

PUREBMC® TWO
GenesisCS Component Concentrating System
Bone Marrow Concentrating System
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® GenesisCS Component 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 GenesisCS Component 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.
16. BMC prepared from bone marrow may contain higher levels of plasma free hemoglobin than PRP prepared from 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® GenesisCS Component 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.

INSTRUCTIONS FOR USE FOR 60mL SYSTEM

PREPARATION PROTOCOL

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

24. **BONE MARROW ASPIRATE DRAW:**
Attach the sterile filter needle onto the 60mL VACLOK syringe. Draw 15mL of (1000 units/mL) into the 60mL syringe. Remove the filter needle from the syringe. Then prime the bone marrow aspirating cannula by injecting 5mL of heparin through it. 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. Then discard heparin leaving 5mL in the VACLOK syringe. Slowly draw 55mL of bone marrow aspirate (BMA) from the patient, filling the syringe to 60mL. 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.
25. **FILTER:** Connect a 60mL syringe to the OUT port of the bone marrow filter. Connect the VACLOK bone marrow syringe to the IN port of the filter. Inject the BMA through the filter into the 60mL syringe. Once completed, clear the remaining bone marrow in the filter by aspirating it into the 60mL syringe.

CONCENTRATING PROTOCOL

26. **LOAD:** Remove and discard the red vented cap from the needle-less port of the Separator Device. Slowly add the filtered and anticoagulated BMA through the port of the Separator Device.
27. **BALANCE:** Make sure the counterbalance device contains the same amount of volume as the Separator Device. Then place them directly opposite to each other in the centrifuge rotor buckets.
28. **FIRST SPIN:**
 - a. Sapphire Series Centrifuge: Close the lid and set to PUREBMC 60 SPIN 1.
 - b. Platinum Series Centrifuge: Close the lid and set to PUREBMC SP SPIN 1.
 - c. Executive Series Centrifuge: Close the lid and set to 3.5 minutes and 4.4 x 1000 RPM (4400 RPM).
 - d. Press the start button. Once the centrifuge stops, remove the **Separator Device**.
29. **FIRST EXTRACTION & TRANSFER:** Attach aspirating accessory to the needle-less port of the Separator Device. Slowly aspirate bone marrow plasma suspension (**BMPS**) into the 60mL syringe. Then open stopcock to 3mL syringe and aspirate 2mL of bone marrow red blood cells (**BMRBC**). Then attach each syringe to the bottom needle-less port of the Concentrator Device. Inject the 2mL of BMRBC and then the BMPS into the Concentrator. **Then PLACE THE CLEAR CAP ON THE BOTTOM PORT!**
30. **BALANCE:** Counterbalance the Concentrator Device, counterbalance with equal volume. Then place them directly opposite to each other in the centrifuge rotor buckets.
31. **SECOND SPIN:**
 - a. Sapphire Series Centrifuge: Close the lid and set to PUREBMC 60 SPIN 2.
 - b. Platinum Series Centrifuge: Close the lid and set to PUREBMC SP SPIN 2.
 - c. Executive Series Centrifuge: Close the lid and set to 6 minutes and 4.4 x 1000 RPM (4400 RPM).
 - d. Press the start button. Once the centrifuge stops, remove the **Separator Device**.

32. SECOND EXTRACTION: Using the 60mL syringe aspirate the plasma leaving 7mL of solution in the Concentrator Device.
33. RESUSPEND THE BMC: Gently swirl the Concentrator Device to re-suspend the bone marrow concentrate (BMC) buffycoat into the plasma.
34. EXTRACT BMC: Attach a sterile 12mL syringe to the Concentrator Device port and aspirate the BMC. Remove sterile syringe and apply a sterile cap.

INSTRUCTIONS FOR USE FOR 30mL SYSTEM
PREPARATION PROTOCOL

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

35. BONE MARROW ASPIRATE DRAW:
Attach the sterile filter needle onto the 30mL VACLOK syringe. Draw 15mL of Heparin Anticoagulant (1000 units/mL) into the 30mL syringe. Remove the filter needle from the syringe. Then prime the bone marrow aspirating cannula by injecting 5mL of heparin through it. 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. Then discard heparin leaving 3mL in the VACLOK syringe. Slowly draw 27mL of bone marrow aspirate (BMA) from the patient, filling the 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.
36. FILTER: Connect a 30mL syringe to the OUT port of the bone marrow filter. Connect the VACLOK bone marrow syringe to the IN port of the filter. Inject the BMA through the filter into the 30mL syringe. Once completed, clear the remaining bone marrow in the filter by aspirating it into the 30mL syringe.

CONCENTRATING PROTOCOL

37. LOAD: Remove and discard the red vented cap from the needle-less port of the Separator Device. Slowly add the filtered and anticoagulated BMA through the port of the Separator Device.
38. BALANCE: Make sure the counterbalance device contains the same amount of volume as the Separator Device. Then place them directly opposite to each other in the centrifuge rotor buckets.
39. FIRST SPIN:
 - a. Sapphire Series Centrifuge: Close the lid and set to PUREBMC 30 SPIN 1.
 - b. Platinum Series Centrifuge: Close the lid and set to PUREBMC SP SPIN 1.
 - c. Executive Series Centrifuge: Close the lid and set to 2.5 minutes and 4.4 x 1000 RPM (4400 RPM).
 - d. Press the start button. Once the centrifuge stops, remove the **Separator Device**.
40. FIRST EXTRACTION & TRANSFER: Attach aspirating accessory to the needle-less port of the Separator Device. Slowly aspirate bone marrow plasma suspension (BMPS) into the 30mL syringe. Then open stopcock to 3mL syringe and aspirate 1mL of bone marrow red blood cells (BMRBC). Then attach each syringe to the bottom needle-less port of the Concentrator Device. Inject the 1mL of BMRBC and then the BMPS into the Concentrator. **Then PLACE THE CLEAR CAP ON THE BOTTOM PORT!**
41. BALANCE: Counterbalance the Concentrator Device, counterbalance with equal volume. Then place them directly opposite to each other in the centrifuge rotor buckets.
42. SECOND SPIN:
 - a. Sapphire Series Centrifuge: Close the lid and set to PUREBMC 30 SPIN 2.
 - b. Platinum Series Centrifuge: Close the lid and set to PUREBMC SP SPIN 2.
 - c. Executive Series Centrifuge: Close the lid and set to 5 minutes and 4.4 x 1000 RPM (4400 RPM).
 - d. Press the start button. Once the centrifuge stops, remove the **Separator Device**.
43. SECOND EXTRACTION: Using the 30mL syringe aspirate plasma leaving 3-4mL of solution in the Concentrator Device.
44. RESUSPEND THE BMC: Gently swirl the Concentrator Device to re-suspend the bone marrow concentrate (BMC) buffycoat into the plasma.
45. EXTRACT BMC: Attach a sterile 12mL syringe to the Concentrator Device port and aspirate the BMC. Remove sterile syringe and apply a sterile cap.

INSTRUCTIONS FOR USE FOR 120mL SYSTEM
PREPARATION PROTOCOL













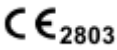

NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.

46. BONE MARROW ASPIRATE DRAW:
Attach the sterile filter needle onto the 60mL VACLOK syringe. Draw 15mL of Heparin Anticoagulant (1000 units/mL) into the 60mL syringe. Remove the filter needle from the syringe. Then prime the bone marrow aspirating cannula by injecting 5mL of heparin through it. 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. Then discard heparin leaving 5mL in the VACLOK syringe. Then attach the sterile filter needle onto the second VACLOK syringe and draw 5mL of Heparin Anticoagulant (1000 units/mL) into it. For each VACLOK syringe, slowly draw 55mL of bone marrow aspirate (BMA) from the patient, filling each syringe to 60mL. 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.
47. FILTER: For each VACLOK syringe do the following steps. Connect a 60mL syringe to the OUT port of the bone marrow filter. Connect the VACLOK bone marrow syringe to the IN port of the filter. Inject the BMA through the filter into the 60mL syringe. Once completed, clear the remaining bone marrow in the filter by aspirating it into the 60mL syringe.

CONCENTRATING PROTOCOL

48. FOR EACH CONCENTRATING DEVICE DO THE FOLLOWING:
49. LOAD: Remove and discard the red vented cap from the needle-less port of each Separator Device. Slowly add the filtered and anticoagulated BMA through the port of each Separator Device.
50. BALANCE: Make sure each Separator Device has equal volume. Then place them directly opposite to each other in the centrifuge rotor buckets.
51. FIRST SPIN:
 - a. Sapphire Series Centrifuge: Close the lid and set to PUREBMC 60 SPIN 1.
 - b. Platinum Series Centrifuge: Close the lid and set to PUREBMC SP SPIN 1.
 - c. Executive Series Centrifuge: Close the lid and set to 3.5 minutes and 4.4 x 1000 RPM (4400 RPM).
 - d. Press the start button. Once the centrifuge stops, remove the **Separator Device**.
52. FIRST EXTRACTION & TRANSFER: For each device, attach aspirating accessory to the needle-less port of the Separator Device. Slowly aspirate bone marrow plasma suspension (BMPS) into the 60mL syringe. Then open stopcock to 3mL syringe and aspirate 2mL of bone marrow red blood cells (BMRBC). Then attach each syringe to the bottom needle-less port of the Concentrator Device. Inject all of the BMRBC and BMPS into the single Concentrator Device. **Then PLACE THE CLEAR CAP ON THE BOTTOM PORT!**
53. BALANCE: Counterbalance the Concentrator Device, with equal volume. Then place them directly opposite to each other in the centrifuge rotor buckets.
54. SECOND SPIN:
 - a. Sapphire Series Centrifuge: Close the lid and set to PUREBMC 60 SPIN 2.
 - b. Platinum Series Centrifuge: Close the lid and set to PUREBMC SP SPIN 2.
 - c. Executive Series Centrifuge: Close the lid and set to 6 minutes and 4.4 x 1000 RPM (4400 RPM).
 - d. Press the start button. Once the centrifuge stops, remove the **Concentrator Device**.
55. SECOND EXTRACTION: Using the 60mL syringe aspirate plasma leaving 14mL or the desired amount of solution in the Concentrator Device.
56. RESUSPEND THE BMC: Gently swirl the Concentrator Device to re-suspend the bone marrow concentrate (BMC) buffycoat into the plasma.
57. EXTRACT BMC: Attach a sterile 20mL syringe to the Concentrator Device port and aspirate the BMC. Remove sterile syringe and apply a sterile cap.


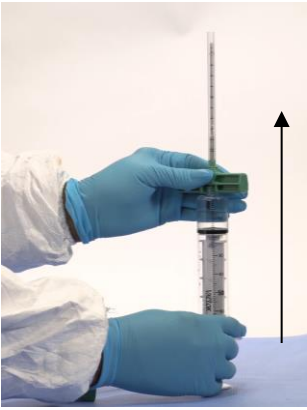



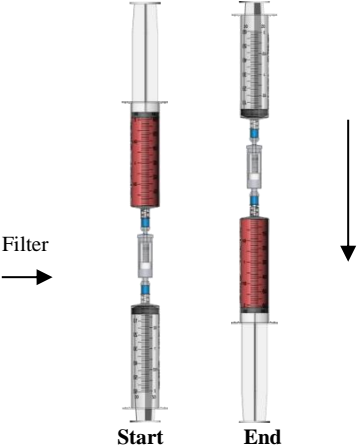
Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

 Do not use if package is damaged	 Single use only	 Store in a dry place
	 Do not re-sterilize	 Attention, read instruction for use
 Consult instruction for use	 Rx Only Prescription Use	 EmCyte Corporation 4331 Veronica S. Shoemaker Blvd. Fort Myers, FL 33916 Phone: 239-481-7725
 Store in a cool place	Australian Sponsor Emergo Australia Level 20 Tower II, Darling Park 201 Sussex Street Sydney, NSW 2000, Australia	 Authorized Representative Emergo Europe Westenvoortsedijk 60 6827 AT Arnhem The Netherlands
 Non-pyrogenic		 Medical Device

BC60-PURE: IFU ILLUSTRATION

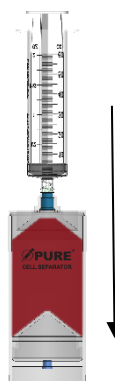
**NOTICES: PLEASE DISCARD RED VENTED CAP FROM CONCENTRATING DEVICE BEFORE USE.
ALWAYS SWAB SELF-SEALING PORT WITH STERILE ALCOHOL PRIOR TO ACCESSING WITH A STERILE SYRINGE.**

PREPARATION PROTOCOL

<p>STEP 1:</p>  <p>Attach the sterile filter needle onto the VACLOK 60mL syringe. Then draw 15mL of Heparin Anticoagulant (1000 units/mL)</p>	<p>STEP 2:</p>  <p>Then prime the bone marrow aspirating cannula by injecting 5mL of heparin through it</p>	<p>STEP 3:</p>  <p>Attach to the OUT port of the bone marrow filter. Fill to prime and then aspirate back into the syringe</p>	<p>STEP 4:</p>  <p>Then discard the residual heparin leaving 5mL in the VACLOK syringe</p>
<p>STEP 5:</p>  <p>Slowly draw 55mL of bone marrow aspirate, filling the syringe to 60mL. Mix the BMA and heparin upon collection to prevent coagulation.</p>	<p>STEP 6:</p>  <p>Connect a 60mL syringe to the OUT port of the bone marrow filter. Connect the VACLOK bone marrow syringe to the IN port of the filter. Inject the BMA through the filter into the 60mL syringe.</p>		

CONCENTRATING PROTOCOL

Step 1:



Load anticoagulated bone marrow aspirate into the **Separator Device**

Step 2:

Counterbalance with equal volume and place at opposite ends in the centrifuge rotor.

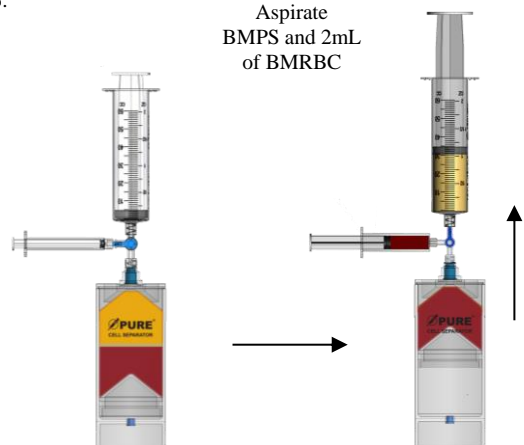
Sapphire Series Centrifuge:
Set to **PUREBMC 60 SPIN 1**

Platinum Series Centrifuge:
Set to **PUREBMC SP SPIN 1**

Executive Series Centrifuge
Set to **3.5 minutes and 4400 RPM**

Step 3:

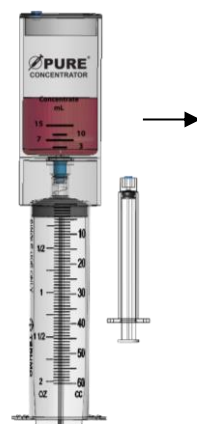
Aspirate
BMPS and 2mL
of BMRBC



Slowly aspirate bone marrow plasma suspension (**BMPS**) into the 60mL syringe. Then open the stopcock to the 3mL syringe and aspirate 2mL of bone marrow red blood cells (**BMRBC**).

Step 4:

Inject
BMPS and 2mL
of BMRBC




**IMPORTANT!!
PLACE CLEAR
CAP ON
BOTTOM PORT**

Transfer the BMPS and 2mL BMRBC into the **Concentrator Device** through the bottom port. Inject the 2mL BMRBC first then the BMPS

**PLACE CLEAR CAP ON BOTTOM PORT
PRIOR TO CENTRIFUGATION!!!**

Step 5:



**IMPORTANT!! MAKE SURE
CLEAR CAP IS PLACED ON
BOTTOM PORT PRIOR TO
CENTRIFUGATION!!!**


Counterbalance with equal volume then place directly opposite to each other in the centrifuge rotor buckets.

Sapphire Series Centrifuge:
Set to **PUREBMC 60 SPIN 2**

Platinum Series Centrifuge:
Set to **PUREBMC SP SPIN 2**

Executive Series Centrifuge
Set to **6 minutes and 4400**

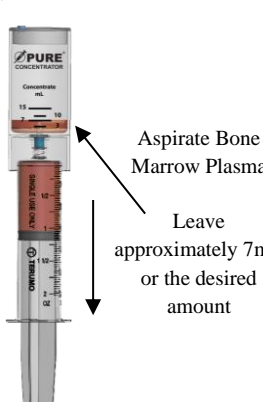
Step 6:



**Bone Marrow
Cell Concentrate**

After centrifugation
The bone marrow cell concentrate separates out at the bottom of the **Concentrator Device**

Step 7:

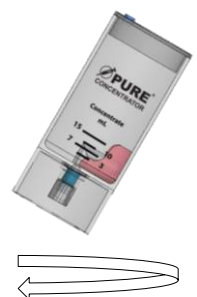


Aspirate Bone Marrow Plasma

Leave approximately 7mL or the desired amount

Attach 60mL syringe to bottom port. Aspirate bone marrow plasma from the **Concentrator Device**. Leave 7mL or the desired amount.

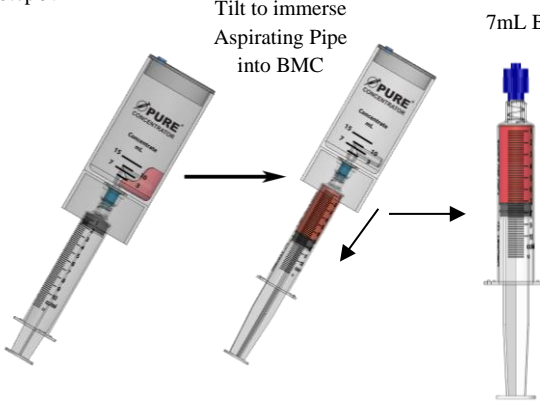
Step 8:



Gently swirl to resuspend the bone marrow cell concentrate into the plasma.

Step 9:

Tilt to immerse Aspirating Pipe into BMC





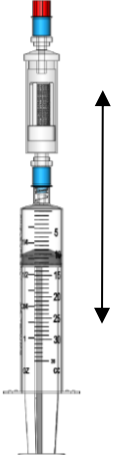

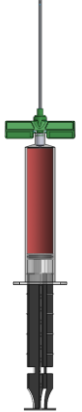
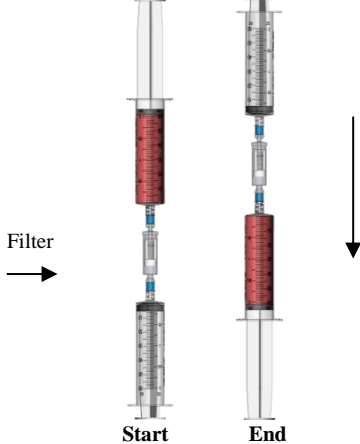
7mL BMC

Tilt to immerse the aspirating pipe into the bone marrow concentrate. Then attach the 12mL syringe to bottom port and aspirate the BMC.

BC30-PURE: 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.**

PREPARATION 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>Then prime the bone marrow aspirating cannula by injecting 5mL of heparin through it</p>	<p>STEP 3:</p>  <p>Attach to the OUT port of the bone marrow filter. Fill to prime and then aspirate back into the syringe</p>	<p>STEP 4:</p>  <p>Then discard the residual heparin leaving 3mL in the VACLOK syringe</p>
<p>STEP 5:</p>  <p>Slowly draw 27mL of bone marrow aspirate, filling the syringe to 30mL. Mix the BMA and heparin upon collection to prevent coagulation.</p>	<p>STEP 6:</p>  <p>Connect a 30mL syringe to the OUT port of the bone marrow filter. Connect the VACLOK bone marrow syringe to the IN port of the filter. Inject the BMA through the filter into the 30mL syringe.</p>		

CONCENTRATING PROTOCOL

Step 1:



Load anticoagulated bone marrow aspirate into the **Separator Device**

Step 2:

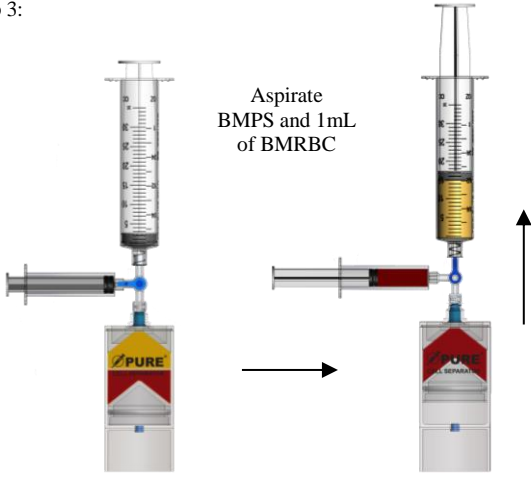
Counterbalance with equal volume and place at opposite ends in the centrifuge rotor.

Sapphire Series Centrifuge:
Set to **PUREBMC 30 SPIN 1**

Platinum Series Centrifuge:
Set to **PUREBMC SP SPIN 1**

Executive Series Centrifuge
Set to **2.5 minutes and 4400 RPM**

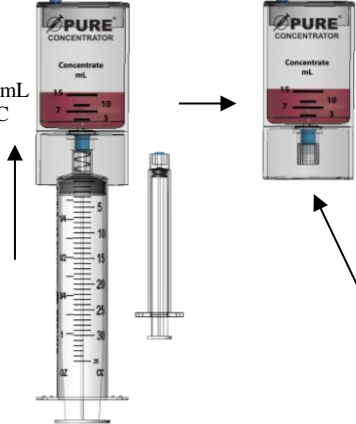
Step 3:



Aspirate **BMPS** and 1mL of **BMRBC**

Slowly aspirate bone marrow plasma suspension (**BMPS**) into the 30mL syringe. Then open the stopcock to the 3mL syringe and aspirate 1mL of bone marrow red blood cells (**BMRBC**).

Step 4:



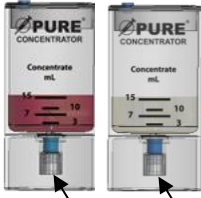
Inject **BMPS** and 1mL of **BMRBC**

IMPORTANT!!
PLACE CLEAR CAP ON BOTTOM PORT

Transfer the **BMPS** and 1mL **BMRBC** into the **Concentrator Device** through the bottom port. Inject the 1mL **BMRBC** first then the **BMPS**

PLACE CLEAR CAP ON BOTTOM PORT PRIOR TO CENTRIFUGATION!!!

Step 5:



IMPORTANT!! MAKE SURE CLEAR CAP IS PLACED ON BOTTOM PORT PRIOR TO CENTRIFUGATION!!!


Counterbalance with equal volume then place directly opposite to each other in the centrifuge rotor buckets.

Sapphire Series Centrifuge:
Set to **PUREBMC 30 SPIN 2**

Platinum Series Centrifuge:
Set to **PUREBMC SP SPIN 2**

Executive Series Centrifuge
Set to **5 minutes and 4400**

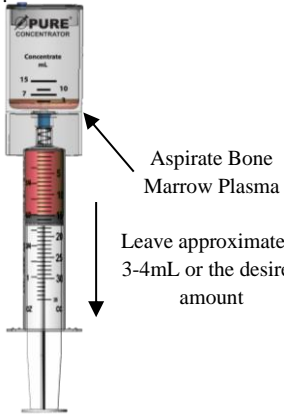
Step 6:



Bone Marrow Cell Concentrate

After centrifugation
The bone marrow cell concentrate separates out at the bottom of the **Concentrator Device**

Step 7:




Aspirate Bone Marrow Plasma

Leave approximately 3-4mL or the desired amount

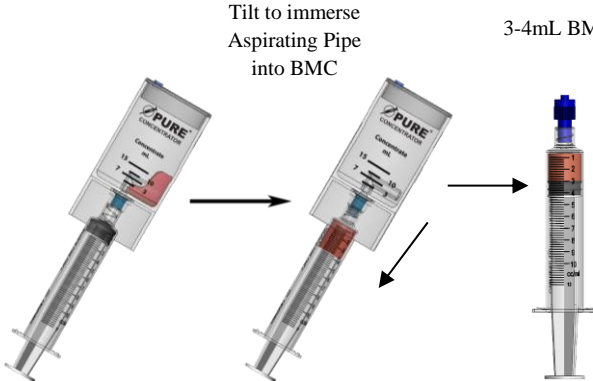
Attach 30mL syringe to bottom port. Aspirate bone marrow plasma from the **Concentrator Device**. Leave 3-4mL or the desired amount.

Step 8:



Attach the 12mL syringe to bottom port and gently swirl to resuspend the bone marrow cell concentrate into the plasma.

Step 9:



Tilt to immerse Aspirating Pipe into **BMC**

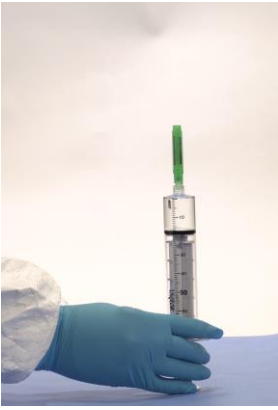
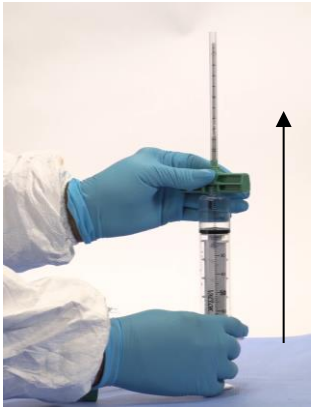


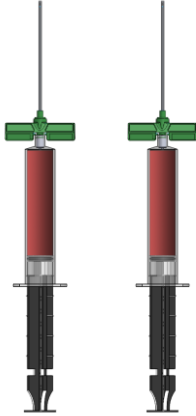
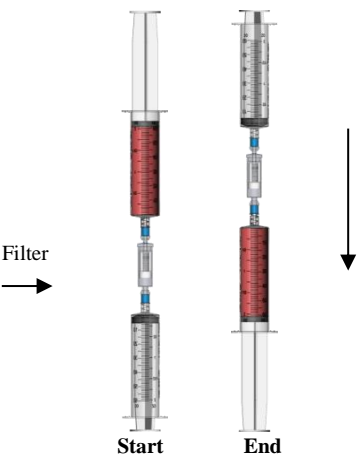
3-4mL **BMC**

Tilt to immerse the aspirating pipe into the bone marrow concentrate. Then attach the 12mL syringe to bottom port and aspirate the **BMC**.

BC120-PURE: IFU ILLUSTRATION

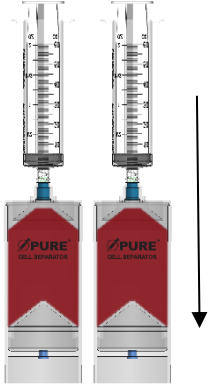
**NOTICES: PLEASE DISCARD RED VENTED CAP FROM CONCENTRATING DEVICE BEFORE USE.
ALWAYS SWAB SELF-SEALING PORT WITH STERILE ALCOHOL PRIOR TO ACCESSING WITH A STERILE SYRINGE.**

PREPARATION PROTOCOL

<p>STEP 1:</p>  <p>Attach the sterile filter needle onto the first VACLOK 60mL syringe. Then draw 15mL of Heparin Anticoagulant (1000 units/mL)</p>	<p>STEP 2:</p>  <p>Then prime the bone marrow aspirating cannula by injecting 5mL of heparin through it</p>	<p>STEP 3:</p>  <p>Attach to the OUT port of the bone marrow filter. Fill to prime and then aspirate back into the syringe</p>	<p>STEP 4:</p>  <p>Then discard the residual heparin leaving 5mL in the first VACLOK syringe. Then draw 5mL of heparin into the second VACLOK syringe</p>
<p>STEP 5:</p>  <p>Slowly draw 55mL of bone marrow aspirate, filling each syringe to 60mL. Mix the BMA and heparin upon collection to prevent coagulation.</p>		<p>STEP 6:</p>  <p>For each BMA syringe/filter: Connect a 60mL syringe to the OUT port of the bone marrow filter. Connect the VACLOK bone marrow syringe to the IN port of the filter. Inject the BMA through the filter into the 60mL syringe.</p>	

CONCENTRATING PROTOCOL

Step 1:



Load anticoagulated bone marrow aspirate into each **Separator Device**

Step 2:

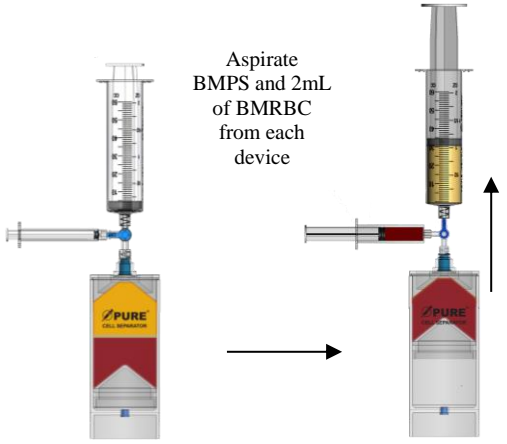
Counterbalance with equal volume and place at opposite ends in the centrifuge rotor.

Sapphire Series Centrifuge:
Set to **PUREBMC 60 SPIN 1**

Platinum Series Centrifuge:
Set to **PUREBMC SP SPIN 1**

Executive Series Centrifuge
Set to **3.5 minutes and 4400 RPM**

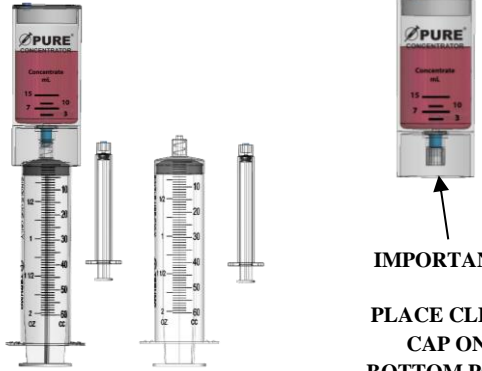
Step 3: **FOR EACH DEVICE DO THE FOLLOWING**



Aspirate BMRBC and 2mL of BMRBC from each device

Slowly aspirate bone marrow plasma suspension (BMPS) into the 60mL syringe. Then open the stopcock to the 3mL syringe and aspirate 2mL of bone marrow red blood cells (BMRBC).

Step 4:




Inject all of the BMPS and BMRBC into the single **Concentrator Device**

IMPORTANT!! PLACE CLEAR CAP ON BOTTOM PORT

Transfer all of the BMPS and BMRBC from both Separator Devices into the single **Concentrator Device** through the bottom port. Inject the BMRBC first then the BMPS

PLACE CLEAR CAP ON BOTTOM PORT PRIOR TO CENTRIFUGATION!!!

Step 5:



IMPORTANT!! MAKE SURE CLEAR CAP IS PLACED ON BOTTOM PORT PRIOR TO CENTRIFUGATION!!!


Counterbalance with equal volume then place directly opposite to each other in the centrifuge rotor buckets.

Sapphire Series Centrifuge:
Set to **PUREBMC 60 SPIN 2**

Platinum Series Centrifuge:
Set to **PUREBMC SP SPIN 2**

Executive Series Centrifuge
Set to **6 minutes and 4400**

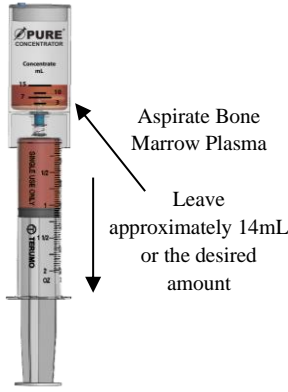
Step 6:



Bone Marrow Cell Concentrate

After centrifugation
The bone marrow cell concentrate separates out at the bottom of the **Concentrator Device**

Step 7:




Aspirate Bone Marrow Plasma

Leave approximately 14mL or the desired amount

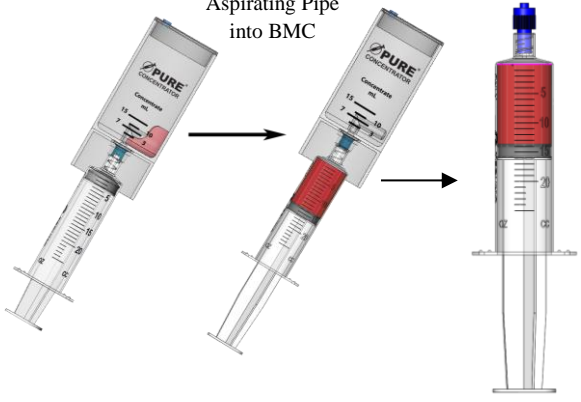
Attach 60mL syringe to bottom port. Aspirate bone marrow plasma from the **Concentrator Device**. Leave 14mL or the desired amount.

Step 8:



Gently swirl to resuspend the bone marrow cell concentrate into the plasma.

Step 9:



Tilt to immerse Aspirating Pipe into BMC

14mL BMC

Tilt to immerse the aspirating pipe into the bone marrow concentrate. Then attach the 20mL syringe to bottom port and aspirate the BMC.