

FINE NEEDLE ASPIRATION TRAY

Intended Use:

This tray contains the Techna-Cut™ Biopsy Needle and Soft Tissue Biopsy accessories, and is used to obtain biopsy material from tissue such as liver, kidney, prostate, breast, thyroid, pancreas, spleen and lung.

Contraindications:

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 a bleeding disorder, uncorrectable coagulopathy or platelet 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 Techna-Cut™ 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 re-shield used needles.
- The following situations should be considered when doing procedure planning:
 - Pulmonary hypertension
 - Patients with a history of COPD and blebs
 - Uncooperative or anxious patient
 - Inability of the patient to lay down
 - Difficulty controlling rate and depth of respiration for cases of abdominal or thoracic biopsies
 - Inability to reach the lesion without traversing important structures

Potential Complications:

The Techna-Cut™ 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, hermatospermia, rectal bleeding)
- Pain or bruising at the biopsy site
- Injury to the surrounding structures
- Pneumothorax
- Fistula formation
- Tumor seeding

How Supplied:

The Techna-Cut™ 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 5 ml syringe with attached hypodermic needle with anesthetic (Lidocaine Hydrochloride USP, 1%).
5. Raise skin wheal with local anesthetic. Attach the longer hypodermic needle for deeper infiltration.
6. A scalpel blade may be used to puncture the skin prior to inserting the biopsy needle.
7. Unlock the 20 ml syringe and depress the plunger to expose the stylet.
8. Insert the needle percutaneously proximal to the area to be sampled.
9. Withdraw plunger until the syringe locks in place to create a vacuum and push forward into the lesion to obtain the sample.
10. Once desired sample length is obtained, draw needle out. Unlock the syringe plunger and advance the plunger to remove sample.
11. Eject the specimen into a vial or place them onto the glass slides. Label slide / vials.
12. 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:

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