IRRA*flow*® Catheter

Instructions for Use

CE 0344

⚠ IMPORTANT

Read all instructions and warnings prior to use.
Users of the IRRA*flow* Catheter must be trained medical personnel with training and experience in neurological/neurosurgical medical care.

IRRAS only accepts responsibility for the equipment's safety, usability and performance if:

- the equipment is used in accordance with its intended use, and
- the equipment is used in accordance with the product documentation.

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1. The Instructions for Use

This Instructions for Use describes the usage of the IRRA*flow* Catheter.

Users must read this manual carefully prior to using the IRRA*flow* Catheter for the first time so that the features are thoroughly understood.

⚠ Failure to follow the instructions in this manual may endanger the patient and/or the operator.

The following symbols are used in this Instructions for Use:

Symbol	Meaning
	Failure to follow the instructions may endanger the patient and/or the operator

2. Safety Regulations

2.1 General Safety Regulations

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

⚠ The shelf life is 18-months, expressed as the expiry date on the package.

⚠ The use of the IRRA*flow* Catheter is limited to less than or equal to 5 days.

2.2 Patient Safety

⚠ The IRRA*flow* Catheter must be unpacked and prepared in a sterile area, under sterile conditions. Sterile gloves and mask must be worn when performing patient care around the area of the Catheter.

⚠ The IRRA*flow* Catheter is not approved for use except for the cleared indications.

⚠ The Catheter accessory "antibacterial unit" does not prevent the Catheter from sliding. The antibacterial unit is for creating an antiseptic area for the surgical insertion site.

⚠ Use the suture holes to attach the antibacterial unit. A suture that is too tight around the collar of the antibacterial unit may occlude the drainage side of the Catheter.

⚠ Use caution when working with sutures and sharp objects near the catheter to avoid damage or device failure. If damage occurs, device may need to be removed and replaced.

⚠ Use a protective Catheter cover if a tunneling procedure is used.

⚠ Precautions must be taken when handling the entrances and Luer connectors to the Catheter to prevent patient infections. In the event that the catheter irrigation lumen is not used, the stopcock must remain in a closed position to ensure sterility of the lumen is maintained. To avoid contamination, the IRRA*flow* Catheter is to be handled with care when being attached.

⚠ The IRRA*flow* Catheter is a single-use Catheter. Using the same Catheter for multiple treatments may potentially injure patients.

⚠ Do not twist or stretch the Catheter.

⚠ Movement of the patient during treatment may result in dislocation of the Catheter tip out of the intended site for the treatment, which could require surgical revision or replacement. The operator must make sure that the Catheter, as indicated by the markings, does not move unintentionally in relation to the skull entrance. The Catheter must be handled with care for the duration of the treatment.

⚠ If the IRRA*flow* Catheter is used in a way that contradicts the intended use, or by individuals who are not properly trained medical personnel indicated experience in neurological/neurosurgical medical care, this could result in injury to the patient and/or the operator.

⚠ Do not use if package is damaged. Do not use if the product sterile barrier system or its packaging is compromised.

⚠ The Catheter guide wire must be removed prior to entering an MR environment. **The guide wires are MR unsafe.**

⚠ A puncture of the ventricle or the opening of the dura is possible, which will result in an intracranial hemorrhage.

⚠ If too much CSF is removed from the ventricles, either during a drainage procedure or when the ventricle is first punctured, the ventricle may collapse and occlude the Catheter.

⚠ To minimize the possibility of infection, meningitis or ventriculitis, the subgaleal tunneling of the ventricular catheter should be approximately one to two inches.

⚠ To avoid possible cracking of the Luer connectors after cleaning with alcohol, allow to air dry completely prior to connecting to the system.

⚠ To ensure against ventricular collapse always perform a drainage maneuver against a positive pressure head on the order of 20 cm H2O or 15 mm Hg. In addition, when the ventricle subarachnoid space is first punctured during the insertion of the catheter, care should be taken so as little CSF as possible is lost.

⚠ Whenever irrigation of the catheter or the performance of the VPR is employed, great care must be used so that pressure waves are not initiated.

⚠ All connections should be finger tightened. Over tightening can cause cracks and leaks to occur.

⚠ Ensure that the cassette tubing is free of any kinks.

⚠ Ensure that any debris and other material is removed from the cassette tubing.

⚠ Leakage from the system, which may result from damaged system components or improper use or handling, may potentially result in over drainage, the need to replace the drainage system and/or other complications to the patient.

2.3 Operational Safety

⚠ Insertion and removal of the Catheter must be performed by a certified neurosurgeon, in this IFU referred as *operator*.

2.4 MRI Information: MR Safe

The IRRA*flow* catheter is MR Safe.

The IRRA*flow* catheter is made from materials that are non-conductive, non-metallic, and nonferro-magnetic and therefore, per ASTM F2503-20, is, by definition, MR Safe. For safety within the MR environment and the MRI system room, always follow the Instructions for Use procedure to ensure that only the catheter inserted within the patient enters the MR environment or the MRI system room.

⚠ The catheters pigtails must be disconnected from the cassette and IRRA*flow* console prior to entering the MRI system room; only the catheter is MR Safe.

⚠ The Catheter guide wire must be removed and not used in the MRI system room. **The guide wire is MR Unsafe.**

⚠ Verify the MRI Information of all other implants and devices prior to those devices entering the MRI system room.

⚠ Refer to this IFU for instructions on preparing the catheter and system for use in the MRI system room.

3. Packaging Labels

3.1 IRRA*flow* Catheter

The IRRA*flow* Catheter and guide wire has been labeled with the following symbols:

Symbol and text	Meaning
	Do not reuse
	Refer to the manual
	Name and address of manufacturer
	European Authorized Representative
9 Fr	Indicates Catheter outer diameter
381 mm	Indicates Catheter length
	Catalogue number
	Batch code
	Use by date
	Sterile
	Do not use if package is damaged. Do not use if the product sterile barrier system or its packaging is compromised
	Store within given temperature range
	The Device Complies with Medical Device Directive 93/42/EEC
	MR Safe – an item that has been demonstrated to pose no known hazards in all MR imaging environments

Symbol and text	Meaning
	MR-Unsafe – an item that is known to pose hazards in all MR environments
R_X Only	Prescription only
	Unique Device Identifier (UDI) 2D Barcode, unique to each device

4. Intended Use

4.1 Intended Users

Users must be medical personnel with training and experience in neurological/neurosurgical medical care.

4.2 Intended Use

The intended use of the IRRA*flow* Catheter is to gain access to intracranial fluid, to be used for intracranial pressure (ICP) monitoring and to externally drain intracranial fluid. The Catheter is for single, short term use.

4.3 Contraindications

The use of the Catheter by a qualified medical professional is indicated when direct measurement of the intracranial pressure is clinically important and when the patient may require CSF drainage in the course of care.

Due to the severity of the underlying pathology, all of the following contraindications for the Catheter are relative and should be considered by the medical professional if applicable; Anticoagulation therapy, Coagulation disorders, Haemophilia, a low thrombocyte count, treatment with Warfarin or Clopidogrel and untreated scalp infections.

5. Description of the IRRA*flow* Catheter

The IRRA*flow* Catheter includes a Catheter with guide wire and an accessory bag. The Catheter is delivered sterile. The sterilization method is gamma rays.

The IRRA*flow* Catheter and guide wire includes (see Figure 1):

- 400mm or 381mm 9 Fr Catheter with stop cock, pinch clamp, double lumens, and graduations every centimeter up to 15 cm from the Catheter tip
- Catheter cover
- Guide wire, rigid
- Guide wire, flexible

The IRRA*flow* Accessory bag includes (see Figure 2):

- Antibacterial unit
- Forceps covers
- Female to female luer connector

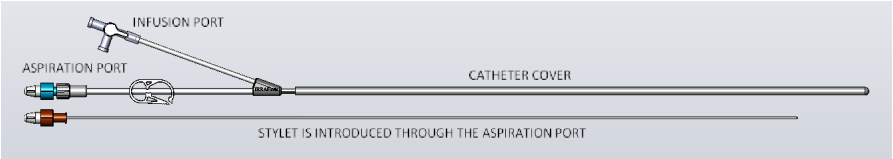

Figure 1: IRRA*flow* Catheter and guide wire

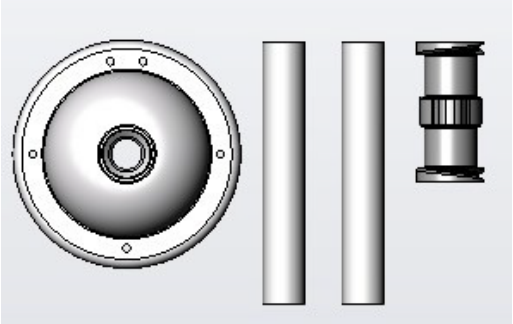

Figure 2: IRRA*flow* Catheter Accessory Kit

6. Environmental and Handling Conditions

Catheter Operation Temperature range	+10 to +40°C
Operation Air humidity	30 – 95%
Operation Ambient pressure	70 – 106 kPa
Storage and transport Temperature range	+2 to +50 °C
Storage and transport Air humidity	20 – 80%
Storage and transport Ambient pressure	50 – 106 kPa
Vibration/Shock/Bump	It is possible to transport the system worldwide by air, road, ship and train.
Drop/Free fall	It is possible to transport the system worldwide by air, road, ship and train.
IRRA*flow* Catheter maximum usage time in a patient	5 days

The Catheter is radiopaque/visible on X-ray.

7. Irrigation Bag and Fluid

Only manufacturer approved Irrigation fluid are to be used for a treatment with the IRRA*flow* Catheter.

The irrigation bag connection to the drip chamber interface must be sterile.

A standardized sterile physiological, isotonic, IV solution (like a 0.9% NaCl solution, Ringer's lactate etc.) is considered approved by the manufacturer.

8. Insertion Instructions

⚠ The Catheter shall be unpacked and prepared in a sterile area.

⚠ The antibacterial unit does not prevent the Catheter from sliding. The antibacterial unit is for creating an antiseptic area for the surgical insertion site.

⚠ Use the suture holes to attach the antibacterial unit. A suture that is too tight around the collar of the antibacterial unit may occlude the drainage side of the Catheter.

⚠ Do not twist or stretch the Catheter.

⚠ Do not contact the Catheter with sharp instruments, as damage may occur. Use the forceps covers. Do not use a damaged Catheter.

⚠ Use the protective Catheter cover if a tunneling procedure is used.

8.1 Inspection Procedure

Make a visual inspection of the Catheter:

The operator is required to check that the IRRA*flow* Catheter packaging has not been damaged prior to use and that its expiration date has not exceeded.

Do not use the Catheter if it is damaged. For questions; contact IRRAS.

8.2 Additional Accessories Needed

Additional accessories needed for Catheter set up:

- 10 ml Syringe

- Antiseptic gel (Povidone-iodine, like Betadine cream, etc.)
- Suture material
- Forceps
- Approved irrigation fluid (see Irrigation Bag and Fluid Section)

8.3 Priming Before Use

1. Remove the transport cover from the Catheter.
2. Slide the antibacterial unit onto the Catheter lumen, *see fig 3*. Make sure that the widest part of the anti-bacterial unit is pointing towards the tip of the Catheter.

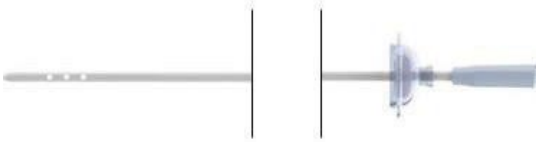

Figure 3: Antibacterial Unit attached to the Catheter

3. Prior to inserting a guidewire, use the syringe and female to female connector for priming the drainage side with an approved irrigation fluid then close the clamps.
4. The Catheter is now ready for surgical insertion.

8.4 Insertion

Common steps:

1. Select the site for Catheter insertion and create a sterile field, surgically prepare and drape the operative site.
2. The Catheter entrance hole through the ossa cranii shall be > 5 mm in diameter and kept smooth without sharp edges.
3. Insert the Catheter per standard surgical procedure and remove the guide wire after surgical insertion.
4. Make sure that irrigation line is free of air, fill the anti-bacterial unit with antiseptic gel (Povidone-iodine, like Betadine cream etc.), and slide it down the Catheter towards the insertion site.
5. Use the suture holes to attach the anti-bacterial unit. A suture that is too tight around the collar of the unit may occlude the drainage side of the Catheter.
6. The operator is responsible for maintaining a free drainage capacity in the Catheter passage through the unit collar.

9. Operation

The Catheter is intended for drainage and irrigation with the IRRA*flow* CNS System. The operator must control the ICP of the patient during the entire treatment. Furthermore, the volume of the drainage fluid must be controlled, as well as any fluid introduced through the irrigation line.

ICP shall be measured with the IRRA*flow* CNS System. Connect the IRRA*flow* Tube Set to the irrigation female connector. For accurate ICP values, the drainage lumen should be clamped during measurements. Refer to the IRRA*flow* CNS System User Manual for the ICP device for correct operation.

10. Cleaning

The Catheter comes sterile for single use and may be used for less than or equal to 5 days.

During treatment at the care unit, disinfectants may be used to clean periphery parts of the Catheter to avoid bacterial growth after handling the Catheter. Appropriate disinfectants include:

- ethanol
- isopropyl alcohol or
- povidone-iodine

11. Care

Sterile gloves and mask must be worn when performing site care, replacing the drainage bag, or obtaining a sample of CSF.

If a drain is to remain open for continuous aspiration, close monitoring of the system and patient is required. Constant observation may be initiated if 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 aspiration.

Movement of the patient during treatment may result in dislocation of the Catheter tip out of the intended site for the treatment, which could require surgical revision or replacement. The operator must make sure that the Catheter markings do not move unintentionally in relation to the skull entrance. The Catheter shall be handled with care during all treatment.

12. Appendix

12.1 Specifications

The IRRA*flow* Catheter is sterilized using β rays.

12.2 Classification

The IRRA*flow* Catheter is classified as Class III per the Medical Devices Directive (MDD 93/42/EEC).

12.3 Catheters and Manual

Please contact your local distributor if you wish to order Catheters or a replacement manual.

- IRRA*flow* Catheter (catalogue no. ICGS 020)
- IRRA*flow* Catheter User Manual (catalogue no. 7000871)

13. Contact

Manufacturer:

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