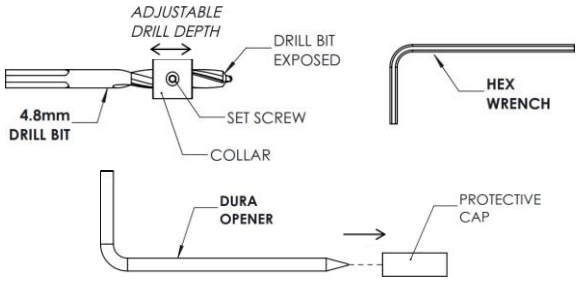
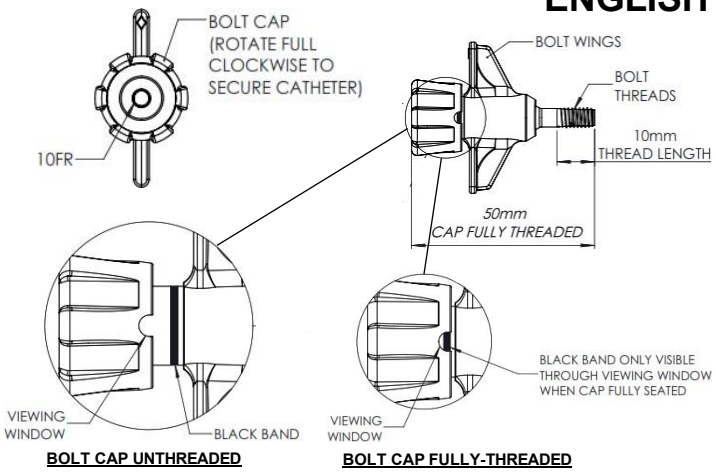
CLEARPOINT® NEURO

ENGLISH

Instructions FOR USE (IFU)

ICB010 IRRA*flow* Cranial Access Bolt





BOLT CAP UNTHREADED **BOLT CAP FULLY-THREADED**

DESCRIPTION OF DEVICE

The IRRA*flow* Cranial Access Bolt contains a Bolt, a Drill Bit with Collar and hex wrench, and a Dura Opener.

The IRRA*flow* Cranial Access Bolt is used with the IRRA*flow* Catheter. The catheter is part of IRRA*flow* Active Fluid Exchange System (AFES) interfacing via the IRRA*flow* Intelligent Digital Cassette.

INTENDED USE

The Bolt is a single-lumen cranial access device designed for use with the IRRA*flow* Dual Lumen Catheter (REF: ICGS 020, ICAT 030) to secure the catheter to the patient's skull while providing a sealed connection that prevents unintentional fluid leakage or entry. The device includes a pre-assembled Bolt with Cap for catheter fixation, a Drill Bit for creating a cranial access hole, and a Dura Opener to aid catheter placement by piercing the dura mater.

INTENDED USER

The Cranial Access Bolt is designed for worldwide use in a clinical setting by qualified medical personnel, including the neurosurgeon, nurse, or healthcare professional.

INTENDED USE ENVIRONMENT

This device shall be used in the Emergency Department (ED), Operating Room (OR), and the Intensive Care Unit (ICU).

INDICATIONS FOR USE

The Cranial Access Bolt is used with the IRRA*flow* Catheter (REF: ICGS020, ICAT030) and indicated when ICP monitoring is required, and for externally draining intracranial fluid as a means of reducing ICP in patients where an external drainage monitoring system is needed.

The use of the Bolt is at the discretion of the healthcare professional (HCP).

CONTRAINDICATIONS

The ICB010 is not designed, sold, or intended for any use except as indicated.

PRECAUTIONS

- Dispose of used product in accordance with accepted medical practice and applicable local and national regulations. Used products may present a potential biohazard.
- Inspect the sterile package carefully. Do not use if:
  - The package or seal appears damaged,
  - Contents appear damaged, or
  - The expiration date has passed.
- It is essential to maintain strict sterile technique during Bolt insertion and Catheter placement.
- Using drill bits other than those provided may compromise Bolt fitment in the skull.
- Using catheters other than the IRRAflow Catheters (ICGS020 or ICAT030) may compromise the Bolt's intended function, including its ability to properly seal and secure the catheter.
- The Catheter must not be connected to the IRRA*flow* Control Unit while setting up the Control Unit for treatment. This could potentially harm the patient.
- Over-drainage of intracranial fluid may cause ventricular collapse and injury to the patient.
- The Catheter may be occluded by ventricular collapse. Always monitor drainage progress by checking the drained volume in the drainage bag.
- Clamping the drainage tube may result in retention of fluid or undesirable patient conditions.
- Read all instructions carefully before use.

PATIENT SAFETY

- The Bolt is single-use. DO NOT re-use.
- The Bolt is approved for use according to the Indications for Use. Injury may result to the user or patient if the device 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 Cranial Access Bolt and accessory components (unpacking, preparing, handling connectors, and the surgical site).
- Operating the devices requires medical personnel with training and experience in neurological/neurosurgical medical care.
- Additions or modifications to the device may interfere with device performance.
- The healthcare professional should monitor the patient for signs of intracranial hemorrhage secondary to puncture of the ventricle or opening of the dura.
- When the Catheter is secured in the Bolt, 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.

OPERATIONAL SAFETY

- Insufficient removal of bone fragments may compromise the seal between the bolt and the catheter, potentially leading to impaired device performance.
- To secure the Catheter within the Bolt, rotate the Bolt Cap clockwise relative to the Bolt until it is **fully tightened**. Verify the black-band indicator is visible through the Cap's viewing window; this indicates the Bolt Cap is fully tightened. Always verify fluid patency and the Catheter is held securely.
- Insertion and removal of the Bolt and Catheter must be per-formed 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.
- DO NOT use the product if the packaging is damaged.

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- DO NOT re-sterilize the device.

WARNINGS

- Only training and experience medical personnel in neurosurgical medical care may use this device. Use in any other way may potentially harm the patient and/or the user.
- Only the IRRA*flow* Catheter can be utilized with the IRRA*flow* Active Fluid Exchange System.
- Take extreme care to avoid damage to the dura and underlying cerebrum.
- The Bolt must be installed concentrically with the twist drill hole. Installing it at an angle may lead to poor Bolt securement and hinder catheter advancement.
- Excessive torque applied to the Bolt during insertion can cause breakage**.**
- Failure to monitor drainage could result in too little or too much drainage.
- Too little drainage may result in the patient's ICP increasing to an undesirable state.
- Too much drainage may result in over-drainage.
- Do not use the Catheter for lumbar placement.
- The use of the Cranial Bolt is limited to < 5 days.

POTENTIAL ADVERSE EVENTS

The following Adverse Events may occur with the use of the Bolt and Bolt with IRRA*flow* Catheter:

- Hemorrhage
- Infection
- Subcutaneous Cerebrospinal Fluid (CSF) leak
- Neurological Sequelae

PREPARING THE SITE & PLACING THE CATHETER:

Preparing the site 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. Pay attention to the pre-procedure CT to determine skull thickness, determine insertion site and Catheter placement location in the ventricular system. Two methods are described: Bolt then Catheter and Catheter then Bolt placement.

INSTRUCTIONS– I. TWIST DRILL HOLE & DURA MATER ACCESS:

1. Use the provided sterile drill bit with collar to create the hole for the Bolt. Adjust the exposed length of the drill bit as needed to penetrate the skull. After drilling, remove all bone fragments.
2. Insert the sterile Dura Opener through the twist drill hole and carefully pierce the dura using its sharp tip.

INSTRUCTIONS– IIA. INSERTION, BOLT THEN CATHETER:

1. Insert the Bolt into the twist drill hole in the skull by rotating it clockwise. Each full rotation advances the Bolt by 1 mm. Continue threading until the threads are fully engaged and buried within the skull so that they are no longer visible, or until the bolt is securely fixed—whichever occurs first. Note: The Bolt is preassembled with the cap loosened to allow Catheter insertion. Note: If the dura is not adequately punctured, the Dura Opener may be inserted through the Bolt to pierce the dura.
2. Insert the Stylet into the catheter's drainage lumen. Insert the catheter into the Bolt, positioning the Catheter at the desired intracranial location. NOTE: The Bolt is approximately 5 cm in length; therefore, if the number "10" is visible at the Cap, 5 cm of the catheter extends beyond the Bolt.
3. Hold the position of the Catheter steady and remove the Stylet and confirm liquid flow through the drainage lumen. Cap the drainage lumen. Position the stopcock on the irrigation inflow port to regulate fluid flow.
4. Secure and seal the catheter by **holding the Bolt steady** and rotating the Bolt Cap clockwise relative to the Bolt until it is **fully tightened as far as possible**. **The Bolt Cap cannot be over-tightened.** Verify that the Bolt's black band is visible only through the Cap's viewing window, confirming the Cap is fully seated.

INSTRUCTIONS– IIB. INSERTION, CATHETER THEN BOLT:

1. Insert the Stylet into the catheter's drainage lumen. Then insert the catheter into the Bolt, ensuring the top of the Bolt aligns with the catheter's hub.
2. Position the Catheter at the desired intracranial location.
3. Hold the position of the Catheter steady and remove the Stylet and confirm liquid flow through the drainage lumen. Cap the drainage lumen and position the stopcock on the irrigation inflow to control fluid flow.
4. While holding the position of the Catheter steady, slide the Bolt down the catheter shaft and into the skull through the twist drill hole by rotating it clockwise. Each full rotation advances the Bolt by 1 mm. Continue threading until the threads are fully engaged and buried within the skull so that they are no longer visible, or until the bolt is securely fixed—whichever occurs first.
5. Secure and seal the catheter by **holding the Bolt steady** and rotating the Bolt Cap clockwise relative to the Bolt until **fully-tightened as far as possible**. **The Bolt Cap cannot be over-tightened.** Verify that the Bolt's black band is visible only through the Cap's viewing window, confirming the Cap is fully seated.

INSTRUCTIONS—III. CONNECT TO IRRA*FLOW* SYSTEM:

1. Reconfirm fluid is observed through the drainage lumen then connect the IRRA*flow* Cassette to the Catheter.
2. Connect the IRRA*flow* Catheter to the IRRA*flow* system per device's Instructions for Use.
3. Confirm the catheter's position before initiating therapy.

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, 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.

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.

OPERATION:

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

A Chlorhexidine Gluconate (CHG) disc may be utilized with the Bolt to assist in prevention of infection.

Periodically check the catheter and system to ensure it is functioning as intended.

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:

- 70% isopropyl alcohol
- Betadine or
- Chlorhexidine Gluconate

USEFUL LIFE:

The Catheter and Bolt are provided sterile and non-pyrogenic for single-use and should not remain implanted for more than 5 days.

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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 to minimize CSF over- or under-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 and IRRA*flow* Catheter IFU for additional troubleshooting steps.

BOLT AND CATHETER REMOVAL

Remove the Catheter and Bolt utilizing proper sterile technique.

1. To remove the catheter, rotate the Bolt Cap counterclockwise to loosen and release the seal. Once loosened, gently withdraw the catheter from the Bolt.
2. To remove the Bolt, rotate it counterclockwise and carefully withdraw it from the twist drill hole in the skull.
3. Close the site per hospital standard of care.
4. Dispose of the devices in accordance with hospital protocols and applicable regulations.

MRI SAFETY INFORMATION (relevant to Bolt only):

MR 1.5T / 3.0T	The IRRAflow Cranial Access Bolt (ICB010 / BLT010) is **MR Conditional** and may be safely scanned under specified conditions; failure to follow these conditions may cause patient injury.
MR	The stylet, drill bit with collar, wrench, and dura opener are **MR-Unsafe**.

MR CONDITIONAL

Parameter	*Condition of Use/Information*
Static Magnetic Field Strength (T)	1.5-Tesla or 3.0-Tesla
Static Magnetic Field Orientation	Horizontal
Maximum Spatial Field Gradient (T/m and gauss / cm)	40-T/m (4,000-gauss/cm)
RF Excitation Polarization	Circularly Polarized (CP) (i.e., Quadrature-Transmission)
Transmit RF Coil	Any transmit RF coil may be used
Receive RF Coil	Any receive-only RF coil may be used
MR System Operating Mode	Normal Operating Mode
Maximum Whole Body Averaged SAR (W/kg)	2-W/kg (Normal Operating Mode)
Maximum Head SAR (W/kg)	3.2-W/kg (Normal Operating Mode)
Scan Duration and Wait Time	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks)
MR Image Artifact	The presence of the IRRAflow Cranial Access Bolt (ICB010/ BLT010) produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the IRRAflow Cranial Access Bolt (ICB010/BLT010) is located in the area of interest.

REORDERING THE ICB010 / REQUESTING AN IFU

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

- IRRA*flow* Cranial Access Bolt (catalogue no. ICB 010)
- Instructions for Use are provided electronically at **www.clearpointneuro.com/eifus/**
- Paper copies of the IFU may be requested (catalogue no. 7001414)

TECHNICAL SPECIFICATION SHEET	
Drill Bit	Diameter: 4.8mm Overall length: ~60mm Flute length: ~ 25mm CenterPoint diam and length: 2mm / 1.5mm
Hex Wrench	Size: 1.6mm (1/16")
Dura Opener	Diameter: 3.5 mm Length from tip to 90° "L": ~60mm
Bolt Assembly	MR Conditional 1.5T/3.0T: Yes Materials: Titanium, Polycarbonate, Silicone Thread: sized for 4.8mm twist drill hole Thread length: 10mm (to bury threads) Length of entire shaft of bolt: ~15mm Overall length: 50mm (tightened cap to end of threads)

SYMBOLOGY:

Symbol and text	Meaning
	Do not re-use
	Consult instructions for use
	Manufacturer
REF	Catalogue number
LOT	Batch code
	Use-by date
STERILE EO	Sterilized using ethylene oxide
	Do not use if package is damaged. (Note: Do not use if the product sterile barrier system or its packaging is compromised.)
50°C 2°C	Store at temperatures within 2°C and 50°C
MR 1.5T / 3.0T	MR Conditional – a device that may safely be used in MR environments under specific conditions.
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

CONTACT / RE-ORDER INFORMATION

Manufacturer:

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