**LimiTorr™ Volume Limiting**
**External CSF Drainage and Monitoring System**

Sterile For Single Use Only

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**Description**

The LimiTorr™ Volume Limiting External CSF Drainage and Monitoring System provides a closed system for the drainage of cerebrospinal fluid (CSF) from the ventricles of the brain or the lumbar subarachnoid space to an external drainage bag. The LimiTorr Volume Limiting External CSF Drainage System was designed to include a volume limiting valve mechanism which reduces the chances for excessive CSF drainage. The burette in the Volume Limiting External CSF Drainage System contains a volume limiting valve which stops drainage when the pre-determined volume (20ml or 30ml) is reached.

The LimiTorr Volume Limiting External CSF drainage system must be in a vertical position for the volume controlling valve to function properly. The system (includes the IV pole and INS400 series Pole Mount) should not tilt more than 5 degrees in any direction.

The LimiTorr Volume Limiting External CSF Drainage System must be used with an Integra Pole Mount (INS400 series) and is compatible with all Integra External CSF Drainage Lumbar or ventricular Catheters. A catheter tubing adapter and luer connector are provided with the drainage...
system. The system includes an antimicrobial hydrophobic vent.

The LimiTorr Volume Limiting External CSF Drainage and Monitoring System is MRI safe, but must be removed from the INS400 series Pole Mount prior to MRI use.

The tubing, drainage bag and burette cap used in this product individually or in combination contains phthalates (DEHP). This device utilizes PVC tubing which is known to contain DEHP in a portion of the drainage path which on occasion is used for sampling and fluid injection. The risk of phthalates exposure to patients, including the male fetus, male neonate, and peri-pubertal male, is not considered significant for the following reasons: Sampled and drained CSF is not intended to be re-introduced into the patient. Injected fluids such as anti-coagulants and saline solution are only used as needed to eliminate or reduce blockage of the ventricular catheter and thus are not continuous in use.

Features and Benefits

The LimiTorr Volume Limiting External CSF Drainage System contains the following features:

- Volume limiting valve mechanism incorporated in burette
- Burette cerebrospinal fluid capacity is determined by burette size (available in 20ml or 50ml burette)
- Graduated burette in ml increments.
- Antimicrobial hydrophobic vent
- SmartSite® needleless sampling port clearly labeled on patient line
- SmartSite needleless sampling port located on stopcock between burette and drainage bag
- Patient line consisting of green striped pressure tubing
- Red capped Transducer mount with stopcock
- End cap at the end of patient line
- Removable 500ml drainage bag with a tethered blue top cap, anti-reflux valve and marked with approximate volume gradations from 25 to 500ml
- SmartSite needleless sampling port at the bottom of drainage bag
- Luer type connector in sterile pack included for catheter connection
- Product lot number clearly visible on panel label
- INS9020 and INS9030 are provided sterile
- INS9020 and INS9030 are MRI safe

*The system meets ASTM F 2903-15, Standard Practice for Marking Medical Devices and other items for Safety in the Magnetic Resonance Environment, for designation of MR safe from determination provided by a scientifically based rationale: MR Safe is defined by the CDHR Magnetic Resonance Working Group (Feb. 7, 1997) draft document, A Primer on Medical Device Interactions with MRI Systems, as "The device, when used in the MRI environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information". Data on file at Integra.

Indications

The LimiTorr system allows for drainage and monitoring of CSF from the lateral ventricles of the brain and the lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF in patients with infected CSF shunts, and to monitor ICP.

Contraindications

- This device is not designed, sold, or intended for use except as indicated.
- ICP Monitoring and External CSF Drainage is contraindicated in the following: anticoagulation therapy and coagulation disorders.
- System use is contraindicated where trained personnel are not available to supervise drainage and monitoring on a 24 hour a day basis.
- Catheter placement is contraindicated in the presence of infections in the surrounding area including the scalp skin, subcutaneous tissue, bone and epidural space.

The use of a lumbar catheter for drainage is contraindicated for patients with noncommunicating hydrocephalus, where lumbar puncture is contraindicated, in the presence of a large intracranial mass, lesion, tumor, hematoma or cyst, with demonstrated blockage of CSF to the subarachnoid space due to trauma, tumor, hematoma or other large mass, and in cases of spinal abnormalities that prevent insertion of a catheter.

Warnings

Patients connected to a cerebrospinal fluid drainage systems must be observed 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 an infant, increased scalp tension at the anterior fontanelle and congestion of scalp veins may be noted.

Failure to 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.

In order to minimize the possibility of infection, meningitis, or ventriculitis, the sampling site should be cleaned according to hospital protocol prior to use. A 70% isopropyl alcohol solution is compatible with the sampling site.

Strict aseptic technique should be used, at all stages of utilization and maintenance, and any time the system must be accessed, changed, or otherwise manipulated.

Precautions

- This product is intended for single use only. Reuse of the device can result in contamination and/or disease transmission.
- This product should not be sterilized. Resterilization may affect the performance characteristics and the safety of the device.
- Inform the patient or their representative of possible complications associated with the use of this system.
- In order for the volume limiting valve to operate correctly, the lumbar drain must remain vertical.
- Do not insert needle into needless sampling site.
- System is not reusable.
- If system is dropped, the volume limiting valve mechanism may be damaged and should be discarded.
- Use of Needle will damage needless sampling site.
- Sterile technique should be observed in preparing the system, connection of the catheter, replacement of the drain bag, and accessing the system. All sampling sites should be cleaned per hospital protocol.
- Do not use device on an IV Pole or INSGoo series Pole Mount that has been damaged and is not capable of a consistent vertical position. (i.e. broken casters, bent pole, etc.)
- If pressure monitoring includes the use of transducers, all personnel should be familiar with the instructions from the manufacturer for proper calibration and performance.
- While the filter is hydrophobic, prolonged contact longer than 30 mins with CSF (i.e. would occur when Lumbar system is placed in horizontal position) may compromise its function.
- When transporting patient, empty burette into drainage bag and turn patient line stopcock off to prevent CSF drainage to burette.
- If CSF has migrated into hydrophobic filter, open the stopcock between burette and drainage bag to drain antimiembrial by drophobic vent.
- The system must be securely attached in a vertical position to an INTEGRA Pole Mount Assembly (INSGoo series) (review Pole Mount Assembly Package Insert for instructions for use).
- All luer connections must be checked during priming of the system and prior to connecting to the patient. Ensure that all connections are secure and leak free.

Integra 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.

Contact with collagen remover, acetone and/or any other incompatible substances with product material may affect the integrity of the device, causing cracks and potential leaks on plastic components.

Do not overtighten or apply excessive force to the luer lock/fluid-filled transducer connection.

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 tolerance 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 foreign body (i.e. the catheter) 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) or mal-positioning of the catheter.

Any failure of the system requires immediate replacement of the drainage system.

**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.

When the Limitorr system is properly connected to the INS400 series Pole Mount, the yellow indicator of the Pole Mount will align with the drip level of the Limitorr. (See Fig. 1)

**Assembly Direction**

Insert the post of bracket through hole of cap in the orientation shown. (See Fig. 2)

**Preparation**

The system should be primed under sterile conditions prior to placement of the catheter. Ensure that all components are securely attached.

The system should be filled with preservative free sterile normal saline prior to connecting to the patient. Check to ensure connections are leak free. Ensure that fluid flows into the drainage bag.

**PRIMING INSTRUCTIONS**

1. To set up the system, first check that all fittings on the Limitorr Volume Limiting Drain are tightened.
2. Turn the pressure transducer stopcock to "open" to the patient line and "open" to the Pressure transducer.
3. Remove sterile cap from the pressure transducer and cap at the catheter connection. Attach 10mL syringe, filled with preservative free normal saline, to the transducer stopcock port and prime tubing of the patient line to the catheter connection.
4. Replace sterile end cap once patient line is primed. Re-orient the stopcock "off" to the patient line.
5. Keeping the 10mL syringe attached, turn pressure transducer stopcock to "open" to graduated burette and "closed" to the patient line. Prime tubing allowing 2-3ml of preservative free normal saline to collect in the graduated burette.
6. Turn the stopcock proximal to the drainage bag "open" to drain 2-3 ml of preservative free normal saline into the drainage bag.
7. Remove 10ml syringe into the drainage bag. Remove 10ml syringe and replace with sterile end cap.
8. Do not fully drain out tube between burette and drainage bag after priming. This can result in an air lock that delays draining.
Align System
The system must be properly aligned relative to the patient for accurate drainage.

The system is designed for use with an Integra Pole Mount Assembly (INS400 series).

CAUTION: The height of the drainage system relative to the patient controls the drainage rate, which can affect intra-cranial or lumbar pressure.

Establish zero pressure
Use Integra lower level or line level to align the zero reference on the Integra INS400 series Pole Mount to patient reference.

Setting Pressure Height
Increase or decrease the height of the pressure level by moving the sliding bracket. Align the top of the sliding bracket with drainage level prescribed (e.g., H2O or mm Hg). Secure the sliding bracket with the thumb screw of the INS400 series Pole Mount.

To Drain CSF
The amount of drainage is controlled by the height of the pressure level of the burette chamber and can affect ICP.

Drain fluid from the burette into the drainage bag by turning the stopcock beneath the burette with the "OFF" lever to the horizontal position. If fluid does not quickly empty into the drain bag, gently pull the bottom of the drainage bag downward. This facilitates flow through the anti-reflux valve in the drainage bag.

To Sample CSF
Sampling of CSF may be accomplished at various sampling sites that have been cleaned according to hospital protocol. The SmartSite needleless ports can be accessed with any standard luer fitting syringe. Access may be accomplished at the patient line Y site immediately distal to the patient stopcock or beneath the burette. In addition, CSF may be sampled from the SmartSite at the bottom of the drainage bag. Do not insert a needle directly into the SmartSite valve or it will be damaged & become unusable.

To Flush System
Flushing of the system requires aseptic technique and should be performed by or on the order of a physician or by qualified personnel.

Drain fluid into drainage bag and leave stopcock open. Flush as needed. Use 10ml of fluid. Repeat as necessary. Ensure burette has emptied each time flush is performed.

Sampling sites that have been cleaned according to hospital protocol may be flushed. Orient the stopcocks to temporarily prevent back flow to the patient. Ensure and verify fluid flush into the drainage bag.

Once flushing has been accomplished, re-orient stopcocks to allow flow from the patient to the burette and into the drainage bag.

To Replace Drainage Bag
Orient the stopcock to temporarily stop flow into the drainage bag. Using aseptic technique, disconnect the drainage bag from the patient line. A blue end cap is provided with the sterile replacement external CSF drainage bag. This end cap may be used to cap the detached drainage bag prior to disposal. Using aseptic technique, connect the sterile replacement drainage bag to burette.

Re-orient burette stopcock to allow flow into the drainage bag. Ensure and verify flow into the drainage bag.

To Empty Drainage Bag
The drainage bag may be emptied using aseptic technique through the SmartSite needleless sampling site located on the bottom of the bag.

CONNECTING TO A PRESSURE TRANSDUCER
Follow the transducer manufacturer's instructions for transducer set up and calibration.

If accurate pressure monitoring is desired with pressure wave forms, the system should be temporarily closed to drainage to the graduated burette. Turn off transducer stopcock with the OFF arm to stop flow to the burette. Refer to picture.
of burette into drainage bag. If it is necessary to transport a patient while the system is in use, it is recommended the system should remain 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 Patient Line stopcock should then be temporarily closed to prevent retrograde flow of CSF from the drain bag line into the burette.

After patient transport has been completed, system use should be re-established with correct zero reference to patient. All stopcocks should be re-oriented to re-establish flow. Ensure and verify flow from the patient into the burette.

If CSF has migrated into the antimicrobial hydrophobic vent during transport, open the stopcock between the burette and drainage bag to drain the antimicrobial hydrophobic vent. Failure to do so could result in under or overdrainage of CSF.

The antimicrobial hydrophobic vent will resist occlusion should there be any residual fluid in the burette during transport.

Specifications

- INS5020: Nominal collection volume: 20ml
- Nominal volume including vented filter: 38ml
- Accuracy of burette graduation: ±0.5ml
- Sealing volume: 20ml +3ml/-5ml
- INS5030: Nominal collection volume: 30ml
- Nominal volume including vented filter: 48ml
- Accuracy of burette graduation: ±0.5ml
- Sealing volume: 30ml +3ml/-5ml

How Supplied

The LimiTor® External CSF Drainage System is supplied sterile and non-pyrogenic in a double wrap package. The system includes a drainage bag. The system is intended for single use only.

A sterile sliding bracket for use with the Pole Mount Assembly is included with each pole mounted system. A sterile catheter luer connector and SmartSite Needleless Site is included with each system. The External CSF Drainage Bag is available separately and is supplied sterile and non-pyrogenic in a double wrap package. The drainage bag is intended for single use only.

The Pole Mount Assembly is supplied non-sterile and is intended to be reusable.

Special Order products may be supplied sterile as indicated on the product package.

Do Not Re-Sterilize

The LimiTor® Volume Limiting External CSF Drainage and Monitoring System and Drainage Bag are disposable devices. Do not re-sterilize.

Disposal

After patient use, the systems must be handled as biohazardous material and disposed of in accordance with local and state environmental requirements following facility protocols.

Product Information Disclosure

INTEGRA HAS EXERCISED REASONABLE CARE IN THE CHOICE OF MATERIALS AND MANUFACTURE OF THIS PRODUCT. INTEGRA DISCLAIMS AND 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 SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. INTEGRA NEITHER ASSUMES OR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THIS DEVICE.

Special Order Products

If this product is a Special Order product as 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 efficacy of the special order product.

Returned Goods Policy

- Authorization, from customer service, must be obtained prior to returning product.
- Sterile product must be returned in unopened, undamaged cartons, packed to prevent damage.
- Non-sterile product must be returned in unused salable condition in original package.
- Custom or special order products will not be accepted for credit.
- Credit will be issued for goods returned prior to ninety days from ship date with a 20% restocking charge. This assumes that the product returned is not damaged and can be verified to have not been used or opened.
Product Order Information

All products can be ordered through your Integra Neurosciences representative.

Integra Neurosciences
311 Enterprise Drive
Plainboro, NJ 08538 USA
Telephone: 1-800-654-2873
Outside the US: 609-275-0300
Fax: 609-275-5363

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Catalog Numbers

CSF Drainage System
INS9020 Volume Limiting External CSF Drainage System with 20ml Burette.
INS9030 Volume Limiting External CSF Drainage System with 30ml Burette.

Collection Bags
INS-2101 Drainage Bag with Anti-Reflux Valve (picted) and Blue Cap.

Pole Mount
INS400 Evolution Pole Mount Assembly with cm H2O and mm Hg Rail with Laser Level and Line Level.
INS400CM Evolution Pole Mount Assembly with cm H2O Rail with Laser Level and Line Level.
INS400MM Evolution Pole Mount Assembly with mm Hg Rail with Laser Level and Line Level.
INS410 Evolution Pole Mount Assembly with cm H2O and mm Hg Rail with Laser Level and Line Level and negative scale of -25 cm H2O/-18 mm Hg.