



ARGON
MEDICAL DEVICES
Instructions for Use

SOFT TISSUE BIOPSY TRAY

Intended Use:

This tray contains accessories used with a biopsy needle (not included) in obtaining percutaneous or surgical histological soft tissue samples (e.g. lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and pancreas).

Contraindications:

These accessories should be used by a physician familiar with the possible side effects, typical findings, limitations, indications and contraindications of soft tissue biopsy. Physician judgement is required when considering biopsy on patients with bleeding disorder, or receiving anti-coagulant medications.

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 soft tissue biopsy 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.

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:

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

- Using the instrument in dense tissue or tumors may result in needle failure or sample insufficiency
- Infection / abscess
- Bleeding / hemorrhage (hematoma, hematuria, hematospermia, rectal bleeding)
- Pain or bruising at the biopsy site
- Injury to the surrounding structures
- Pneumothorax
- Fistula formation
- Tumor seeding

How Supplied:

The Soft Tissue Biopsy 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. Open hospital wrap using sterile technique and position towel under patient.
2. Prepare puncture site with the swab sticks and antiseptic.
3. Drape patient.

4. Fill a small syringe with anesthetic (Lidocaine Hydrochloride USP, 1%)
5. Raise skin wheal with local anesthetic using the 25 G needle. Use a 20 or 22 G x 1½" needle for deeper infiltration.
6. A scalpel blade may be used to puncture the skin prior to inserting the biopsy needle. **Note:** *biopsy needle is not included in the tray.*
7. Perform biopsy procedure according to the manufacturer's instruction. The larger syringe can be attached to a biopsy needle.
8. Eject the specimen into a vial or plate them onto the glass slides. Label slide / vials.
9. 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		Contains phthalate: DEHP
	Do Not Use if Open or Damaged		Not made with natural rubber latex		Batch Code		Manufacturer

Manufactured by:

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