Hummingbird®

Quad ICP Monitoring

Instructions for Use

REF **H610**

DESCRIPTION:

Integrated Intracranial Parenchymal Pressure Monitoring and Ventricular Drainage with Dual Port Probe Access (for 2 brain probes)

KIT CONTENTS:

1 Parenchymal ICP / Ventricular Drainage Catheter Kit:

- **Catheter with Stylet**
- **Bolt**
- **Bolt Insert**
- **Bolt Stops**
- **Drill Bit / Collar**
- **Hex Wrench**
- **Tripod**
- **PAS Introducer**

1 Skull Thickness Caliper

1 Stab Incision Knife

MR
1.5T / 3.0T

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TABLE OF CONTENTS

List of Symbols and Terminology 3
List of Symbols 3
Terminology 4

System Overview 4
Description 4
Clinical Benefit 5
Indications 5
Contraindications 5
Intended User 6
Sterility 6
MR Compatibility 6
Shipping 6
Storage 6
Components of the H610 7

Illustration of the HICP200 and H610 Accessories 8

H610 Insertion Procedure 9
H610 Insertion Summary Figures 9
H610 Insertion Procedure Instructions 10

Maintenance of the H610 and Bolt Insertion Site 17

Probe/Catheter Removal Procedure 17

Maintenance and Care of the HICP200 19

Troubleshooting the System 19

Technical Support 20

H610 Technical Specifications 21

MR Conditional Information 22

Skull Thickness Caliper Quick Guide 23

Probe Access System (PAS) Quick Guide 24
Probe Access System Procedure Summary Figures 25
Probe Access System Directions for Use 26

Warnings 29

Cautions 30

IRRAS Warranty 30

Return Goods Policy 31

General Information 31
Contact 31
Ordering and Customer Service 31

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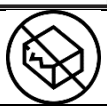
List of Symbols and Terminology

List of Symbols

Symbol	Meaning
	Manufacturer
	Refer to the Instructions for Use (also available at www.irras.com/eifu)
	Expiration Date expressed as year-month-day (yyyy-mm-dd).
	Non-Pyrogenic
	Do not reuse after opening
	Contents
	Model number
	Lot Number
	Sterile unless package is open. Method of sterilization – ethylene oxide.
	Temperature limits
	Relative humidity limits
	Keep dry
	Keep out of direct sunlight
	Medical Device
	Do not use if package is damaged
	General Warning
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	MR Unsafe
	MR conditional (refer to MR Conditional Information section): • 1.5 Tesla • 3.0 Tesla

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Terminology

ICP	Intracranial Pressure
ICP Monitoring System	The system is comprised of the HICP200 and H610
HICP200	The HICP200 is comprised of the Control Module, Patient Cable Module, Monitor Cable and AC Power Supply.
ICP Lumen	The air lumen that connects the pressure-sensing air bladder to the pressure transducer located in the Patient Cable Module and provides communication between the parenchymal ICP monitoring site and the pressure transducer housed in the Patient Cable Module.
PAS	Probe Access System

SYSTEM OVERVIEW

Description

The **Hummingbird H610:**

- Ventricular Catheter
- Drill Bit Assembly (consisting of Depth Limiting Collar and 7.1mm diameter drill bit) and hex wrench
- Tripod
- Bolt Stops
- Bolt
- Insert Assembly
- ICP Lumen Connector with Protective Cap
- CSF Drainage Lumen Luer Fitting & Cap
- PAS (Probe Access System)
- Skull Thickness Caliper
- Stab Knife

The H610 has integrated features to enable simultaneous intracranial pressure (ICP) monitoring within the parenchyma, and ventricular drainage. The PAS, which is part of the H610 kit, provides dedicated probe access with dimensions of 1.5mm diameter (.06") with a 30° exit angle. It allows the insertion of probes to a depth of approximately 30mm below the dura, and into virgin cerebral white matter lateral to the disturbed tissue pathway of the ventricular catheter.

NOTE: *The H610 delivers probes 1.5mm in diameter (.06") at a 30° exit angle.*

NOTE: *The H610 accommodates a probe length (with male Luer) of 5.8" from tip to Luer.*

Caution: Prior to inserting each specific probe, read the probe IFU and follow the instructions.

Probes must be removed prior to an MRI procedure.

Kit contents are sterile and non-pyrogenic if package is undamaged and unopened. Do not re-sterilize. For single-use only—Do not reuse. If opened and unused, discard immediately.

The H610, when used with HICP200 comprises a system whose principle of operation is based on air-coupled pressure transduction. The H610 measures ICP with a pressure sensing air bladder located in the parenchyma. The HICP200 employs air rather than fluid to transduce pressure waves to the reusable pressure sensor housed in the Patient Cable Module, thus providing for ICP waveform display and calculation of mean ICP pressure. It also enables ventricular drainage and concurrent parenchymal ICP monitoring. Refer to the HICP200 IFU for operating instructions. The Patient Cable Module requires no leveling and can be zeroed in-situ.

The H610 is made with radiopaque-striped polyurethane tubing and the catheter body is approximately 20cm long, with airline an additional 25cm. The zero-mark is length is marked approximately 5 cm from the catheter's distal tip to accommodate for the reference position at the top of the bolt. The scale is numeric from 0 to 8 cm in 1 cm increments.

⚠ The H610 has not been tested for drug compatibility and therefore is not intended for drug administration.

NOTE: *The following required items are **not provided** and must be obtained separately in order to place the H610, measure ICP, and to collect and monitor the CSF fluid drained through the H610:*

- *A cranial access kit that includes a hand drill*
- *An external CSF drainage collection/monitoring system*
- *HICP200* with the proper connector for the patient monitor
- *Probes, if employing multimodal monitoring*

Clinical Benefit

The Hummingbird System delivers a unique approach to neuromonitoring by, offering:

- The most accurate parenchymal ICP monitor (*Note: Hummingbird ICP monitoring is the only product on the market that meets NS28 accuracy standards; see Technical Specifications*)
- Ability to be re-zeroed in situ
- Automatic recalibration
- ICP reading independent of patient position
- MR Conditional: 1.5T / 3.0T

Indications

The H610 is designed for use with HICP200. Together, they comprise a system that is indicated for use in those conditions where continuous monitoring of ICP is required. The use of the Ventricular Catheter by a qualified neurosurgeon is indicated when direct measurement of intracranial pressure is clinically important; when patients may require CSF drainage in the course of their care; and when data from other cerebral parameters may be deemed useful for optimum patient management.

Contraindications

Invasive ICP monitoring should not be performed where components of the monitoring system will come into direct contact with any infected tissue. The H610 is contraindicated:

⚠
- When the patient is receiving anticoagulants
- When the patient is known to have a bleeding diathesis
- If trained personnel are not available to continuously supervise ICP monitoring

The Hummingbird H610 is not recommended for skull thicknesses less than 4 mm. Bolt stops are provided to enable the surgeon to attain the desired skull penetration depth; the decision is the surgeon's discretion.

Intended User

The H610 is intended to be used by trained and experienced medical and biomedical professionals:

- A qualified neurosurgeon should perform the placement and handling of the ICP catheter.
- Qualified hospital staff (e.g. neurosurgeon, nurse, intensivist, trauma physician, or physician's assistant) should oversee ICP monitoring.

It is recommended that all physicians, nurses, and technicians who will be using, operating, and maintaining the H610, review the IFU prior to using the system.

If there are questions after reading this IFU, contact IRRAS USA.

Sterility

This product is provided sterile and is for SINGLE USE ONLY. DO NOT RESTERILIZE.

Kit contents are sterile and non-pyrogenic if package is undamaged and unopened. Do not re-sterilize. For single-use only—Do not reuse. If opened and unused, discard immediately.

The H610 has not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. These devices are intended to come into contact with the central nervous system and the ability does not currently exist to destroy possible contaminants such as Creutzfeldt-Jakob Disease agents. Reuse can also compromise device performance and any usage beyond the design intent of this single-use device can result in unpredictable use hazards or loss of functionality.

MR Compatibility

The Hummingbird H610 has been found to be MR conditional at:

- 1.5 Tesla
- 3.0 Tesla

Please refer to the MR Conditional Information section.

The HICP200 Control Module, Monitor Cable, Patient Cable Module and AC Adaptor must not enter the MRI field.

The probes must not enter the MRI field

Shipping

Refer to H610 Technical Specifications for shipping conditions.

Storage

Store this product in a cool, dry location, away from direct sunlight. Do not remove the product from the packaging until it will be used. Refer to H610 Technical Specifications for storage conditions.

Components of the H610

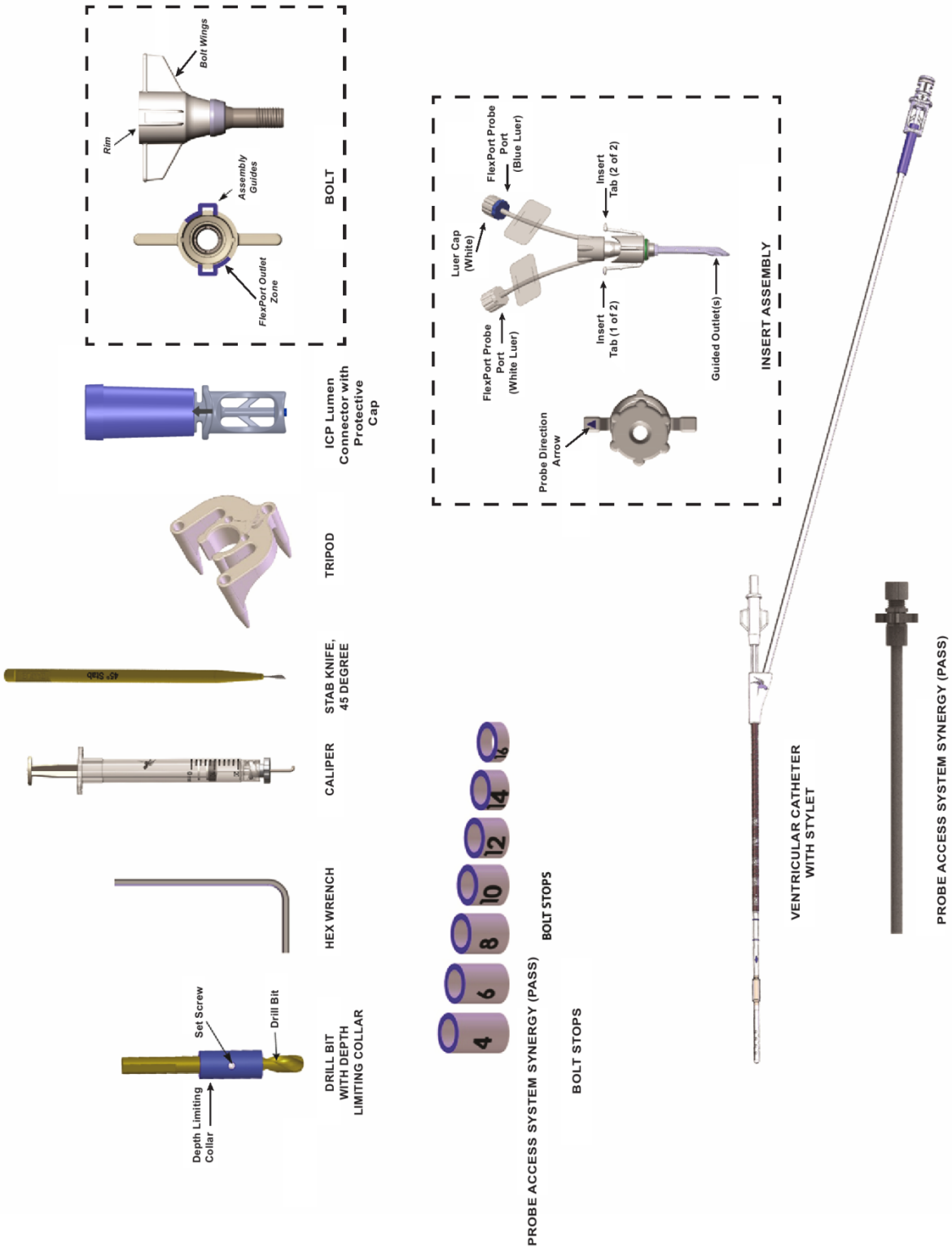

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ILLUSTRATION OF THE HICP200 AND H610 ACCESSORIES

I HUMMINGBIRD ICP

II PATIENT CABLE MODULE

III MONITOR CABLE

IV AC POWER SUPPLY CABLE

Item	REF #	Contents	Description	Image
ICP Lumen Connector with Protective Cap	ICP-CONNECTOR	1ea. ICP Lumen Connector	Replacement ICP Lumen Connector	
		1ea. Connector Protective Cap	Placed on the Hummingbird ICP Lumen Connector during transport to protect from debris and fluid ingression.	
ICP Lumen Connector Protective Cap	ICP-CAP	1ea. Connector Protective Cap	Placed on the Hummingbird ICP Lumen Connector during transport to protect from debris and fluid ingression.	
Patient Cable Module Protective Connector with Swabs	ICP-SWAB	1ea. Protective Connector	Placed in the housing of the Patient Cable Module to protect from debris and fluid ingression	
		2ea. Swabs	Used to remove any fluid and debris from the Patient Cable Module connector	

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H610 Insertion Procedure

H610 Insertion Summary Figures

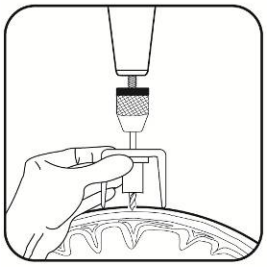

Figure 1: Drill hole in skull using the drill bit provided within the H610MR kit.

Figure 2: Irrigate the twist drill hole thoroughly to remove bone shards.

Figure 3: Using a cruciate cut, incise the dura carefully using a scalpel.

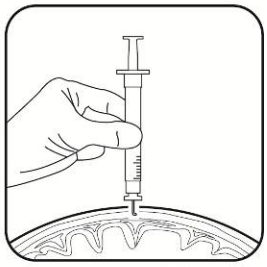

Figure 4: Esimate skull thickness using caliper.

Figure 5: Select Bolt Stop size and slide onto bolt of the Bolt Assembly.

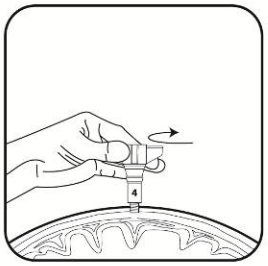

Figure 6: Advance Bolt Assembly to level of inner table.

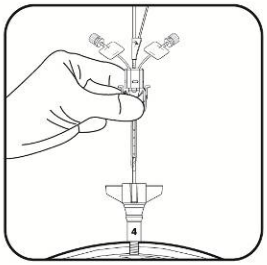

Figure 7: Advance Ventricular Catheter through Bolt and position in ventricle.

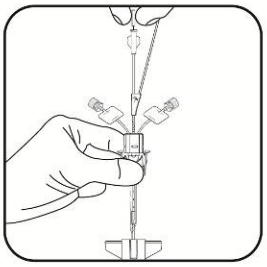

Figure 8: Remove Stylet.

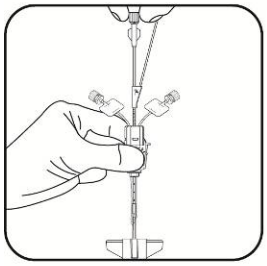

Figure 9: Place end cap on Catheter Hub and tighten.

Figure 10: Slide Insert Assembly down Catheter.

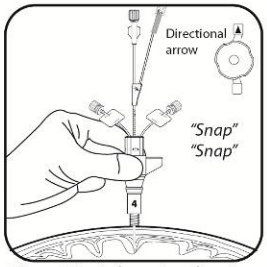

Figure 11: Referencing directional arrow on insert, and confirming direction of probe insertion, listen for 2 "snaps" when placing the insert.

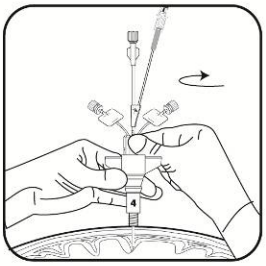

Figure 12: Tighten Touhy-Borst Cap securing catheter into place.

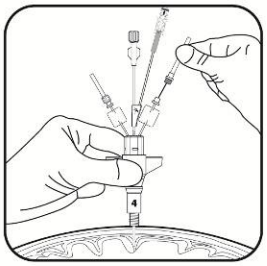

Figure 13: Insert probes into Probe Ports (blue luer/white luer) and advance to connect to female luer.

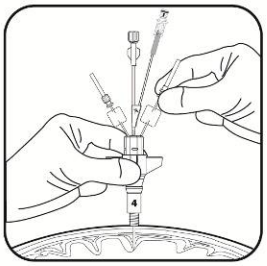

Figure 14: Rotate male luers clockwise

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H610 Insertion Procedure Instructions

Step 1 – Procedure Preparation

- The following supplies are required:
  - A cranial access kit that includes a hand drill
  - H610 Kit
  - HICP200 with the proper connector for the patient monitor
  - An external CSF drainage collection/monitoring system
  - Probes, if employing multimodal monitoring
- Ensure the HICP200 has been properly prepared for the procedure. (For details see the Maintenance and Care section for the HICP200.)
- Connect the HICP200 to the patient monitor a minimum 15 minutes before beginning the procedure to allow the transducer to rise to an equilibrium temperature.
- Open the H610 kit using aseptic technique.

Step 2 –Estimate Skull Thickness and Prepare Drill Bit Assembly

- Estimate skull thickness using CT scan(s).
- Adjust the Drill Bit Assembly by loosening the set screw on the Depth Limiting Collar with the provided hex wrench.
- Position the Depth Limiting Collar, exposing the tip of the drill just enough to completely drill through the skull's inner table. The tip of the drill bit should not penetrate the inner table by more than 1 mm.

Ensure that the set screw is tight enough to prevent movement of the Depth Limiting Collar on the Drill Bit. However, do not over-torque the set screw.

Step 3 – Providing Access for the H610

- Select the catheter insertion site for access to the ventricle.
- The operative site should be aseptically cleaned and draped.

  NOTE: *To minimize risk of surgical site infections, it is recommended to prepare the surgical area in accordance with evidenced-based guidelines*, such as Mangram et al. Guideline for Prevention of Surgical Site Infection, 1999. **Infection Control and Hospital Epidemiology**, 20(4), pp. 257-258 and Nichols RL. Preventing Surgical Site Infections: **A Surgeon's Perspective. Emerging Infectious Diseases**. 7(2), Mar-Apr 2001.
- Make an incision in the scalp and expose the bone with a self-retaining type retractor, or similar device.
- Using the Drill Bit Assembly, and the supplied Tripod to ensure perpendicularity, drill a minimum 7.1mm diameter hole through the skull. Ensure that the hole extends through the inner table of the skull and exposes the dura.

Care should be exercised to prevent excessive penetration and/or damage to the dura, cortex, and cortical vessels

- Irrigate the drill hole with sterile saline, ensuring that it is cleared of any debris and/or bone shards.

Bone shards must be removed prior to catheter insertion. Failure to remove bone shards may damage the catheter's pressure-sensing bladder.

- Open the dura by making a cruciate incision, using a stab knife or equivalent, making sure the entry site in the dura is of adequate size to allow the catheter to pass through without excessive force.

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Step 4 – Measure Skull Thickness

Refer to the Skull Thickness Caliper Quick Guide section measure the skull thickness.

Step 5 – Bolt Stop Placement

Based on the skull thickness (in millimeters), select the Bolt Stop number that closely matches the thickness of the skull (e.g., a skull thickness of 4mm requires Bolt Stop #4, which exposes 4mm of the distal end of the Bolt) and slide it onto the distal end of the Bolt.

NOTE: *If skull thickness falls between two Bolt Stop numbers, use the smaller numbered Bolt Stop.*

Step 6 – Fixation of Bolt

- Position the Bolt/Bolt Stop, in the drill hole.
- To advance the Bolt/Bolt Stop, screw it in.
- Stop advancing the Bolt/Bolt Stop once the Bolt Stop provides resistance against the skull bone.

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Ensure that the scalp and surrounding tissue are not compressed underneath the Bolt Stop and ensure that the distal end of the Bolt contacts only the skull.

If the bolt is loose, the insertion procedure must be repeated at a new site.

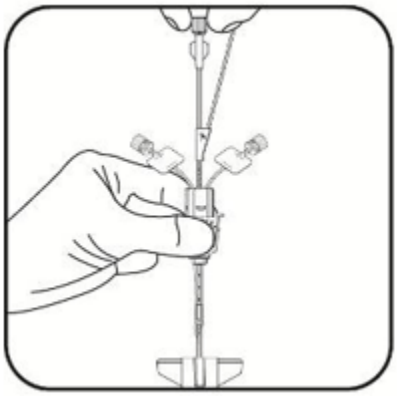
NOTE: *Use the blue FlexPort outlet zone guide on the bolt to ensure that the orientation of the Bolt is compatible with the direction in which the probes will deploy when placed into the white matter.*

Step 7 – Placement of Catheter

- Assure Catheter is free to slide inside of Insert:
  - Confirm the Insert-to-Catheter Tuohy-Borst connection is loose,
  - Remove Stylet from Catheter CSF Drainage Lumen and temporarily set it aside within the sterile field,
  - Partially withdraw from, then return to original position Catheter within Insert; a 5mm to 10mm displacement is sufficient to confirm free movement of Catheter,
  - Re-insert Stylet into Catheter CSF Drainage Lumen.
- Remove the insert warning tag from the Insert, advance the Catheter through the Bolt and position it in the ventricle using approved surgical techniques.

- While holding the Insert/Catheter in position, remove the Stylet.

- Verify its placement in the ventricle, check for CSF flow and then connect the CSF Drainage Lumen Luer Fitting & Cap to the Catheter Hub.

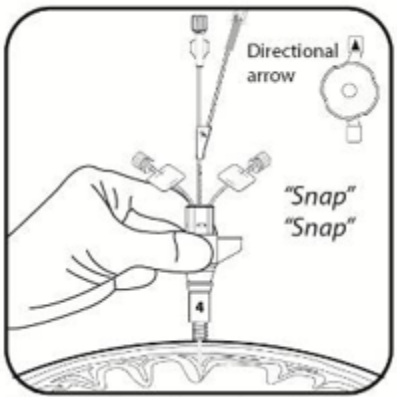


⚠ Do not remove the silicone finger grip from the Stylet. Fully insert the stylet within the catheter so the stylet's tip is positioned at the distal end of the catheter.

Step 8 – Fixation of Insert Assembly

- While holding the catheter in position, slide the Insert down the catheter.

- Referencing the arrow on the Insert tab and confirming the direction of probe insertion, line up both Insert snap tabs with the Bolt snap tab guides.
- Slide the Insert into the Bolt. Confirm two (2) audible "SNAPS" as the indication that both Insert snap tabs are fully engaged into the Bolt snap tab guides.



If a tab on the Insert breaks, replace the insert.

- Rotate the Tuohy-Borst Cap clockwise until the cap cannot be turned further to stabilize the catheter at the desired depth. Confirm the catheter is secured.

NOTE: *The arrow on the Insert tab indicates the direction the probe will deploy into the white matter.*

NOTE: *Ensure the orientation of the Insert is compatible with the desired direction of probe deployment.*

Step 9 – Connecting the external CSF drainage collection/monitoring system

- Set up the CSF external drainage collection/monitoring system as recommended by the manufacturer.
- Clamp the CSF drainage lumen with a soft jawed hemostat approximately 2cm from the CSF drainage lumen luer fitting.
- Remove the CSF drainage lumen connector cap.
- Connect the CSF drainage luer fitting to the CSF external drainage collection/monitoring system.
- Remove the hemostat clamp from the CSF drainage lumen.

Step 10 – Connecting the Catheter and Activating the ICP Monitoring System

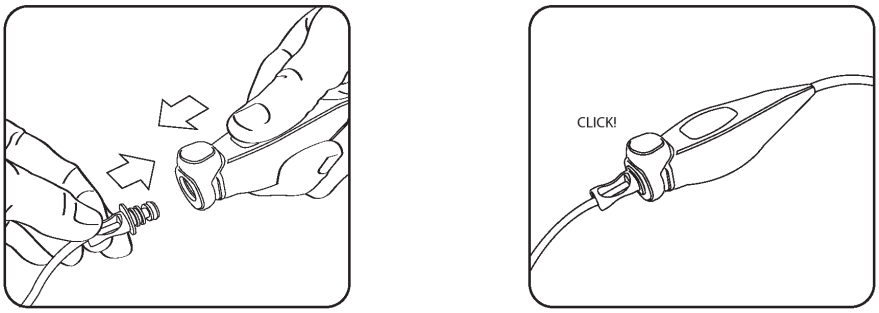
- Remove the protective cap from the ICP lumen connector and connect the catheter to the HICP200 Patient Cable Module.
- Set up the HICP200 per its instructions for use.
- Ensure the patient monitor has been zeroed per the HICP200 IFU, remembering to

disconnect the ICP lumen connector, or HICP200 Plug, if connected. The objective is to ensure that the Patient Cable Module is open to atmosphere.

Disconnect the ICP catheter from the Patient Cable Module prior to zeroing the patient monitor, as failure to do so may result in inaccuracy. The Patient Cable Module must communicate with atmospheric pressure when zeroing the patient monitor.

- Connect the ICP lumen connector to the HICP200 Patient Cable Module. A secure connection can be confirmed by a tactile and audible indication.

CONNECTION / INSERTION



- Operate the HICP200 following the HICP200 IFU.

Caution: Verify proper placement and integrity of all tubing junctions to prevent obstruction of the drainage and ICP lumens and/or tearing of the tubing.

Caution: To ensure adequate drainage, waveform reproduction and pressure monitoring, care should be exercised to not kink, occlude, or otherwise interfere with the fluid drainage and pressure sensing lumens of the catheter.

The HICP200 is contraindicated for use in a Magnetic Resonance (MR) environment.

Step 11 – Insertion of Probes

Do not place probes into the FlexPort lumen that are larger than the dimensions specified.

Do not place a probe until its length has been set per the PAS procedure and has the PAS Tuohy-Borst attached.

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Caution: Prior to inserting each specific probe, read the probe IFU and follow the instructions.

Maintenance of the H610 and Bolt Insertion Site

In general, there is a risk of infection due to use of intracranial catheters. It is recommended that the H610 not be left in place for more than 5 days.

ICP Lumen Connector Maintenance

Before cleaning the surface of the H610, note the following:

- Use particular care when cleaning around the connectors. Be sure to wipe any excess fluid that accumulates in these areas.
- Always use the ICP Protective Cap (REF ICP-CAP) when the ICP Lumen Connector is disconnected from the HICP200 Patient Cable Module.

Caution: **The ICP Lumen Connector must be kept dry.** In the event liquid enters the ICP Lumen Connector, a filter inside the connector will turn blue, indicating that the ICP Lumen Connector needs to be replaced (REF ICP-CONNECTOR). The ICP-Connector contains the instructions for replacing the connector. Ensure the ICP Protective Cap is installed on the ICP Lumen Connector when not connected to the HICP200.

Bolt Insertion Site Maintenance

Maintain the Bolt insertion site during ICP monitoring according to standard hospital protocol. Avoid pulling on any of the lines or cables attached to the Bolt/Insert Assemblies or striking the Bolt.

Probe/Catheter Removal Procedure

Step 1 – Disconnect the Patient Cable Module:

- Disconnect the catheter from the Patient Cable Module.
- Before insertion of the Protective Connector into the Patient Cable Module, inspect the connection port. Use an IPA-moistened ICP-SWAB to ensure that any debris has been carefully removed.

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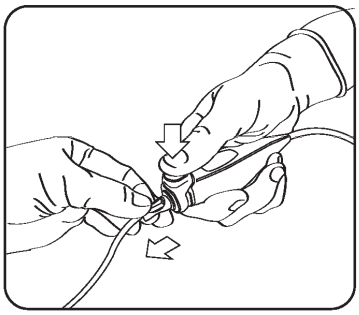
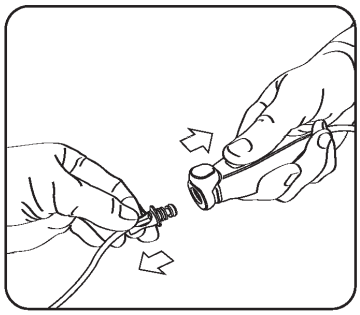
DISCONNECTION / REMOVAL





Step 2 – Decouple the H610 from the CSF External Drainage Collection/Monitoring System:

- Adjust the stopcock to stop flow to the CSF drainage collection/monitoring system.
- Clamp the CSF drainage lumen with a soft jawed hemostat approximately 2cm from the end.
- Disconnect the H610 from the CSF external drainage collection/monitoring system.
- Connect a sterile endcap to the CSF Drainage Lumen Luer Fitting.
- Remove the hemostat clamp from the CSF Drainage Lumen.

Step 3 – Remove all probes from the Insert Assembly.

Remove the probe(s) from the Hummingbird H610 by rotating the male FlexPort luer connector counter-clockwise. Place sterile luer caps on the FlexPort luer fittings, which are now open.

⚠ Remove all probes from the FlexPort Probe Ports prior to removing the Insert Assembly.

Step 4 – Carefully remove the Catheter per hospital protocol and the steps below.

- Holding the Bolt-Wings, rotate the Tuohy-Borst cap counter-clockwise to loosen.

  NOTE: Ensure that the Tuohy-Borst cap is in the fully-up position and that the Insert's locking tabs can be depressed.

- Remove the Catheter from the Insert Assembly.

Step 5 – Remove the Insert

Depress both the snap tabs on the Insert and withdraw it from the Bolt.

Step 6 – Remove the Bolt

Turn the Bolt counter-clockwise to remove it from the skull.

Step 7 – Close surgical site

Close cranial access site per standard hospital procedure.

Step 8 – For cleaning and care of the HICP200 and its components, refer to the HICP200 IFU, summarized below.

Maintenance and Care of the HICP200

It is recommended that the Control Module and its components be cleaned as soon as is reasonably practical after use. Reference HICP200 IFU for maintenance and cleaning procedures.

Inspect the HICP200 and the cables for wear or damage (e.g., frayed power cord, pinched cable, or cracked enclosure). Do NOT use the HICP200 if there is any sign of wear or damage.

⚠ Do not autoclave, use automated cleaning methods, or immerse the Control Module in liquid as damage may occur. If the Control Module is exposed to liquids, remove the AC Power Supply, dry the unit thoroughly, and send to biomed staff for evaluation before reapplying power.

Recommended Manual Cleaning Method

Using either 70% IPA with a lint free wipe or a Diversey Oxivir-Tb Wipes®, thoroughly wipe all surfaces at least three (3) times and then inspect the surfaces for visible residues. If residues remain, use a new Diversey Oxivir-Tb Wipes® or lint free wipe soaked with 70% IPA and continue wiping the surfaces until they are visibly free of residues.

Recommended Disinfection Agents

The HICP200 has been tested and shown to withstand exposure to 70% IPA and Diversey Oxivir-Tb Wipes®. If used follow standard hospital procedures and manufacturer's IFU.

Troubleshooting the System

Complete the following steps until the problem is resolved:

Check the ICP Lumen Connector

The HICP200 Patient Cable Module and ICP Lumen Connector must be kept dry. Fluid that enters the connector may cause a dampened or flat pressure waveform and/or an inaccurately high-pressure reading. Visually inspect the filter within the ICP Lumen Connector and replace the ICP Lumen Connector as required.

Rezero the HICP200

When in Prime Mode, Priming Mode, Run Mode, or Fault Mode, press the "STOP" button to go to Zero Wait Mode and clear any error code. Press the "STOP" button and disconnect the ICP Lumen Connector from the Patient Cable Module. Perform the standard protocol for zeroing the patient monitor.

⚠ **Disconnect the ICP catheter from the Patient Cable Module prior to zeroing the patient monitor**, as failure to do so may result in inaccuracy. The Patient Cable Module must communicate with atmospheric pressure when zeroing the patient monitor.

Confirm that the HICP200 has light indication

If the HICP200 has no light indication, ensure the Monitor Cable is properly connected to the patient monitor and the monitor is turned on. If the HICP200 is plugged into the patient monitor and has no light indication, (a) plug the AC Power Supply Cable into a compatible outlet, (b) plug the HICP200 into a separate patient monitor module or (c) replace the HICP200 Monitor Cable.

If there is a large change in ICP pressure and waveform, press “PRIME SYSTEM” button on the HICP200.

If the previous trouble shooting steps did not result in a change in status, replace the HICP200.

If none of the above steps remedy the problem, consideration should be given to replace the catheter.

For additional information on troubleshooting, cleaning, and use questions regarding the HICP200, please consult the HICP200 IFU.

Technical Support

If any component of the ICP Monitoring System fails to perform as specified, and the cause cannot be determined, contact IRRAS USA, Inc. for technical support. Any ‘serious incident’ involving IRRAS product should also be reported:

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

H610 TECHNICAL SPECIFICATIONS

Item	Specification
Principle Technology	Pressure Sensor Type: Solid State strain gauge pressure transducer
Operating Atmospheric Pressure (Absolute)	600 to 800 mmHg
Operation Limits	• Temperature = 15 °C to 39 °C • Humidity = 15% to 95% relative humidity, non-condensing
Shipping/Storage Limits	• Temperature = 5 °C to 40 °C • Humidity = Relative humidity ranging from 5% to 95% non-condensing
Rated ICP Accuracy Range	0 to 100 mmHg
Rated Pressure Accuracy	±2 mmHg or 10% whichever is greater **NOTE:** ±2 mmHg from 0-20 mmHg and ±10% from 20 to 100 mmHg (per ANSI / AAMI NS28)
Time of Use (for Assured Accurate Performance)	To maintain accuracy, re-prime is required if the Hummingbird ICP is exposed to a 10 °C (or greater) or 25%RH (or greater) change.
Stability over Temperature Range of 20 to 39°C (68 to 102°F):	Stable if used within 10 °C and 25%RH of initial set-up. **NOTE:** Re-prime required if exposed to a 10 °C (or greater) or 25%RH (or greater) change.
Drift of the Zero Point Reading	The zero point drift does not exceed ±0.15 mmHg per 24 hour period. Re-zeroing the transducer can be performed in-situ and is recommended if the user operates the system outside of the manufacturer's recommendations (temperature or barometric pressure) or the user questions the pressure value displayed on the patient monitor.
Maximum Frequency Response *	10Hz
Slew Rate *	200 mmHg/sec (zero to peak), 180 mmHg/sec (peak to zero)
Time Constant for Full Scale Deflection of the System *	0.04 sec (increasing and decreasing pressures)
Catheter Size	8.5 French (0.112")
Drainage Lumen Dead Space Volume	0.80 mL
Drill Hole	7.1mm (0.281")
Pyrogenicity	This device has been evaluated for bacterial endotoxins and complies with bacterial endotoxin limits for neurological devices contacting cerebral spinal fluid of < 2.15 EU/device. The Kit is supplied sterile and non-pyrogenic as long as the outer tray in not opened or damaged.

MR Conditional Information

Non-clinical testing has demonstrated the bolt is MR-Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient field of 1100 Gauss/cm (11 Tesla/m)
- Maximum whole body averaged specific absorption rate (SAR) of 2.1 W/kg for 15:00 minutes of scanning

MR Displacement Force and Torque
Entering the MR system using the recommended MR parameters is safe for the bolt in regards to magnetically induced displacement force and torque as long as the bolt is properly affixed to the skull. Non-clinical magnetic displacement force and torque testing have not been performed on the bolt.

MR RF Induced Heating
In non-clinical testing, the bolt produced a temperature rise of less than 0.2°C at a maximum SAR of 2.1 W/kg, as assessed by calorimeter for 15:00 minutes of MR scanning in a 1.5 Tesla Philips Intera (software release 10.6.2.0, 2006-03-10) MR scanner.

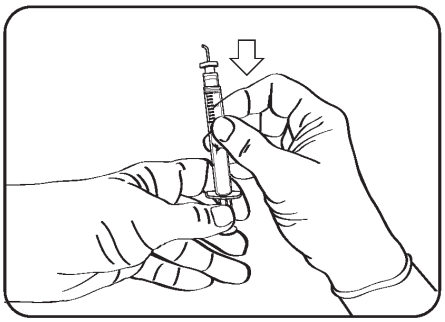
In non-clinical testing, the bolt produced a temperature rise of less than 0.3°C at a maximum SAR of 1.6 W/kg, as assessed by calorimeter for 15:00 minutes of MR scanning in a 3.0 Tesla Philips Intera (software: Numaris/4, syngo MR A30) MR scanner.

Image Artifact
MR Image quality may be compromised if the area of interest is in the same area or relatively close to the position of the bolt. Therefore, it may be necessary to optimize the MR imaging parameters for the presence of the device.

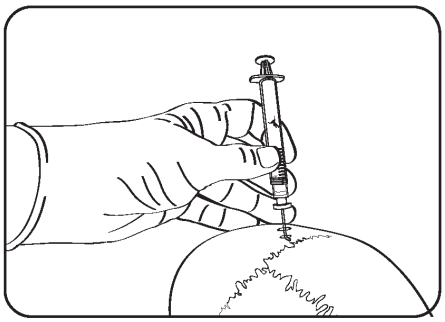
MR induced Nerve or Tissue Stimulation
No tests have been performed on possible nerve or other tissue stimulation due to strong gradient magnetic fields resulting in induced voltages. Due to the compact size of the bolt, it can be assumed that induced voltages would result in eddy currents and therefore would contribute to device heating rather than tissue or cell stimulation.

The HICP200 Control Module, Monitor Cable, Patient Cable Module and AC Adaptor should not enter the MRI field.

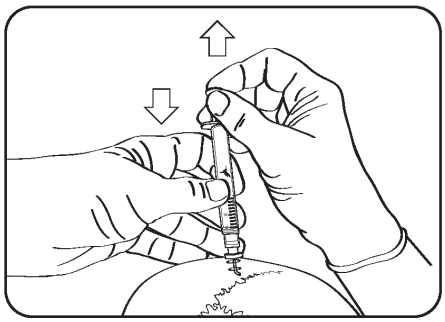
Skull Thickness Caliper Quick Guide



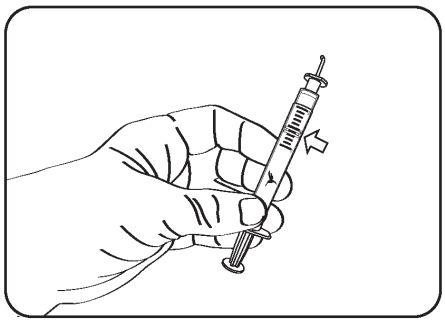
Expose the "L" shaped hook by
moving the syringe body downward.



Fit and secure the "L" shaped
hook under the shelf of the bone.



Holding the plunger, securely advance the
syringe body onto the suface of the outer table.



Remove the Skull Thickess Caliper.
The skull thickness is indicated by the plunger position.
Gradations are in 2mm increments from 0mm to 20mm.

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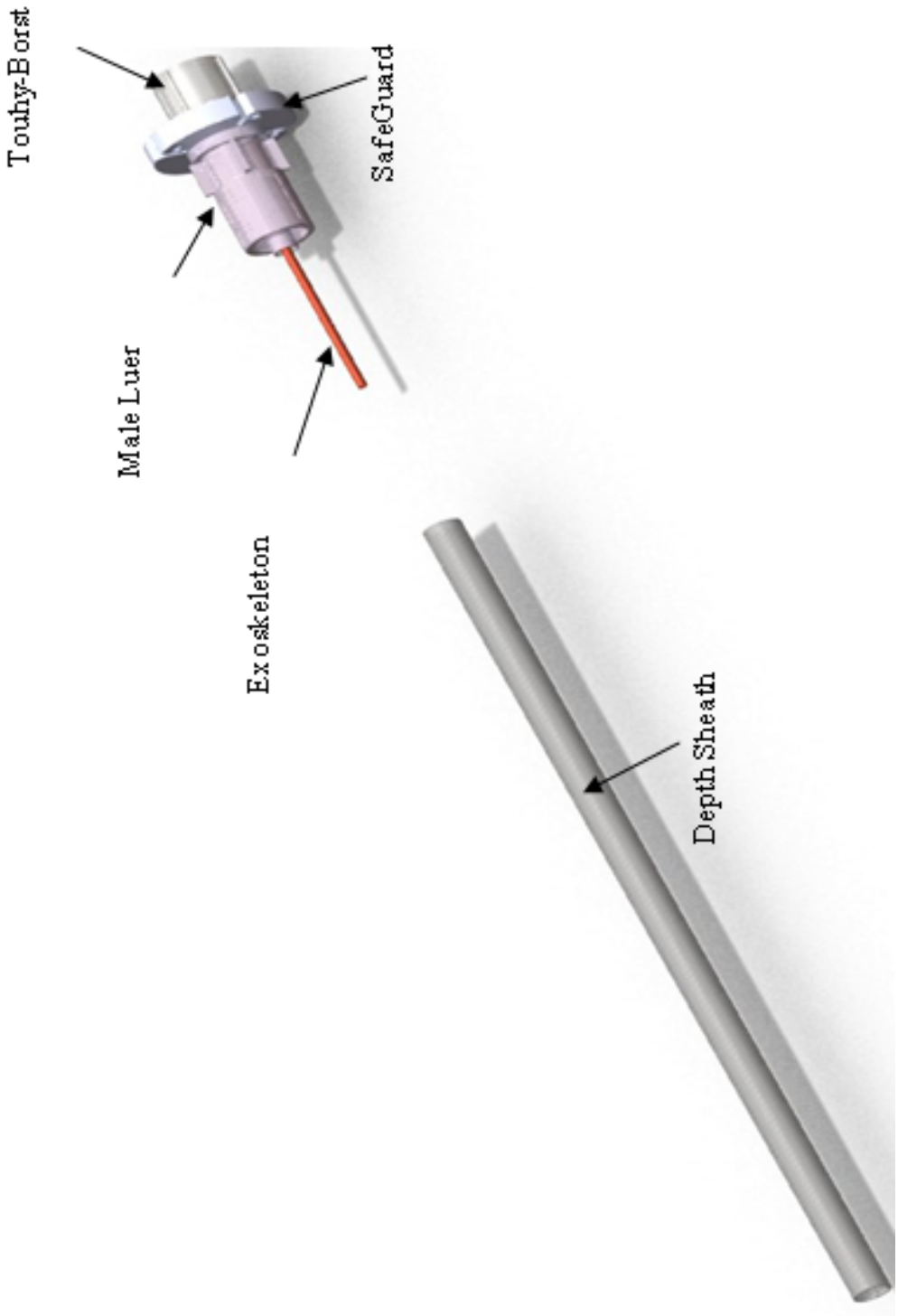
PROBE ACCESS SYSTEM (PAS) QUICK GUIDE



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Probe Access System Procedure Summary Figures

Figure 1: Place probe through Touhy-Borst.

Figure 2: Advance probe to end of depth sheath.

Figure 3: Tighten Touhy-Borst.

Figure 4: Remove sheath from Touhy-Borst.

Figure 5a: Insert probe into probe port (blue luer) and advance.

Figure 5b: Rotate blue male luer clockwise to connect to female luer.

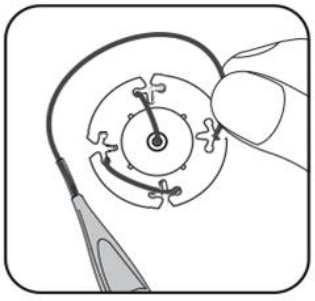

Figure 6: Place excess probe length into SafeGuard forming figure eights to provide strain relief.

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Probe Access System Directions for Use

Follow Steps 1 through 4, below, for both probes, one for the blue FlexPort lumen and one for the white FlexPort lumen.

Caution: Prior to inserting each specific probe, read the probe IFU and follow the instructions.

⚠ Do not place probes into the FlexPort lumen that are larger than the dimensions specified.

Step 1 – Insertion of Probe into Probe Access System

- Ensure that the depth sheath is firmly seated in the male Luer.
- Insert the probe into the Tuohy-Borst valve and advance.

- Advance the probe to the end of the Depth Sheath ensuring that the tip of the probe stops at the end of the Depth Sheath.

Step 2 – Fixation of Probe in PAS

- When the tip of the probe is at the end of the Depth Sheath, secure the probe by tightening the Tuohy-Borst.

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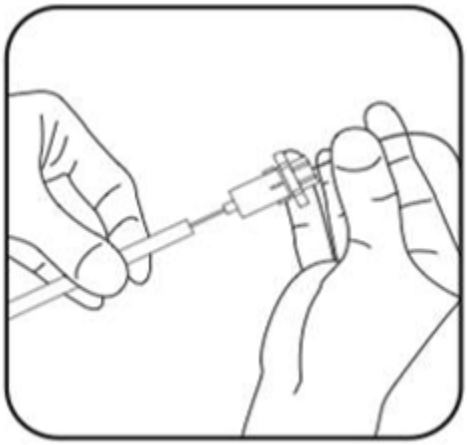
- Remove the Depth Sheath (PAS Procedure, Figure 4) from the Tuohy-Borst Luer.



CAUTION: DO NOT advance the distal end of the probe beyond the Depth Sheath.

Step 3 – Insertion of Probes

NOTE: *Be aware of the direction in which the probe(s) will deploy as it enters into white matter.*

- Advance the probe through the FlexPort on the Insert Assembly. After it is fully inserted, lock the Tuohy-Borst Luer to the FlexPort Luer.

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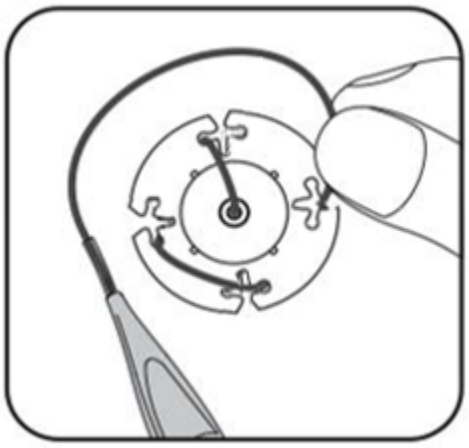
CAUTION: Do not place probes into the FlexPort that are larger than the dimensions specified.

Step 4 - Fixation of Probes in SafeGuard

Take the excess probe length and place it in the track of the SafeGuard, then form a figure eight to secure.



NOTE: *SafeGuard provides strain relief for the probe. Care must be taken to ensure the probe is not forcibly removed during patient care or transport.*

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Warnings

Note: Failure to observe one or more of the following warnings could compromise patient safety or result in ICP measurement errors.

Probes must be removed prior to an MRI procedure.

Kit contents are sterile and non-pyrogenic if package is undamaged and unopened. Do not re-sterilize. For single-use only—Do not reuse. If opened and unused, discard immediately.

The H610 has not been tested for drug compatibility and therefore is not intended for drug administration.

The H610 is contraindicated

- When the patient is receiving anticoagulants
- When the patient is known to have a bleeding diathesis
- If trained personnel are not available to continuously supervise ICP monitoring

The Hummingbird H610 is not recommended for skull thicknesses less than 4 mm; the decision is the surgeon's discretion. Bolt stops are provided to enable the surgeon to attain the desired skull penetration depth.

It is recommended that all physicians, nurses, and technicians who will be using, operating, and maintaining the H610, review the IFU prior to using the system. If there are additional questions after reading this IFU, contact IRRAS USA, Inc.

The H610 has not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. These devices are intended to come into contact with the central nervous system and the ability does not currently exist to destroy possible contaminants such as Creutzfeldt-Jakob Disease agents. Reuse can also compromise device performance and any usage beyond the design intent of this single-use device can result in unpredictable use hazards or loss of functionality.

The HICP200 Control Module, Monitor Cable, Patient Cable Module and AC Adaptor should not enter the MRI field.

The probes must not enter the MRI field

Ensure that the set screw is tight enough to prevent movement of the Depth Limiting Collar on the Drill Bit. However, do not over-torque the set screw.

Care should be exercised to prevent excessive penetration and/or damage to the dura, cortex, and cortical vessels

Bone shards must be removed prior to catheter insertion. Failure to remove bone shards may damage the catheter's pressure-sensing bladder.

Ensure that the scalp and surrounding tissue are not compressed underneath the Bolt Stop and ensure that the distal end of the Bolt contacts only the skull.

If the bolt is too loose, the insertion procedure must be repeated at a new site.

Do not remove the silicone finger grip from the Stylet. Ensure the stylet is positioned so its tip terminates at the distal end of the catheter.

If a tab on the Insert breaks, replace the insert.

Do not place probes into the FlexPort lumen that are larger than the dimensions specified.

Disconnect the ICP catheter from the Patient Cable Module prior to zeroing the patient monitor, as failure to do so may result in inaccuracy. The Patient Cable Module must communicate with atmospheric pressure when zeroing the patient monitor.

The HICP200 is contraindicated for use in a Magnetic Resonance (MR) environment.

Remove all probes from the FlexPort Probe Ports prior to removing the Insert Assembly.

In general, there is a risk of infection due to use of intracranial catheters. It is recommended that the H610 not be left in place for more than 5 days.

Do not place a probe until its length has been set per the PAS procedure and has the PAS Tuohy-Borst attached.

Do not autoclave, use automated cleaning methods, or immerse the Control Module in liquid as damage may occur. If the Control Module is exposed to liquids, remove the AC Power Supply, dry the unit thoroughly, and send to biomed staff for evaluation before reapplying power.

Cautions

Note: *Caution statements are used to highlight information relating to special care that should be exercised to ensure the safe and effective use of the* ICP Monitoring System*.*

- Verify proper placement and integrity of all tubing junctions to prevent obstruction of the drainage and ICP lumens and/or tearing of the polyurethane tubing.
- To ensure adequate drainage, waveform reproduction and pressure monitoring, care should be exercised to not kink, occlude, or otherwise interfere with the fluid drainage and pressure sensing lumens of the catheter.
- **The ICP Lumen Connector must be kept dry.** In the event liquid enters the ICP Lumen Connector, a filter inside the connector indicates the ICP Lumen Connector needs to be replaced.
- The HICP200 Control Module, Monitor Cable, Patient Cable Module and AC Adaptor should not enter the MRI field.
- Prior to inserting each specific probe, read the probe IFU and follow the instructions.
- DO NOT advance the distal end of the probe beyond the Depth Sheath.
- Do not place probes into the FlexPort that are larger than the dimensions specified.

IRRAS Warranty

WARRANTY

All devices bearing the IRRAS USA, Inc. brand are guaranteed to be free of functional defects in workmanship and materials when used normally for their intended surgical use. Any IRRAS USA, Inc. device proving to be defective will be replaced. Any type of misuse or abuse will render the warranty void. IRRAS USA, Inc. assumes no liability if the device is misused.

LIMITATIONS OF LIABILITY
IRRAS USA, Inc. has exercised reasonable care in the manufacture of this device. IRRAS USA, Inc. excludes all warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of MERCHANTABILITY or FITNESS, since storage and handling of this device by the user, as well as other factors relating to the patient, the diagnosis, treatment, surgical therapy, and other matters beyond IRRAS USA, Inc. control directly affect this device and the results obtained from its use. IRRAS USA, Inc. will not be liable for INCIDENTAL or CONSEQUENTIAL LOSS, DAMAGE, or EXPENSE directly or indirectly arising from the use of this device. IRRAS USA, Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional LIABILITY or RESPONSIBILITY in connection with this device.

IRRAS USA, Inc. makes no claim for or representations as to the performance characteristics of this product if it is used in conjunction with components of other manufacturers.

Return Goods Policy

Products must be returned in unopened packages, with manufacturer's seals intact to be accepted for replacement or credit, unless returned due to a complaint or product defect.

Determination of a product defect will be made by IRRAS USA, Inc., which determination will be final. Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.

General Information

Contact

Manufacturer

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

Ordering and Customer Service

All products can be ordered through your IRRAS USA, Inc. sales or Customer Service representative.

USA
Email: US.customerservice@irras.com
Tel: 1-800-946-0458

Global
Email: Global.customerservice@irras.com
Tel: +31-20-210-1098

CAUTION: Federal law restricts this device to sale by or on the order of a physician (licensed healthcare practitioner). Do not use if the package has been opened or damaged.

Hummingbird is a registered trademark of IRRAS USA, Inc.
Manufactured under one or more of U.S. Patent Nos. 7,654,967 and 8,876,729; other U.S. and foreign patents issued and pending.

SynergyDuo is a registered trademark of IRRAS USA, Inc.
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