

PureBMC® SupraPhysiologic Concentrating System

GenesisCS Component Concentrating System

Date: August 2023

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 PureBMC® Supraphysiologic Concentrating System is manufactured by EmCyte Corporation. The kit prepares platelet poor plasma and platelet concentrate from a small sample of blood and a cell concentrate from bone marrow at the point of care. The system contains syringes, a bone marrow needle accessory and the concentrating device accessories.

MATERIALS

2. The materials used are syringes, needles, tubing, connectors, and concentrating devices. The materials 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.

INDICATIONS FOR USE STATEMENTS

3. The PureBMC® SupraPhysiologic Concentrating System is intended to be used in a clinical laboratory or intraoperatively at the point of care for the safe and rapid preparation of platelet poor plasma and platelet concentrate from a small sample of blood and for a preparation of a cell concentrate from bone marrow. The safety and effectiveness of this device for in vivo indications for use has not been established.
4. The safety and effectiveness of this device for in vivo indications for use, such as bone healing and hemostasis, have not been established.
5. The PRP and BMC prepared by this device has not been evaluated for any clinical indications.
6. The PRP and BMC prepared by this device is NOT indicated for delivery to the patient's circulatory system.

USER POPULATION

7. The intended user population is medical professionals who are licensed or certified in clinical practice. The operational context of the device requires users to be trained on aseptic technique and understand blood components. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.

DEVICE USE ENVIRONMENT

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

WARNING AND PRECAUTIONS

9. Use proper safety precautions to guard against needle sticks.
10. Follow manufacturer instructions when using centrifuge. Use only EmCyte provided general purpose centrifuge. Outcomes using centrifuges from other manufacturers are unknown.
11. When using the bone marrow aspiration needle, follow manufacturer's instruction for use.

12. Do not use sterile components of this system if package is opened or damaged.
13. Single use device. Do not reuse. Do not attempt to clean or re-sterilize this product.
14. Do not use after expiration date.
15. Use prepared BMC, PPP or PRP within 4 hours after drawing blood or bone marrow aspirate according to current AABB guidelines.
16. BMC prepared from bone marrow may contain higher levels of plasma free hemoglobin than PRP prepared whole blood.

POSSIBLE RISKS

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













POSSIBLE ADVERSE EFFECTS

19. Damage to blood vessels, hematoma, delayed wound healing and/or infection is associated with blood draw, bone marrow harvest and/or surgical procedure.
20. Temporary or permanent nerve damage that may result in pain or numbness is associated with blood draw, and/or surgical procedure.
21. Early or late postoperative infection is associated with surgical procedure.
22. Pain associated with site of bone marrow harvest.

STERILITY

23. The PureBMC® SupraPhysiologic Concentrating System kits are sterilized by ETO exposure. Do not use any component from an opened or damaged package. Do not resterilize. Discard if kit packaging is damaged or open.

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

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

INSTRUCTIONS FOR USE FOR 60mL SYSTEM

PROTOCOL:

24. NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.
25. BONE MARROW ASPIRATE DRAW: Attach the sterile filter needle onto the 60mL syringe. Draw 15mL of Heparin Anticoagulant (1000 units/mL) into the 60mL syringe.
26. Remove the filter needle from the syringe. Then prime the bone marrow aspirating cannula and introducer by injecting 5mL of heparin through it. Attach the heparin syringe to the OUT port of the bone marrow filter. Fill to prime and then aspirate the heparin back into the syringe.
27. Connect the female connector to the 60mL heparin syringe and inject 1mL of heparin each into five (5) 12mL syringes.
28. For each 12mL heparinized syringe, slowly draw 11mL of bone marrow aspirate (BMA) from the patient, filling each heparin syringe to 12mL.
29. Follow the bone marrow needle manufacturer's package insert to obtain bone marrow aspirate. Gently, but thoroughly mix the BMA and heparin upon collection to prevent coagulation.
30. FILTER: Connect an empty 60mL syringe to the OUT port of the bone marrow filter. Connect each bone marrow containing syringe to the IN port of the filter. Inject the BMA from each syringe through the filter into the 60mL syringe. After the last syringe is injected, clear the remaining bone marrow in the filter by aspirating it into the 60mL syringe.

CONCENTRATING PROTOCOL:

31. LOAD: Remove and discard the red vented caps from the top and bottom needle-less ports of the Concentrating Device. IMPORTANT: Then attach a sterile non-vented clear cap to the bottom port of the device. The clear cap MUST be always attached to the bottom port before centrifugation. Slowly add the filtered and anticoagulated BMA into the top port of the Concentrating Device.
32. BALANCE: Make sure the counterbalance device contains the same amount of volume as the Concentrating Device. Then place them directly opposite to each other in the centrifuge rotor buckets. Close the lid.
33. FIRST SPIN:
 - a. **Sapphire Series Centrifuge: PUREBMC 60 SPIN 1**
 - b. **Platinum Series Centrifuge: PUREBMC SPIN 1**
 - c. **Executive Series Centrifuge: 3.5 minutes 4400 RPM**
34. Press the start button. Once the centrifuge stops, remove the Concentrating Device.
35. FIRST EXTRACTION & TRANSFER: Attach the Aspirating Accessory to the top port. With the stopcock open to the 60mL syringe, slowly aspirate bone marrow plasma into the 60mL syringe. Then open the stopcock to the 3mL syringe and aspirate 2mL of bone marrow red blood cells. Remove clear cap from bottom port. Disconnect the syringes from the stopcock. Inject the 2mL BMA RBC through the bottom port. Then inject the BMA Plasma through the bottom port. Recap bottom port with sterile clear cap.
36. SECOND SPIN: Place Concentrating Device back into the centrifuge rotor bucket directly opposite the counterbalance device.
 - a. **Sapphire Series Centrifuge: PUREBMC 60 SPIN 2**
 - b. **Platinum Series Centrifuge: PUREBMC SPIN 2**
 - c. **Executive Series Centrifuge: 6 minutes 4400 RPM**
37. Close the centrifuge lid and press the start button. Once the centrifuge stops, remove the Concentrating Device.
38. SECOND EXTRACTION: Remove the clear cap from the bottom port. Using the 60mL syringe, aspirate plasma leaving 7mL of BMC in the device.
39. RESUSPEND THE BMC: Gently swirl the Concentrating Device to re-suspend the bone marrow concentrate (BMC) buffycoat into the plasma.
40. EXTRACT BMC: Attach a sterile 12mL syringe to the bottom port. Tilt and aspirate the BMC through the aspirating port. Remove sterile syringe and apply a sterile cap.

INSTRUCTIONS FOR USE FOR 30mL SYSTEM

PROTOCOL:

NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.

41. BONE MARROW ASPIRATE DRAW: Attach the sterile filter needle onto the 30mL syringe. Draw 15mL of Heparin Anticoagulant (1000 units/mL) into the 30mL syringe.
42. Remove the filter needle from the syringe. Then prime the bone marrow aspirating cannula and introducer by injecting 5mL of heparin through it.
43. Attach the heparin syringe to the OUT port of the bone marrow filter. Inject 5mL into the filter to prime and then aspirate the heparin back into the syringe.
44. Connect the female to female connector to the 30mL heparin syringe.
45. Inject 1mL of heparin each into three (3) 12mL syringes. For each 12mL heparinized syringe, slowly draw 9mL of bone marrow aspirate (BMA) from the patient, filling each heparin syringe to 12mL. Follow the bone marrow needle manufacturer's package insert to obtain bone marrow aspirate. Gently, but thoroughly mix the BMA and heparin upon collection to prevent coagulation.
46. FILTER: Connect an empty 30mL syringe to the OUT port of the bone marrow filter. Connect each bone marrow containing syringe to the IN port of the filter. Inject the BMA from each syringe through the filter into the 30mL syringe. After the last syringe is injected, clear the remaining bone marrow in the filter by aspirating it into the 30mL syringe.

CONCENTRATING PROTOCOL:

47. LOAD: Remove and discard the red vented caps from the top and bottom needle-less ports of the Concentrating Device. IMPORTANT: Then attach a sterile non-vented clear cap to the bottom port of the device. The clear cap MUST be always attached to the bottom port before centrifugation. Slowly add the filtered and anticoagulated BMA into the top port of the Concentrating Device.
48. BALANCE: Make sure the counterbalance device contains the same amount of volume as the Concentrating Device. Then place them directly opposite to each other in the centrifuge rotor buckets.
49. FIRST SPIN:
 - a. **Sapphire Series Centrifuge: PUREBMC 30 SPIN 1**
 - b. **Platinum Series Centrifuge: PUREBMC SPIN 1**
 - c. **Executive Series Centrifuge: 2.5 minutes 4400 RPM**
50. Press the start button. Once the centrifuge stops, remove the Concentrating Device.
51. FIRST EXTRACTION & TRANSFER: Attach the Aspirating Accessory to the top port. With the stopcock open to the 30mL syringe, slowly aspirate bone marrow plasma into the 30mL syringe. Then open the stopcock to the 3mL syringe and aspirate 1mL of bone marrow red blood cells. Remove clear cap from bottom port. Disconnect the syringes from the stopcock. Inject the 1mL BMA RBC through the bottom port. Then inject the BMA Plasma through the bottom port. Recap bottom port with sterile clear cap.
52. SECOND SPIN: Place Concentrating Device back into the centrifuge rotor bucket directly opposite the counterbalance device.
 - a. **Sapphire Series Centrifuge: PUREBMC 30 SPIN 2**
 - b. **Platinum Series Centrifuge: PUREBMC SPIN 2**
 - c. **Executive Series Centrifuge: 5 minutes 4400 RPM**
 - d. Close the centrifuge lid and press the start button. Once the centrifuge stops, remove the Concentrating Device
53. SECOND EXTRACTION: Using the 30mL syringe, remove the clear cap from the bottom port and aspirate plasma leaving 4mL of solution in the device.
54. RESUSPEND THE BMC: Gently swirl the Concentrating Device to re-suspend the bone marrow concentrate (BMC) buffycoat into the plasma.
55. EXTRACT BMC: Attach a sterile 12mL syringe to the bottom port. Tilt and aspirate the BMC through the aspirating port. Remove sterile syringe and apply a sterile cap.

INSTRUCTIONS FOR USE FOR 120mL SYSTEM

PREPARATION PROTOCOL:

NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.

56. **BONE MARROW ASPIRATE DRAW:** Attach the sterile filter needle onto the 60mL syringe. Draw 20mL of Heparin Anticoagulant (1000 units/mL) into the 60mL syringe.
57. Remove the filter needle from the syringe. Then prime the bone marrow aspirating cannula and introducer by injecting 5mL of heparin through it. Attach the heparin syringe to the OUT port of the bone marrow filter. Fill to prime and then aspirate the heparin back into the syringe.
58. Connect the female to female connector to the 60mL heparin syringe
59. Inject 3mL of heparin each into four (4) 30mL syringes.
60. For each 30mL heparinized syringe, slowly draw 27mL of bone marrow aspirate (BMA) from the patient, filling each heparin syringe to 30mL. Follow the bone marrow needle manufacturer's package insert to obtain bone marrow aspirate. Gently, but thoroughly mix the BMA and heparin upon collection to prevent coagulation.
61. **FILTER:** Connect an empty 60mL syringe to the OUT port of the bone marrow filter. Connect two (2) bone marrow syringes to the IN port of the filter. Inject 30mL of BMA from each bone marrow containing syringe through the filter into the 60mL syringe. After the second syringe is injected, clear the remaining bone marrow in the filter by aspirating it into the 60mL syringe. Repeat these steps for a second 60mL syringe.

CONCENTRATING PROTOCOL:


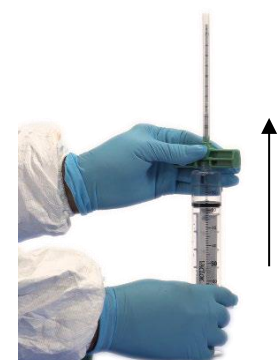
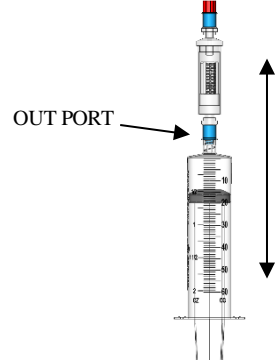
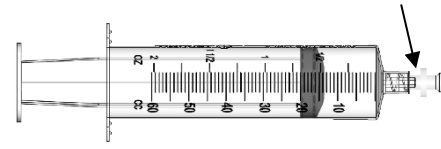
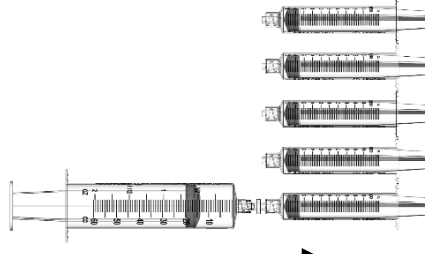
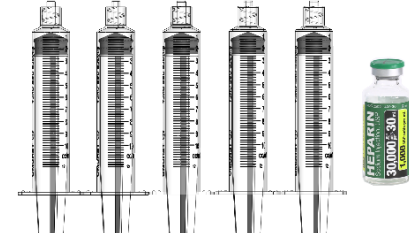
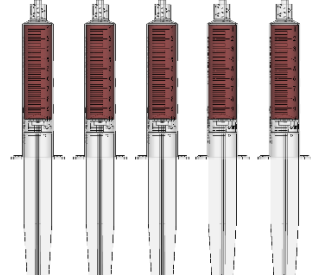
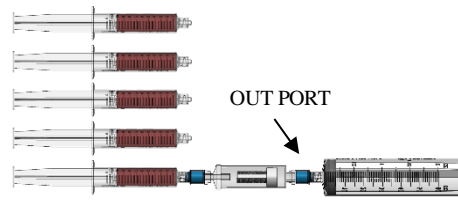

62. **LOAD:** For each Concentrating Device do the following steps. Remove and discard the red vented caps from the top and bottom needle-less ports of the Concentrating Device. **IMPORTANT:** Then attach a sterile non-vented clear cap to the bottom port of the device. The clear cap **MUST** be always attached to the bottom port before centrifugation. Slowly add 60mL of filtered and anticoagulated BMA into the top port of a Concentrating Device.
63. **BALANCE:** Make sure each Concentrating Device contains the same amount of volume. Then place them directly opposite to each other in the centrifuge rotor buckets.
64. **FIRST SPIN:**
 - a. **Sapphire Series Centrifuge: PUREBMC 60 SPIN 1**
 - b. **Platinum Series Centrifuge: PUREBMC SPIN 1**
 - c. **Executive Series Centrifuge: 3.5 minutes 4400 RPM**
65. Press the start button. Once the centrifuge stops, remove the Concentrating Devices.
66. **FIRST EXTRACTION & TRANSFER:** For each device, attach the Aspirating Accessory to the top port. With the stopcock open to the 60mL syringe, slowly aspirate bone marrow plasma into the 60mL syringe. Then open the stopcock to the 3mL syringe and aspirate 2mL of bone marrow red blood cells. Remove clear cap from bottom port. Disconnect the syringes from the stopcock. Inject the 2mL BMA RBC through the bottom port. Then inject the BMA Plasma through the bottom port. Recap bottom port with sterile clear cap.
67. **SECOND SPIN:** Place both Concentrating Devices back into the centrifuge rotor bucket directly opposite each other. Close the lid
 - a. **Sapphire Series Centrifuge: PUREBMC 60 SPIN 2**
 - b. **Platinum Series Centrifuge: PUREBMC SPIN 2**
 - c. **Executive Series Centrifuge: 6 minutes 4400 RPM**

64. **SECOND EXTRACTION:** For each Concentrating Device do the following steps. Using a 60mL syringe remove the clear cap from the bottom port and aspirate plasma leaving 7mL of solution in the device.
65. **RESUSPEND THE BMC:** Gently swirl each Concentrating Device to re-suspend the bone marrow concentrate (BMC) buffycoat into the plasma.
66. **EXTRACT BMC:** Attach a sterile 12mL syringe to the bottom port of each Concentrating Device and aspirate the BMC. Remove sterile syringe and apply a sterile cap

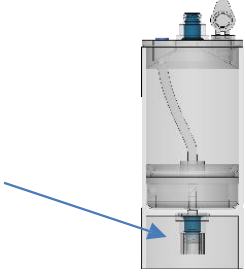

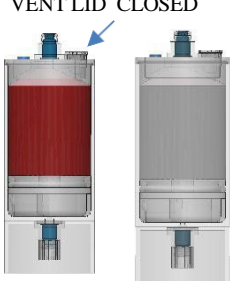

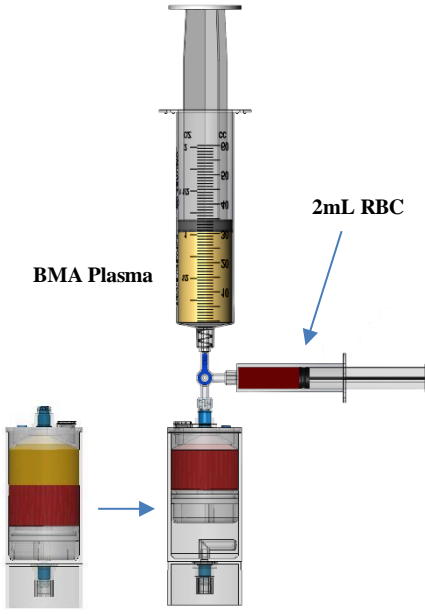
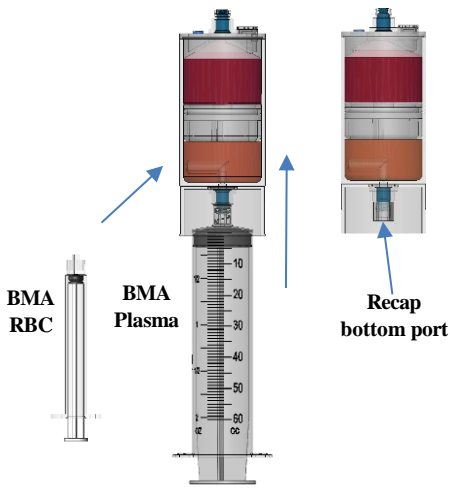


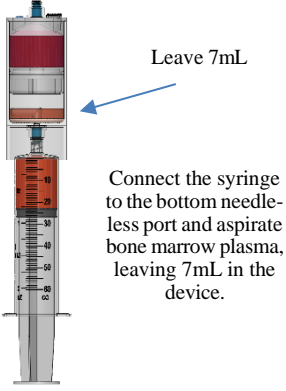
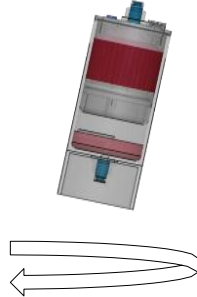
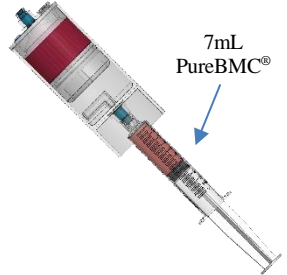
BC60-SP: IFU ILLUSTRATION

NOTICES: PLEASE DISCARD RED VENTED CAP FROM CONCENTRATING DEVICE BEFORE USE
ALWAYS SWAB SELF-SEALING PORT WITH STERILE ALCOHOL PRIOR TO ACCESSING WITH A STERILE SYRINGE
ALWAYS ADD CLEAR CAP TO THE BOTTOM PORT PRIOR TO CENTRIFUGATION

PROCESSING PROTOCOL:

<p>Step 1:</p>  <p>Attach the sterile filter needle onto the 60mL syringe. Draw 15mL of Heparin Anticoagulant (1000 units/mL) into the 60mL syringe</p>	<p>Step 2:</p>  <p>Remove the filter needle from the syringe. Then prime the bone marrow aspirating cannula by injecting 5mL of heparin through it.</p>	<p>Step 3:</p>  <p>Attach the heparin syringe to the OUT port of the bone marrow filter. Fill to prime and then aspirate the heparin back into the syringe.</p>
<p>Step 4:</p>  <p>Connect the Female-Female connector to the Heparin syringe.</p>	<p>Step 5:</p>  <p>Connect five (5) 12mL syringes to the other end of the Female-Female connector and inject 1mL of Heparin in each syringe.</p>	<p>Step 6:</p>  <p>Collect 11mL of bone marrow aspirate in each syringe filling each syringe to 12mL.</p>
<p>Step 7:</p>  <p>Collect 11mL of BMA in each syringe filling to 12mL. Collect a total of 60mL of BMA solution.</p>	<p>Step 8:</p>  <p>Connect the 60mL syringe to the OUT port of the BMA filter. Filter five (5) 12mL BMA syringes into the 60mL syringe.</p>	<p>Step 9:</p>  <p>The bone marrow aspirate is now properly anticoagulated and filtered, and prepared for processing.</p>

CONCENTRATING PROTOCOL 60mL:

<p>Step 1</p>  <p>Attach clear non vented cap to the bottom port.</p> <p>ALWAYS add clear cap to the bottom port prior to centrifugation</p>	<p>Step 2</p>  <p>VENT LID OPEN</p> <p>With VENT LID OPEN Inject anticoagulated filtered bone marrow aspirate through the top needleless port</p>	<p>Step 3</p> <p>VENT LID CLOSED</p>  <p>Close VENT LID and counterbalance device with equal volume</p>  <p>Place in the centrifuge rotor at opposite ends.</p>	<p>Step 4</p> <p>Sapphire Series Centrifuge Set to: PUREBMC 60 SPIN 1</p> <p>Platinum Series Centrifuge Set to: PUREBMC SPIN 1</p> <p>Executive Series Centrifuge Set to: 3.5 minutes / 4400 RPM</p>
<p>Step 5</p>  <p>BMA Plasma</p> <p>2mL RBC</p> <p>Connect the aspirating assembly syringes to the top port and aspirate the BMA plasma into the 60mL syringe. Then open the stopcock to the 3mL syringe and aspirate an additional 2mL of BMA RBC.</p>	<p>Step 6</p>  <p>BMA RBC</p> <p>BMA Plasma</p> <p>Recap bottom port</p> <p>Inject the 2mL BMA RBC through the bottom port. Then inject the BMA Plasma through the bottom port.</p> <p>Recap bottom port with sterile clear cap.</p>	<p>Step 7</p>  <p>Place back in centrifuge rotor</p> <p>Sapphire Series Centrifuge Set to: PUREBMC 60 SPIN 2</p> <p>Platinum Series Centrifuge Set to: PUREBMC SPIN 2</p> <p>Executive Series Centrifuge Set to: 6 minutes / 4400 RPM</p>	
<p>Step 8</p>  <p>Bone marrow buffy-coat at the bottom of the device</p> <p>After centrifugation the bone marrow buffy-coat will be separated at the bottom of the device</p>	<p>Step 9</p>  <p>Leave 7mL</p> <p>Connect the syringe to the bottom needleless port and aspirate bone marrow plasma, leaving 7mL in the device.</p>	<p>Step 10</p>  <p>Gently swirl to resuspend the bone marrow buffy-coat into the plasma</p>	<p>Step 11</p>  <p>7mL PureBMC®</p> <p>Connect the 12mL syringe and aspirate the remaining 7mL of PureBMC® supraphysiologic</p>

BC30-SP: IFU ILLUSTRATION



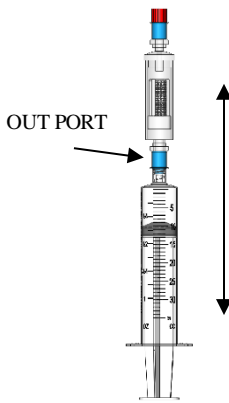
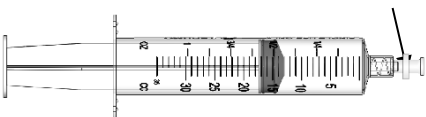
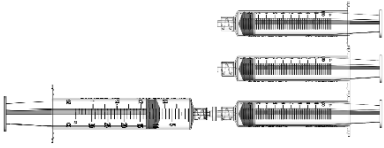
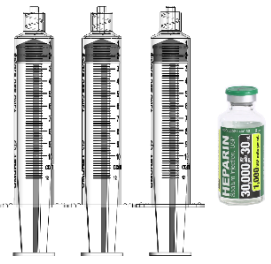
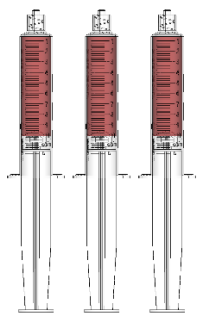
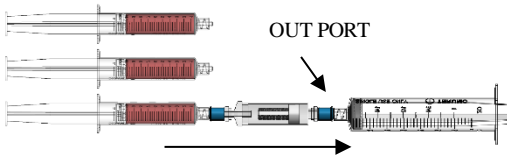
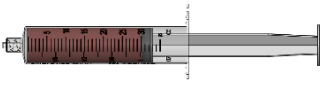
NOTICES:

PLEASE DISCARD RED VENTED CAP FROM CONCENTRATING DEVICE BEFORE USE

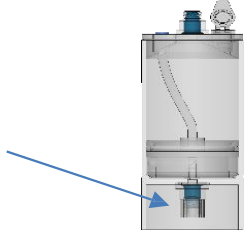

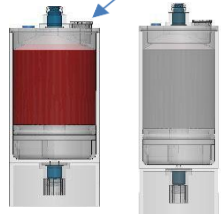

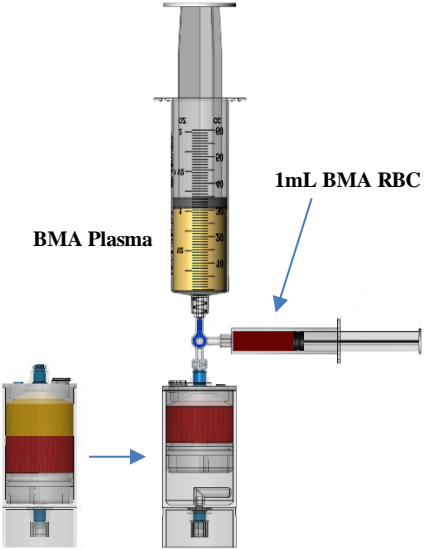
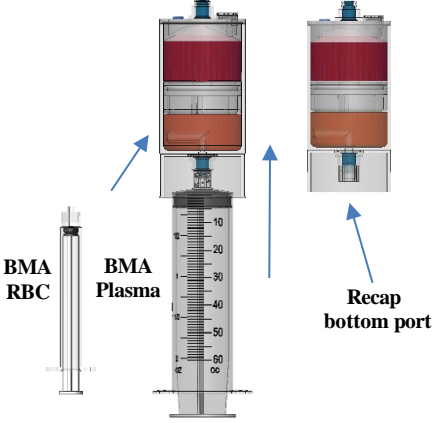




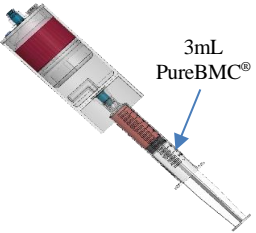
ALWAYS SWAB SELF-SEALING PORT WITH STERILE ALCOHOL PRIOR TO ACCESSING WITH A STERILE SYRINGE

ALWAYS ADD CLEAR CAP TO THE BOTTOM PORT PRIOR TO CENTRIFUGATION

PROCESSING PROTOCOL

<p>Step 1:</p>  <p>USE HEPARIN 1000 units/mL</p> <p>To begin priming, attach the sterile filter needle onto a 30mL syringe. Draw 15mL of Heparin Anticoagulant.</p>	<p>Step 2:</p>  <p>Remove the filter needle from the syringe. Then prime the bone marrow aspirating cannula by injecting 5mL of heparin through it.</p>	<p>Step 3:</p>  <p>Attach the heparin syringe to the OUT port of the bone marrow filter. Fill to prime and then aspirate the heparin back into the syringe.</p>
<p>Step 4:</p>  <p>Connect the Female-Female connector to the Heparin syringe.</p>	<p>Step 5:</p>  <p>Consecutively connect three (3) 12mL syringes to the other end of the Female-Female connector and inject 1mL of Heparin in each syringe.</p>	<p>Step 6:</p>  <p>Make sure that three (3) 12mL syringes have 1mL of Heparin in each prior to aspirating bone marrow.</p>
<p>Step 7:</p>  <p>Collect 9mL of BMA in each syringe filling each syringe to 10mL. Collect a total of 30mL of BMA solution.</p>	<p>Step 8:</p>  <p>Connect one (1) 30mL syringe to the OUT port of the BMA filter. Consecutively filter three (3) 12mL BMA syringes into the 30mL syringe.</p>	<p>Step 9:</p>  <p>30mL of bone marrow aspirate is now properly anticoagulated, filtered and ready for processing.</p>

CONCENTRATING PROTOCOL 30mL:

<p>Step 1</p>  <p>Attach clear non vented cap to the bottom port.</p> <p>ALWAYS add clear cap to the bottom port prior to centrifugation</p>	<p>Step 2</p>  <p>VENT LID OPEN</p> <p>With VENT LID OPEN Inject anticoagulated filtered bone marrow aspirate through the top needleless port</p>	<p>Step 3</p> <p>VENT LID CLOSED</p>  <p>Close VENT LID and counterbalance device with equal volume</p>  <p>Place in the centrifuge rotor at opposite ends.</p>	<p>Step 4</p> <p>Sapphire Series Centrifuge Set to: PUREBMC 30 SPIN 1</p> <p>Platinum Series Centrifuge Set to: PUREBMC SPIN 1</p> <p>Executive Series Centrifuge Set to: 2.5 minutes / 4400 RPM</p>
<p>Step 5</p>  <p>BMA Plasma</p> <p>1mL BMA RBC</p> <p>Connect the aspirating assembly syringes to the top port and aspirate the BMA plasma into the 30mL syringe. Then open the stopcock to the 3mL syringe and aspirate an additional 1mL of BMA RBC.</p>	<p>Step 6</p>  <p>BMA RBC</p> <p>BMA Plasma</p> <p>Recap bottom port</p> <p>Inject the 1mL BMA RBC through the bottom port. Then inject the BMA Plasma through the bottom port.</p> <p>Recap bottom port with sterile clear cap.</p>	<p>Step 7</p>  <p>Place back in centrifuge rotor</p> <p>Sapphire Series Centrifuge Set to: PUREBMC 30 SPIN 2</p> <p>Platinum Series Centrifuge Set to: PUREBMC SPIN 2</p> <p>Executive Series Centrifuge Set to: 5 minutes / 4400 RPM</p>	
<p>Step 8</p>  <p>Bone marrow buffy-coat at the bottom of the device</p> <p>After centrifugation the bone marrow buffy-coat will be separated at the bottom of the device</p>	<p>Step 9</p>  <p>Leave 3mL</p> <p>Connect the syringe to the bottom needleless port and aspirate bone marrow plasma, leaving 3mL in the device.</p>	<p>Step 10</p>  <p>Gently swirl to resuspend the bone marrow buffy-coat into the plasma</p>	<p>Step 11</p>  <p>3mL PureBMC®</p> <p>Connect the 12mL syringe and aspirate the remaining 3mL of PureBMC® Supraphysiologic</p>

BC120-SP: IFU ILLUSTRATION



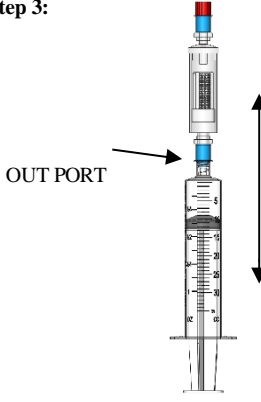
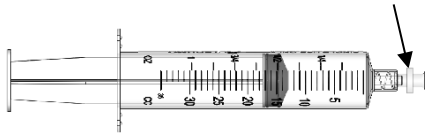
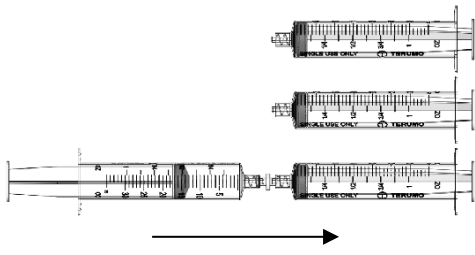
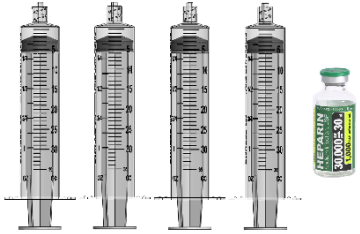
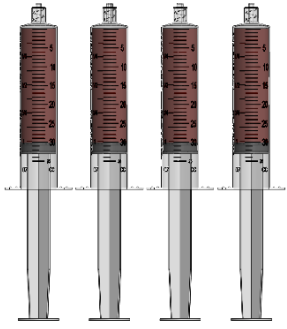
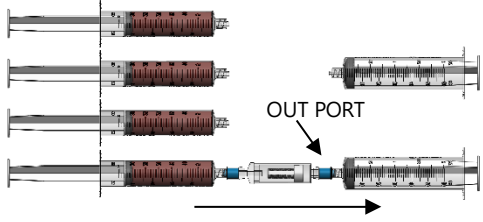
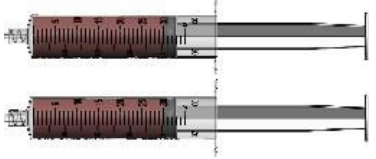
NOTICES:

PLEASE DISCARD RED VENTED CAP FROM CONCENTRATING DEVICE BEFORE USE

ALWAYS SWAB SELF-SEALING PORT WITH STERILE ALCOHOL PRIOR TO ACCESSING WITH A STERILE SYRINGE

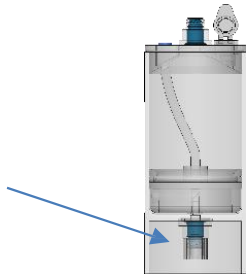
ALWAYS ADD CLEAR CAP TO THE BOTTOM PORT PRIOR TO CENTRIFUGATION

PROCESSING PROTOCOL:

<p>Step 1:</p>  <p>USE HEPARIN 1000 units/mL</p> <p>To begin priming, attach the sterile filter needle onto a 30mL syringe. Draw 20mL of Heparin Anticoagulant.</p>	<p>Step 2:</p>  <p>Remove the filter needle from the syringe. Then prime the bone marrow aspirating cannula by injecting 5mL of Heparin through it. Leave approximately 15mL of Heparin in the syringe.</p>	<p>Step 3:</p>  <p>Attach the Heparin syringe to the OUT port of the bone marrow filter. Fill to prime and then aspirate the Heparin back into the syringe. Leave approximately 15mL in syringe.</p>
<p>Step 4:</p>  <p>Connect the Female-Female connector to the Heparin syringe.</p>	<p>Step 5:</p>  <p>Consecutively connect three (3) 30mL syringes to the other end of the Female-Female connector and inject 3mL of Heparin in each syringe.</p>	<p>Step 6:</p>  <p>Make sure that four (4) 30mL syringes have 3mL of Heparin in each prior to aspirating bone marrow.</p>
<p>Step 7:</p>  <p>Collect 27mL of BMA in each syringe filling to 30mL. Collect a total of 120mL of BMA solution.</p>	<p>Step 8:</p>  <p>Consecutively connect two (2) 60mL syringes to the OUT port of the BMA filter. Filter two (2) 30mL BMA syringes into each 60mL syringe.</p>	<p>Step 9:</p>  <p>120mL of bone marrow aspirate is now properly anticoagulated, filtered and ready for processing.</p>

CONCENTRATING PROTOCOL 120mL

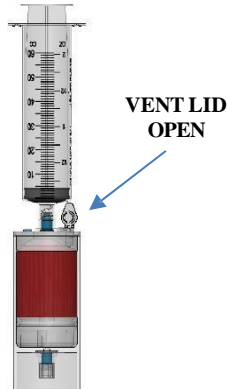
Step 1: DO FOR EACH DEVICE



Attach clear non vented cap to the bottom port.

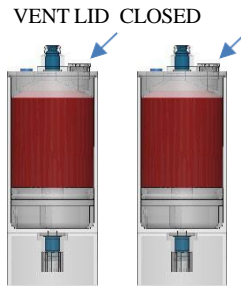
ALWAYS add clear cap to the bottom port prior to centrifugation

Step 2: DO FOR EACH DEVICE



With **VENT LID OPEN** Inject anticoagulated filtered bone marrow aspirate through the top needleless port

Step 3



Close **VENT LID** and counterbalance device with equal volume



Place in the centrifuge rotor at opposite ends.

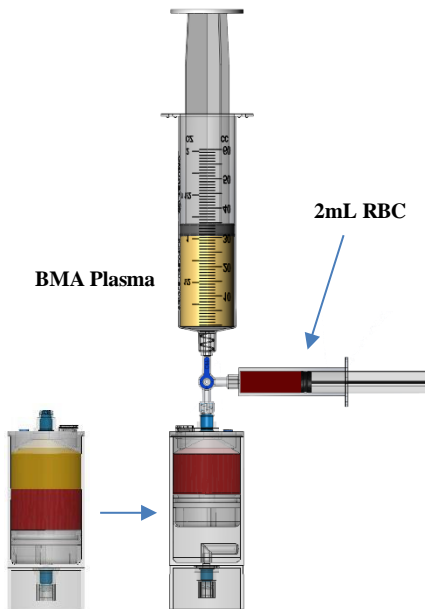
Step 4

Sapphire Series Centrifuge
Set to:
PUREBMC 60 SPIN 1

Platinum Series Centrifuge
Set to:
PUREBMC SPIN 1

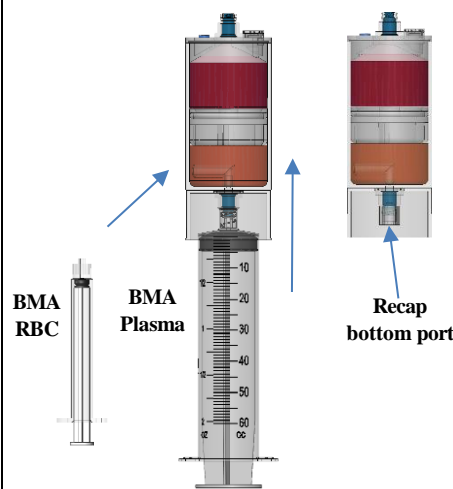
Executive Series Centrifuge
Set to:
3.5 minutes / 4400 RPM

Step 5: DO FOR EACH DEVICE



Connect the aspirating assembly syringes to the top port and aspirate the BMA plasma into the 60mL syringe. Then open the stopcock to the 3mL syringe and aspirate an additional 2mL of BMA RBC.

Step 6: DO FOR EACH DEVICE



Inject the 2mL BMA RBC through the bottom port. Then inject the BMA Plasma through the bottom port.

Recap bottom port with sterile clear cap.

Step 7



Place back in centrifuge rotor

Sapphire Series Centrifuge
Set to:
PUREBMC 60 SPIN 2

Platinum Series Centrifuge
Set to:
PUREBMC SPIN 2

Executive Series Centrifuge
Set to:
6 minutes / 4400 RPM

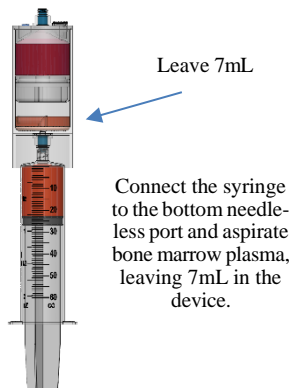
Step 8: DO FOR EACH DEVICE

Bone marrow buffy-coat at the bottom of the device



After centrifugation the bone marrow buffy-coat will be separated at the bottom of the device

Step 9: DO FOR EACH DEVICE



Leave 7mL

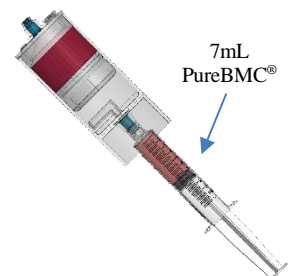
Connect the syringe to the bottom needleless port and aspirate bone marrow plasma, leaving 7mL in the device.

Step 10: DO FOR EACH DEVICE



Gently swirl to resuspend the bone marrow buffy-coat into the plasma

Step 11: DO FOR EACH DEVICE



Connect the 12mL syringe and aspirate the remaining 7mL of PureBMC[®] supraphysiologic

