

ASPIRE™
BONE MARROW HARVESTING SYSTEM
PN: ABN-1115
Instruction for use

ATTENTION OPERATING SURGEON

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.

DESCRIPTION

1. The ASPIRE™ Bone Marrow Harvesting System is manufactured by EmCyte corporation. The system includes the ASPIRE Harvesting Needle, ASPIRE Introducer and the ASPIRE Trocar Needle.

MATERIALS

2. The materials used are consist of medical grade polymers, elastomers and stainless steel that are suitable for use in medical devices. All components in this system are packaged, labeled and sterilized as indicated by the manufacturer’s labeling. All components in this system are latex-free.

3. INDICATIONS FOR USE

The ASPIRE™ Bone Marrow Needle is intended for use in aspirating bone marrow.

4. 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.

DEVICE USE ENVIRONMENT

5. The device is intended to be used in in a health care setting such as a surgery room, clinic or outpatient care center.

6. WARNINGS AND PRECAUTIONS

For Single Patient Use Only. Do not attempt to clean or re-sterilize this product. Handle in a manner which will prevent accidental puncture. Dispose in accordance with applicable laws and regulations.

POSSIBLE RISKS

7. The patient is to be made aware of the general risks associated with aspiration. These risks include, but are not limited to: hemorrhage, seroma formation, infection, and/or persistent pain at the site of aspiration.
8. Reuse may be a potential biohazard.

POSSIBLE ADVSERSE EFFECTS

9. Damage to blood vessels, hematoma, delayed wound healing and/or infection is associated with bone marrow aspiration, and/or surgical procedure.
10. Temporary or permanent nerve damage that may result in pain or numbness is associated with bone marrow aspiration, and/or surgical procedure.
11. Early or late postoperative infection is associated with surgical procedure.
12. Pain associated with site of bone marrow harvest.

STERILITY

13. The ASPIRE™ Bone Marrow Harvesting System is sterilized by ETO exposure. Do not use any component from an opened or damaged package. Do not re-sterilize. Discard if kit packaging is damaged or open.

14. CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a physician.

15. 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.

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

HEPARIN ANTICOAGULATION PREPARATION PROCEDURE

1. Withdraw 12 mL of Heparin (1000 units/mL) from the vial into 12mL syringe.
2. Remove Trocar from Introducer Needle. Connect Heparin-filled syringe to the shorter Introducer Needle and inject Heparin until needle is fully rinsed (is flowing through end of the needle). Insert Trocar back into Introducer needle, twist it and lock in place.
3. Remove the blue cap from the Aspiration Needle. Connect Heparin-filled syringe into the longer Aspiration Needle and fully prime the needle.
4. For the Non-Concentrating Technique – Prime (1) 12mL syringe with Heparin, then remove leaving only residual heparin in the syringe.
5. For the Concentrating Technique – Prime five (5) 12ml syringes with the remaining Heparin ensuring contact between heparin and the inner surface of the syringes. Leave 1mL of heparin in each 12ml syringe after priming.

BONE MARROW ASPIRATION PROCEDURE

1. Place the patient in prone position.
2. Palpate the posterior pelvic anatomy to select desired entry point. Using imaging guidance locate the most prominent portion of the posterior superior iliac spine (PSIS) and mark the skin with surgical marker.
3. Following sterile technique disinfect aspiration site with appropriate disinfection product and then drape the procedural site to ensure an adequate field.
4. Infiltrate the subcutaneous and intramuscular areas with local anesthetic, especially the periosteum.
5. Carefully make a skin incision over the marked area.
6. Hold the introducer and trocar needle with the proximal end in palm and the index finger against the shaft near the tip. This position stabilizes the needle and allows a better control.
7. Insert the introducer and trocar needle through the incision down to the bone. Locate the center of the PSIS by palpating with the tip of the needle for the inner and outer tables of the ilium.
8. Applying gentle, but firm pressure, advance the needle tip through the periosteum by rotating the needle in altering clockwise, counterclockwise rotation or gently taping the needle handle with a mallet until the introducer is firmly secured. Anticipate a decrease in resistance as the cortex is penetrated.
9. Gently remove trocar by rotating the upper section of the handle and pulling slowly straight out.

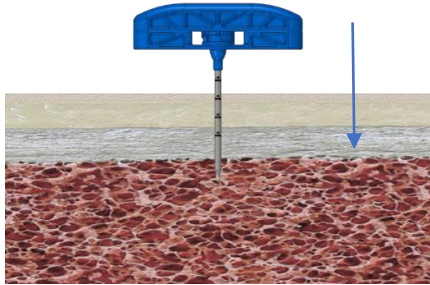
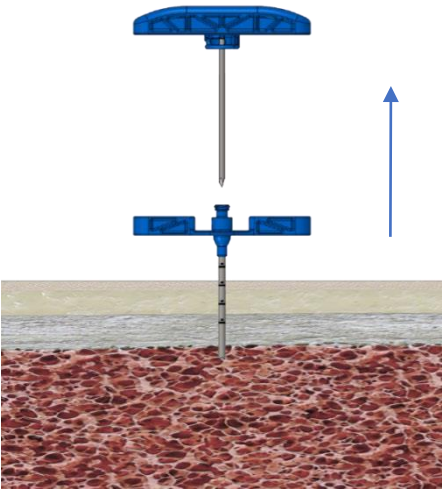
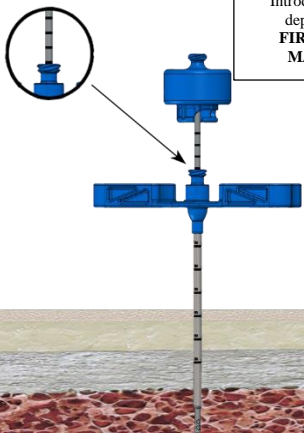
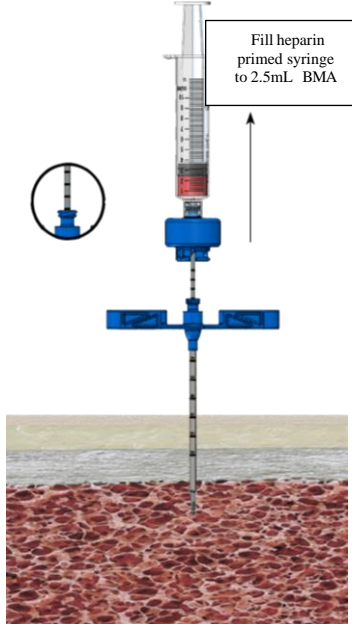
NON-CENTRIFUGATION COLLECTION TECHNIQUE

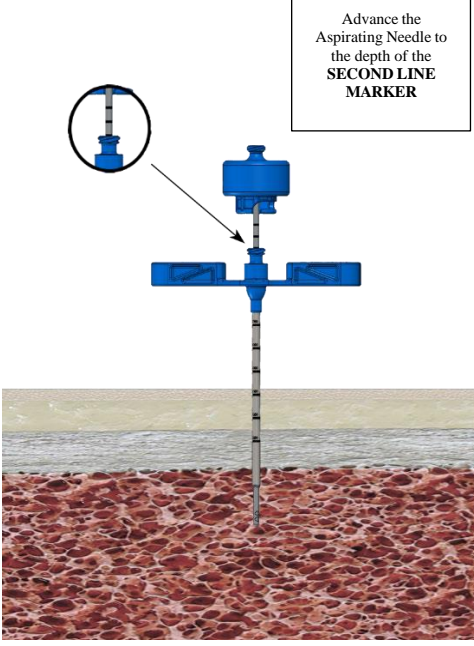
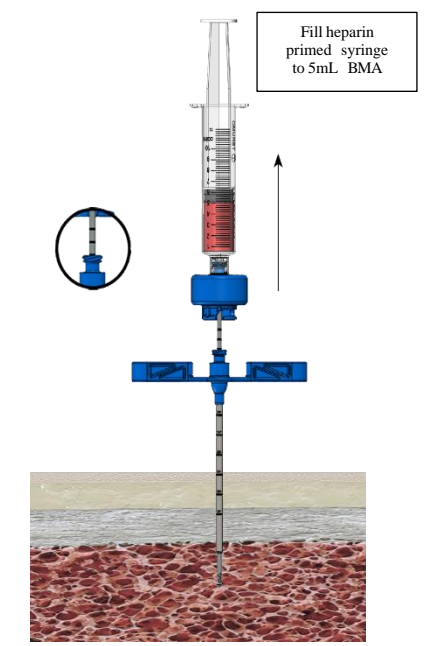
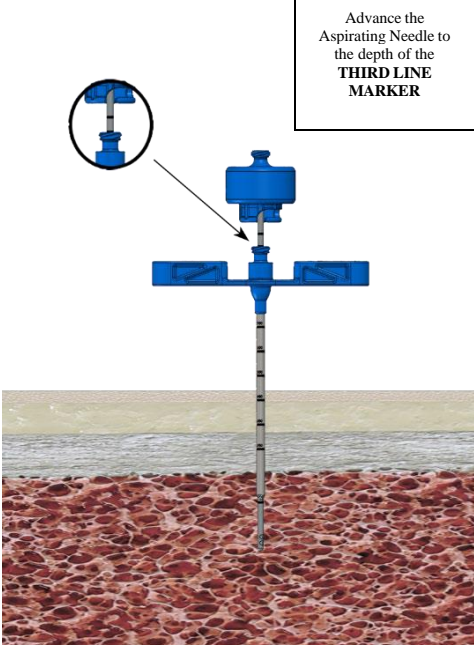
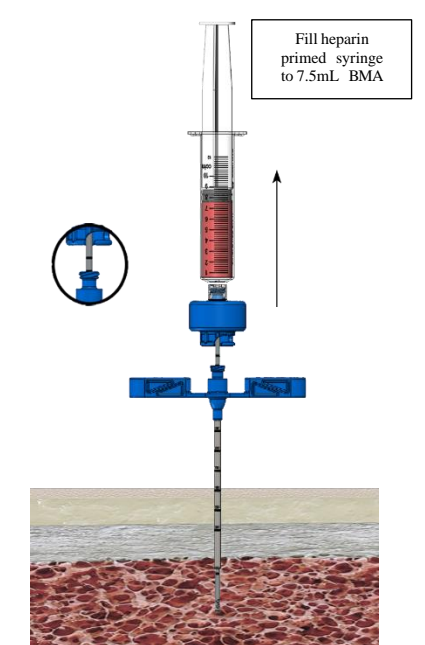
10. Introduce the blunt tip aspirating needle through the introducer until it reaches the depth of the FIRST LINE MARKER on the aspirating needle.
11. Attach the 12mL syringe to the aspirating needle and draw 2.5mL of bone marrow aspirate while rotating the needle in 90-degree increments. Needle rotation repositions the fenestration to access new regions of trabecular bone marrow.
12. Slowly advance the aspirating needle to the SECOND LINE MARKER along the same trajectory with small clockwise and counterclockwise rotations. Draw another 2.5mL of bone marrow aspirate, filling to 5mL.
13. Slowly advance the aspirating needle to the THIRD LINE MARKER along the same trajectory with small clockwise and counterclockwise rotations. Draw another 2.5mL of bone marrow aspirate, filling to 7.5mL.
14. Slowly advance the aspirating needle to the FORTH LINE MARKER along the same trajectory with small clockwise and counterclockwise rotations. Draw another 2.5mL of bone marrow aspirate, filling to 10mL.
15. Using the same clockwise/counter-clockwise motion, slowly remove the Introducer and Aspirating Needle. Cover the aspiration site with sterile gauze and apply firm pressure until the bleeding stops

CENTRIFUGATION COLLECTION TECHNIQUE

16. Introduce the blunt tip aspirating needle through the introducer until it reaches the depth of the FIRST LINE MARKER on the aspirating needle.
17. Attach 1st 12mL syringe to the aspirating needle and draw 11mL of bone marrow aspirate, filling to 12mL, while rotating the needle in 90-degree increments. Needle rotation repositions the fenestration to access new regions of trabecular bone marrow.
18. Slowly advance the aspirating needle to the SECOND LINE MARKER along the same trajectory with small clockwise and counterclockwise rotations. Attach the 2nd 12mL syringe to the aspirating needle and draw another 11mL of bone marrow aspirate, filling to 12mL.
19. Slowly advance the aspirating needle to the THIRD LINE MARKER along the same trajectory with small clockwise and counterclockwise rotations. Attach the 3rd 12mL syringe to the aspirating needle and draw another 11mL of bone marrow aspirate, filling to 12mL.
20. Slowly advance the aspirating needle to the FORTH LINE MARKER along the same trajectory with small clockwise and counterclockwise rotations. Attach the 4th 12mL syringe to the aspirating needle and draw another 11mL of bone marrow aspirate, filling to 12mL.
21. Slowly advance the aspirating needle to the RIM DECK along the same trajectory with small clockwise and counterclockwise rotations. Attach the 5th 12mL syringe to the aspirating needle and draw another 11mL of bone marrow aspirate, filling to 12mL.
22. Using the same clockwise/counter-clockwise motion, slowly remove the Introducer and Aspirating Needle. Cover the aspiration site with sterile gauze and apply firm pressure until the bleeding stops

NON-CENTRIFUGATION COLLECTION TECHNIQUE 10mL

<p>ADVANCE INTRODUCER 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.</p> <p>WITHDRAW TROCAR Slowly and gently remove the trocar needle.</p>		
<p>INSERT ASPIRATING NEEDLE Insert Aspirating Needle through the Introducer to the depth of the FIRST LINE MARKER on the aspirating needle.</p> <p>ASPIRATE 2.5mL BMA Attach the 12mL heparinized syringe and draw 2.5mL of bone marrow aspirate, while rotating the needle in 90-degree increments. Fill the syringe to 2.5mL</p>	 <p>Insert Aspirating Needle through the Introducer to the depth of the FIRST LINE MARKER</p>	 <p>Fill heparin primed syringe to 2.5mL BMA</p>

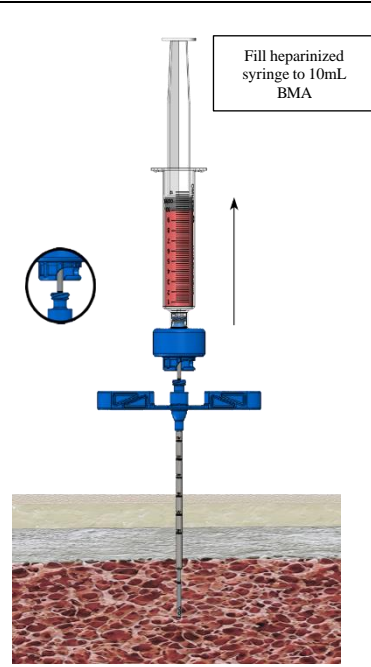
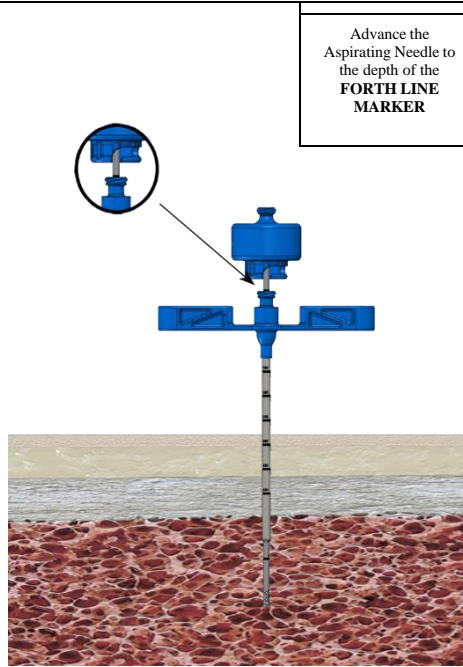
<p>ADVANCE ASPIRATING NEEDLE NEEDLE Advance the Aspirating Needle to the depth of the SECOND LINE MARKER</p> <p>ASPIRATE 2.5mL BMA Aspirate ANOTHER 2.5mL of bone marrow aspirate, while rotating the needle in 90-degree increments. Fill the syringe to 5mL.</p>	<p>Advance the Aspirating Needle to the depth of the SECOND LINE MARKER</p> 	<p>Fill heparin primed syringe to 5mL BMA</p> 
<p>ADVANCE ASPIRATING NEEDLE NEEDLE Advance the Aspirating Needle to the depth of the THIRD LINE MARKER</p> <p>ASPIRATE 2.5mL BMA Aspirate ANOTHER 2.5mL of bone marrow aspirate, while rotating the needle in 90-degree increments. Fill the syringe to 7.5mL.</p>	<p>Advance the Aspirating Needle to the depth of the THIRD LINE MARKER</p> 	<p>Fill heparin primed syringe to 7.5mL BMA</p> 

ADVANCE ASPIRATING NEEDLE

Advance the Aspirating Needle to the depth of the FORTH LINE MARKER

ASPIRATE 2.5mL BMA

Aspirate ANOTHER 2.5mL of bone marrow aspirate, while rotating the needle in 90-degree increments. Fill the syringe to 10mL.



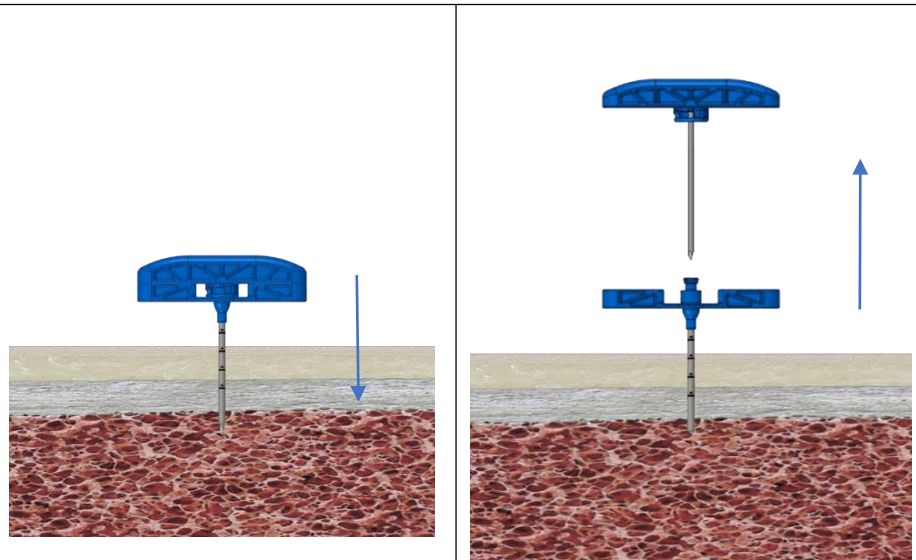
CENTRIFUGATION COLLECTION TECHNIQUE 60mL

ADVANCE INTRODUCER

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 TROCAR

Slowly and gently remove the trocar needle.

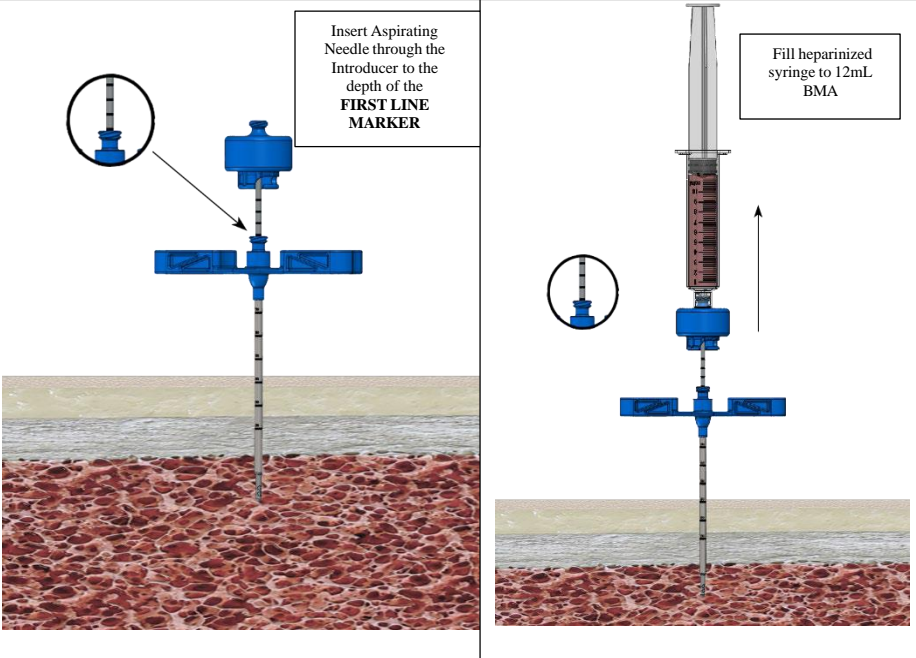


INSERT ASPIRATING NEEDLE

Insert Aspirating Needle through the Introducer to the depth of the FIRST LINE MARKER on the aspirating needle.

ASPIRATE 12mL HEPARINIZED BMA

Attach the 1st heparinized 12mL syringe to the aspirating needle and draw 11mL of bone marrow aspirate, filling to 12mL, while rotating the needle in 90-degree increments.

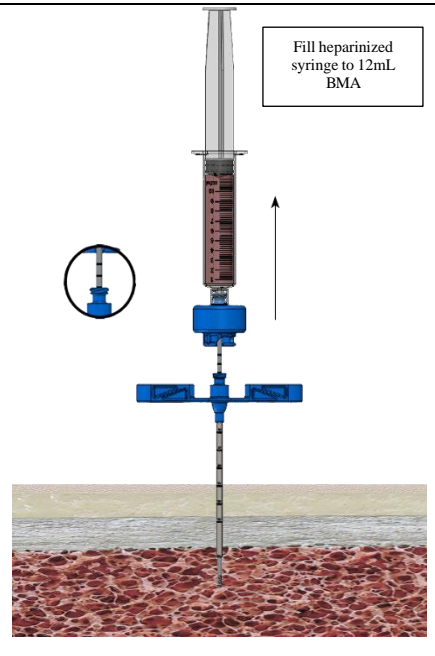
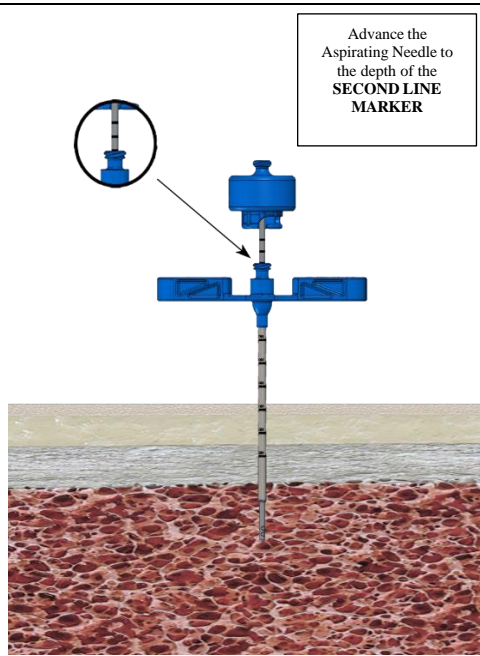
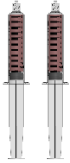


ADVANCE ASPIRATING NEEDLE

Advance the Aspirating Needle to the depth of the **SECOND LINE MARKER**

ASPIRATE 12mL HEPARINIZED BMA

Attach the 2nd heparinized 12mL syringe to the aspirating needle and draw 11 mL of bone marrow aspirate, filling to 12mL, while rotating the needle in 90-degree increments.

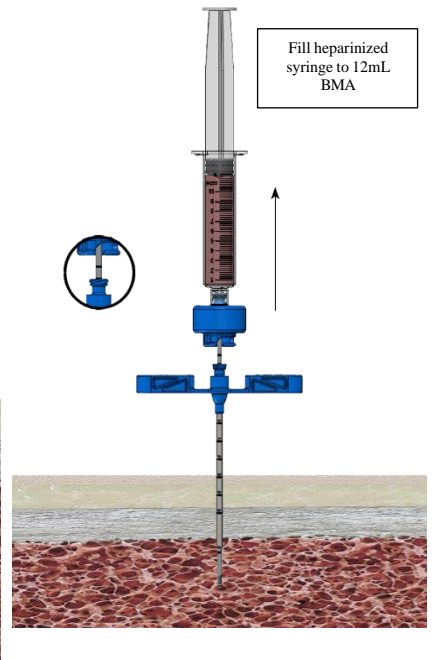
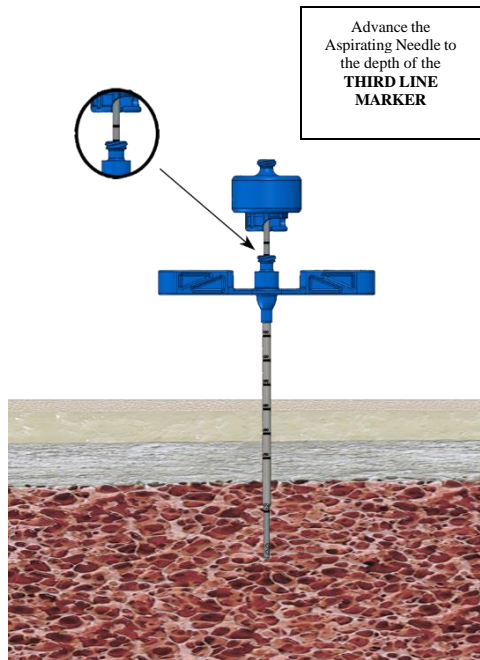
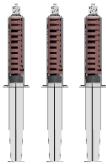


ADVANCE ASPIRATING NEEDLE

Advance the Aspirating Needle to the depth of the **THIRD LINE MARKER**

ASPIRATE 12mL HEPARINIZED BMA

Attach the 3rd heparinized 12mL syringe to the aspirating needle and draw 11 mL of bone marrow aspirate, filling to 12mL, while rotating the needle in 90-degree increments.



ADVANCE ASPIRATING NEEDLE

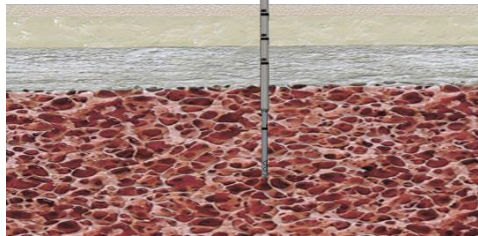
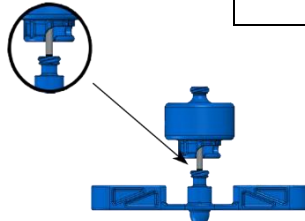
Advance the Aspirating Needle to the depth of the FORTH LINE MARKER

ASPIRATE 12mL HEPARINIZED BMA

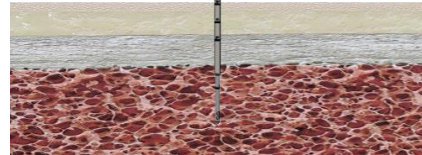
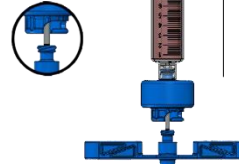
Attach the 4th heparinized 12mL syringe to the aspirating needle and draw 11mL of bone marrow aspirate, filling to 12mL, while rotating the needle in 90-degree increments.



Advance the Aspirating Needle to the depth of the **FORTH LINE MARKER**



Fill heparinized syringe to 12mL BMA

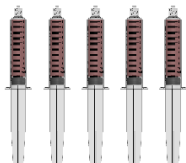


ADVANCE ASPIRATING NEEDLE

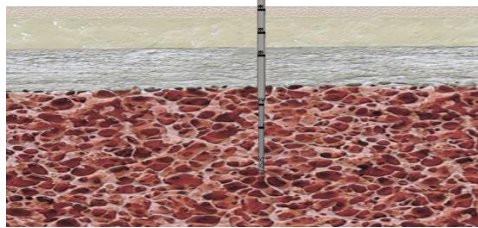
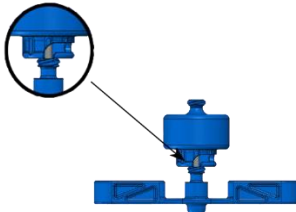
Advance the Aspirating Needle to the depth of the LOCK RIM

ASPIRATE 12mL HEPARINIZED BMA

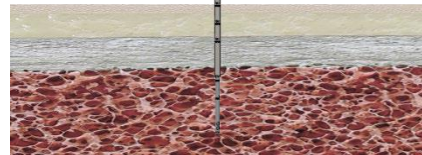
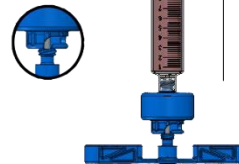
Attach 5th 12mL syringe to the aspirating needle and draw 11mL of bone marrow aspirate, filling to 12mL, while rotating the needle in 90-degree increments.



Advance the Aspirating Needle to the depth of the **LOCK RIM**



Fill heparinized syringe to 12mL BMA



60mL Bone Marrow Aspirate