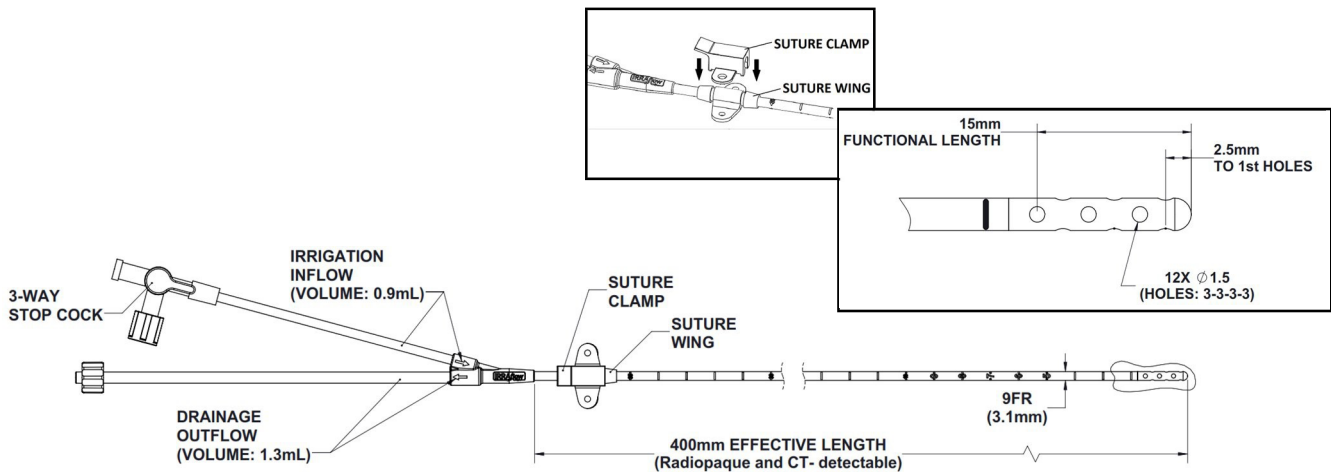


IRRAflow Dual Lumen Catheter

Instructions For Use

REF ICAT 030



IRRAflow Dual Lumen Catheter Overview

General Description

The IRRAflow Dual-Lumen Catheter (herein Catheter) is provided sterile and non-pyrogenic for use with the IRRAflow Active Fluid Exchange System and is supplied with flexible and rigid stylets, suture wings and suture clamps for catheter securement, a dura mater probe to verify durotomy completion, male and female luer caps, and a sterile 4-way stopcock for additional fluid control.

The Catheter Kit includes:

- 9Fr, dual lumen, catheter (400mm effective length) with integral 3-way stopcock, and graduations every centimeter up to 35 cm from the Catheter's closed-ended tip
- Catheter cover
- Stylet, rigid
- Stylet, flexible

The IRRAflow pouched Accessory includes:

- 2x Suture wings
- 2x Suture clamp (covers the suture wing)
- 4-way stopcock
- 2x female luer caps
- 2x male luer caps
- Dura mater probe
- Female-to-female Luer connector (male-to-male coupler)

Intended Use

The IRRAflow Tube Set 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.

The Catheter is indicated to gain access to intracranial fluid, for direct measurement of intracranial pressure (ICP) monitoring, and to externally drain intracranial fluid.

Intended Users

The IRRAflow system and catheter are designed for use in a clinical setting by qualified medical personnel, including the neurosurgeon, nurse, or healthcare professional, who can perform the operation of the IRRAflow system.

Intended Use Environment

This device should be used in hospital inpatient settings where neuro-critical care is available.

Indications for Use

The use of IRRAflow Active Fluid Exchange 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.

Contraindications

Due to the severity of the underlying pathology, all the following contraindications for the use of the Catheter may be relevant and considered by the medical professional if applicable: anticoagulation therapy, coagulation disorders, hemophilia, a low thrombocyte count, treatment with Warfarin or Clopidogrel and untreated scalp infections.

General Safety Warnings and Precautions

Warnings

- The Catheter is a single-use Catheter. DO NOT re-use.
- The Catheter is approved for use according to the Indications for Use. Injury may result to the user or patient if the Catheter is used in a way that is not per the indication.
- Prior to surgery, the surgeon should inform the prospective patient and/or their representatives of the warnings, precautions, and possible complications associated with this product.
- Always use aseptic technique when handling the catheter (unpacking, preparing, handling connectors, and the surgical site).
- Operating the device requires medical personnel with training and experience in neurological/neurosurgical medical care.
- Additions or modifications to the device may interfere with de-vice performance.
- Patient should be monitored for signs of intracranial hemorrhage secondary to puncture of the ventricle or opening of the dura.
- Patient movement may result in dislocation of the Catheter tip from the desired location. The Healthcare Professional must ensure that the Catheter placement remains in the desired location.
- If cleaning the connectors with alcohol, allow to air dry completely prior to reconnecting to the system.
- Connections should be two-finger neuro-tightened. DO NOT overtighten.

Precautions

- Shelf life is indicated on the package labeling.
- Insertion and removal of the Catheter must be performed by medical personnel with training and experience in neurological / neurosurgical medical care.
- Product Storage conditions are located on the product packaging.
- Always verify the product's expiration date (located on the product's packaging) prior to use.
- Never use the product if the package is damaged.
- Never re-use the catheter. The catheter is for single use only.
- DO NOT re-sterilize the device.

- Dispose of used product in accordance with accepted medical practice and applicable local and national regulations. Used products may present a potential biohazard.
- Sterile gloves and mask must be worn when performing site care, re-placing the drainage bag, or obtaining a CSF sample.
- During continuous drainage, careful monitoring of the system and patient is required. Constant observation is necessary to assure that the patient's position and activity is controlled at a level that will not increase or decrease the amount of CSF drainage.

Preparing the Site and Placing the Catheter

Preparing the site and placing the catheter may be accomplished through a variety of surgical techniques. The method used should be based on the surgeon's practice, training, and what is best for the patient.

Priming Before Use

Using a syringe and sterile saline, prime the irrigation and drainage channels. Shut-off flow to the irrigation channel to retain the sterile saline fluid within the irrigation channel. To prime the drainage channel, use the female-to-female luer connector.

Forward Tunneling Instructions (As Required)

1. Make a secondary incision 3 to 5 cm from the catheter insertion site.
2. Insert the desired stylet into the drainage lumen of the catheter. The Catheter is now ready for surgical insertion.
3. Use the catheter cover (tunneling device) with the catheter to tunnel the catheter from the secondary insertion site to the catheter insertion site.

Insertion Instructions (As Required)

1. Use a minimum 4.0 mm drill bit with stop for ventricular catheter placement.
2. Ensure the stylet is inserted in the catheter's drainage lumen to the tip of the catheter and introduce and position the catheter to the desired intracranial position.
3. Remove the stylet and verify the location of the catheter. Excessive finger pinching of the catheter may increase resistance during stylet removal, making it difficult to extract. Do not use excess force when removing stylet.
4. Maintaining catheter location, remove excess catheter slack.

Secure the Catheter to the Patient (As Required)

Secure the catheter to the patient per standard surgical procedure.

Use care when using instruments to handle, insert, tunnel, secure, or re-position the catheter. Improper use may result in nicks, tears, punctures, slitting, breakage, or crushing of

the IRRAf^{low} Catheter components. Such damage may lead to device failure, potentially requiring device removal and replacement. After catheter is secured, physician can consider utilizing a chlorhexidine patch over the catheter insertion site.

Note: suture wings and suture clamps are provided in the accessory pouch. The suture clamps are placed over the suture wing to provide fixation and protection to the catheter.

Controlling Fluid Flow

To control fluid flow through the catheter prior to connecting the catheter to the IRRAf^{low} System, use the provided stopcocks and Luer caps. Instruction on controlling fluid flow once the catheter is connected to the system can be found in the IRRAf^{low} Control Unit IFU.

MRI Information

	Catheter, suture wings & suture clamps, 4-way stopcock are MR Safe .
	The stylets are MR Unsafe .

Operation

Prior to CSF exchange, it is recommended to obtain a CT scan to confirm catheter location.

The user must only use the product as indicated. Throughout treatment, the operator must monitor the patient's ICP and the fluid balance (inflow 'bolus' volume versus outflow drainage volume) of fluid.

ICP is measured through the catheter's irrigation lumen via a liquid-coupled pressure transducer located in the ICDS Tube Set.

The female-to-female Luer connector is provided to allow the user to adapt the catheter's drainage Luer to a device terminated with a male Luer connector (e.g. syringe, external drainage collection).

Cleaning

This device has been tested and demonstrated to be compatible with the following cleaning agents when applied 1 time per day for the useful life of the product:

- Isopropyl Alcohol, 70%
- Denatured Ethanol, 70% or,
- Povidone-Iodine, 10%

Useful Life

The Catheter is provided sterile and non-pyrogenic for single use and may be used for a maximum of 21 days.

Disposal

Dispose of used product in accordance with accepted medical practice and applicable local and national regulations. Used products may present a potential biohazard.

Troubleshooting

If the catheter exhibits poor drainage, verify the catheter is not kinked or flow is not obstructed. Review the IRRAf^{low} Control Unit IFU for additional troubleshooting steps.



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



Manufactured by:
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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 irradiation
	Do not use if the product sterilization barrier or its packaging is compromised
	Temperature limits
	MR Safe
	MR Unsafe
	Prescription only
	Unique Device Identifier (UDI) 2D Barcode
	Non-pyrogenic
	Not made with natural rubber latex
	Double sterile barrier system