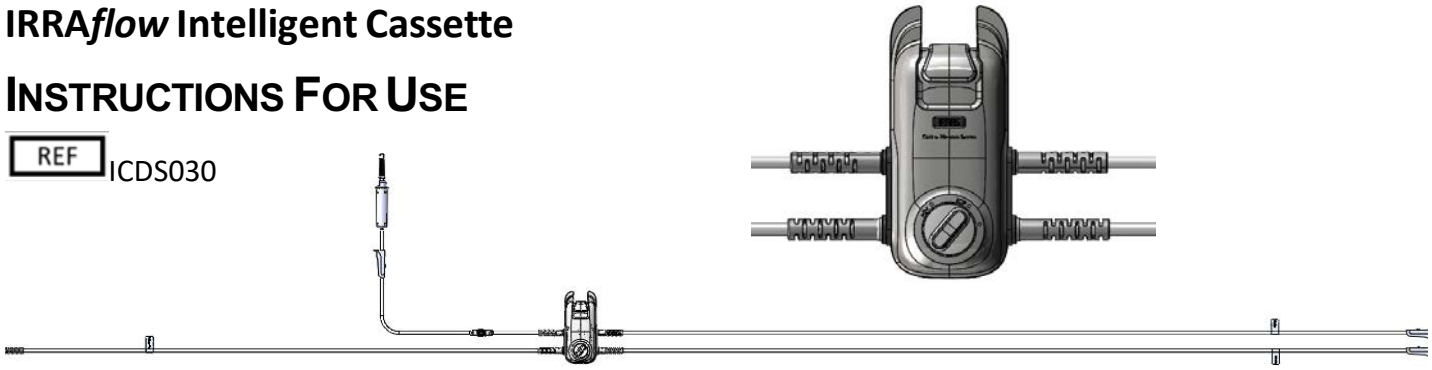
CLEARPOINT NEURO

IRRA*flow* Intelligent Cassette

INSTRUCTIONS FOR USE

REF ICDS030



DEVICE DESCRIPTION

The IRRA*flow* Intelligent Cassette is a sterile, single use medical device that consists of: the Intelligent Cassette, IV bag spike and tubing, irrigation tubing, and drainage tubing. The Intelligent Cassette docks and locks onto the IRRA*flow* Control Unit and facilitates the measurement of intracranial pressure (ICP), irrigation of fluids and drainage of intracranial fluids (such as blood, infectious material and CSF).

INDICATIONS FOR USE

The use of IRRA*flow* Active Fluid Exchange (AFES) 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.

KEY FUNCTIONS:

- Provides accurate ICP measurements to IRRA*flow* Active Fluid Exchange System.
- Acts as a means to zero ICP values to atmospheric pressure. Intuitive design has prominent calibration knob and diagrams to assure correct orientation.
- Provides fluid delivery and drainage through sterile tubing per IRRA*flow* AFES settings.
- Incorporates a universal irrigation tubing spike compatible with standard IV fluid bags.
- Provides additional flow controls (roller clamps) for controlled fluid management.
- When the cassette is mounted to the Control Unit, the Control Unit pump and solenoid inhibits fluid flow through the irrigation and drainage lines.

INTENDED USE

The IRRAflow Intelligent Cassette and Active Fluid Exchange System are intended to be used for ICP monitoring and drainage of intracranial fluid. The System consists of the IRRAflow Control Unit and three disposable parts: the IRRAflow Tube Set, the IRRAflow Catheter, and the IRRAflow Drainage Collection System.
IRRAflow Intelligent Cassette and 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.

INTENDED USERS

The user profile for the IRRA*flow* Cassette is medical personnel with training and experience in neurological/neurosurgical medical care.

CONTRAINDICATIONS

The IRRA*flow* Intelligent Cassette is not suitable for lumbar drainage.

The use of the Intelligent Cassette is contraindicated when trained personnel to supervise monitoring and drainage are not available.

The Intelligent Cassette is MR Unsafe.

WARNINGS

- Only medical personnel with training and experience in neurosurgical medical care may perform treatments using this device. Use by unqualified medical personnel, or in a manner that is inconsistent with instructions provided herein, may potentially harm the patient and/or user.
- The IRRA*flow* Intelligent Cassette must only be used with IRRA*flow* Control Unit, IRRA*flow* Catheter and IRRA*flow* Drainage Collection System. Using with other components may injure patients.
- To reduce the risk of interference from outside sources, Do Not use the IRRA*flow* Intelligent Cassette near strong sources of electromagnetic radiation (e.g., diathermy equipment, MRI).
- Treatment may not be conducted if the surrounding temperature or the atmospheric pressure exceeds any of the limits stated in IRRA*flow* device component IFUs .
- ICP measurements are not reliable during defibrillation, and necessary precautions need to be taken in such an event.
- The equipment is not intended for use in oxygen rich environments or in the presence of flammable anaesthetic mixtures or other flammable gases.
- Modification or disassembly of the Intelligent Cassette is not permitted. Unauthorized modifications to the Cassette can cause a malfunction resulting in serious patient injury, damage to internal circuitry or electric shock.
- Failure to monitor drainage could result in under drainage or over drainage.
- Under drainage may increase patient ICP to an undesirable level.
- Over drainage may result in collapsing the ventricles, pulling the brain tissue away from the dura thus tearing cortical veins and leading to subdural hematoma.
- The IRRA*flow* Intelligent Cassette is a single-use medical device- not to be reused, reprocessed or re-sterilized when open but unused.
- The IRRA*flow* Intelligent Cassette should be replaced with a new Intelligent Cassette every 5 days. Device failure risk increases with usage beyond 5 days.

PRECAUTIONS

- Use care when securing the Control Unit to the IV pole to avoid Cassette tubing from being pinched by the mounting clamp.
- IRRA*flow* Intelligent Cassette is a sterile, single-use AFES component. Using the same component for multiple treatments is prohibited.
- To avoid contamination, the IRRA*flow* Intelligent Cassette should be handled as prescribed when being attached to the IRRA*flow* Cathe-ter. Special care should be taken to prevent contamination of the connections between the Intelligent Cassette and the Catheter, and the connection to the IRRA*flow* Drainage Collection System.
- Use sterile technique when attaching a new IRRA*flow* Drainage Collection System to prevent contamination.

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- Use sterile technique to prevent contamination when disconnecting the IRRA*flow* Catheter from the IRRA*flow* Intelligent Cassette.
- Clamp all tubing prior to removing the IRRA*flow* Intelligent Cassette from the *IRRAflow* Control Unit.
- Only irrigation fluids specified in IRRA*flow* device component IFUs should be used when conducting treatments with the IRRA*flow* Active Fluid Exchange System. A completely new bag of sterile irrigation fluid must be used for each irrigation fluid bag change. To ensure correct ICP measurements, and thus properly set pressure alarm levels, the 0-point of the control unit must always be aligned with the Catheter tip position intracranially, which corresponds to the patient's external auditory meatus or top of the eyebrow. When moving the patient, readjust the height of the control unit before restarting treatment.
- Misalignment of the IRRAflow Cassette on the Control Unit may result in unimpeded flow of irrigation solution.
- When treating patients, the irrigation solution should be positioned above the catheter tip matching the prescribed ICP limit.
- Perform cleaning per the cleaning procedures described in the Cleaning Section. If these instructions are not followed, the unit may be damaged, and/or the patient or user may be exposed to pathogens.
- If the IRRA*flow* Intelligent Cassette is used in a way that contradicts the intended use or by medical personnel without the proper training and experience in neurological/ neurosurgical care, injury to the patient and/or the user may occur.
- Over-drainage of intracranial fluid may cause ventricular collapse and injury to the patient. Always monitor drainage progress by closely monitoring the drained volume in the Drainage Collection System.
- Never pour liquids on any part of the IRRA*flow* Intelligent Cassette. If this occurs, dry off with a clean cloth.
- No tools need to be, nor should be, used when handling the IRRA*flow* Intelligent Cassette.
- Only accessories delivered with the unit or provided by ClearPoint Neuro or ClearPoint Neuro official representative should be used. Using accessories from third parties may create a safety risk and voids any warranty.

OPERATIONAL SAFETY

Setup and Removal of the Intelligent Cassette must be performed by medical personnel with training and experience in neurological/neurosurgical medical care.

ADDITIONAL INSTRUCTIONS:

- Refer to Product Storage Conditions located on the product packaging.
- Always verify product expiration dating (located on the product packaging) prior to use.
- Never use the product if the package is damaged.
- Never re-use the Intelligent Cassette. The Intelligent Cassette is for single use only.
- DO NOT re-sterilize the device.

PREPARATION OF INTELLIGENT CASSETTE

1. Obtain the Intelligent Cassette and Drainage Collection System and inspect the packaging for any damage.
2. Verify the expiration date on the packing label.
3. Visually verify the sterile barrier seal is intact and uncompromised.
4. Open the DCS bag and use the sterile blue drape to create a sterile field.
5. Slide the sterile tubing cover over the connection of the irrigation and drainage tubing.
6. Attach the Drainage Collection System Bag to the Drainage tubing.

CONNECT INTELLIGENT CASSETTE TO IRRIGATION FLUID BAG

1. Close clamp below drip chamber.
2. Remove the Drip Chamber spike cap and, while maintaining sterility, pierce the port of chosen irrigation fluid bag.
3. During the priming sequence, verify the drip chamber fills with fluid and irrigation bag connection is free of leaks.

Caution: *A new sterile irrigation bag must be used for each irrigation fluid replacement.*

IRRIGATION BAG AND IRRIGATION FLUIDS:

ClearPoint Neuro has tested the use of sterile, IV solution in 500- or 1000-mL bags including 0.9% solution NaCl or Ringer's Lactate solution.

Tachypnea (rapid breathing) has been reported in some cases when normal saline is used as an irrigant with the IRRA*flow* Active Fluid Exchange System. Exercise caution when selecting normal saline as the irrigation solution to minimize potential risks.

The temperature of the irrigation fluid is at the discretion of the physician.

ATTACHING THE CASSETTE TO THE IRRAflow CONTROL UNIT

To attach the Intelligent Cassette to the Control Unit:

1. Power ON the Control Unit. Wait for the system to complete the self-check mode before continuing.
2. Open the cassette door.
3. Following the Control Unit prompts, attach the Cassette, close the Cassette lever, and then close the Cassette door.
4. Verify the Control Unit's user interface screen displays a Continue button, indicating the Tube Set is correctly seated on the Control Unit.

Caution: *If the Cassette is not appropriately attached, this may result in unimpeded flow of irrigation solution.*

Note: To attach the Cassette, the pins must be aligned. Once aligned, press the Cassette to the Control Unit, then press firmly down on the Cassette. Verify the Cassette is firmly seated. The Cassette lever should go down easily and lock the Cassette into place. If excessive resistance is felt, open the Cassette lever, re-insert the Cassette, fully seat the cassette down, and then attempt to close the lever.

CALIBRATE INTELLIGENT CASSETTE:

The Intelligent Cassette must be calibrated or zeroed to atmospheric pressure. Calibrating considers the atmospheric pressure in the room to ensure the transducers are reading the accurate ICP. To calibrate the Intelligent Cassette:

1. Turn the cassette knob to the zero position, (displayed as the zero icon), and wait for the Control Unit to calibrate.
2. When calibration is complete, the Control Unit screen will confirm Calibration success. Once confirmed, turn the cassette knob back to the starting position, labeled as ICP. **Note:** The caregiver will be prompted to do this once per every 24 hours.

Caution: *Using calibration as a form of troubleshooting is not recommended. Bench testing has demonstrated that rapid, repeated calibrations may increase the likelihood of a leak in the cassette.*

INSERTING IRRIGATION TUBING INTO THE BUBBLE SENSOR

Prior to starting treatment, the irrigation tubing must be inserted into the bubble sensor on the Control Unit. To insert the irrigation tubing into the Bubble Sensor:

1. Mount the irrigation tubing on the left side of the Cassette in the air sensor slot on the left panel of the Control Unit (when seen from the front).
2. Ensure that the tubing in the air sensor slot is mounted all the way into the slot to facilitate appropriate contact between tube and air sensor.

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PRIMING

Before priming, open all tubing clamps.

Priming is done to replace air in the system with sterile fluid so that when connecting the tubing to the Catheter, there is minimal need to open the system during subsequent operation.

Follow the instructions provided in the IRRA*flow* Control Unit IFU to facilitate priming.

1. Priming occurs after pressing the prime button and will take approximately 60 seconds.
2. When priming is complete, examine the tubing for significant air bubbles.
3. If desired priming is achieved follow the prompts on the software to go to the next screen.

Note: *If further priming is needed, either press and hold the manual prime button and release once complete or press the auto-prime but-ton. If there are no bubbles observed in the tubing, clamp off the roller clamps on the irrigation and drainage tubing. This will ensure that the tubing will not lose its prime when connecting the tubing to the Cathe-ter.*

ATTACH CATHETER

To attach the *IRRAflow catheter*, use sterile technique:

1. Verify clamps are closed on the Intelligent Cassette tubing.
2. Disconnect the Intelligent Cassette tubing that was connected for
3. priming.
4. Use color coded Connectors to prevent mismatch: purple connectors are irrigation lines and transparent connectors are drain-age lines.
5. Once the catheter is connected, check to make sure **all** roller clamps and stopcocks are Open.

MRI INFORMATION

The Intelligent Cassette is MR Unsafe.

CLEANING:

During treatment at the bedside, disinfectants may be used to clean the Cassette to remove any pathogens present from handling the Catheter or other sources. Appropriate disinfectants include:

- ethanol
- isopropyl alcohol or
- povidone-iodine

CARE

Sterile gloves and a mask must be worn when performing catheter insertion site care, reconnecting the drainage bag during replacement, or when obtaining a CSF sample.

During continuous Catheter drainage, careful monitoring of the system and patient is required. Continual observation is necessary to assure that the patient's position and activity is controlled at a level that will not lead to an increase or decrease the amount of CSF drainage.

TROUBLESHOOTING:

If the Cassette exhibits poor drainage, verify the Cassette is not kinked or flow is not obstructed. Review the IRRA*flow* Control Unit IFU for additional troubleshooting steps.

SYMBOLS AND LABELS

Symbol and text	Meaning
	Single use
	Do not resterilize
	Consult instructions for use
	Manufacturer
	Date of Manufacture
	Catalog number
	Batch code
	Use by date
	Sterilized using ethylene oxide
	Do not use if the product sterilization barrier or its packaging is compromised
	Temperature limits
	MR Unsafe
	Prescription only
	Unique Device Identifier (UDI) 2D Barcode
	Non-pyrogenic
	Not made with natural rubber latex
	Single sterile barrier system

http://www.clearpointneuro.com/eifus/

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