



## Instructions for Use

### **BONE MARROW BIOPSY TRAY (“I” STYLE BONE MARROW ASPIRATION NEEDLE)**

#### **Intended Use:**

This tray is intended for harvesting of bone marrow specimens from the sternal or iliac crest.

#### **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 re-shield used needles.
- Ensure all Luer connections are tightened.
- This tray should be used by a specially trained operator familiar with performing bone marrow aspiration. Bone marrow aspiration 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
  - Bone marrow aspiration is sometimes required in patients with thrombocytopenia or abnormal coagulation tests. When possible, any clotting defect should be corrected before aspiration 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
- Increased tenderness, pain, 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. Open hospital wrap using sterile technique and position towel under patient.
2. Prepare puncture site with antiseptic
3. Drape patient.
4. Fill a 5 ml syringe with anesthetic (Lidocaine Hydrochloride USP, 1%) by aspirating with the hypodermic needle.
5. Raise skin wheal with local anesthetic using the hypodermic needle.
6. A scalpel blade may be used to puncture the skin prior to inserting the needle.

**Sternal Aspiration**

- a) Adjust the needle stop for correct needle length. The adjustable screw-stop allows for a minimum needle length of 3/8"; when the screw-stop is removed, the needle length is 1 7/8". Note: Do not use for sternal puncture with stop assembly removed. (See Iliac Crest Instructions).
- b) Insert needle into sternum.

**Iliac Crest Aspiration**

- a) The screw-stop can be removed from the screw thread for a needle length of 1 7/8". If more length is desired, screw-stop all the way up (with needle guard in place), grab stop assembly and pull briskly straight along needle. The entire needle stop assembly will now be removed and the needle length will be 2 5/8". Note: Do not use if needle is bent.
  - b) Insert needle into iliac crest.
7. Once needle tip is positioned in marrow cavity, remove stylet by rotating upper section of handle 90°, and pulling straight out.
  8. A Luer-lock connection is provided for syringe connection. Note: Either Luer-lock or Luer slip syringe may be used.
  9. Apply negative pressure by quickly withdrawing the syringe plunger. Disconnect the syringe and eject aspirated specimens into vials.
  10. If desired, direct smears should be made immediately on the slides provided.
  11. Label specimens appropriately.
  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		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