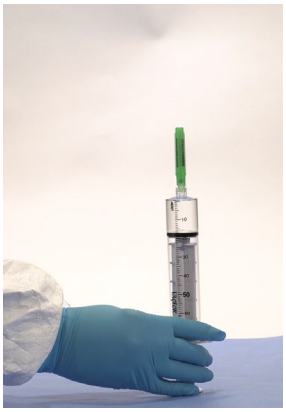
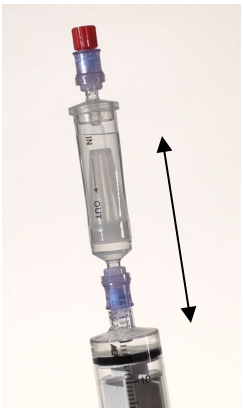
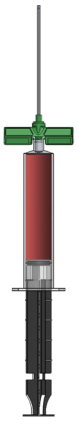
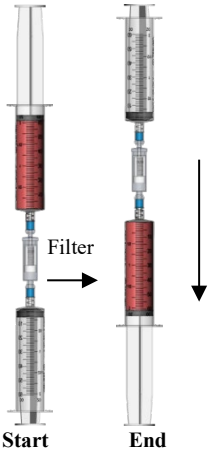
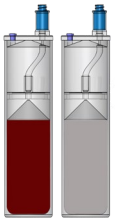
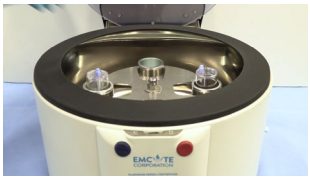
BC30-PURE: IFU ILLUSTRATION

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

STEP 1:	**STEP 2:**	**STEP 3:**	**STEP 4:**
			
Attach the sterile filter needle onto the VACLOK 30mL syringe. Then draw 15mL of Heparin Anticoagulant **(1000 units/mL)**	Then prime the bone marrow aspirating cannula by injecting 5mL of heparin through it	Attach to the OUT port of the bone marrow filter. Fill to prime and then aspirate back into the syringe	Then discard the residual heparin leaving 3mL in the VACLOK syringe

CONCENTRATING PROTOCOL

STEP 1:	**STEP 2:**	**STEP 3:**	**STEP 4:**
			 
Slowly draw 27mL of bone marrow aspirate, filling the syringe to 30mL. Mix the BMA and heparin upon collection to prevent coagulation.	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.	Inject anticoagulated & filtered BMA into the **Concentrating Device**	Counterbalance with the same volume as the Concentrating Device. Then place them directly opposite to each other in the centrifuge rotor buckets.

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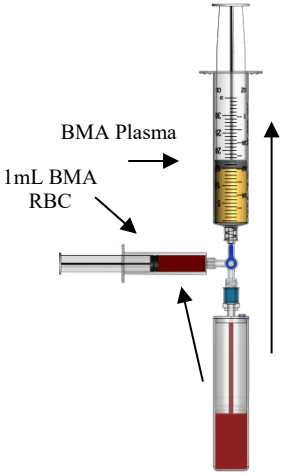
STEP 5:

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

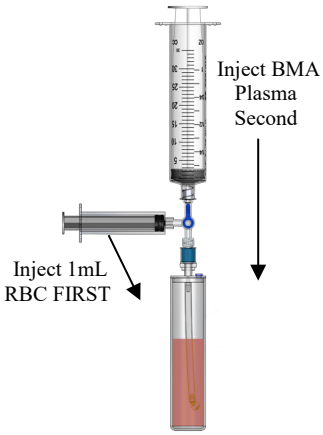
Executive Series
Set to **1 minute and 4200 RPM**

STEP 6:



Aspirate the BMA plasma into the 30mL syringe.
Then open the stopcock to the 3mL syringe and aspirate 1mL of BMA RBC

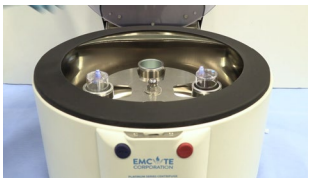
STEP 7:



Transfer the BMA RBC from the 3mL syringe first, then transfer the BMA plasma from the 60mL syringe into the **Concentrating Accessory**

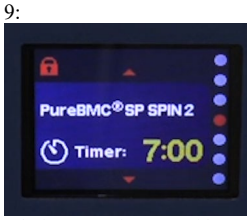
STEP 8:

Counterbalance with the same volume as the Concentrating Accessory.



Then place them directly opposite to each other in the centrifuge rotor buckets

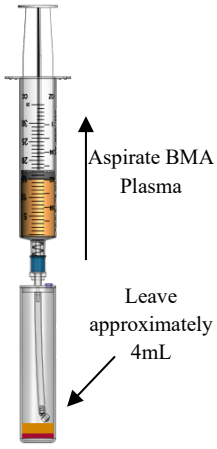
Step 9:



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

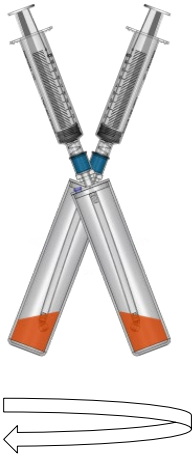
Executive Series
Set to **5 minutes and 4200 RPM**

Step 10:



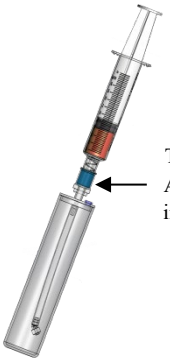
Aspirate BMA plasma from the Concentrating Accessory. Leave 4mL of plasma.

Step 11:



Attach the 12mL syringe and swirl to resuspend the BMA buffycoat into the plasma.

Step 12:



Tilt to immerse the Aspirating Pipe into the PureBMC®

Aspirate BMC into the 12mL syringe.

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PureBMC® Bone Marrow Concentrating System

GenesisCS Component Concentrating System

Date: May 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® 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 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 Concentrating Device. Slowly add the filtered and anticoagulated BMA through the port of the Concentrating Device.
27. 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.
28. FIRST SPIN:
    a. Platinum Series Centrifuge: Close the lid and set to PUREBMC SP SPIN 1.
    b. Executive Series Centrifuge: Close the lid and set to 2.5 minutes and 3.8 x 1000 RPM (3800 RPM).
    c. Press the start button. Once the centrifuge stops, remove the Concentrating Device.
29. FIRST EXTRACTION & TRANSFER: Attach the Aspirating Accessory to the needle-less port of the Concentrating Device. With the stopcock open to the 60mL syringe, slowly aspirate bone marrow plasma into the 60mL syringe. Aspirate plasma until the pipe completely fills with red blood cells (RBCs). Then open the stopcock to the 3mL syringe and aspirate 2mL of bone marrow red blood cells. Disconnect the Aspirating Accessory. Then attach it to the needle-less port of the Concentrating Accessory. Transfer the RBCs and then the bone marrow plasma into the Concentrating Accessory.
30. BALANCE: Using the Concentrating Accessory Counterbalance, counterbalance with the same amount of volume as the Concentrating

Accessory. Then place them directly opposite to each other in the centrifuge rotor buckets.

31. SECOND SPIN:
    a. Platinum Series Centrifuge: Close the lid and set to PUREBMC SP SPIN 2.
    b. Executive Series Centrifuge: Close the lid and set to 7 minutes and 3.8 x 1000 RPM (3800 RPM).
    c. Press the start button. Once the centrifuge stops, remove the Concentrating Accessory.
32. SECOND EXTRACTION: Using the 60mL syringe aspirate plasma leaving 7mL of solution in the Concentrating Accessory device.
33. RESUSPEND THE BMC: Gently swirl the Concentrating Accessory to re-suspend the bone marrow concentrate (BMC) buffycoat into the plasma.
34. EXTRACT BMC: Attach a sterile 12mL syringe to the Concentrating Accessory 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 Concentrating Device. Slowly add the filtered and anticoagulated BMA through the port of the Concentrating Device.
38. 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.
39. FIRST SPIN:
    a. Platinum Series Centrifuge: Close the lid and set to PUREBMC SP SPIN 1.
    b. Executive Series Centrifuge: Close the lid and set to 1 minute and 4.2 x 1000 RPM (4200 RPM).
    c. Press the start button. Once the centrifuge stops, remove the Concentrating Device.
40. FIRST EXTRACTION & TRANSFER: Attach the Aspirating Accessory to the needle-less port of the Concentrating Device. With the stopcock open to the 30mL syringe, slowly aspirate bone marrow plasma into the 30mL syringe. Aspirate plasma until the pipe completely fills with red blood cells (RBC). Then open the stopcock to the 3mL syringe and aspirate 1mL of bone marrow red blood cells. Disconnect the Aspirating Accessory. Then attach it to the needle-less port of the Concentrating Accessory. Transfer the RBCs and then the bone marrow plasma into the Concentrating Accessory.
41. BALANCE: Using the Concentrating Accessory Counterbalance, counterbalance with the same amount of volume as the Concentrating Accessory. Then place them directly opposite to each other in the centrifuge rotor buckets.
42. SECOND SPIN:
    a. Platinum Series Centrifuge: Close the lid and set to PUREBMC SP SPIN 2.
    b. Executive Series Centrifuge: Close the lid and set to 5 minutes and 4.2 x 1000 RPM (4200 RPM).
    c. Close the centrifuge lid and press the start button. Once the centrifuge stops, remove the Concentrating Accessory.
43. SECOND EXTRACTION: Using the 30mL syringe aspirate plasma leaving 4mL of solution in the Concentrating Accessory device.
44. RESUSPEND THE BMC: Gently swirl the Concentrating Accessory to re-suspend the bone marrow concentrate (BMC) buffycoat into the plasma.
45. EXTRACT BMC: Attach a sterile 12mL syringe to the Concentrating Accessory 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. LOAD: For each Concentrating Device do the following steps. Remove and discard the red vented cap from the needle-less port of the Concentrating Device. Slowly add 60mL of the filtered and anticoagulated BMA through the port of the Concentrating Device.
49. 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.
50. FIRST SPIN:
    a. Platinum Series Centrifuge: Close the lid and set to PUREBMC SP SPIN 1.
    b. Executive Series Centrifuge: Close the lid and set to 2.5 minutes and 3.8 x 1000 RPM (3800 RPM).
    c. Press the start button. Once the centrifuge stops, remove the Concentrating Devices.
51. FIRST EXTRACTION & TRANSFER: For each Concentrating Device do the following steps. Attach the Aspirating Accessory to the needle-less port of each Concentrating Device. With the stopcock open to the 60mL syringe, slowly aspirate bone marrow plasma into the 60mL syringe. Aspirate plasma until the pipe completely fills with red blood cells (RBC). Then open the stopcock to the 3mL syringe and aspirate 2mL of bone marrow red blood cells. Disconnect the Aspirating Accessory. Then attach it to the needle-less port of the Concentrating Accessory. Transfer the RBCs and then the bone marrow plasma into the Concentrating Accessory.
52. BALANCE: Using the Concentrating Accessory Counterbalance, counterbalance with the same amount of volume as the Concentrating Accessory. Then place them directly opposite to each other in the centrifuge rotor buckets.
53. SECOND SPIN:

a. Platinum Series Centrifuge: Close the lid and set to PUREBMC SP SPIN 2.
b. Executive Series Centrifuge: Close the lid and set to 7 minutes and 3.8 x 1000 RPM (3800 RPM).
c. Close the centrifuge lid and press the start button. Once the centrifuge stops, remove the Concentrating Accessory.

54. SECOND EXTRACTION: Using the 60mL syringe aspirate plasma leaving 14mL of solution in the Concentrating Accessory.
55. RESUSPEND THE BMC: Gently swirl the Concentrating Accessory to re-suspend the bone marrow concentrate (BMC) buffycoat into the plasma.
56. EXTRACT BMC: Attach a sterile 20mL syringe to the Concentrating Accessory 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
STERILE EO	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	EC REP	Authorized Representative Emergo Europe, Westervoortsedijk 60 6827 AT Arnhem The Netherlands
Non-pyrogenic	CE 2803	MD Medical Device