

THORACENTESIS CATHETER 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 or paracentesis.

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 5 ml syringe with anesthetic (Lidocaine Hydrochloride USP, 1%).
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. If desired, grasp needle at hub and separate collar-sleeve that covers the catheter from the needle hub.
9. Assemble and secure the connection of the stopcock and syringe to the distal tip of the needle catheter.
10. Use the scalpel to nick the skin.
11. Using the tip of the needle, puncture the skin and advance the needle into the pleural cavity while applying negative pressure to the syringe.
12. Advance the catheter into the pleural cavity. Gently advance the catheter one inch at a time until the desired indwelling depth is achieved.
13. Withdraw catheter / needle until the tip of the needle is out of the patient but the rest of the catheter is still in the patient.
14. Withdraw fluid into the syringe to confirm fluid return.
15. Place the bevel cover over the needle and clamp shut to prevent needle stick.
16. Secure catheter and bevel cover to the skin with an appropriate securement device or taping technique to prevent catheter movement.
17. Remove the syringe and attach the drainage tube to drain in the following methods:

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 off to the side port. Aspirate fluid into 60 ml syringe. Turn stopcock off to patient. Express fluid into drainage bag.
- c) Repeat step "b" until all fluid is aspirated.

Vacuum Bottle Drainage:

- a) Connect drainage tubing and vacuum needle and attach to the stopcock.
 - b) Insert vacuum needle into vacuum bottle.
 - c) Open stopcock to allow drainage.
 - d) Upon completion of drainage, turn the stopcock flow control off (sideport position) and remove the needle from the bottle.
18. Grasp the catheter / needle hub and remove from the patient.
 19. 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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