ARGON MEDICAL DEVICES

Instructions for Use

SKATER™ SAFETY CENTESIS CATHETER with AIR LOCK VALVE

Intended Use:
The SKATER™ Safety centesis catheter with Air Lock Valve is intended for aspiration of fluid from the body. In thoracentesis, the fluid is removed from the pleural cavity. In paracentesis, ascitic fluid is removed from the peritoneal cavity.

Contraindications:
There are no absolute contraindications for thoracentesis. The absolute contraindication for paracentesis is acute abdomen that requires surgery. This tray should be used by a physician familiar with the possible side effects, typical findings, and limitations associated with thoracentesis or paracentesis procedures. The benefits of the procedure should always be weighed against the risks 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 Catheter 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 the catheter components before use. If a component appears damaged, use a replacement catheter.
- In thoracentesis procedures fluid should be removed in stages not to exceed 1.5 L/day due to hypotension, pulmonary edema risks.
- Tighten all Luer connections.
- The air-lock valve is designed to prohibit the introducer needle from being reinserted into the device after it has been fully withdrawn and minimize the potential for pneumothorax.
- Should the physician change the original modular configuration: Do not reinsert the introducer needle into the catheter once you begin to withdraw. Otherwise the catheter may be damaged by the needle tip upon reinsertion.

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. Procedure must be performed by trained personnel.
- 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 needle.
- The following situation should be considered when doing procedure planning, and the clinician should proceed with caution:

Thoracentesis
- 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

Paracentesis
- Severe thrombocytopenia (platelet count < 20 x 10^3/µL) and coagulopathy
- Coagulation disorders
- Pregnancy
- Distended intra-abdominal organs
- Abdominal wall cellulitis
- Intra-abdominal adhesions and surgical scars

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

Thoracentesis
- Iatrogenic pneumothorax
- Hemoptysis
- Postexpansion pulmonary edema
- Hemothorax
- Pain, bleeding, cough, and infection
- Perforation or injury of organs
- Vasovagal syncope

Paracentesis
- Postparacentesis hypotension
- Persistent leakage of ascetic fluid
- Pain, bleeding complications, and infection
- Perforation or injury of organs

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How Supplied:
The Catheter is supplied with or without an accessories tray. If using the accessories tray, consult the instructions for use associated with the tray. All components are sterilized by ethylene oxide gas and are 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 and position the patient for the procedure according to standard aseptic technique.
2. Use the scalpel to nick the skin.
3. Hold stopcock and remove needle protector. Ensure that the sharp needle bevel extends beyond catheter tip. Reposition if necessary.
4. Insert the catheter assembly through the skin nick.
5. Under ultrasound or CT guidance, advance the catheter assembly until fluid can be aspirated through the needle into the 5 ml syringe. ***Note:*** *Push on the syringe while pulling back on the plunger to ensure the needle syringe instrument does not separate from the catheter.*
6. Withdraw introducer needle until completely out of the air-lock valve. ***Warning:*** *Do not advance the needle after it has been partially withdrawn. Any forward movement may damage the catheter.*
7. Select one of the three suggested drainage options below.
8. If diagnostic samples are required, attach the 60 ml syringe to the stopcock sideport and position the stopcock handle off to air lock valve.
9. Once the desired amount of sample is obtained, turn hand off to side port. Remove syringe and expel fluid into specimen vials.
10. At completion of procedure, remove catheter quickly to prevent hydrostatic dysfunction, and cover puncture site with bandage.

Three Drainage Procedure Options:

Option 1: Manual Drainage Set

1. Attach patient drainage port (shortest length tubing) to side port of stopcock.
2. Connect drainage bag port to drainage bag.
3. Connect drainage syringe port to 60 ml syringe.
4. Tighten all connections with push-twist motion.
5. Turn stopcock flow control arm off to air-lock valve to open side port.
6. Begin drainage procedure by slowly applying an alternating aspiration and injection motion with a 60 ml syringe.
7. Upon completion of drainage, turn the stopcock flow control off (sideport position) and remove the drainage tubing from the stopcock.
8. Quickly remove catheter from patient to avoid introduction of atmospheric air. Protect puncture site with a bandage.

Option 2: Vacuum Assisted Drainage

1. Attach male Luer end of vacuum bottle drainage tubing to side port of stopcock.
2. Tighten all connections with push-twist motion
3. Remove protector from needle and puncture vacuum bottle.
4. Turn stopcock off to air-lock valve. This will start fluid flow into the bottle.
5. Upon completion of drainage, turn the stopcock flow control off (sideport position) and remove the drainage tubing from the stopcock.
6. Quickly remove catheter from patient to avoid introduction of atmospheric air. Protect puncture site with a bandage.

Option 3: Wall Suction Drainage

1. Attach male Luer end of vacuum bottle drainage tubing to side port of stopcock.
2. Remove and dispose of vacuum needle with protector and replace with 5-in-1 drainage adapter.
3. Tighten all connections with push-twist motion prior to proceeding.
4. Insert 5-in-1 adapter firmly into wall suction drainage tubing.
5. Start wall suction drainage and turn stopcock off to air-lock valve.
6. Upon completion of drainage, turn the stopcock flow control off (sideport position) and remove the drainage tubing from the stopcock.
7. Quickly remove catheter from patient to avoid introduction of atmospheric air. Protect puncture site with a 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

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