



**ARGON**  
MEDICAL DEVICES  
Instructions for Use

**AMNIOCENTESIS TRAY**

**Intended Use:**

The Amniocentesis Tray is intended for the removal of amniotic fluid from the uterus.

**Contraindications:**

This tray should be used by a physician familiar with the possible side effects, typical findings, limitations associated with amniocentesis. The following are known contraindications with use of this product:

- Active skin infection on the proposed needle placement site.
- The anterior uterine wall is completely covered by the placenta.
- Insufficient amniotic fluid.
- Patients who are in their first 16 weeks of pregnancy; as there is an increased risk of miscarriage and premature rupture of membranes.
- Patients who are seropositive for HIV, hepatitis B and hepatitis C with high viral load.
- Patient who have isoimmunization.

**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 Amniocentesis 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. 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 resheat used needles.

**Potential Complications:**

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

- Infection or injury to the baby
- Miscarriage
- Leaking of amniotic fluid
- Bleeding or cramping from the puncture site or the vagina

**How Supplied:**

The Amniocentesis Tray is supplied sterile by ethylene oxide gas. The device has no components made of natural rubber latex.

**Preparation and Instructions for Use:**

1. Use appropriate imaging to determine position of fetus and prepare a detailed map of determined location.
2. Prepare patient for the procedure according to standard aseptic technique and ensure patient will remain in proper position throughout the procedure.
3. Open hospital wrap using sterile technique and position towel under patient.
4. Prepare puncture site with ChloroPrep®. **Note:** *Detailed instructions enclosed for the use of ChloroPrep®.*
5. Drape patient.
6. Fill a 5 ml syringe with anesthetic (Lidocaine Hydrochloride USP, 1%).
7. Anesthetize the puncture site using a short hypodermic needle. Use a longer hypodermic needle for deeper infiltration.
8. Under ultrasonographic imaging, advance the spinal needle through the abdomen and uterine wall into the amniotic sac. Remove the stylet. If clear fluid appears at the hub, attach the 20 ml syringe to the needle and aspirate the fluid. **Note:** *If blood is present, reposition the needle or reintroduce the stylet, or withdraw the needle and insert a new needle at a fresh site. The centimeter depth markings on the needle may aid in placement of the needle.*
9. Withdraw the desired amount of fluid. Eject the fluid into the specimen vials, cap and protect from light. Label vials.
10. Remove the needle and 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	RxOnly	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		

**Manufactured by:**

**Argon Medical Devices, Inc.**  
**1445 Flat Creek Road Athens, Texas 75751 USA**  
**Tel: 800-927-4669 Tel: +1 903-675-9321**  
**www.argonmedical.com**