CLEARPOINT® NEURO

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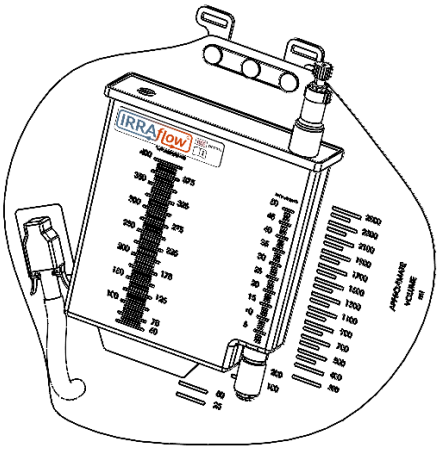


INSTRUCTIONS FOR USE

DCS010 IRRA*flow* Drainage Collection System

INTENDED USE / INTENDED PURPOSE

The IRRA*flow* Active Fluid Exchange System is intended to be used for ICP monitoring and drainage of intracranial fluid. The System consists of the IRRA*flow* Active Fluid Exchange System and three disposable parts, the Cassette, Catheter and Drainage Collection System.

The IRRA*flow* Active Fluid Exchange System may only be used by medical professionals specifically trained in relevant clinical conditions. The user must monitor both the patient and the equipment throughout the entire treatment.

The IRRA*flow* Drainage Collection System is composed of a dual-chamber 400mL measuring device with 2500mL overflow bag that facilitates drainage with no venting required. It is equipped with sampling ports on the measuring chamber and overflow bag and interfaces with the IRRA*flow* Tube Set via a female Luer adaptor.

INTENDED USERS

Medical personnel with training and experience in neurological / neurosurgical medical care are the intended users of this device.

INTENDED PATIENT POPULATION

The intended patient population for ICP monitoring and drainage of intracranial fluid include:

- Patients requiring an emergent, lifesaving procedure for management of hydrocephalus or intracranial hypertension.
- Patients experiencing neurosurgical conditions such as severe traumatic brain injuries (TBI), chronic subdural hematoma, hemorrhagic stroke, comatose, traumatic subarachnoid hemorrhage (SAH), diffuse axonal injury (DAI) and bifrontal contusions in non-comatose patients.
- Patients requiring monitoring following neurological procedures such as decompressive craniotomy or evacuation of a mass lesion.

INTRUCTIONS FOR USE

To setup the DCS 010:

1. Remove Drainage Collection System from the sterile packaging.
2. Remove the Drainage Collection System's protective cap from female Luer adapter.
3. Connect male Luer from Tube Set (ref: ICDS) to Drainage Collection System's female Luer connector. Check the male to female Luer connection is secure.
4. Secure the Drainage Collection System to the AFES system via the "bag hanger" clip. Verify the Device is secure by lightly tugging on the Drainage Collection System. Position the Collection System as recommended in the IRRA*flow* AFES IFU.
5. Position tubing to ensure there is unobstructed flow from the Catheter to the Drainage Collection System.
6. To measure liquid volume, the Drainage Collection System pro-vides dual integrated fluid meters and drainage bag. Chamber 1 measures volumes to 50mL and Chamber 2 and the drainage bag measure larger volumes. When performing a liquid volume measurement, ensure the liquid volume is measured and recorded in accordance with best medical practice.
   Note: liquid will overflow from chamber 1 to chamber 2 when the liquid volume in container 1 exceeds approximately 50mL.
7. To collect a sample of liquid from the Drainage Collection System, clean the sampling valve in accordance with best medical practice. Access the liquid by opening the threaded blue valve. Always verify the valve is closed after taking a sample.

To empty contents of the Drainage Collection System dual chamber fluid meter with drainage bag:

1. Follow hospital procedures and practices for personal protective equipment.
2. Hold bottom of drainage bag between forefinger and thumb.
3. Lift and tilt meter to transfer contents from 400mL chamber to Drainage Collection System's drainage bag.
4. Remove drain tube from holder.
5. Open drainage spout and empty bag into collection vessel. Once drainage is completed, verify the drainage spout is closed.
6. For continued use, after emptying the bag, close drainage spout and cleanse end of drain before replacing in holder.

GENERAL WARNINGS AND PRECAUTIONS

- Warning: There are no known and reliable means of cleaning, disinfecting, repairing, and sterilizing these devices that returns them to original specifications and renders them safe and effective for reuse.
- Warning: Do not use the device if the product is expired.
- Warning: Examine product packaging and contents for damage or deterioration prior to use. Do not use the device if any of the parts are damaged.
- Warning: Avoid allowing any of the Drainage Collection System's containers to completely fill. Never allow the Drainage Collection System to be overfilled with liquid.
- NOTES
  - Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and appropriate Competent Authority of the Member State in which the incident occurred.
  - Safe disposal of the device: Empty the contents of the bag before disconnecting the drainage collection system from the IRRAflow

Tube Set. The device shall be treated as biohazardous material and shall be disposed of according to hospital policy.

- Product is not made with Natural Rubber Latex
- Sterile in unopened, undamaged package
- Do not re-sterilize
- Single patient use
- Rx Only
- Cancer and Reproductive Harm – www.P65Warning.ca.gov

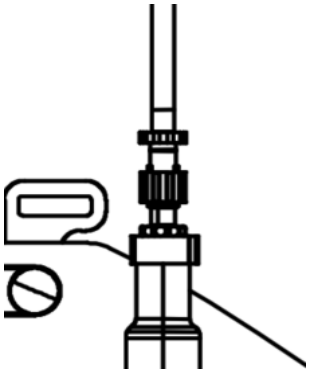
CARE

To clean the Drainage Collection System, use one of the following approved cleaning solutions:

- Povidone Iodine
- Isopropyl Alcohol
- Ethanol

TROUBLESHOOTING

In any drainage collection system, the tubing should hang straight from bedside to the drainage bag.



Periodic observations of this system and the Drainage Collection System drip feature should be made to ensure fluid is flowing freely. If standing column of fluid is observed, check for correct positioning of bag and tubing and then for a physical obstruction or removal of obstruction. If correct positioning or removal of obstruction does not allow free flow, the bag may need to be changed.

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Symbol and Text	Meaning
EC REP	Authorized Representative
REF	Catalogue Number
	Use-by Date (YYYY-MM-DD)
	Unique Device Identifier (UDI) 2D Barcode, unique to each device
	Manufacturer
	Date of Manufacture
	Consult Instructions for Use
LOT	Batch Code
STERILE EO	Sterilized using ethylene oxide
	Double sterile barrier system
	Single Use
	Temperature limits
	Do not use if the product sterilization barrier or its packaging is compromised
	Do not resterilize
	Not made with natural rubber latex
Rx Only	Prescription Device
MD	Medical Device
	MR Unsafe

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