



ARGON
MEDICAL DEVICES
Instructions for Use

LUMBAR PUNCTURE TRAY

Intended Use:

The Lumbar Puncture (Spinal Tap) Tray is used to collect cerebrospinal fluid (CSF), and to measure pressure of cerebrospinal fluid (CSF) in the space surrounding the spinal cord.

Contraindications:

This tray 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
- Suspected 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 Lumbar Puncture Tray is designed for single use only.
- Do not re-use, re-process, or re-sterilize the tray or any items provided in the tray. Re-use, re-processing, or re-sterilization may compromise the structural integrity and the intended function of the product which could result in patient injury.
- Verify the integrity of all items in the tray before use. Do not use if an item appears 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.
- To avoid needle breakage, do not attempt to straighten a bent needle; discard and complete the procedure with a replacement needle.
- Do not reshield used needles.
- During CSF collection never aspirate with the syringe.

Potential Complications:

Lumbar punctures 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 Lumbar Puncture Tray is supplied sterile by ethylene oxide gas as a single use product. The tray is surrounded by a wrap and sealed in a plastic pouch. Do not use the tray if the package is open or appears to be damaged or defective. The tray has no components made of natural rubber latex.

Preparation and Instructions for Use:

1. Open hospital wrap using sterile technique and position pad under patient.
2. Prepare puncture site. The swab sticks and prep well provided may be used with desired antiseptic.
3. Drape the patient.

4. Raise skin wheal with local anesthetic with the 5 ml syringe and the short hypodermic needle. Use the longer hypodermic needle to anesthetize the deeper tissues of the back.
5. Penetrate the subcutaneous tissue with the spinal needle, then angle the needle at a slightly cephalad angle as if aiming toward the umbilicus. Advance until there is a fall in resistance; occasionally a characteristic “pop” is felt when the needle penetrates the dura. Remove stylet and check for CSF flow.

Note: *In the absence of fluid return, reinsert the stylet and advance or withdraw the needle a few millimeters, removing it at approximate 2 mm intervals to continue to assess and detect CSF flow. If there is no CSF flow or it is sluggish, rotate the needle 90 degrees to clear obstruction or redirect needle bevel to a cephalad position.*

CSF Pressure Measurement

- If CSF pressure measurement is desired, the patient must be in the lateral decubitus position.
 - Attach the stopcock to the needle hub. Connect the manometer set up to the stopcock.
 - 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.
 - 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.*
 - Proceed with the rest of the lumbar puncture procedure (eg. collect CSF specimens, if required).
 - Detach the manometer.
6. To collect specimens in vials, hold vial below the hub of the needle allowing the CSF to drip into the vial. If possible the CSF that is in the manometer should be used for the first vial. If the CSF flow is too slow, ask the patient to cough or bear down as in the Valsalva maneuver or ask an assistant to press intermittently on the patient’s abdomen to increase the flow. Alternatively the needle can be rotated 90 degrees so that the bevel faces cephalad.
 7. Screw caps on firmly. Stand filled vials upright in the tray depressions.
 8. Replace the stylet into the needle and remove the needle.
 9. Clean off the skin preparation solution and cover puncture site with a sterile dressing.

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		Contains phthalate: DEHP
	Do Not Use if Open or Damaged		Not made with natural rubber latex		Batch Code		Manufacturer

Manufactured by:

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