

## THORACENTESIS NEEDLE TRAY

### Intended Use:

The Thoracentesis Tray is intended for aspiration of fluid from the body. In thoracentesis, the fluid is removed from the pleural cavity.

### Contraindications:

There are no absolute contraindications for thoracentesis. This tray should be used by a physician familiar with the possible side effects, typical findings, limitations associated with thoracentesis. The benefits of the procedure should always be weighed against the risk before the procedure is performed.

### 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 thoracentesis tray was designed, tested and manufactured for single use only.
- Do not use the contents if package is open or damaged.
- Do not reuse, reprocess or re-sterilize. Reuse or reprocessing has not been evaluated and may lead to product failure and subsequent patient illness, infection, or other injury.
- Verify the integrity of all items in the tray before use. If an item appears damaged, replace the item.
- Tighten all Luer connections.
- In thoracentesis procedures fluid should be removed in stages not to exceed 1.5 L/day due to hypotension, pulmonary edema risks.

### 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 resheath used needle.
- The following situation should be considered when doing procedure planning, and the clinician should proceed with caution:
  - Uncorrected bleeding diathesis, coagulopathy, thrombocytopenia, or other bleeding disorders
  - Altered chest wall anatomy or chest wall cellulitis at the puncture site
  - Elevated INR
  - Patient is under mechanical ventilation
  - Uncertain fluid location by examination or minimal fluid volume
  - Hemodynamic or respiratory instability
  - Severe pulmonary disease that would make complications life threatening

### Potential Complications:

Thoracentesis should not be attempted by physicians unfamiliar with the possible complications. Possible complication may include, but are not limited to the following:

- Iatrogenic pneumothorax
- Hemoptysis
- Postexpansion pulmonary edema
- Hemothorax
- Pain, bleeding, cough, and localized infection
- Puncture of the spleen or liver

- Vasovagal syncope

**How Supplied:**

The thoracentesis tray is supplied sterile by ethylene oxide gas. It is intended for single use only. Do not use the device if 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. Prepare patient for the procedure according to standard aseptic technique.
2. Open hospital wrap using sterile technique and position towel under patient.
3. Prepare puncture site with desired antiseptic (not included with the tray).
4. Drape patient.
5. Fill a 5ml syringe with anesthetic (may or may not be included in the tray).
6. Raise skin wheal with anesthetic using a 25 G needle. Use 22 G x 2” needle for deeper infiltration.
7. Hang fluid collection bag from a convenient location.
8. Attach the stopcock, in the closed position, onto the 16 G aspiration needle hub.
9. The spring clip on the needle slides up and down to provide a reference point and to prevent accidental overinsertion.
10. Proceed with thoracentesis. Use the scalpel to nick the skin. Insert and advance the needle into the desired position of the pleural cavity.
11. Attach the syringe to the stopcock for fluid sampling or attach the drainage tube and drain as follow:

**Drainage Bag:**

- a) Tightly connect the male connector of the drainage tube to the female connector on the bag. (Suspend fluid collection bag below the level of the patient.)
  - b) Turn the stopcock to open the side port. Aspirate fluid into 60 ml syringe. Turn stopcock to open the drainage port to the drainage bag.
  - c) Repeat step “b” until all fluid is aspirated.
12. When drainage is complete, withdraw the needle
  13. Cover puncture site with bandage.













**Disposal:**

After use, this product may be a potential biohazard. Handle in a manner which will prevent accidental puncture. 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		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		Contains phthalate: DEHP

**Manufactured by:**

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