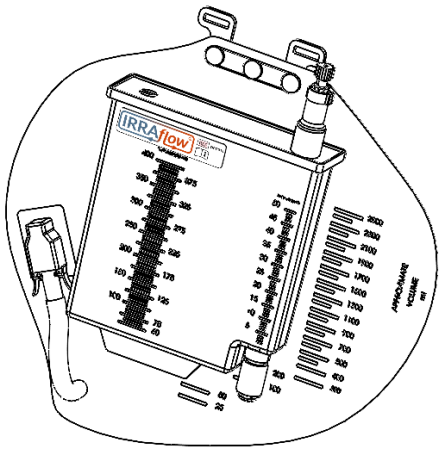
ENGLISH

INSTRUCTIONS FOR USE

DCS010 IRRA*flow*® Drainage Collection System



INTENDED USE

The use of IRRAflow® Active Fluid Exchange System is indicated when intracranial pressure monitoring is required and for externally draining intracranial fluid as a means of reducing intracranial pressure in patients where an external drainage and monitoring system is needed.

DESCRIPTION OF DEVICE

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.

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 provides 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.

PATIENT SAFETY

- Prior to use, always visually inspect the pouch and product for damage, imperfections, or surface deterioration. *Never use damaged product or product within damaged packaging.*
- Avoid allowing any of the Drainage Collection System's containers to completely fill. *Never allow the Drainage Collection System to be overfilled with liquid.*
- Cancer and Reproductive Harm – www.P65Warning.ca.gov
- Product is Latex Free and not made with Natural Rubber Latex
- Sterile in unopened, undamaged package
- Do not re-sterilize
- Single patient use
- Rx Only

CARE

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

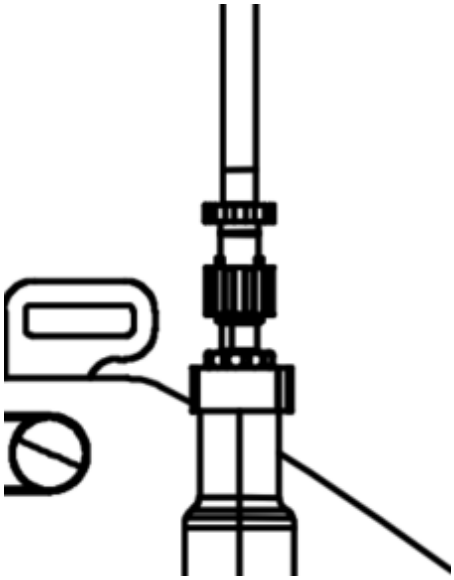
- Povidone Iodine
- Isopropyl Alcohol
- Ethanol

OPERATIONAL SAFETY

Always treat the Drainage Collection System as a biohazard. Handle and dispose of in accordance with best medical practice and applicable local, state, and federal laws and regulations.

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.

Symbol and Text	Meaning
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
	Use-by Date (YYYY-MM-DD)
	Unique Device Identifier (UDI) 2D Barcode, unique to each device
	Manufacturer
	Consult Instructions for Use
LOT	Batch Code
STERILE EO	Sterile; sterilized using ethylene oxide
CE	The Device Complies with Medical Device Directive 93/42/EEC
	Do not reuse
	Store within given temperature range
	Do not use if package is damaged. Do not use the product if the sterile barrier system or its packaging is compromised.
STERILIZE	Do not resterilize

CONTACT / RE-ORDER INFORMATION

Manufacturer:

IRRAS USA, Inc.
10965 Via Frontera,
San Diego, CA 92127
Tel: 1-800-213-4604
US.customerservice@irras.com