AbsoluteBMC™

GenesisCS Component Concentrating System

Instruction for Use
Cell Concentrate from Bone Marrow
Date: September 2023

ATTENTION OPERATING SURGEON

1. NOTE: DEVICE IS FOR SINGLE USE ONLY. Discard the entire disposable system after one use, using an acceptable disposal method for products potentially contaminated with blood.
2. DESCRIPTION
   The AbsoluteBMC™ 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.
3. MATERIALS
   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.
4. INDICATIONS FOR USE STATEMENTS
   a. 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.
   b. The safety and effectiveness of this device for in vivo indications for use, such as bone healing and hemostasis, have not been established.
   c. The PRP and BMC prepared by this device has not been evaluated for any clinical indications.
   d. The PRP and BMC prepared by this device is NOT indicated for delivery to the patient's circulatory system.
5. USER POPULATION
   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.
6. DEVICE USE ENVIRONMENT
   The device is intended to be used in in a health care setting such as a surgery room, clinic or outpatient care center.
7. WARNING AND PRECAUTIONS
   a. Use proper safety precautions to guard against needle sticks.
   b. Follow manufacturer instructions when using centrifuge. Use only EmCyte provided general purpose centrifuge. Outcomes using centrifuges from other manufacturers are unknown.
   c. When using the bone marrow aspiration needle, follow manufacturer's instruction for use.
   d. Do not use sterile components of this system if package is opened or damaged.
   e. Single use device. Do not reuse. Do not attempt to clean or re-sterilize this product.
   f. Do not use after expiration date.
   g. Use prepared BMC, PPP or PRP within 4 hours after drawing blood or bone marrow aspirate according to current AABB guidelines.
   h. BMC prepared from bone marrow may contain higher levels of plasma free hemoglobin than PRP prepared from whole blood.
8. POSSIBLE RISKS
   a. 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.
   b. Reuse may be a potential biohazard
9. POSSIBLE ADVERSE EFFECTS
   a. Damage to blood vessels, hematoma, delayed wound healing and/or infection is associated with blood draw, bone marrow harvest and/or surgical procedure.
   b. Temporary or permanent nerve damage that may result in pain or numbness is associated with blood draw, and/or surgical procedure.
   c. Early or late postoperative infection is associated with surgical procedure.
   d. Pain associated with site of bone marrow harvest.
10. STERILITY
    a. The AbsoluteBMC™ 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:

11. NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.
12. 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 marow filter. Inject Heparin filling 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.
13. 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:

14. 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.
15. 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.
16. CENTRIFUGATION:
    a. Sapphire Series Centrifuge: ABSOLUTEPRP/BMC
    b. Platinum Series Centrifuge: ABSOLUTEPRP/BMC
    c. Executive Series Centrifuge: 5 minutes 4400 RPM
17. Press the start button. Once the centrifuge stops, remove the Concentrating Device.
18. BMC EXTRACTION: Using the 60mL syringe, aspirate the BMA plasma into the 60mL syringe until the Aspirating Disc touches the red cell interface, trapping the BMA buffycoat. Using the 12mL syringe aspirate 7-8mL of BMC. Dilute the BMC with plasma to adjust the cell concentrations.

INSTRUCTIONS FOR USE FOR 30mL SYSTEM

PREPARATION PROTOCOL:

19. NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.
20. 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 marow filter. Inject Heparin filling 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.
21. 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:

22. 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.
23. 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.
24. CENTRIFUGATION:
    a. Sapphire Series Centrifuge: ABSOLUTEPRP/BMC
    b. Platinum Series Centrifuge: ABSOLUTEPRP/BMC
    c. Executive Series Centrifuge: 5 minutes 4400 RPM
25. Press the start button. Once the centrifuge stops, remove the Concentrating Device.
26. BMC EXTRACTION: Using the 30mL syringe, aspirate the BMA plasma into the 30mL syringe until the Aspirating Disc touches the red cell interface, trapping the BMA buffycoat. Using the 12mL syringe aspirate 3-4mL of BMC. Dilute the BMC with plasma to adjust the cell concentrations.

INSTRUCTIONS FOR USE FOR 120mL SYSTEM

PREPARATION PROTOCOL:

27. NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.
28. 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 marow 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.
29. 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:

30. 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 the filtered and anticoagulated BMA through the port of the Concentrating Device.
31. 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.
32. CENTRIFUGATION:
    a. Sapphire Series Centrifuge: ABSOLUTEPRP/BMC
    b. Platinum Series Centrifuge: ABSOLUTEPRP/BMC
    c. Executive Series Centrifuge: 5 minutes 4400 RPM
33. Press the start button. Once the centrifuge stops, remove the Concentrating Device.
34. BMC EXTRACTION: For each Concentrating Device do the following steps. Using the 60mL syringe, aspirate the BMA plasma into the 60mL syringe until the Aspirating Disc touches the red cell interface, trapping the BMA buffycoat. Using the 12mL syringe aspirate 7-8mL of BMC. Dilute the BMC with plasma to adjust the cell concentrations.

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	EC REP Authorized Representative Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	Store in a cool place
STERILE EO	Do not re-sterilize	Attention, read instruction for use	Store in a dry place
Consult instruction for use	Rx Only Prescription Use	EmCyte Corporation 4331 Veronica S. Shoemaker Blvd. Fort Myers, FL 33916 Phone: 239-481-7725	

GSBMA-30: IFU ILLUSTRATION

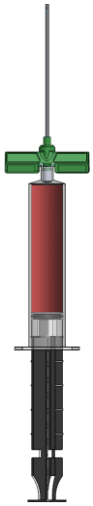
NOTICES:
PLEASE DISCARD RED VENTED CAP FROM CONCENTRATING DEVICE BEFORE USE
ALWAYS SWAB SELF-SEALING PORT WITH STERILE ALCOHOL PRIOR TO ACCESSING WITH A STERILE SYRINGE

PROCESSING 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

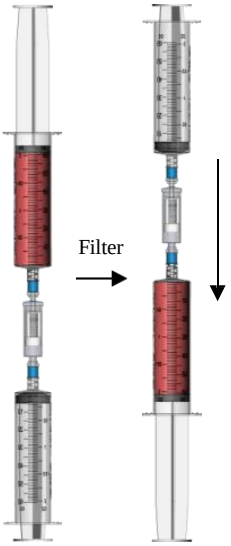
CONCENTRATING PROTOCOL

Step 1:



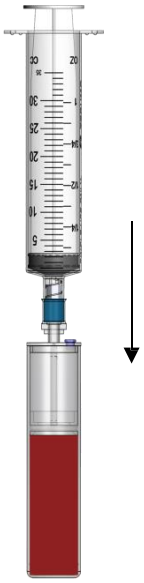
Slowly draw 27mL of bone marrow aspirate, filling the syringe to 60mL. Mix the BMA and heparin upon collection to prevent coagulation.

Step 2:



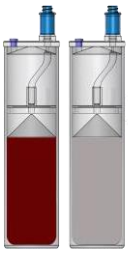
Connect a 30mL syringe to the OUT port of the bone marrow filter. Connect the VACLOK bone marrow syringe to the IN port of the filter. Inject the BMA through the filter into the 30mL syringe.

Step 3:

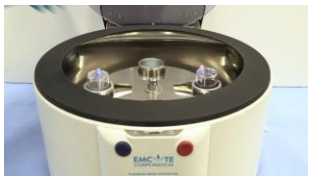


Inject anticoagulated & filtered BMA into the **Concentrating Device**

Step 4:



Counterbalance with the same volume as the Concentrating Device.



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

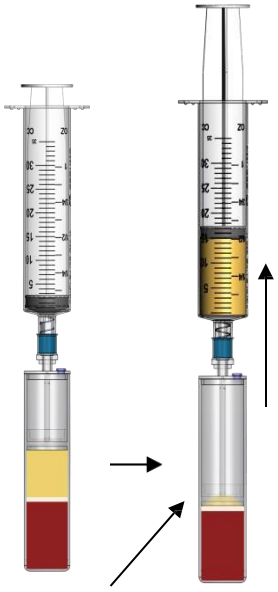
Step 5:

Sapphire Series Centrifuge
Set to:
ABSOLUTEPRP/BMC

Platinum Series Centrifuge
Set to:
ABSOLUTEPRP/BMC

Executive Series Centrifuge
Set to:
5 minutes / 4400 RPM

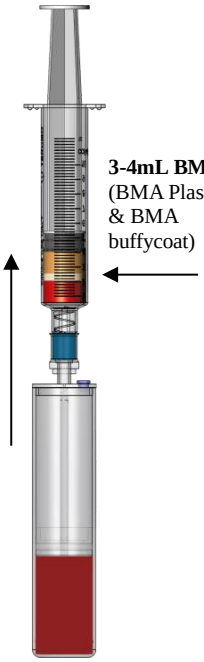
Step 6:



Piston touches the RBC Interface (trapping plasma & BMA buffycoat inside)

Attach the 30mL syringe and aspirate the BMA plasma until the piston touches the RBC interface (trapping the BMA plasma & buffycoat inside), then stop aspirating

Step 7:



Attach the 12mL syringe and aspirate 7-8mL of BMC (Gently rock the syringe to re-suspend the buffycoat into the BMA plasma)

GSBMA-60: IFU ILLUSTRATION

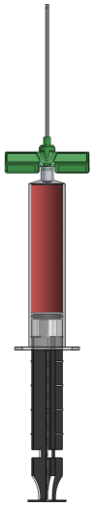
NOTICES:
PLEASE DISCARD RED VENTED CAP FROM CONCENTRATING DEVICE BEFORE USE
ALWAYS SWAB SELF-SEALING PORT WITH STERILE ALCOHOL PRIOR TO ACCESSING WITH A STERILE SYRINGE

PROCESSING PROTOCOL:

Step 1:	Step 2:	Step 3:	Step 4:
			
Attach the sterile filter needle onto the VACLOK 60mL 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 5mL in the VACLOK syringe

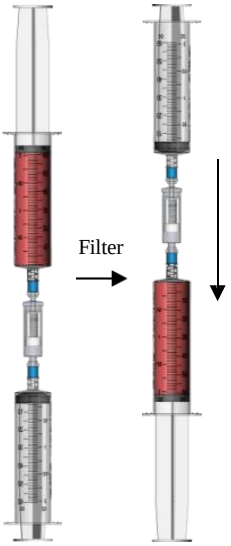
CONCENTRATING PROTOCOL

Step 1:



Slowly draw 55mL of bone marrow aspirate, filling the syringe to 60mL. Mix the BMA and heparin upon collection to prevent coagulation.

Step 2:

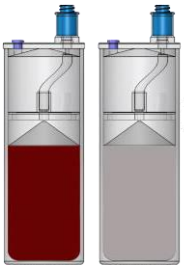


Connect a 60mL syringe to the OUT port of the bone marrow filter. Connect the VACLOK bone marrow syringe to the IN port of the filter. Inject the BMA through the filter into the 60mL syringe.

Step 3:

Inject anticoagulated & filtered BMA into the **Concentrating Device**

Step 4:



Counterbalance with the same volume as the Concentrating Device.

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

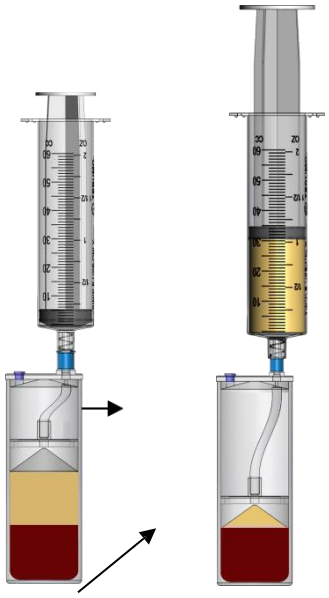
Step 5:

Sapphire Series Centrifuge
Set to:
ABSOLUTEPRP/BMC

Platinum Series Centrifuge
Set to:
ABSOLUTEPRP/BMC

Executive Series Centrifuge
Set to:
5 minutes / 4400 RPM

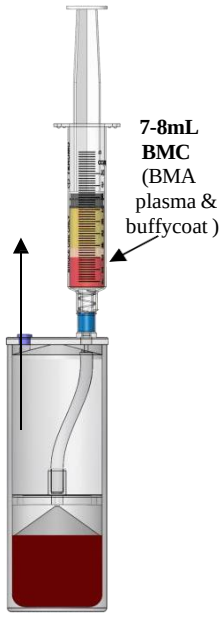
Step 6:



Piston touches the RBC Interface (trapping plasma & BMA buffycoat inside)

Attach the 60mL syringe and aspirate the BMA plasma until the piston touches the RBC interface (trapping the BMA plasma & buffycoat inside), then stop aspirating

Step 7:



Attach the 12mL syringe and aspirate 7-8mL of BMC (Gently rock the syringe to re-suspend the buffycoat into the BMA plasma)

GSBMA-120: IFU ILLUSTRATION

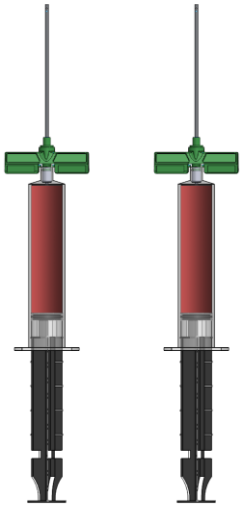
NOTICES:
PLEASE DISCARD RED VENTED CAP FROM CONCENTRATING DEVICE BEFORE USE
ALWAYS SWAB SELF-SEALING PORT WITH STERILE ALCOHOL PRIOR TO ACCESSING WITH A STERILE SYRINGE

PREPARATION PROTOCOL:

Step 1:	Step 2:	Step 3:	Step 4:
			
Attach the sterile filter needle onto the VACLOK 60mL 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 5mL in each VACLOK syringe

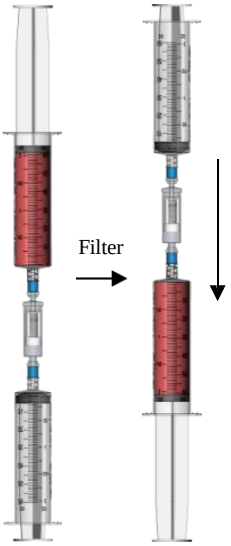
CONCENTRATING PROTOCOL

Step 1:



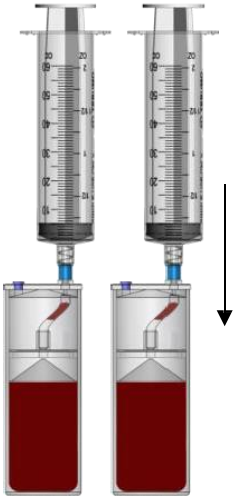
Slowly draw 55mL of bone marrow aspirate, filling each syringe to 60mL. Mix the BMA and heparin upon collection to prevent coagulation.

Step 2:



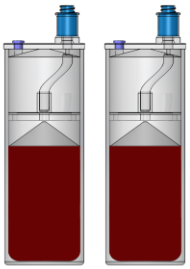
For each BMA syringe filter the BMA in the direction indicated on the filter.

Step 3:



Inject 60mL of anticoagulated & filtered BMA into each **Concentrating Device**

Step 4:



Counterbalance with the same volume in each Concentrating Device.

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

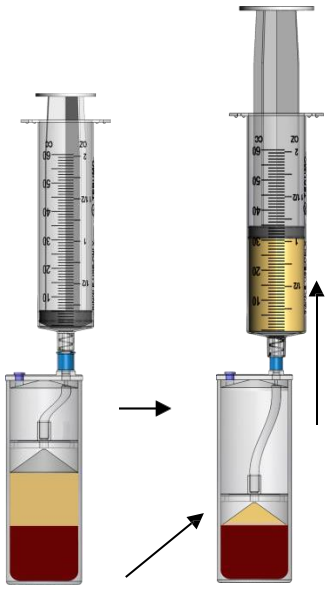
Step 5:

Sapphire Series Centrifuge Set to: ABSOLUTEPRP/BMC

Platinum Series Centrifuge Set to: ABSOLUTEPRP/BMC

Executive Series Centrifuge Set to: 5 minutes / 4400 RPM

Step 6:

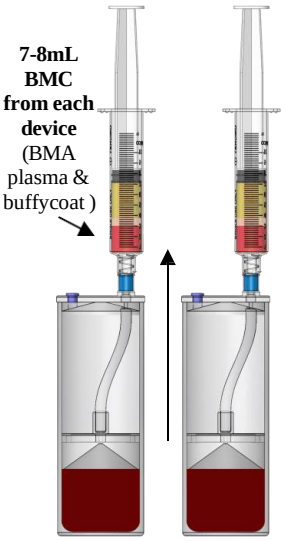


Piston touches the RBC Interface (trapping plasma & BMA buffycoat inside)

REPEAT FOR EACH CONCENTRATING DEVICE:

Attach the 60mL syringe and aspirate the BMA plasma until the piston touches the RBC interface (trapping the BMA plasma & buffycoat inside), then stop aspirating

Step 7:



Attach a12mL syringe to each device and aspirate 7-8mL of BMC from each device.

(Gently rock the syringe to re-suspend the buffycoat into the BMA plasma)