ARGON
MEDICAL DEVICES

Instructions for Use

BONE MARROW BIOPSY TRAY
(T-LOK™ BONE MARROW BIOPSY NEEDLE)

Intended Use:
This tray is intended for harvesting bone and/or bone marrow specimens. Aspiration should be done prior to biopsy.

Contraindications:
For use only for biopsies of bone/bone marrow as determined by a licensed physician. These needles should be used by a physician familiar with the possible side effects, typical findings, limitations, indications and contraindications of bone biopsy. Physician judgment 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 bone marrow 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 items in this tray.
- 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 needles.
- Ensure all Luer connections are tightened.
- This tray should be used by a specially trained operator familiar with performing harvesting bone/bone marrow specimen. Harvesting bone and/bone marrow specimen should be preceded by evaluation of the medical history and clinical features, examination of a blood film and assessment of results of a full blood count, other laboratory tests, and radiological investigations. The following situations should be considered when doing procedure planning, and the clinician should proceed with caution in the following situations:
    - Exercise particular care in patient with suspected multiple myeloma and in elderly patients who may have osteoporosis or previous irradiation of a site
    - Harvesting bone and/bone marrow specimen is sometimes required in patients with thrombocytopenia or abnormal coagulation tests. When possible, any clotting defect should be corrected before procedure is performed

Potential Complications:
Bone marrow biopsy should not be attempted by physicians unfamiliar with the possible complications. Possible complication may include, but are not limited to the following:
- Excessive bleeding or drainage from the biopsy site
- Infection of the bone (osteomyelitis) at the biopsy site
- Tumor seeding
- redness or swelling at the aspiration site
- Fever

How Supplied:
The bone marrow 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. Place patient in a right or left lateral position, with the back comfortably flexed and the top knee drawn toward the chest. Patient may also be placed in a prone position.
2. Locate the posterior superior iliac spine and mark.
3. Open hospital wrap using sterile technique and position towel under patient.
4. Prepare puncture site with povidone iodine swabs.
5. Drape patient.
6. Fill a 5 ml syringe with anesthetic and aspirate with the 20 G x 1½" needle.
7. Raise skin wheal with local anesthetic using a hypodermic needle.
8. A scalpel blade may be used to puncture the skin prior to inserting the biopsy needle.

20-1100-13/0615A

Aspiration Procedure

a) Hold the handle securely in the palm of the hand and index finger against the shaft for stability and control.
b) Introduce the needle through the incision and, using firm pressure; slowly advance the needle while rotating the needle 45° in an alternating clockwise-counterclockwise motion. Entrance into the marrow cavity is generally detected by decreased resistance.
c) Rotate the stylet 90° counterclockwise and pull the stylet out of the handle.
d) Attach a syringe to the cannula hub.
e) Apply negative pressure by quickly withdrawing the syringe plunger. Disconnect the syringe and eject aspirated specimen into vials.
f) If desired, direct smears should be made immediately on the slides provided.

Biopsy Procedure (only performed after aspiration)

a) Using the same skin incision, choose a different location to enter the bone. For a biopsy only, follow steps 1-8 of the preparation procedure and continue as follows:
b) With the stylet removed, slowly advance the needle a millimeter at a time, with a slight clockwise-counterclockwise motion until adequate marrow is obtained. ***Note:*** *Sample specimen may be damaged with excessive clockwise, counterclockwise movement.*
c) Pull the needle back two or three millimeters and, with minimal pressure, direct its tip at a slightly different angle. ***Note:*** *Excessive pressure may cause needle to bend.* Advance the needle two or three millimeters further, and rotate 360° two more times. This procedure further helps to sever the specimen before withdrawing the needle.
d) Rotate the needle along its axis with quick, full twists-several times to the right and to the left. Slowly remove the needle with alternating rotary motions. Once specimen is obtained releasing it may performed with several techniques:

Negative Pressure:

1. Insert the probe into the cutting cannula to check the sample length in the needle lumen.
2. Attach a syringe to the fitting on the hub on the cannula handle and draw negative pressure to hold your specimen.
3. Remove needle.
4. Push the specimen out with the probe.

Mechanically with the use of the T-Lok™ Extraction cannula:

1. Insert the probe into the cutting cannula to check the sample length in the needle lumen.
2. Remove the probe and insert the T-Lok™ Extraction cannula fully into the needle cannula.
3. Slowly rotate and remove the needle and T-Lok™ Extraction cannula together.
4. Remove the T-Lok™ Extraction cannula from the needle cannula and push the specimen out with the probe.

Other Technique:

1. Slip larger opening end of anti-stick probe guide over the needle tip. Push the anti-stick probe guide down on needle until it fits snugly. Insert probe into smaller opening and push gently to expel specimen from proximal end of needle into a vial. Remove probe from anti-stick probe guide.
    a. For safety and convenience, there is an Anti-Stick Probe Guide on the T-Lok™ Bone Marrow Needle. The purpose of this device is two-fold: provide an easier method to align the probe in the needle tip for specimen expulsion.
2. If another specimen is to be taken remove anti-stick probe guide and reassemble needle stylet and cannula. Wipe cannula and stylet tip clean and then repeat biopsy procedure.
3. If no other specimens are to be obtained, leave guide in place to cover tip of needle and discard needle assembly.

9. Label specimens appropriately.
10. 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		

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