



Hummingbird™

Ventricular

Complete kit for:

- ⇒ Ventricular Drainage
- ⇒ ICP Monitoring
- ⇒ MRI Conditional

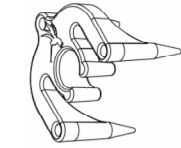
Instructions for Use

Model **HUMV-200MR**



Hummingbird™ Ventricular

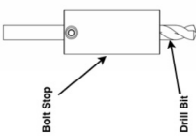
Model HUMV-200MR Contents



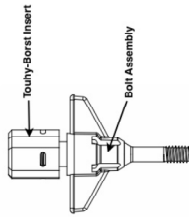
TRIPOD



HEX WRENCH



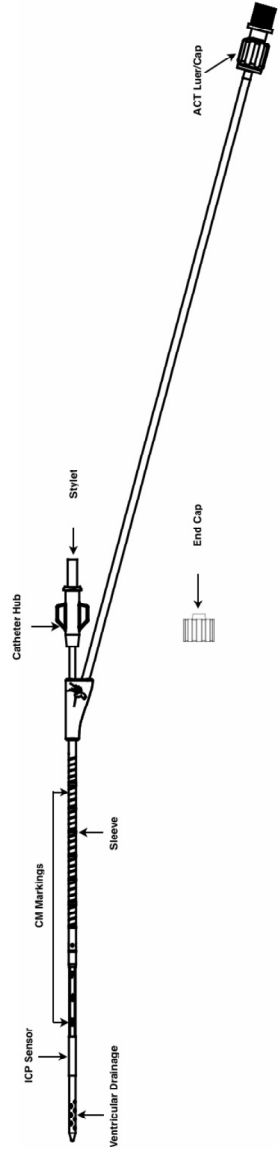
DRILL BIT ASSEMBLY



BOLT ASSEMBLY

- 4
- 6
- 8
- 10
- 12

BOLT STOPS



HUMMINGBIRD INSERTION PROCEDURE SUMMARY

After drilling hole in skull and penetrating the dura:

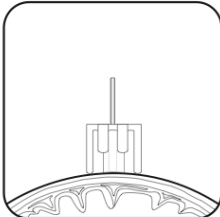


Figure 1: Place Drill Bit Assembly into Tripod and position perpendicularly on cranium.

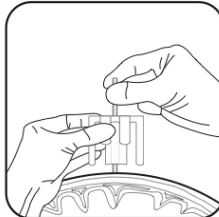


Figure 2: Holding position of Drill Bit Assembly, remove Tripod.



Figure 3: Select Bolt Stop size and slide onto bolt of the Bolt Assembly.

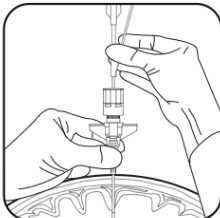


Figure 4: Advance ventricular catheter into ventricle.

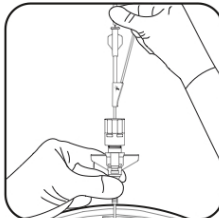


Figure 5: Remove stylet.

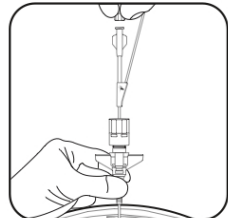


Figure 6: Attach End Cap onto Catheter Hub and tighten.

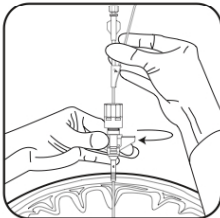


Figure 7: Advance Bolt Assembly/Bolt Stop and screw in.

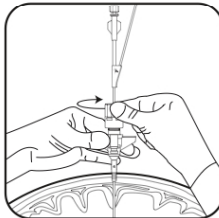


Figure 8: Tighten Touhy-Borst Cap until **GREEN** completely fills window and can't be tightened any further.

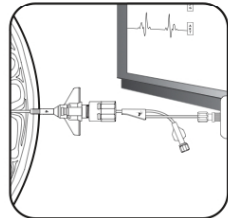


Figure 9: Zero patient monitor. Connect blue luer on Catheter Assembly to AMS luer.

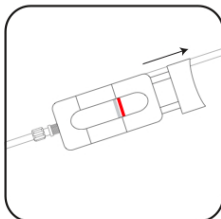


Figure 10: Slide the actuation piston on the AMS to the full back position. A **RED** indicator light is displayed.

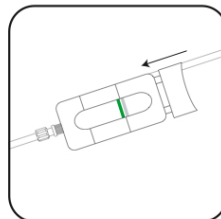


Figure 11: Slide the actuation piston on the AMS to the full forward position. A **GREEN** indicator light is displayed.



SYSTEM DESCRIPTION

The Hummingbird **Ventricular System (Model HUMV-200MR)** consists of a sterile Drill Assembly, Bolt Assembly, Bolt Stops and a Ventricular Catheter (VC) Assembly. The VC Assembly has an integrated design to enable ventricular drainage and intracranial pressure (ICP) monitoring. The system is used for simultaneous monitoring of ICP while enabling continuous or intermittent CSF drainage.

ICP Sensing

The **AirPulse™ ICP System** senses pressure by utilizing a proprietary bladder partially filled with air. This unique technology carries pressure waves to a reusable transducer housed in the **AirPulse Air Management System (AMS)** on the terminal end of the patient monitoring cable. The leveling problems inherent in fluid-filled systems are eliminated resulting in precise and positionally insensitive measurement, and an artifact-free, high-fidelity waveform trace. The bladder is connected to an air-filled lumen that terminates into the AirPulse Luer. When the AMS is cycled, air is removed and a small amount of air is replaced, charging the AirPulse System. The AirPulse Luer is removed from the AMS housing to zero/recalibrate the transducer.

Transducer Cable

The Hummingbird AirPulse AMS is a standard patient monitoring cable that terminates in a connector compatible with the user-specified patient monitor. The cable is provided **SEPARATELY, NONSTERILE**.

The AMS cable/transducer requires no leveling and can be zeroed *in situ*.

Cleaning Cable

The AirPulse cable should be treated as a high quality pressure sensing device. It requires the same care as any precision device. After each use, wash off all debris using a soft brush and mild detergent. Pay attention to all crevices and seams. Ensure that the cap is placed on the proximal AMS Luer, prior to cleaning. In any event, ensure no fluid is deposited into proximal luer.

KIT CONTENTS

Each Hummingbird Ventricular Kit comes **STERILE** and contains each of the following accessory items for use with the Hummingbird Catheter:

WARNING: Kit contents are sterile and non-pyrogenic in its unopened, undamaged package. For single use only. Do not re-sterilize. Do not reuse. If opened and unused, discard immediately.

NOTE: A cranial access kit and various standard surgical instruments are required to

place the Hummingbird Ventricular System.

Item
Bolt Assembly
Drill Assembly—4.7m (.1875 inch) diameter drill bit with drill stop
Tripod
Ventricular Catheter Assembly
Hex Wrench
Bolt Stops

INDICATIONS

The use of the HUMV-200MR Hummingbird Ventricular by a qualified neurosurgeon is indicated when direct measurement of intracranial pressure is clinically important.

CONTRAINDICATIONS

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

The Hummingbird Ventricular is Contraindicated when:

- ⇒ The patients' skull thickness ≤ 3 mm
- ⇒ Pediatric patients in whom the distance from the base of the skull and top ventricle is < 4 cm
- ⇒ The patient is receiving anticoagulants
- ⇒ The patient is known to have a bleeding diathesis
- ⇒ Trained personnel are not available to continuously supervise ICP monitoring

ADVERSE EVENTS

Complications that may result from the use of this product include those associated with medications and methods utilized in the surgical procedure, as well as the patient's degree of tolerance to any foreign object implanted in the body. The principle complications associated with cerebrospinal fluid drainage are catheter obstruction, infection and intracranial hypotension/hypertension. Complications include, but are not limited to infections, thrombosis and hemorrhage.

DIRECTIONS FOR USE

Step 1 - Preparation

- ⇒ Gather supplies for skull access and have available a **Ventricular System** and an AMS monitoring cable with the proper connector for the patient monitor that will be used
- ⇒ Connect the AMS cable to the patient



monitor before beginning the procedure to allow transducer to rise to an equilibrium temperature

- ⇒ Open the Hummingbird Ventricular Kit using an aseptic technique

Step 2 - Drilling Preparation

- ⇒ Estimate the thickness of the skull and adjust the Drill Stop by loosening the set-screw on the Drill Bit Assembly, ensuring that the set-screw remains in the drill flute. Slide the Drill Stop until the exposed tip of the Drill is just long enough to completely drill through the skull's inner table. The tip of the Drill should not penetrate the inner table by more than 1mm.
- ⇒ Tighten the Drill Stop set-screw.
CAUTION: Do not over-torque the set-screw on the drill stop.
- ⇒ Attach the Drill Bit to a hand drill. Do not use a powered drill, such as those driven by compressed air or electricity.
- ⇒ Surgically prepare an appropriate site on the skull using approved surgical technique.
- ⇒ Place the Drill Assembly into the Tripod and ensure all three legs of the Tripod are in contact with the scalp or skull. Use the Tripod to position the Drill Assembly (Fig. 1) perpendicularly on the cranium.
- ⇒ Holding the position of the Drill Assembly (Fig.2), remove the Tripod.
- ⇒ Drill the twist-drill hole. Do not change the direction of the Drill Bit while drilling as this could cause the hole to become too wide or conical. Care must be taken when penetrating the inner table of the skull to prevent damage to the dura or the brain. Remove the Drill Bit and rinse the hole with sterile isotonic solution.
CAUTION: Check the twist drill hole to ensure that no sharp bone shards exist.
- ⇒ Incise the dura carefully with a sterile scalpel blade, securing hemostasis as necessary.

Step 3 - Placement of Bolt Stop

- ⇒ Use the CT Scan to determine the thickness of the skull. Based on the skull thickness, select the appropriate sized bolt stop (e.g. 4, 6, 8, 10, 12mm) and slide it onto the bolt (Fig. 3) on the Bolt Assembly, holding it into place.

Step 4 - Catheter Insertion

- ⇒ While holding the Bolt Assembly/Bolt Stop in place, advance the ventricular

catheter into the ventricle (Fig. 4) and remove the stylet (Fig.5), verifying the catheter's placement into the ventricle. Check for free flow of CSF and then attach the luer cap on the catheter hub (Fig. 6). **CAUTION: Do not remove silicone finger grip from stylet.**

Step 5 - Fixation of Bolt Assembly

- ⇒ Slide the Bolt Assembly/Bolt Stop down the Ventricular Catheter and place the Bolt Assembly/Bolt Stop in the twist drill hole.
- ⇒ Advance the Bolt Assembly/Bolt Stop and screw in (Fig. 7).
- ⇒ Stop advancing the Bolt Assembly/Bolt Stop once the Bolt Stop provides resistance against the skull bone.
CAUTION: Ensure that the scalp and surrounding tissue are not compressed underneath or around the Bolt Stop.

NOTE: The base of the Bolt Stop should come to rest on the skull only.

NOTE: If the bolt is too loose, a new hole must be drilled.

Step 6 - Fixation of Ventricular Catheter

- ⇒ To stabilize the catheter at the desired depth, rotate the Touhy-Borst Cap clockwise (Fig. 8) until the 'green' indicator completely fills the Touhy-Borst Cap's window and the Cap cannot be tightened further.

Step 7 - ICP Activation

- ⇒ Use standard hospital protocol to "Zero" the patient monitor from Step 1 above.
- ⇒ Connect the blue AirPulse Luer on the catheter to the luer connection on the AMS. Tighten luers to ensure a secure connection (Fig. 9).
- ⇒ Slide the actuation piston on the AMS to the full back position (Fig. 10). A **RED** indicator light is displayed.
- ⇒ Slide the actuation piston on the AMS full forward (Fig. 11). A **GREEN** indicator light is displayed.
- ⇒ Slide the actuation piston to the full back and full forward position once more and ensure that the **GREEN** indicator light is displayed.

NOTE: Connecting the AirPulse Luer into the AMS Luer and sliding the actuation piston backward and forward will inject the requisite amount of air into the bladder for proper operation of the ICP system.

NOTE: The AMS has a **RED** and **GREEN**



indicator light. A pulsating **RED** light indicates the actuation piston needs to be recycled. When the piston has been cycled, the **GREEN** light will be displayed.

NOTE: If the AMS has no light indication, the AMS needs to be plugged into the patient monitor. If the AMS is plugged into the patient monitor and has no light indication, the AMS cable needs to be replaced.

ICP MAINTENANCE

⇒ Slide the actuation piston on the AMS to the full back and full forward position when a pulsating **RED** indicator light is visible, confirming the AMS indicator light shows **GREEN**. **CAUTION: If the actuator piston is not cycled, the air in the bladder will eventually become depleted and understate the mean**

Color	Event
Green	Bladder charged; timing the 8 hours
Steady Red	Recharge Cycle in process
Pulsating Red	Recharge Required — displayed after 8 hrs. or if faulty recharge cycle is detected
Flash Red	Recharge AMS

pulse pressure.

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

TRANSDUCER CALIBRATION

- ⇒ Check the zero on the transducer at the patient monitor. To re-zero transducer, remove the AirPulse Luer from the AMS Luer and press zero on the patient monitor. Reconnect the AMS Luer to the AirPulse Luer and tighten.
- ⇒ Slide the actuation piston on the AMS to the full back and full forward position when the pulsating **RED** indicator light is visible, confirming the AMS indicator light shows **GREEN**.

ICP TROUBLESHOOTING

⇒ With the actuation piston in the closed position, the presence of a pulsating **RED** indicator light on the AMS may

indicate depletion of air from the system. Cycle the actuation piston in the full back and full forward position to ensure air in the bladder has been refreshed.

- ⇒ The transducer can be zeroed at any-time by separating the AMS luer from the AirPulse Luer and pressing the “zero” function on the patient monitor.
- ⇒ A significant drop in the ICP pressure can be caused by the following:
 1. Air was not replaced into the bladder and loss of air caused the ICP to read low.
 2. None of the above - **REPLACE THE CABLE.**

REMOVING VENTRICULAR CATHETER ASSEMBLY

- ⇒ Remove the AMS Luer from the AirPulse Luer.
- ⇒ After removing the CSF drainage bag, place a sterile luer cap on the now opened Ventricular Catheter Assembly Hub.
- ⇒ Holding the Bolt Wings, loosen the thumb-screw on the Touhy-Borst.
- ⇒ Holding the Bolt Wings, rotate the Touhy-Borst cap counter-clockwise to loosen. Ensure that the Touhy-Borst cap is in the up position (green in windows will no longer be visible).
- ⇒ Remove the Ventricular Catheter Assembly from the Touhy-Borst Insert on the Bolt Assembly.

NOTE: Ensure the Touhy-Borst Cap is in the fully-up position. The green indicator light will no longer be visible through the Touhy-Borst Cap’s window.

BOLT REMOVAL

⇒ Turn the Bolt Assembly counterclockwise to remove it from the skull.



Warnings

- ⇒ Read the entire Instructions for Use before using the Hummingbird Ventricular System.
- ⇒ Facilities for the neurosurgical treatment of an intracranial bleed must be available in the hospital.
- ⇒ The AirPulse Luer must be kept dry. Any liquid that enters the Luer may cause a dampened or flat pressure waveform and/or an inaccurately high pressure reading.
- ⇒ In general, there is a risk of infection



due to use of intracranial catheters. It is recommended that the Hummingbird Ventricular not be left in place for more than 3 days.

- ⇒ Patients undergoing ICP monitoring must be kept under close supervision for signs and symptoms of changing intracranial pressure due to system failure. These signs and symptoms will vary from patient to patient. Increasing intracranial pressure is characterized by headache, vomiting, irritability, listlessness, drowsiness, other signs of deterioration of consciousness and nuchal rigidity.
- ⇒ The AMS monitoring cables that are kinked or have damaged housings must not be used. The cable's AirPulse housing on cable must be cleaned after each use to ensure saline or body fluid deposition has been removed.
- ⇒ Aseptic technique should be used whenever inserting or handling components of the Hummingbird Ventricular System.
- ⇒ Use of excessive force on the components of the Hummingbird Ventricular System or cables may cause damage. All mechanical features of the HUMV-200MR System can be operated without the use of excessive force.
- ⇒ At pressures above 70 mmHg, cycle the AMS every 30 minutes.



Precautions

- ⇒ Prior to the procedure, prospective patients or their representatives should be informed of the possible complications associated with this product.
- ⇒ InnerSpace, 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.
- ⇒ This product is intended for use only with the catheters/accessories specified herein.
- ⇒ Only use the Hummingbird Ventricular System if sterile packaging is not open, damaged or broken and contents are intact.
- ⇒ Only use the Hummingbird Ventricular System before the expiration date labeled on the package.
- ⇒ Do not cut or tear the AirPulse tubing connected to the catheter. A Ventricular System with a cut or tear in the tubing will no longer function.
- ⇒ Use the Drill Bit Assembly provided. If a

drill bit other than that provided with the kit is used, the hole may be too large or too small.

- ⇒ In order to avoid hemorrhage in the area of implantation, blood coagulation must be carefully monitored during invasive brain monitoring, especially during total body hypothermia, or in patients in hepatic coma or suffering from other diseases that could impair coagulation.
- ⇒ If excessive force is applied, the Bolt Assembly may become stuck or even break. Components never require excessive force.
- ⇒ If the dura is not properly incised (with a small cutting instrument) before the Ventricular Catheter Assembly is advanced, the dura could be torn away from the skull, possibly resulting in hemorrhage.
- ⇒ The device must not be placed too near the sagittal line in order to avoid the sagittal sinus and major cerebral veins.
- ⇒ The Hummingbird Ventricular System is intended for use in pediatrics where the distance from the base of the skull to the top of ventricle is ≥ 4 cm.

MAGNETIC RESONANCE IMAGING

The Hummingbird Ventricular has been found to be MRI conditional under the following conditions:

- ⇒ 1.5 Tesla-unshielded
- ⇒ 3.0 Tesla-unshielded

Please refer to the MRI Fact Sheet for information on MRI settings.

CAUTION

The AirPulse AMS and cable should not enter the MRI field.

DISCLOSURE

InnerSpace, Inc. has exercised reasonable care in the manufacture of this device. InnerSpace, 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 InnerSpace, Inc. control directly affect this device and the results obtained from its use. InnerSpace, Inc. will not be liable for INCIDENTAL or CONSEQUENTIAL LOSS, DAMAGE, or EXPENSE directly or indirectly arising from the use of this device. InnerSpace,



Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional LIABILITY or RESPONSIBILITY in connection with this device.

WARRANTY

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

HOW SUPPLIED

The Hummingbird Ventricular System is supplied sterile and non-pyrogenic, as noted on the individual package labels and is supplied in a double-wrap packaging system. Do not use if package is damaged or open.

DO NOT RESTERILIZE

The Hummingbird Ventricular System is a disposable device and cannot be resterilized.

STORAGE CONDITIONS

Store in a cool, dry place.

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 of product defect or mislabeling.








Determination of a product defect or mislabeling will be made by InnerSpace, Inc., and such 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.



ORDER INFORMATION

All products can be ordered through your InnerSpace, Inc. sales or customer service representative.

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SPECIFICATIONS	
System Performance	±2 mmHg to 20 mmHg, 10% or better above 20 mmHg
Range	(5) - 100 mmHg
Operating Time	Recharge every 8 hours.
	At pressures above 70 mmHg, cycle the AMS every 30 minutes
SYMBOLS USED ON LABELING	
	See instruction for use
	Expiration Date
	Do not reuse after opening
	Lot Number
	Sterile unless package is open. Method of sterilization—ethylene oxide.
	Manufacturer
	MRI Conditional

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

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P/N 50394 Rev B

Manufactured under one or more of U.S. Patent No. 5,573,007 and 7,780,679; other U.S. and foreign patents issued and pending.

