

Instruction for Use
 GenesisCS Component Concentrating System
 Platelet Concentrating System
 Rev. 4
 Date: 07/27/2022
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 PurePRP® GenesisCS Component Concentrating System is manufactured by EmCyte Corporation. The kit prepares platelet rich plasma from a small sample of blood at the point of care. The Protein Concentrator concentrates the protein in the platelet poor plasma. The system contains syringes, needles 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 designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP can be mixed with autograft and allograft bone prior to application to an orthopedic surgical site as deemed necessary by the clinical use requirements.
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 prepared by this device has not been evaluated for any clinical indications.
6. The PRP 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. Do not use sterile components of this system if package is opened or damaged.
12. Single use device. Do not reuse. Do not attempt to clean or re-sterilize this product.
13. Do not use after expiration date.
14. Use prepared PRP within 4 hours after drawing blood.

POSSIBLE RISKS

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

POSSIBLE ADVERSE EFFECTS

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

STERILITY

21. The PurePRP® 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.

 Single use only	 Only Prescription Use	 Do not use if package is damaged
 STERILE EO	 Do not re-sterilize	 Attention, read instruction for use
 Non-Pyrogenic	 Store in a dry place	 CE 2803
 Store in a cool place	Emergo Australia Level 20 Tower II, Darling Park 201 Sussex Street, Sydney, NSW 2000, Australia .	
 EC REP	Authorized Representative Emergo Europe Prinsesgracht 20 2514 AP The Hague The Netherlands	 EmCyte Corporation 4331 Veronica S. Shoemaker Blvd. Fort Myers, FL 33916 Phone: 239-481-7725

INSTRUCTIONS FOR USE FOR THE FC-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.

1. **WHOLE BLOOD DRAW:** Attach the sterile filter needle onto two sterile 60mL syringes. Draw 6mL of Sodium Citrate Anticoagulant into each 60mL syringe. Remove the filter needle from the syringe. Attach the butterfly needle onto the first 60mL syringe and prime with the anticoagulant. Slowly draw 54mL of whole blood into each syringe from the patient filling each syringe to 60mL. Gently, but thoroughly mix the blood and anticoagulant upon collection to prevent coagulation. Collect a total of 120mL

CONCENTRATING PROTOCOL

1. **LOAD:** For each concentrating device do the following steps. Remove and discard the red vented cap from the needle-less port of each Concentrating Device. Slowly add the 60mL of anticoagulated whole blood through the needle-less port into each Concentrating Device. **OPTIONAL STEP:** Using the 3mL syringe, purge the tubing with 1.5 mL of Sodium Citrate Anticoagulant to clear the residual line blood.
2. **BALANCE:** Make sure each device contains the same amount of volume. Then place them directly opposite to each other in the centrifuge rotor buckets.
3. **FIRST SPIN:**
4. **Platinum Series Centrifuge:** Close the lid and set to PUREPRP SP PUREPRP SPIN 1.
5. **Executive Series Centrifuge:** Close the lid and set to 1.5 minutes and 3.8 x 1000 RPM (3800 RPM).
6. Press the start button. Once the centrifuge stops, remove the Concentrating Device.
7. **FIRST EXTRACTION & TRANSFER:** Attach the sterile 60mL syringe to the needle-less port of each Concentrating Device. For each Device slowly aspirate the platelet plasma suspension into the 60mL syringe. Aspirate until the pipe completely fills with RBC. It is normal to aspirate a small amount of RBC into the syringe during this step. Remove the red vented cap from the Concentrating Accessory and transfer the platelet plasma suspension from each Device through the needle-less port into the Concentrating Accessory.
8. **SECOND SPIN:** Counterbalance the Concentrating Accessory with equal volume and place them directly opposite to each other in the centrifuge rotor buckets.
9. **Platinum Series Centrifuge:** Close the lid and set to PUREPRP SP SPIN 2.
10. **Executive Series Centrifuge:** Close the lid and set to 7 minutes and 3.8 x 1000 RPM (3800 RPM).
11. Press the start button. Once the centrifuge stops, remove the Concentrating Accessory.
12. **SECOND EXTRACTION:** Using the 60mL syringe, aspirate plasma from the needle-less port leaving 7mL in the Concentrating Accessory.
13. **RESUSPEND THE PRP:** Gently swirl the Concentrating Accessory to re-suspend the platelet concentrate into the plasma.
14. **EXTRACT PRP:** Attach a sterile 20mL syringe to the needle-less port and tilt the Concentrating Accessory to immerse the aspirating pipe, then aspirate the platelet rich plasma. Remove sterile syringe and apply a sterile cap.

PROTEIN CONCENTRATION PROTOCOL



1. Connect the platelet poor plasma syringe to the protein concentrator (any side). Connect an empty 60mL syringe to the other port of the concentrator. Connect VacLok syringe to the open evacuation port and apply 60mL of suction.
2. Transfer the plasma into the empty syringe then transfer the plasma back into the first syringe. Continue to transfer the plasma back and forth until 5mL is left in the starting syringe.
3. Remove the empty syringe and replace with the vent.
4. Aspirate the additional 8mL of the remaining plasma into the 60mL syringe.
5. Total volume collected is 13mL.

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

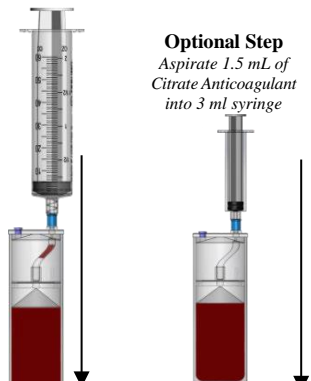
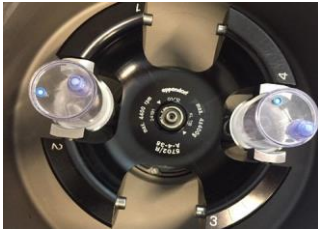


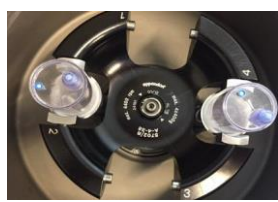

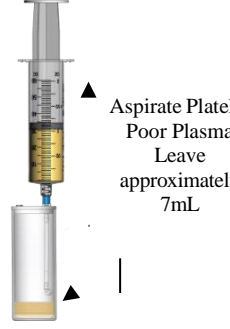

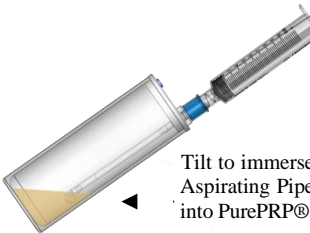
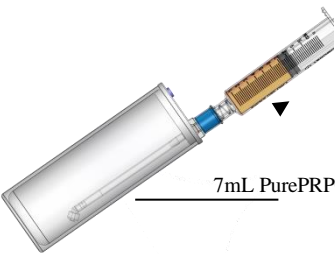
FC120-PURE PLEASE DISCARD RED VENTED CAP FROM CONCENTRATING DEVICE BEFORE USE ****

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

PREPARATION PROTOCOL

<p>Step 1: Draw 6mL of Sodium Citrate Anticoagulant into each 60mL Syringe</p> 	<p>Step 2: Draw 54mL whole blood from the patient into each syringe, filling each syringe to 60mL. Gently, but thoroughly mix the blood and anticoagulant upon collection to prevent coagulation. Collect a total of 120mL.</p> 
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CONCENTRATING PROTOCOL

<p>Step 3: Do for each device</p> <p>Optional Step Aspirate 1.5 mL of Citrate Anticoagulant into 3 ml syringe</p>  <p>Load the anticoagulated whole blood into each Concentrating Device</p>	<p>Step 4:</p>  <p>Counterbalance at opposite ends and process the Concentrating Device at</p> <p>Executive Series Centrifuge Set to 1.5 minutes and 3800</p> <p>Platinum Series Centrifuge: Set to PUREPRP SP SPIN 1</p>	<p>Step 5:</p>  <p>Using the 60mL syringe, aspirate the platelet plasma suspension (PPS) from each device. Aspirate until the RBC fills the aspirating pipe. <i>(Its normal to aspirate small amounts of RBC into the syringe during this process)</i></p>	<p>Step 6:</p>  <p>Transfer the platelet plasma suspension (PPS) from the 60mL syringe into the Concentrating Accessory</p>
<p>Step 7:</p>  <p>Counterbalance at opposite ends and process the Concentrating Accessory at</p> <p>Executive Series Centrifuge Set to 7 minutes and 3800</p> <p>Platinum Series Centrifuge: Set to PUREPRP SP SPIN 2</p>	<p>Step 8:</p>  <p>Platelet concentrate buffycoat separates out at the bottom of the Concentrating Accessory</p>	<p>Step 9:</p>  <p>Aspirate Platelet Poor Plasma Leave approximately 7mL</p> <p>Using the 60mL syringe, Aspirate platelet poor plasma from the Concentrating Accessory Leave 7mL of plasma.</p>	<p>Step 10:</p>  <p>Attach the 20mL syringe and gently swirl to resuspend the platelet buffycoat into the plasma.</p>
<p>Step 11:</p>  <p>Tilt to immerse Aspirating Pipe into PurePRP®</p> <p>Tilt to immerse the Aspirating Pipe into the PurePRP®</p>	<p>Step 12:</p>  <p>7mL PurePRP®</p> <p>Extract the PurePRP® into the 20mL syringe.</p>		

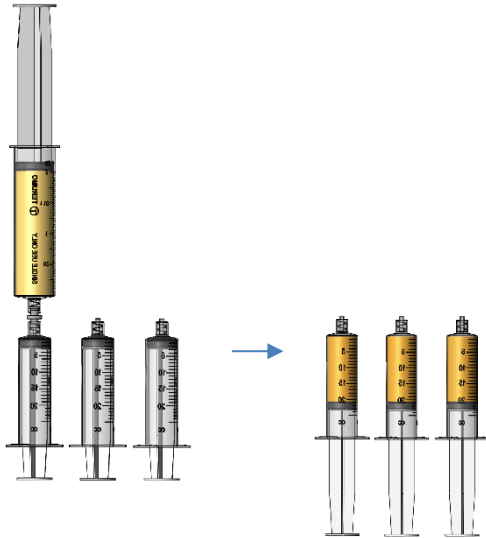
CORE™ ULTRAFILTRATION PROTOCOL

CORE™ Ultrafiltration System



Step 13:

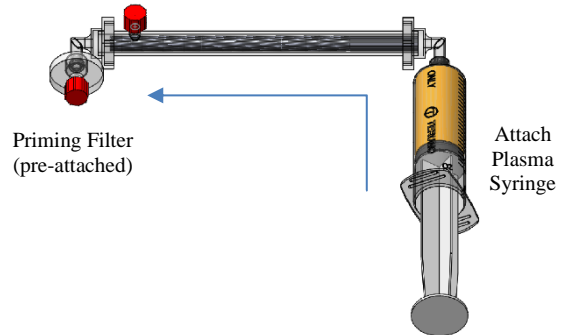
Plasma Transfer



Using the double female connector, transfer the plasma to 20mL syringes, filling each syringe to 20mL. (Fill the last syringe with the remaining volume even if it's less than 20mL)

Step 14:

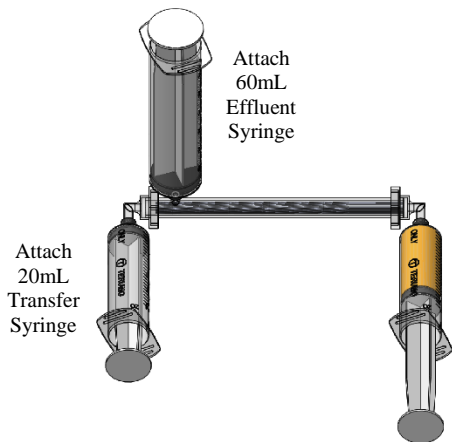
PRIME Ultrafiltration Device



GENTLY attach a Plasma Syringe to the opposite side of the Priming Filter. Inject the plasma through the device until it reaches the filter.

Step 15:

ATTACH Final Syringe Accessories

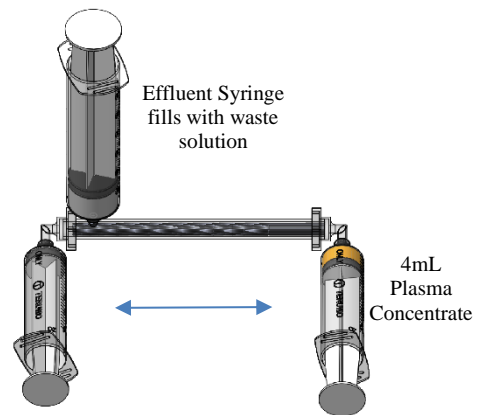


Remove the priming filter and red caps, then attach the 20mL Transfer Syringe and 60mL Effluent Syringe as shown.

Leave the CLEAR CAP ATTACHED (NOT SHOWN)

Step 16:

FILTRATION Process

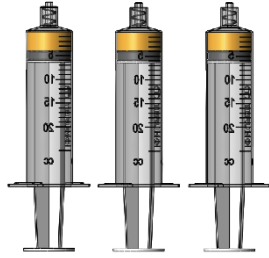


For EACH 20mL Plasma Syringe, transfer solution back and forth from the Plasma Syringe to the Transfer Syringe until 4mL of plasma concentrate is left in the Plasma Syringe.

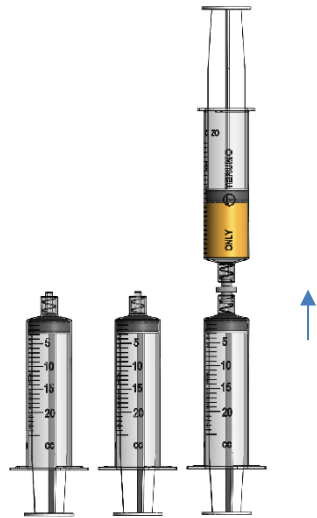
USE 2 HANDS PER SYRINGE WHEN TRANSFERRING

Step 17:

Plasma Concentrate Collection



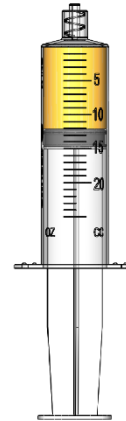
Collect 4mL of plasma concentrate in each 20mL syringe.



Using the double female connector, transfer the plasma concentrate to a single 20mL syringe.

Step 18:

FINAL Plasma Concentrate Volume



Final Plasma Concentrate Volume