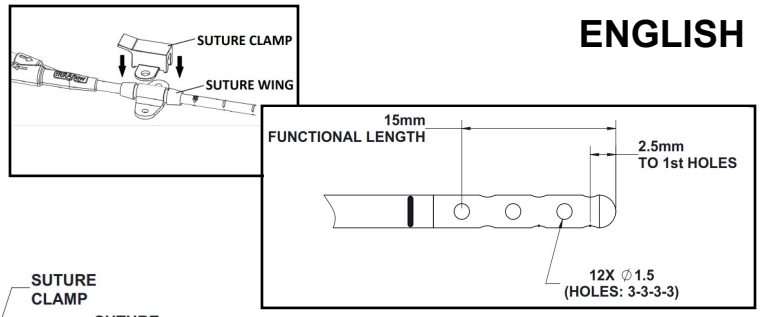
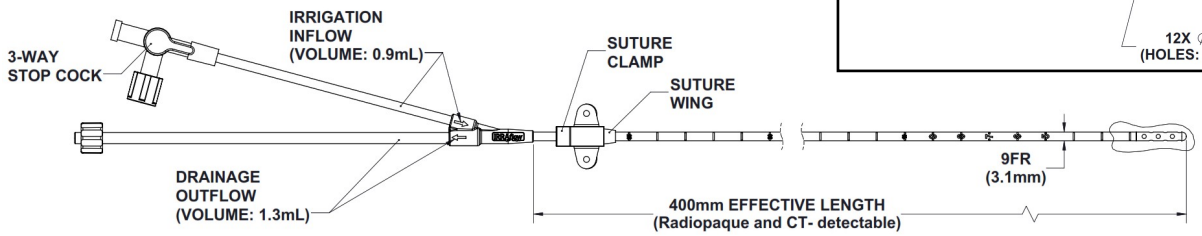
INSTRUCTIONS FOR USE (IFU)

ENGLISH

ICAT030 IRRA*flow*® Dual Lumen Catheter





CLASSIFICATION

The IRRA*flow*® Dual Lumen Catheter is classified as Class II Medical Device in the US and a Class III Medical Device in the EU.

DESCRIPTION OF DEVICE

The IRRA*flow* Dual-Lumen Catheter (herein Catheter) is provided sterile and non-pyrogenic for use with IRRA*flow* Active Fluid Exchange System and is supplied with flexible and rigid stylets, the 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 IRRA*flow* 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 Catheter is indicated to gain access to intracranial fluid, for direct measurement of intracranial pressure (ICP) monitoring, and to externally drain intracranial fluid.

INTENDED USER

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

INTENDED USE ENVIRONMENT

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

INDICATIONS FOR USE

The use of IRRA*flow* 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.

PRECAUTIONS

- Dispose of used product in accordance with accepted medical practice and applicable local and national regulations. Used products may present a potential biohazard.
- Shelf life is indicated on the package labeling.

PATIENT SAFETY

- 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 device 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 re-connecting to the system.
- Connections should be two-finger neuro-tightened. DO NOT overtighten.

OPERATIONAL SAFETY

- 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 products 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.

PREPARING THE SITE & 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.

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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 reposition the catheter. Improper use may result in nicks, tears, punctures, slitting, breakage, or crushing of the IRRA*flow* Catheter components. Such damage may lead to device failure, potentially requiring device removal and replacement. After catheter is secured, physician can consider utilizing a chlorohexidine 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 IRRA*flow* 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 IRRA*flow* Control Unit IFU.

MRI INFORMATION:

MR	• The catheter, suture wings & suture clamps, 4-way stopcock, Luer caps, and female-to-female Luer connector are **MR-Safe**.
MR	• 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.

CARE:

Sterile gloves and mask must be worn when performing site care, replacing 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.

TROUBLESHOOTING:

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

SYMBOLOGY:

Symbol and text	Meaning
	Do not re-use
	Consult instructions for use
	Manufacturer
REF	Catalogue number
LOT	Batch code
	Use-by date
STERILE R	Sterilized using irradiation
	Do not use if package is damaged. (Note: Do not use if the product sterile barrier system or its packaging is compromised.)
	Temperature limit (lower and upper)
MR	MR Safe – an item that has been demonstrated to pose no known hazards in all MR imaging environments
MR	MR Unsafe – an item which poses unacceptable risks to the patient, medical staff or other persons within an MR environment.
Rx Only	Prescription only
	Unique Device Identifier (UDI) 2D Barcode, unique to each device
	Non-pyrogenic

REORDERING THE CATHETER OR REQUESTING AN IFU

Please contact your local distributor if you wish to order catheters or a replacement instructions for use.

- IRRA*flow* Catheter (catalogue no. ICAT030)
- IRRA*flow* Catheter Instructions for Use are provided electronically at: www.irras.com/product/eIFU
- Paper copies of the IFU may be requested (catalogue no. 7001389)

CONTACT / RE-ORDER INFORMATION

Manufacturer:

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