe clockwise onto the injection site until tight. Gently pull the plunger to fill the syringe.
3. To disconnect, twist the syringe counterclockwise until loose. When the syringe is removed, the injection site is closed; do not cap.
4. Flush the site in accordance with the facility's protocol.

### C. Flushing the System
To flush the system, use a 10 mL LUER-LOK syringe and a volume of flushing medium that can flush the system from the needle-free injection/sampling site to the collection bag. Flush the system by performing the following procedure.

1. Turn the patient line stopcock to the *Closed* position.
2. Turn the system stopcock to the *Drainage Only* position.
3. Place the Drip Chamber stopcock in the *Drainage Only* position.
4. Verify that all slide clamps are in the open position.
5. Swab the silicone seal of the injection site with 70% isopropyl alcohol prior to use. Allow to dry for 1 minute.
6. Use a male slip luer syringe or a male luer lock syringe. Grasp the injection site and firmLy push and twist the syringe clockwise onto the injection site until tight.
7. Inject flushing medium until the patient line is cleared.
8. To disconnect, twist the syringe counterclockwise until loose. When the syringe is removed, the injection site is closed; a cap is not required.

### Transporting a Patient Connected to the EDS 3 Unit
#### A. Instructions Prior to Transporting
1. Turn Patient Line stopcock to the *Closed* position and verify that drainage into Drip Chamber has ceased.
2. Drain Drip Chamber into drainage bag by placing the Drip Chamber stopcock into the *Drainage Only* position.
3. When the CSF has drained completely into the collection bag, place the Drip Chamber stopcock into the *Drip Chamber* position.
4. Replace the collection bag by referring to the instructions for use accompanying the collection bag.
5. Transport the patient.

#### B. Instructions after Transporting
1. Install EDS 3 device on the I.V. pole.
2. Level the EDS 3 device to the floor and the patient.
3. Verify proper Drip Chamber height settings.
4. Resume drainage by placing the Patient Line stopcock and the System stopcock in the *Drainage Only* positions.