

ASPIRE™
BONE MARROW HARVESTING SYSTEM
PN: ABN-1115
Instruction for Use
Date: August 2020

ATTENTION OPERATING SURGEON

1. **NOTE: DEVICE IS FOR SINGLE USE ONLY.** Discard the entire disposable system after one use, using an acceptable disposal method for products potentially contaminated with blood.
2. **INDICATIONS FOR USE**
The ASPIRE™ Bone Marrow Needle is intended for use in aspirating bone marrow.
3. **USER POPULATION**
Use only for bone marrow aspiration as determined by a licensed physician. The device is intended to be used by a physician familiar with the possible side effects, typical findings, limitations, indications, and contraindications of bone marrow aspiration. The procedure should be performed on patients that are suitable for such procedure only.
4. **WARNINGS AND PRECAUTIONS**
For Single Patient Use Only. Do not attempt to clean or re-sterilize this product. 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.
5. **CAUTION**
Federal Law (USA) restricts this device to sale by or on the order of a physician.
6. **NOTE**
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.

ANTICOAGULATION PREPARATION PROCEDURE

For Heparin Anticoagulant

1. Prime the Aspirating Cannula, stylet, introducer needle, filter and five 12mL syringes with Heparin 1000 units/mL. Leave 1mL Heparin in each 12mL syringe after priming.

For Citrate Anticoagulant

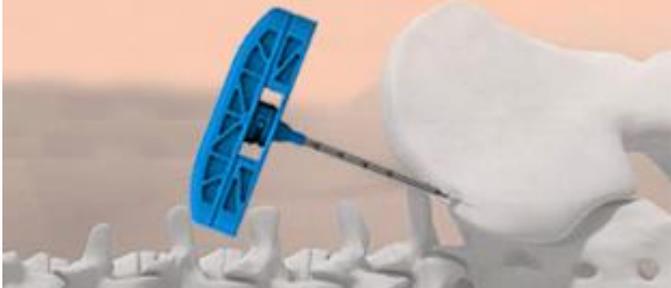
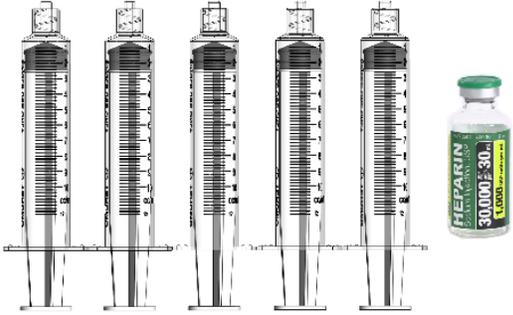
2. Prime the Aspirating Cannula, stylet, introducer needle, filter and five 12mL syringes with citrate anticoagulant. Leave 1mL in each 12mL syringe.

ASPIRATION PROCEDURE

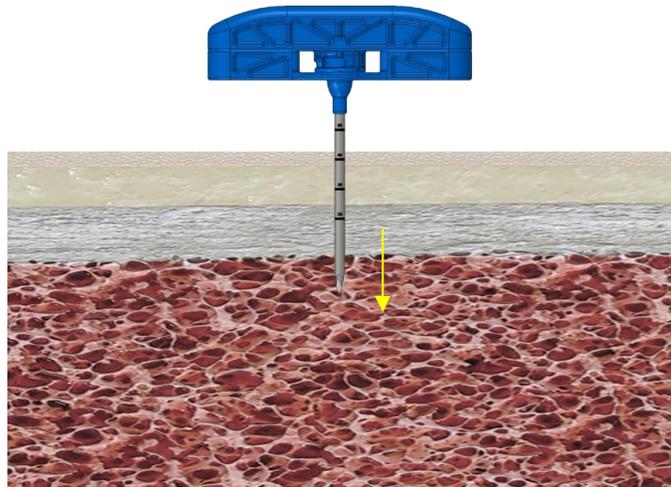
1. Place the patient in a right or left lateral position, with the back comfortably flexed and the top knee drawn toward the chest.
2. Locate the posterior superior iliac spine and mark.
3. Using sterile technique, prepare the skin with antiseptic and drape.
4. Infiltrate the marked area with local anesthetic, especially the periosteum.
5. Make a skin incision with a scalpel blade over the marked area.
6. Hold the introducer and stylet needle with the proximal end in palm and the index finger against the shaft near the tip. This position stabilizes the needle and allows better control.
7. Introduce the introducer and stylet needle through the incision bringing it into contact with the posterior iliac spine.
8. Using gentle, but firm pressure, advance the needle tip through the periosteum, then through the cortex until the marrow cavity is penetrated and the introducer is firmly secured.
9. Gently remove stylet by rotating the upper section of the handle and pulling straight out.
10. Introduce the blunt tip Aspirating Cannula through the introducer until it reaches the depth of the last hash marker on the Aspirating Cannula.
11. Attach two (2) twelve mL syringes to the Aspirating Cannula and draw 12mL of BMA in each. Rotate 90 degrees after each syringe.
12. Advance the Aspirating Cannula approximately 1cm. Attach two additional 12mL syringes and draw another 12mL in each. Rotate 90 degrees after each syringe.
13. Advance the Aspirating Cannula approximately 1cm once again. Attach one additional 12mL syringe and draw another 12mL.
14. Collect a total of 60mL of BMA. Collect 12mL in five 12mL syringes.

 Do not use if package is damaged	 Single use only	 Store in a cool place	 Store in a dry place
	 Do not re-sterilize	 EmCyte Corporation 4331 Veronica S. Shoemaker Blvd. Fort Myers, FL 33916 Phone: 239-481-7725	

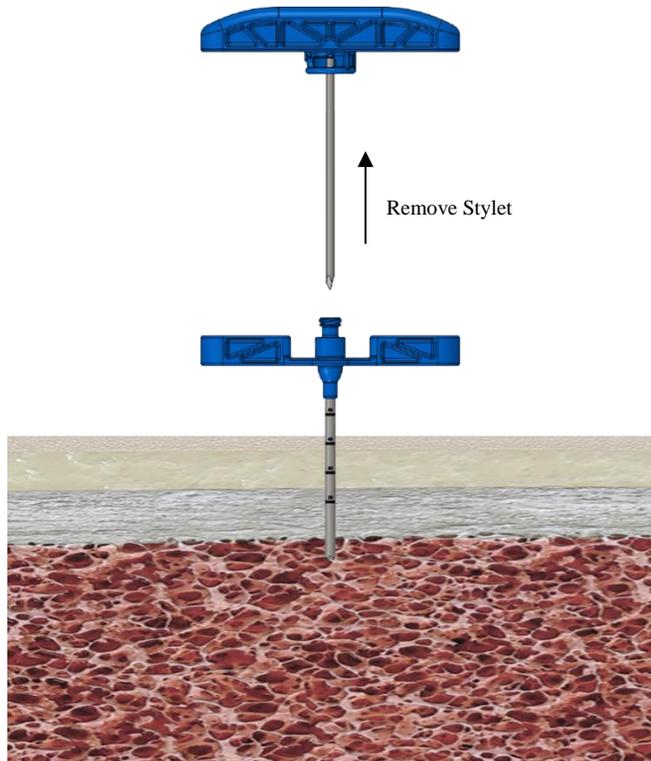
Collection Technique

<ul style="list-style-type: none">• Anterior approach: Medially in line with the pelvic wing, as gauged by palpation of the inner and outer tables. The trajectory should be aimed slightly posteriorly at the iliac tubercle, to enter the medullary canal just beneath it.	 Anatomical diagram showing the anterior approach to the iliac crest. A blue fan-shaped guide is positioned over the iliac crest, and a needle is inserted through it, angled slightly posteriorly towards the iliac tubercle.
<ul style="list-style-type: none">• Posterior approach: 40° lateral from the sagittal plane and 35°–40° inferior from the transverse plane. Aim at the tip of the greater trochanter.	 Anatomical diagram showing the posterior approach to the iliac crest. A blue fan-shaped guide is positioned over the greater trochanter, and a needle is inserted through it, angled 40 degrees lateral from the sagittal plane and 35-40 degrees inferior from the transverse plane.
<ul style="list-style-type: none">• Lateral approach: Horizontally and introduce it through the prepared incision site into the center of the posterior iliac prominence, with the initial trajectory 15° caudal.	 Anatomical diagram showing the lateral approach to the iliac crest. A blue fan-shaped guide is positioned over the posterior iliac prominence, and a needle is inserted through it, angled 15 degrees caudal.
<p>Prime the needle and prepare the 12mL syringes with anticoagulant.</p> <ul style="list-style-type: none">• For Heparin: Prime each 12mL syringe with Heparin 1000 units/mL. Leave 1mL of Heparin in each syringe.• For Citrate Anticoagulant: Prime each 12mL syringe with Citrate Anticoagulant. Leave 1mL of Citrate Anticoagulant in each syringe.	<p>Leave 1mL of Heparin or Citrate Anticoagulant in five 12mL syringes</p>  Five 12mL syringes are shown in a row, each containing 1mL of anticoagulant. To the right of the syringes is a small vial of Heparin 1000 units/mL. The vial is labeled 'HEPARIN 1000 30,000 30mL'. The syringes are marked with 1mL increments.

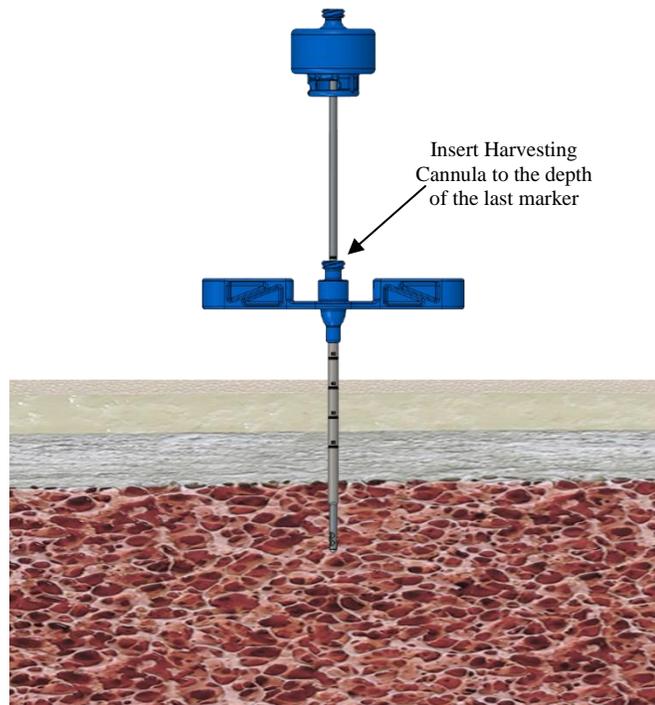
- **Advance Introducer Needle:** Advance the Introducer Needle using gentle but firm pressure. Rotate the needle in alternating clockwise-counterclockwise motion or gently tap the needle handle with a mallet. Advance until the introducer penetrates the cortex and is firmly secured within marrow cavity.



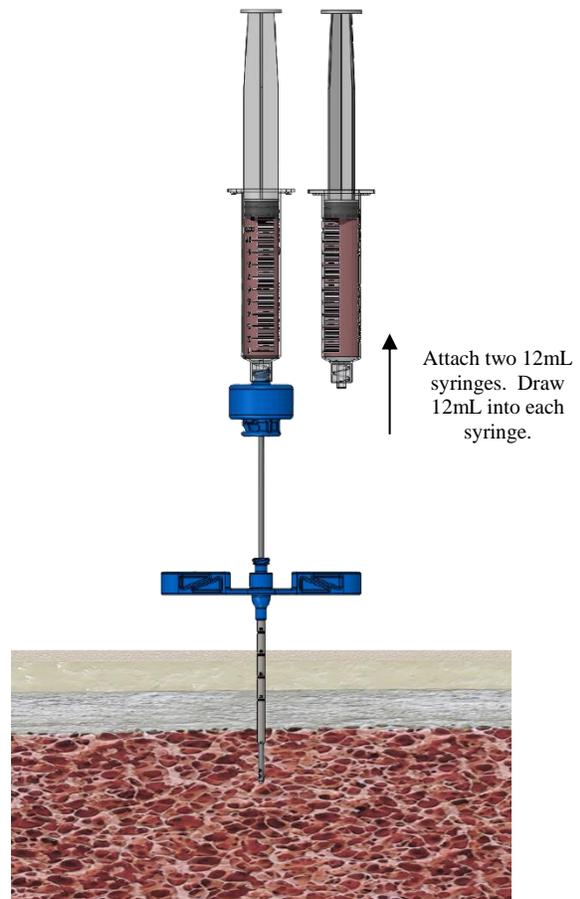
- **Withdraw Stylet:** Remove the stylet after the Introducer has gained access to the marrow cavity.



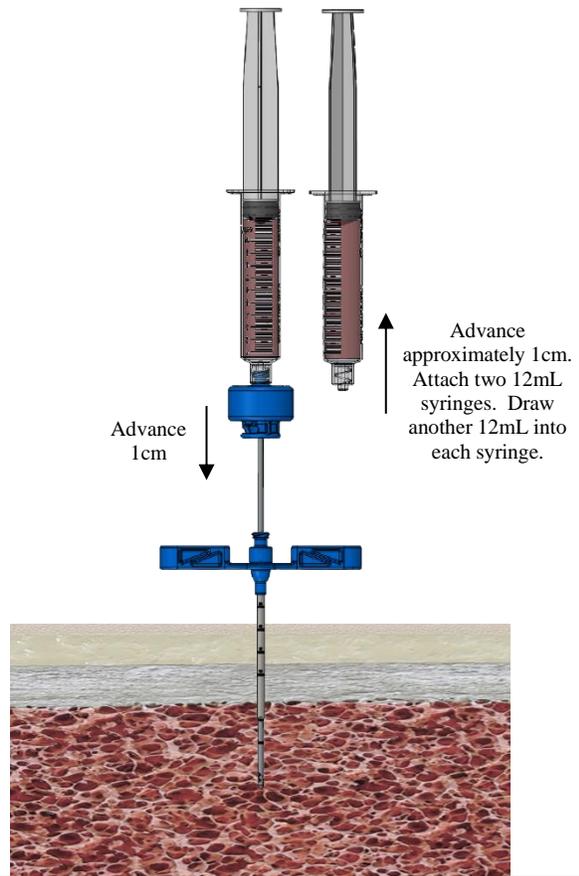
- **Insert Harvesting Cannula:** Insert Harvesting Cannula through the Introducer to the depth of the last marker on the introducer.



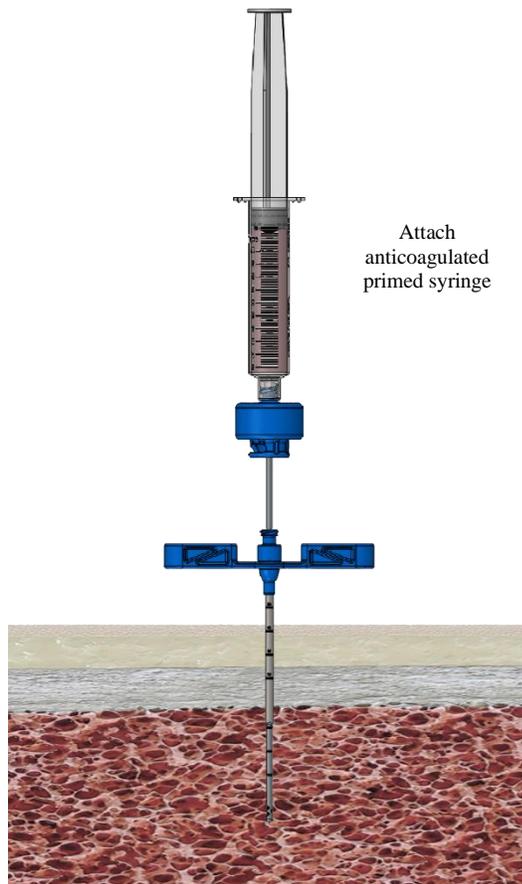
- **Draw 24mL:** Attach two (2) twelve mL syringes and draw 12mL in each. Rotate 90 degrees after each syringe.



- Advance and draw 24mL:**
 Advance the aspirating needle approximately 1cm. Attach two additional 12mL syringes and draw another 12mL in each. Rotate 90 degrees after each syringe.



- Advance and draw 12mL:**
 Advance the aspirating needle approximately 1cm. Attach one additional 12mL syringe and draw another 12mL in each.



- Collect a total of 60mL BMA. Five syringes with 12mL per syringe.
- Proceed to concentration.

Collect a total of
60mL BMA

