Codman®
LimiTorr™ Volume Limiting CSF Drainage System

Codman® SPECIALTY SURGICAL
A DIVISION OF INTEGRA LIFESCIENCES

LIMITORR SET-UP WITH A FLUSHLESS EXTERNAL TRANSDUCER

This chart is not intended to replace the LimiTorr™ Instructions for Use; please refer to the product's package insert for complete instructions. The following steps provide a visual aid in familiarizing responsible personnel with the use and function of the various components of the system, as described in the Instructions for Use. Always use sterile technique in setting up the LimiTorr™ system.

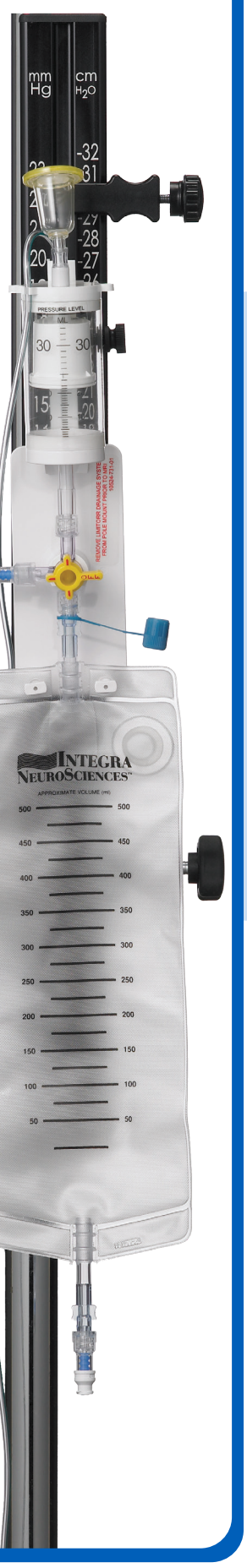
1 Attaching the System to the Pole

Attach sliding bracket (included with system) to LimiTorr™ sytem by inserting sliding bracket up into hole behind graduated burette top cap.

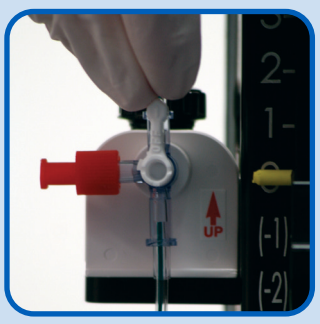
Mount the LimiTorr system to the Evolution Pole Mount assembly (INS400 series).

When the LimiTorr system is properly connected to the Evolution Pole Mount, the yellow indicator of the Pole Mount will align with the drip level of the LimiTorr.

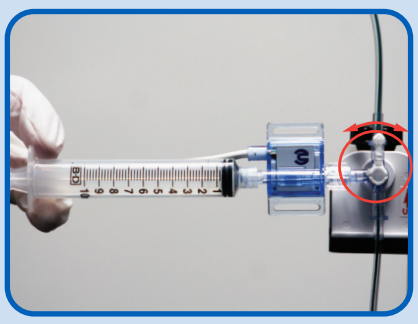
Insert manifold into slot of Pole Mount.



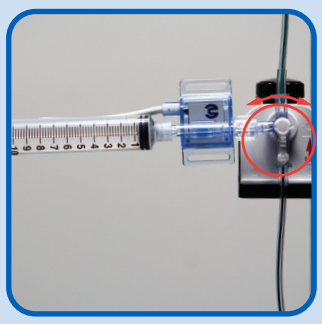
2 Priming the System With a Flushless External Transducer
(this is completed prior to attaching tubing to ventricular or lumbar catheter)



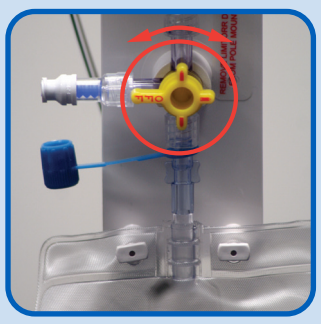
First check that all fittings on the LimiTorr Volume Limiting Drain are tightened. Turn the pressure transducer stopcock to "open" to the patient line and "open" to the pressure transducer.



Remove sterile red caps from the pressure transducer and catheter connections. Attach 10mL syringe, filled with preservative free normal saline, to transducer stopcock port and prime tubing of patient line to catheter connection. Replace sterile end cap once patient line is primed. Re-orient stopcock "off" to patient line.



Keeping the 10mL syringe attached, turn pressure transducer stopcock to "open" to graduated burette and "closed" to patient line. Prime tubing allowing 2-3mL of saline to collect in the graduated burette.

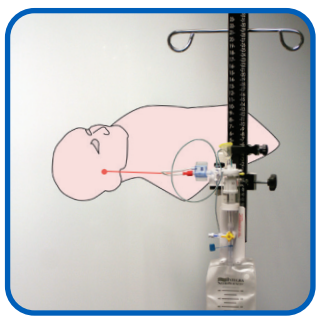


Drain 2-3mL saline into the drainage bag. Do not fully drain out tube between burette and drainage bag after priming. This can result in an air lock that delays draining. Remove 10mL syringe and replace with sterile end cap.

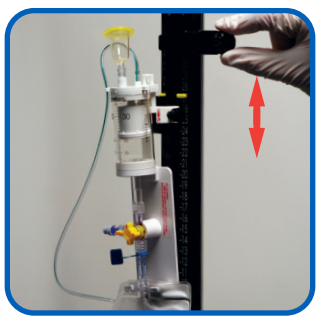
3 Setting the Pressure Level and Securing the System

The system must be properly aligned relative to patient for accurate drainage. LimiTorr sytem 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.

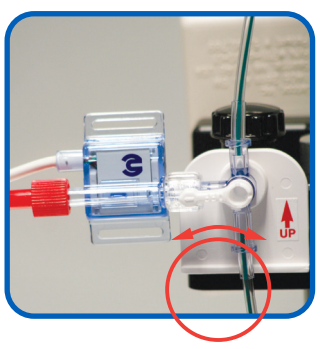


Establish zero pressure: Use Integra Laser Level or Line Level to align the zero reference on the Integra INS400 series Pole Mount at the external landmark of the patient as ordered by the physican (i.e. foramen of monro for ventricular catheters).



Setting Pressure Height: Align the yellow indicator with drainage level prescribed (cm H2O or mm Hg) by moving the sliding bracket. Secure with the thumb screw.

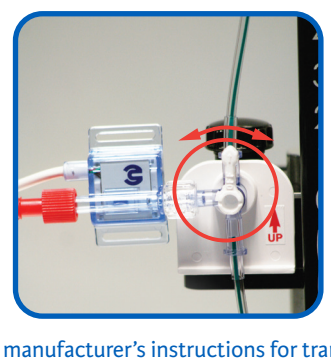
4 Draining CSF



To drain CSF, position both pole mount and patient line stopcocks as shown.

To drain fluid from burette into drainage bag turn the yellow "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.

5 Monitoring ICP



Follow 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.

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LIMITORR SET-UP

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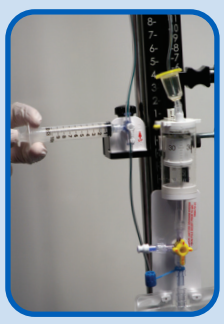
When the LimiTorr system is properly connected to the Evolution Pole Mount, the yellow indicator of the Pole Mount will align with the drip level of the LimiTorr.

Insert manifold into slot of Pole Mount.

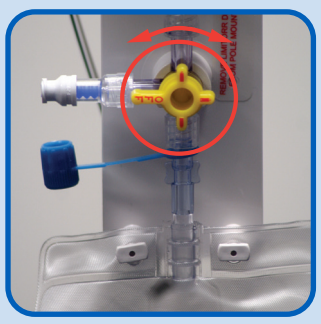
2 Priming the System
(this is completed prior to attaching tubing to ventricular or lumbar catheter)

First check that all fittings on the LimiTorr Volume Limiting Drain are tightened. Turn the pressure transducer stopcock to "open" to the patient line.

Attach 10mL syringe, filled with preservative free normal saline, to transducer stopcock port and prime tubing of patient line to catheter connection. Replace sterile end cap once patient line is primed. Re-orient stopcock "off" to patient line.



Keeping the 10mL syringe attached, turn pressure transducer stopcock to "open" to graduated burette and "closed" to patient line. Prime tubing allowing 2-3mLof saline to collect in the graduated burette.

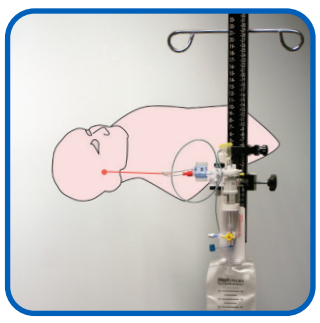


Drain 2-3mL saline into the drainage bag. Do not fully drain out tube between burette and drainage bag after priming. This can result in an air lock that delays draining. Remove 10mL syringe and replace with sterile end cap.

3 Setting the Pressure Level and Securing the System

The system must be properly aligned relative to patient for accurate drainage. LimiTorr sytem 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.



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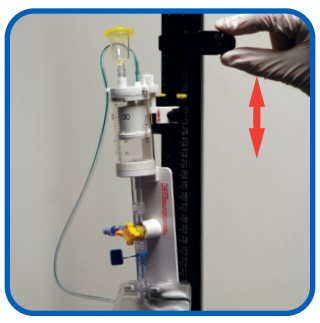

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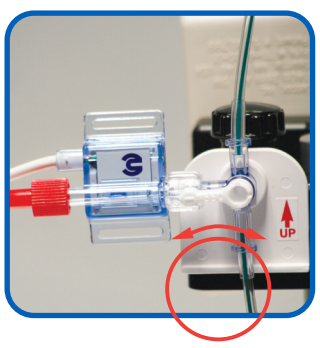
4 Draining CSF



To drain CSF, position both pole mount and patient line stopcocks as shown.

To drain fluid from burette into drainage bag turn the yellow "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.

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 set-up 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:** 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 needleless 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 needleless 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 INS 400 series Pole Mount that has been damaged and is not capable of a consistent vertical position. (ie. 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. as 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 antimicrobial hydrophobic vent. The system must be securely attached in a vertical position to an Integra Pole Mount Assembly (INS400 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.

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