AccuDrain™ External CSF Drainage Systems
Sterile For Single Use Only

Description
The AccuDrain™ External CSF Drainage System is used to drain cerebrospinal fluid (CSF) from the ventricles of the brain or the lumbar subarachnoid space to a drainage bag. System components facilitate CSF drainage, CSF sampling and Intracranial Pressure (ICP) monitoring.

Monitoring of intracranial Pressure (ICP) is usually performed in selected patients with severe head injury, subarachnoid hemorrhage, Reyes syndrome or similar encephalopathies, hydrocephalus, hydrocephalic shunt infections, intracranial hemorrhage and pre and/or post operative monitoring.

Common features to the System include a closed sterile fluid path, calibrated 75ml graduated burette, 700ml drainage bag, anti-microbial hydrophobic vent, two needleless sampling sites, a patient stopcock, a four-way high flow burette stopcock, cord suspension, red burette height indicator, and integral pole attachment feature. A line level or laser device can be attached. The transparent graduated burette provides visualization of the flow and clarity of the CSF, and allows for volumetric readings to be made prior to fluid entering the drainage bag.

The AccuDrain™ External CSF Drainage Systems can be used with all of the Integra NeuroSciences Ventricular and Lumbar Catheters. A tubing connector with a luer connector is provided to facilitate the catheter connection to the drainage system.

A fluid filled ICP monitoring transducer (not included) can be attached to the red burette stopcock.
demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information. Refer to Figure 2 for information on the MR environment to which the device was tested. Data on file at Integra.

**Indications**

Draining and monitoring of Cerebrospinal Fluid (CSF) flow from the ventricles of the brain or lumbar subarachnoid space is indicated in select patients to:

- Reduce Intracranial Pressure (ICP)
- Monitor Intracranial Pressure (ICP)
- Monitor Cerebrospinal Fluid (CSF)
- Provide temporary CSF drainage

**Contraindications**

This device is not designed, sold, or intended for use except as indicated. The External Drainage System is contraindicated in the following:

- Anticoagulation therapy. Coagulation disorders, Untreated scalp infections.
- System use is contraindicated where trained personnel are not available to supervise drainage and monitoring on a 24-hour a day basis.

**Warnings**

Patients with cerebrospinal fluid drainage systems must be kept under close observation for signs and symptoms of changing intracranial pressure. These signs and symptoms may vary from patient to patient. Increased intracranial pressure may be characterized by, but not limited to, headache, vomiting, irritability, listlessness, drowsiness, other signs of deterioration of consciousness and nuchal rigidity. In the infant, increased scalp tension at the anterior fontanelle and congestion of scalp veins may be noted.

Failure to appropriately adjust the rate of CSF outflow through the external drainage system may result in potentially serious injury to the patient. Improper drainage system setup can lead to overdrainage or underdrainage and potentially serious injury to the patient.

Proper alignment of the drainage system is critical whenever the system is open to drainage. When open, the height of the drainage system in relation to the patient affects the amount of CSF drainage and therefore, effects ICP. It is essential that neither the patient nor the drainage system be raised or lowered inadvertently. Whenever the device or patient is moved, the system should be realigned. Height changes should only be made by qualified personnel on the orders of the physician.

It is possible that the drainage system may lead to a false pressure reading. Reasons include: (but are not limited to) the pressure line becoming clogged or kinked or from an air bubble lodged in the system. An incorrect pressure reading may lead to the wrong treatment for the patient.

In order to minimize the possibility of infection, meningitis or ventriculitis, the sampling site should be cleaned according to hospital protocol prior to use. Strict aseptic technique should be used during initial set-up, at all stages of utilization and maintenance, and any time the system must be accessed, changed, or otherwise manipulated in any way that opens the closed system once it is connected to the patient.

If monitoring is not used, it is imperative to keep the red end cap located on the panel mount ICP monitoring port securely tightened.
Precautions

Do not insert a needle into the needleless sampling site. While the filter is hydrophobic, some manipulation may be required to reestablish drainage after repeated prolonged contact with CSF.

Integra NeuroSciences makes no claim for or representation as to the performance characteristics of this product if it is used in conjunction with components of other manufacturers.

Complications

Complications which may result from the use of this product include the risks associated with the medications and methods utilized in the surgical procedure, as well as the patient’s degree of intolerance to any foreign object implanted in the body.

The principal complications associated with cerebrospinal fluid drainage are infection, obstruction, or intracranial hypotension/hypertension.

The presence of a foreign body (i.e., the catheter system) may trigger infection or adverse reaction. Infection is a common and serious complication of a drainage system and is most frequently caused by skin contaminants. The incidence of these infections can be reduced by using aseptic technique. Risk of infection or other complications may be reduced by following hospital protocol for duration of use. Septicemia can result from infections anywhere in the body and may develop with few or no symptoms. Obstruction, partial obstruction, or irregular flow, may occur. Causes may include (but not limited to) obstruction by particulate matter (blood clots, fibrin, brain fragments), or malpositioning of the ventricular catheter.

Failure of the drainage system may be evidenced by continuing symptoms of increased ICP. Any failure of the system requires immediate replacement of the drainage system or the affected component.

Instructions for Use

Prior to system use, it is necessary for all responsible personnel to understand the use and function of the system components, system preparation, and system control.

Preparation and Alignment

The system should be prepared under sterile conditions prior to the placement of ventricular or lumbar catheter by a qualified health care professional. Irrigation with preservative-free sterile normal saline may be performed prior to use as determined by hospital protocol. Caps may be temporarily loosened to allow air to escape. Check to ensure the absence of any residual air bubbles that may affect pressure transducer monitoring. Ensure that fluid flows from the burette to the drainage bag. When the panel mount ICP monitoring port is not in use, the red end cap must be in place to help prevent contamination.

1. Suspend the drainage system from the IV pole using the cord lock. Next, secure the drainage system to the IV pole by squeezing the pole attachment feature. Ensure that the AccuDrain™ is securely attached to the pole.

2. Once the system is secured, use the enclosed line level or laser level (not included) to ensure that the system has been properly adjusted with the zero reference on the pressure scale leveled to the external landmark as ordered by the physician, i.e., Foramen of Monro for ventricular catheters. Note: the line level or laser level is attached by inserting the fastener into the circular opening located on the back of the panel at the level of the zero reference point. Once attached, the system can be leveled with the line level by pulling the string taut to the anatomical landmark and aligning the bubble in the viewfinder. Once leveled, the line level can be attached by affixing the black o-ring to the hook located at the top back panel of the system. The system can be leveled with the laser level by aligning the bubble in the viewfinder and rotating the laser towards the patient’s anatomical landmark and then activating the laser to emit pointer beam. Caution: Read the instructions for use (IFU) for the Integra laser level device before using laser.

3. Tighten the suspension cord over the IV pole by moving the cord lock so that the suspension cord is taut. Secure the pole straps by pulling around the IV pole and inserting into the notch on each handle.

4. If an external transducer is to be used for monitoring ICP calibration of the transducer should be completed, according to manufacturers instructions, prior to connecting to the patient. Hospital protocol should be used when using external transducers.

Caution: Method of transducer calibration may be affected by the presence of a one-way valve.

To Set Pressure Level

Place the zero reference at the level of the external landmark ordered by the physician. Increase or decrease the height of the pressure level by manipulating the squeeze-lok™ to move the burette up or down relative to the patient. Align the center of the red pressure indicator with the pressure level ordered (mmHg or cmH₂O) by the physician.

To Monitor Pressure

If closed system pressure monitoring and waveforms are desired, the AccuDrain™ System should be temporarily closed to drainage into the graduated burette. Turn stopcock OFF to burette to stop flow to the burette.

Note: reorient stopcock to resume drainage.

To Monitor Pressure
To Drain CSF

Turn patient stopcock to allow CSF flow into the burette. The ICP is affected by the volume of CSF drained and by the height of the pressure level of the burette. It is critical that neither the patient nor the drainage system be raised or lowered accidentally. Height changes should only be made by qualified personnel on the orders of a qualified physician.

To Collect and Measure CSF

Accurate determination of fluid accumulation may be accomplished with the graduated burette from 1ml to 75ml in 1ml increments. The burette stopcock should be OFF to the burette.

To Measure CSF Flow

To Sample CSF

Sampling of CSF may be accomplished at the various sampling sites that have been cleaned according to hospital protocol. The needleless site can be accessed with any standard luer fitting syringe. Access may be accomplished at the patient line stopcock or the Y-site immediately distal to the patient stopcock or beneath the burette. If CSF access is desired from the burette, use the sampling site at the burette stopcock. Do not insert a needle into the needleless sampling site. In addition, CSF may be sampled from the bottom of the drainage bag using a syringe with a 25-gauge or applicable gauge needle according to hospital protocol.

To Flush System

Sampling sites must be cleaned and flushed by qualified personnel, according to hospital protocol. Orient the stopcocks to temporarily prevent flow back to the patient. Ensure that fluid flushes into the drainage bag.

Once flushing has been accomplished, reorient stopcocks to allow flow from the patient to the burette and into the drainage bag as ordered.

To Replace Drainage Bag

Orient the burette stopcock to temporarily stop flow into the drainage bag. Following hospital protocol clean the connection site between the burette and drainage bag.

Using aseptic technique, disconnect the drainage bag from the stopcock, attach tethered blue cap and detach bag from the system panel. Connect the sterile replacement drainage bag to drain tube. Attach bag to system panel. Reorient burette stopcock to allow flow from the burette into the drainage bag. Verify flow into the drainage bag.

To Empty Drainage Bag

The drainage bag may be emptied using sterile technique, and a sterile syringe with a 25-gauge or applicable gauge needle.

To Transport Patient

If it is necessary to transport a patient while system is in full use, the system should remain vertical and correctly aligned with the patient for desired pressure level and drainage. If this is not possible, the graduated burette should be emptied into the drainage bag. The burette stopcock should then be temporarily closed to prevent retrograde flow back into the burette. The panel mount stopcock should be oriented to temporarily stop flow from the patient to the burette.

CAUTION: If it becomes necessary to remove the system from the vertical secured position, orient the system burette side up and support the weight of the drainage bag when lifting or during movement.

The patient should then be transported as required and the system maintained according to physician orders and hospital protocol.

After patient transport has been completed, system use should be re-established with the correct pressure level reference relative to patient according to physician's orders. All stopcocks should be reoriented to re-establish flow. Ensure and verify flow from the patient into the burette.
Product Information
Disclosure
INTEGRA NEUROSCIENCES HAS EXERCISED REASONABLE CARE IN THE CHOICE OF MATERIhALS AND MANUFACTURE OF THIS PRODUCT. INTEGRA NEUROSCIENCES 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 FOR A PARTICULAR PURPOSE. INTEGRA NEUROSCIENCES SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. INTEGRA NEUROSCIENCES NEITHER ASSUMES OR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THIS DEVICE.

Special Order Products
If this product is a Special Order product, i.e. requested by a physician, there may be differences between the enclosed product and the product description in this brochure. These differences will not affect the safety or effectiveness of the special order product.

How Supplied
Integra NeuroSciences External CSF Drainage Systems are supplied sterile and non-pyrogenic in single wrap packaging.

Do Not Resterilize
All External CSF Drainage Systems are disposable devices. Integra NeuroSciences does not recommend resterilization of these products.

Returned 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 Integra NeuroSciences, 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.

Product Order Information
All products can be ordered through your Integra NeuroSciences Neuro Specialist or customer service representative or by contacting:

Integra NeuroSciences
311 Enterprise Drive
 Plainsboro, NJ 08536 USA
Telephone: 1-800-664-2873
Outside the US: 1-609-275-0500
Fax: 609-275-5363

or

Integra NeuroSciences, LTD
Newbury Road, Andover
Hampshire SP10 4DR England
Tel: +44(0) 1264-345-700
Fax: +44 (0) 1264-332-113

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.

Catalog Numbers

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>INS-8400</td>
<td>AccuDrain™ External CSF Drainage System with Needleless sampling Sites, without anti-reflux valve</td>
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<tr>
<td>INS-84001</td>
<td>AccuDrain™ External CSF Drainage System with Anti-Reflux Valve and Needleless sampling Sites</td>
</tr>
<tr>
<td>INS-8700</td>
<td>Integra External CSF Drainage System Replacement Bags/WDrain Tube</td>
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<tr>
<td>INS-8902</td>
<td>Integra Laser Level Device</td>
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Symbols Used On Labeling

- See instructions for use
- Expiration date
- Do not reuse after opening
- Lot number
- Sterile unless package is opened or damaged
- Product complies with requirements of directive 93/42/EEC for medical devices
- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
- Manufacturer
**Figure 2**

MR environment to which the device was tested:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
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<tbody>
<tr>
<td>Scan Parameters</td>
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<tr>
<td>Sequence</td>
<td>Fast Spin Echo</td>
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<tr>
<td>Plane</td>
<td>Sagittal</td>
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<tr>
<td>TR (sequence repetition rate)</td>
<td>9000 milliseconds (ms)</td>
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<tr>
<td>TE (echo delay time)</td>
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<tr>
<td>Echo Train Length</td>
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<tr>
<td>FLIP/TL (flip angle)</td>
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<tr>
<td>ThK/S (slice thickness)</td>
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<tr>
<td>Number of Slices</td>
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<tr>
<td>Distance between slices</td>
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<tr>
<td>NEX (number of excitations)</td>
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<td>FOV (Field of View)</td>
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<td>Static Magnetic Field Strength</td>
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<td>Matrix</td>
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<tr>
<td>Transmit Gain</td>
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<tr>
<td>Coil Frequency</td>
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<tr>
<td>Coil RF Power Max</td>
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<tr>
<td>Max Estimated SAR (Specific Absorption Rate)</td>
<td>7.74 watt/kilogram (W/kg)</td>
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</table>

**Bibliography**