



ARGON
MEDICAL DEVICES
Instructions for Use

MANOMETER

Intended Use:

The Manometer is used to measure pressure of cerebrospinal fluid (CSF) in the space surrounding the spinal cord.

Contraindications:

This manometer should be used by a physician familiar with performing lumbar puncture. The following are known contraindications with use of this product:

- Local skin infection
- Increased intracranial pressure
- Known medical history of coagulopathy
- Suspect spinal epidural abscess

Cautions:

- **Rx Only:** Federal Law (USA) restricts this device to sale by or on the order of a physician. Read instructions prior to use.
- The manometer is designed for single use only.
- Do not re-use, re-process, or re-sterilize the device.
- Re-use, re-processing, or re-sterilization may compromise the structural integrity and the intended function of the device which could result in patient injury.
- Verify the integrity of the device before use. Do not use the device if package is open or damaged.

Warnings:

- These instructions are NOT meant to define or suggest any medical or surgical technique. The individual practitioner is responsible for the proper procedure and techniques to be used with this device.
- During CSF collection never aspirate with the syringe.

Potential Complications:

Cerebrospinal fluid pressure measurement should not be attempted by physicians unfamiliar with the possible complications. Possible complications may include, but are not limited to the following:

- Post lumbar puncture headache
- Infection
- Bleeding
- Cerebral herniation
- Minor neurologic symptoms such as radicular pain or numbness
- Late onset of epidermoid tumors of the thecal sac
- Back pain

How Supplied:

The manometer is supplied sterile by ethylene oxide gas as a single use product. The device is packaged in a plastic pouch. Do not use the device if the package is open or appears to be damaged or defective. The device has no components made of natural rubber latex.

Preparation and Instructions for Use:

1. Under aseptic techniques, assemble the manometer by connecting the manometer tubing and stopcock.
2. Place the patient in a lateral decubitus position to ensure accuracy of the pressure measurement
3. After the spinal needle is inserted and flow back of cerebrospinal fluid (CSF) fluid is obtained, connect the manometer to the needle.
4. Position manometer so that the “zero” mark is at the level of the spinal needle. Ensure that the connecting tube between the stopcock and the manometer is at the same level of the spinal needle.
5. Relax the patient, slightly straightening his or her legs, and take the pressure measurement after the column of fluid

stops rising. This is the opening pressure. **Note:** *there will be a slight up and down variation with respiration.*

6. Proceed with the rest of the lumbar puncture procedure (eg. collect CSF specimens, if required).
7. Detach the manometer.

Handling and Disposal:

Handle in a manner which will prevent accidental puncture, percutaneous injuries and exposure to bloodborne pathogens. After use, this product may be a potential biohazard. Dispose in accordance with applicable laws and regulations.

Storage:

Store at standard ambient temperature.

Symbols:

	Sterilized using Ethylene Oxide		Use Before Date		Do not Re-Sterilize	RxOnly	Prescription Use Only
	Consult instructions for use		Single Use Only		Catalogue number		Manufacturer
	Do Not Use if Open or Damaged		Not made with natural rubber latex		Batch Code		

Manufactured by:

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