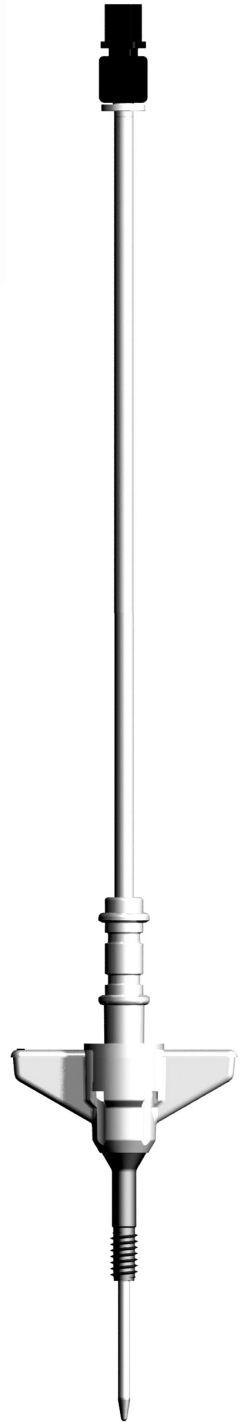




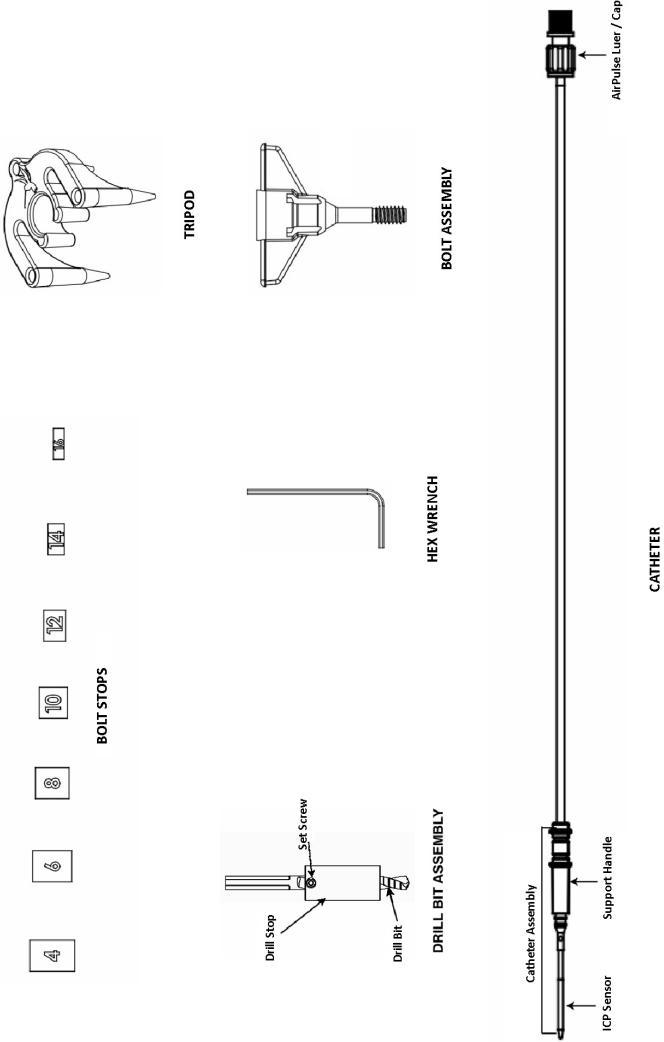
Hummingbird[™]
Parenchyma

Complete Kit for:
ICP Monitoring
Instructions for Use
Model **H100MR**





Model **H100MR** Contents



HUMMINGBIRD INSERTION PROCEDURE SUMMARY

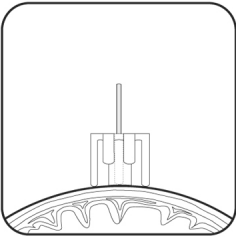


Figure 1: Place Drill Bit Assembly into Tripod and position perpendicularly on cranium.

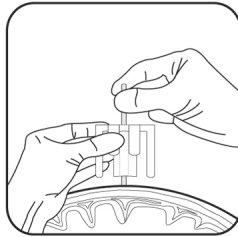


Figure 2: Holding position of Drill Bit Assembly, remove Tripod. Drill hole in skull.

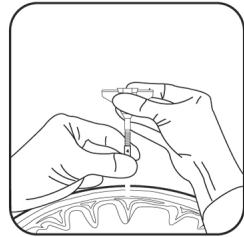


Figure 3: Select Bolt Stop size and slide onto bolt of the Bolt Assembly.

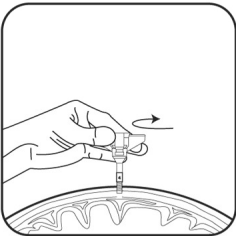


Figure 4: Advance Bolt Assembly/Bolt Stop and screw in.

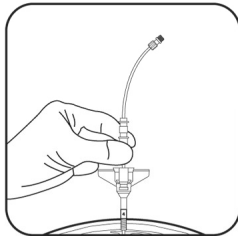


Figure 5: Place fingers on support handle and insert Catheter in bolt.

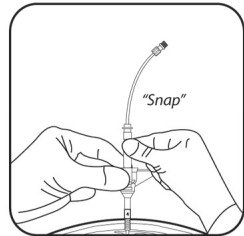


Figure 6: Press down on Support Handle until Catheter "snaps" into bolt.

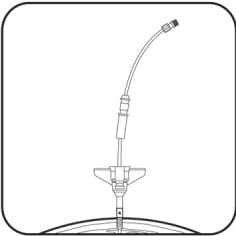


Figure 7: Pull up on Support Handle and slide into position on tube.

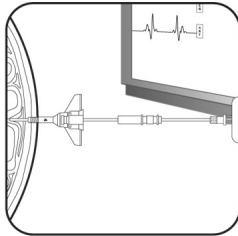


Figure 8: Zero patient monitor. Connect blue luer on Catheter to AMS luer.

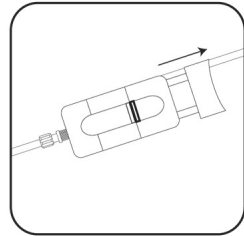


Figure 9: Slide the AirPulse Handle full-back. A RED indicator light is displayed.

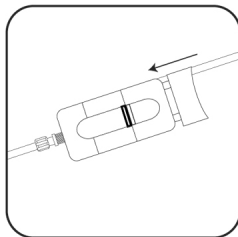


Figure 10: Slide the AirPulse Handle full-forward. A GREEN indicator light is displayed.



Hummingbird Components

(Sold Separately)

Description	Model #
AirPulse Air Management System Cable	AMS-100

SYSTEM DESCRIPTION

The **Hummingbird Parenchyma System (Model H100MR)** consists of a sterile Drill Bit Assembly, Bolt Assembly, Hex Wrench, Catheter, Bolt Stops and Tripod. The Catheter has an integrated ICP sensor to be used as a diagnostic tool to monitor intracranial pressure.

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 ICP System. The AirPulse luer is removed from the AMS housing to zero/recalibrate the transducer.

Transducer Cable

The Hummingbird AirPulse AMS (AMS-100) is a standard patient monitoring cable that terminates in a connector compatible with the user-specified patient monitor. The cable is provided separately, NON-STERILE, and may be cleaned with alcohol prior to each use.

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

Cleaning the Cable

The AirPulse AMS cable should be treated as a high quality pressure sensing device. It requires the same care as any precision device. After each use, ensure that the cap is placed on the proximal luer and wash off all debris using a cloth and isopropyl alcohol. Pay attention to all crevices and seams. At all times, ensure no fluid is deposited into the proximal luer.

INDICATIONS

The use of the Hummingbird Parenchyma System 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 H100MR 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

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. Complications include, but are not limited to infections, thrombosis and hemorrhage.

KIT CONTENTS

Each H100MR Kit comes STERILE and contains each of the following accessory items for use with the Hummingbird Catheter (reference contents section):

WARNING: Kit contents are sterile and non-pyrogenic if the package is unopened and undamaged and are 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 H100MR System.

DIRECTIONS FOR USE

Step 1 - Preparation

- ⇒ Gather supplies for skull access and have available an H100MR and an AMS monitoring cable with the proper connector for the patient monitor that will be used.
- ⇒ Connect the AMS monitoring cable to the patient monitor before beginning the procedure to allow the transducer to rise to an equilibrium temperature.



- ⇒ Open the H100MR Kit using an aseptic technique.

Step 2 - Drilling Preparation

- ⇒ Estimate the thickness of the skull using CT scans and adjust the Drill Stop by loosening the Drill Stop Screw on the Drill Bit Assembly. Slide the Drill Stop down the drill bit to the desired depth.
- ⇒ Tighten the Drill Stop set screw within the drill's flute. **CAUTION: Do not over-torque the set-screw on the drill stop.**
- ⇒ Attach the Drill Bit Assembly 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.
- ⇒ Position the Drill Assembly in the Tripod, then use the Tripod to position the Drill Assembly perpendicularly on the cranium (Fig. 1).
- ⇒ Holding the position of the Drill Assembly, remove the Tripod (Fig. 2).
- ⇒ Drill the twist-drill hole. Do not change the direction of the Drill 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 Assembly and rinse the hole with sterile isotonic solution. **CAUTION: Check the drill hole to ascertain that no sharp bone shards exist.**
- ⇒ Incise the dura carefully with a number eleven (#11) blade, securing hemostasis as necessary. **CAUTION: Failure to properly incise the dura could cause the dura to tear during insertion of the H100MR.**

NOTE: Should undue resistance be encountered when drilling, do not use excessive force. If necessary, drill inner table again.

Step 3 - Placement of Bolt Stop

- ⇒ Use a CT Scan to determine the thickness of the skull and select a Bolt Stop number that most closely matches the skull thickness.

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

NOTE: If skull thickness is greater than 16mm, advance Bolt completely into skull bone, without the Bolt Stop, until the Bolt provides resistance against the skull bone.

- ⇒ Slide the Bolt Stop onto the Bolt Assembly with the blue surface facing up. (Fig.3).

Step 4 - Fixation of Bolt

- ⇒ Hold the Bolt Stop on the Bolt Assembly and place in the twist drill hole.
- ⇒ Advance the Bolt Assembly/Bolt Stop and screw it in (Fig. 4).
- ⇒ 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 loose, a new hole must be drilled.

Step 5 - Catheter Insertion

- ⇒ Hold the Support Handle on the Catheter and insert it into the Bolt Assembly (Fig. 5). Press down on the Support Handle firmly until the Catheter snaps (Fig. 6) into the Bolt.
- ⇒ Slide the Support Handle back on the Catheter by pulling it up and into position on the tubing (Fig. 7).

Step 6 - ICP Activation

- ⇒ Use standard hospital protocol to "Zero" the patient monitor from Step 1 above.
- ⇒ Remove the Cap and connect the Catheter's blue AirPulse luer to the AMS luer connection. Tighten the luers to ensure a secure connection (Fig. 8).
- ⇒ Slide the AMS handle to the full back position (Fig. 9). A solid **RED** indicator light is displayed.
- ⇒ Slide the AMS handle to the full forward position (Fig. 10). A solid **GREEN** indicator light is displayed.



- ⇒ Slide the actuation handle to the full-back position and full forward position **once more** and ensure that the **GREEN** indicator light is displayed.

NOTE: Connecting the Catheter's AirPulse luer to the AMS luer and sliding the handle full back and full forward will inject the requisite amount of air into the bladder for proper operation of the ICP system.

NOTE: The AMS has **RED** and **GREEN** indicator lights. A pulsating **RED** light indicates the actuation handle needs to be cycled. When the handle 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, replace the AMS.

ICP MAINTENANCE

- ⇒ Slide the AMS handle to the full back position and full forward position when the **RED** indicator light is displayed. Confirm the AMS indicator light turns **GREEN**. *CAUTION: If the actuation handle is not cycled, the air in the bladder will eventually become depleted and understate the mean pulse pressure.*
- ⇒ Maintain the Bolt Assembly insertion site during ICP monitoring according to standard hospital protocol. Avoid pulling on the lines or cable attached to the Bolt Assembly or striking the Bolt Assembly.

TRANSDUCER CALIBRATION

- ⇒ To zero the transducer, remove the Catheter's AirPulse luer from the AMS luer and press the "zero" function on the patient monitor. Reconnect the AMS luer to the AMS luer and tighten, ensuring a secure fit.
- ⇒ Slide the handle on the AMS to the full-back position and full-forward position when the **RED** indicator light is visible and confirm the AMS indicator light shows **GREEN**.

ICP TROUBLESHOOTING

- ⇒ With the AMS handle in the full-forward position, the presence of a **RED** indicator light may indicate depletion of air from the system. Cycle the handle through the full-back and full-forward

position to ensure the air in the bladder has been refreshed.

- ⇒ The transducer can be zeroed at any time by disconnecting the AMS luer from the Catheter's 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. - **RECHARGE THE SYSTEM.**
 2. Cable is not functioning properly - **REPLACE THE CABLE.**

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

BOLT REMOVAL

- ⇒ Disconnect the Catheter's AirPulse luer from the AMS luer.
- ⇒ Turn the Bolt Assembly counterclockwise to remove it from the skull.
- ⇒ Remove the Bolt Stop from the site.



Precautions

- ⇒ Read the entire Instructions for Use before using the H100MR.
- ⇒ Prior to the procedure, prospective patients or their representatives should be informed of the possible complications associated with this product.
- ⇒ Do not use the H100MR System if sterile packaging is open, damaged or broken.
- ⇒ Do not use the H100MR System after the expiration date labeled on the package.
- ⇒ Never add to or modify the system, as this may interfere with performance.
- ⇒ 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 catheter and accessories specified herein.
- ⇒ Never connect a syringe to the Catheter's AirPulse luer.
- ⇒ Do not cut or tear the Hummingbird ICP tubing connected to the catheter. A H100MR with a cut or tear in the tubing will no longer function.
- ⇒ The device must not be placed too near the sagittal line in order to avoid the sagittal sinus and major cerebral veins.
- ⇒ The H100MR System is recommended for skull thicknesses greater than 4mm.
- ⇒ Aseptic technique must be used when inserting or handling components of the H100MR System.
- ⇒ Use of excessive force on the components of the H100MR System or cables may cause damage. All mechanical features of the H100MR System can be operated without the use of excessive force.
- ⇒ Any AMS monitoring cables that are kinked or that have a damaged housing must not be used. The cable's transducer housing must be cleaned after each use to ensure saline or body fluid deposition has been removed.
- ⇒ 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.
- ⇒ If the dura is not incised (with a small cutting instrument) before the Catheter is advanced, the dura could be torn away from the skull, possibly resulting in hemorrhage.
- ⇒ If excessive force is applied, the Bolt Assembly may become stuck or even break.
- ⇒ Cycle the AMS when the indicator light is **RED** (every 8 hours) to replenish air lost by diffusion.
- ⇒ At pressures above 30mmHg, cycle the AMS before administering therapy.
- ⇒ Never bend or kink the tubing.
- ⇒ If a change in elevation occurs, cycle the AMS before administering therapy.
- ⇒ Facilities for the neurosurgical treatment of an intracranial bleed must be available in the hospital.
- ⇒ 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.

- ⇒ 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.
- ⇒ In general, there is a risk of infection due to the use of intracranial catheters. It is recommended that the H100MR not be left in place for more than 3 days.

MAGNETIC RESONANCE IMAGING

The Hummingbird Parenchyma 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 H100MR System is supplied sterile and non-pyrogenic, as noted on the individual package labels and is supplied in a double-sterile packaging system. Do not use if package is damaged or open.

DO NOT RESTERILIZE

The H100MR System is a single-use disposable device. This device cannot be resterilized.

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.

1622 Edinger Avenue, Suite C

Tustin, CA 92780

Phone: 888-391-5238

Fax: 877-235-6902









www.innerspacemedical.com

innerspace
Access for Life

SPECIFICATIONS

Pressure Range	0 - 100 mmHg
System Performance	± 2 mmHg from 0 to 20 mmHg, 10% or better from 20 to 100 mmHg
Pressure Amplitude	70% or better over the pressure range
Operating Time	Recharge every 8 hours. At pressures above 30mmHg, cycle the AMS every 30 minutes.
Catheter	6Fr., 2 cm insertion
Drill Hole	4mm (0.156")

SYMBOLS USED ON LABELING

	Follow Operating Instructions
	Warning
	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 50389 Rev A

Manufactured under one or more of U.S. Patent Nos. 5,573,007 and 7,780,679; other U.S. and foreign patents issued and pending.

