

PERITONEAL LAVAGE TRAY

Intended Use:

Used to infuse and drain rinsing solutions in the peritoneal cavity after blunt or penetrating abdominal trauma.

Contraindications:

The only absolute contraindication for Peritoneal Lavage is the obvious need for laparotomy. This tray should be used by a physician familiar with the possible side effects, typical findings, and limitations associated with Peritoneal Lavage. The value of the procedure should always be weighed against the risks before 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 Peritoneal Lavage 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 the contents if package is open or damaged.
- This tray is not for dialysis.
- Do not withdraw the guidewire back through the metal cannula of the needle after it has been inserted as it may damage the guidewire.
- Withdrawal, pullback, or manipulation of the guidewire when resistance is met may cause the guidewire to break or damage.

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 re-shield used needles.
- This tray should be used by a physician familiar with performing diagnostic peritoneal lavage and abdominal surgery. The following situations should be considered when doing procedure planning, and clinician should proceed with caution:
 - History of abdominal adhesions/previous abdominal surgery
 - Abdominal wall infections
 - Cirrhosis/large volume ascites
 - Known medical history of coagulopathy
 - Morbid obesity, making technical performance of the procedure difficulty
 - Second or third-trimester pregnancy

Potential Complications:

Peritoneal Lavage should not be attempted by physicians unfamiliar with the possible complications.

Possible complications may include, but are not limited to the following:

- Intra-peritoneal injury
- Peritonitis
- Abdominal wall injuries or infection
- Fluids not returning from the peritoneal cavity
- Repair laparotomy for visceral perforation
- Dyspnea/respiratory difficulty as a result of pressure of the fluid against the diaphragm

How Supplied:

The Peritoneal Lavage 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 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. Place patient in supine position.
2. Open hospital wrap using sterile technique and position pad under patient.
3. Prepare insertion site, midline, one-third of the way down from the umbilicus to the symphysis pubis with Povidone-iodine swabs and drape the patient.
4. Use 5 ml syringe to aspirate local anesthetic if desired.
5. Raise skin wheal with local anesthetic using a 25 G x 5/8" needle. Use a 21 G x 1 1/2 " needle for deeper infiltration
6. A scalpel blade may be used to puncture the skin prior to inserting the needle.
7. Introduce an 18 G guidewire introducer needle through the incision and into the peritoneal cavity, angled toward the pelvis at approximately a 45-degree angle with the skin. The penetration through the linea alba and the peritoneum is felt as two separate "pops". Avoid insertion through or immediately adjacent to a previous abdominal incision.
8. Insert the floppy end of the guidewire through the needle into the peritoneum.
9. After approximately half the length of the guidewire is in the peritoneum, remove the 18 G needle.
10. Insert the catheter over the guidewire into the peritoneal cavity, using a twisting motion and guided inferiorly toward the pelvis.
11. Remove the guidewire and attach a 10 ml syringe to the catheter for aspiration.
12. Allow the peritoneal fluid to drain out of the peritoneal cavity by gravity until the fluid return slows.
13. If no return persists, utilize a new guidewire to introduce a new catheter. Remove the guidewire and connect the catheter for return of lavage fluid.
14. When solution flow has stopped, disconnect the bag from the tubing. Place a dressing over the puncture site after the tube is removed from abdomen by the physician.

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		Prescription Use Only
	Caution		Single Use Only		Catalogue number		Manufacturer
	Do Not Use if Open or Damaged		Batch Code		Not made with natural rubber latex		

Manufactured by:

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