




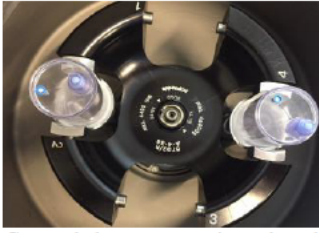







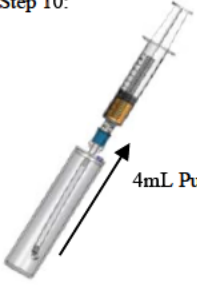
GS30-PURE II: IFU ILLUSTRATION

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

PREPARATION PROTOCOL

<p>Step 1: Using the filtered needle, draw 3mL of Citrate Anticoagulant into 30mL Syringe</p> 	<p>Step 2: Using the butterfly needle, draw 27mL whole blood from the patient, filling the syringe to 30mL</p> 
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CONCENTRATING PROTOCOL

<p>Step 1:</p>  <p>Load anticoagulated whole blood into the Concentrating Device</p>	<p>Step 2:</p>  <p>Counterbalance at opposite ends and process the Concentrating Device at Platinum Series Centrifuge: Set to PUREPRP SP SPIN 1</p>	<p>Step 3:</p>  <p>Using the 30mL syringe, aspirate the platelet plasma suspension (PPS) until RBC fills the aspirating pipe.</p> <p><i>(Its normal to aspirate small amounts of RBC into the syringe during this process)</i></p>	<p>Step 4:</p>  <p>Transfer the platelet plasma suspension (PPS) into the Concentrating Accessory</p>
<p>Step 5:</p>  <p>Counterbalance at opposite ends and process the Concentrating Accessory at Platinum Series Centrifuge: Set to PUREPRP SP SPIN 2</p>	<p>Step 6:</p>  <p>Platelet Concentrate Buffycoat</p> <p>Platelet concentrate buffycoat separates out at the bottom of the Concentrating Accessory</p>	<p>Step 7:</p>  <p>Aspirate Platelet Poor Plasma</p> <p>Leave approximately 4mL</p> <p>Aspirate platelet poor plasma from the Concentrating Accessory. Leave 4mL of plasma.</p>	<p>Step 8:</p>  <p>Attach the 12mL syringe and gently swirl to resuspend the platelet buffycoat into the plasma.</p>
<p>Step 9:</p>  <p>Tilt to immerse Aspirating Pipe into PurePRP®</p> <p>Tilt to immerse the Aspirating Pipe into the PurePRP®</p>	<p>Step 10:</p>  <p>4mL PurePRP®</p> <p>Extract the PurePRP® into the 12mL syringe.</p>		

PurePRP® GenesisCS Component Concentrating System

Instruction for Use

Platelet Concentrating System

Date: August 2020

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 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 system contains syringes, needles 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 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.
 - 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 prepared by this device has not been evaluated for any clinical indications.
 - d. The PRP 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 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. Do not use sterile components of this system if package is opened or damaged.
 - d. Single use device. Do not reuse. Do not attempt to clean or re-sterilize this product.
 - e. Do not use after expiration date.
 - f. Use prepared PRP within 4 hours after drawing blood according to current AABB guidelines.
8. POSSIBLE RISKS
 - a. 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.
 - 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, 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 whole blood harvest.
10. STERILITY
The PurePRP® SupraPhysiologic Concentrating System kits are sterilized by ETO exposure. Do not use any component from an opened or damaged package. Do not re-sterilize. 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. WHOLE BLOOD DRAW: Attach the sterile filter needle onto the sterile 60mL syringe. Draw 6mL of Sodium Citrate Anticoagulant into the 60mL syringe. Remove the filter needle from the syringe. Attach the butterfly needle onto 60mL syringe and prime the needle with the anticoagulant. Slowly draw 54mL of whole blood from the patient filling the syringe to 60mL. Gently, but thoroughly mix the blood and anticoagulant upon collection to prevent coagulation.

CONCENTRATING PROTOCOL:

13. LOAD: Remove and discard the red vented cap from the needle-less port of the Concentrating Device. Slowly add the anticoagulated whole blood through the needle-less port of the Concentrating Device. OPTIONAL STEP: Using the 3mL syringe, purge the tubing with 1mL of Sodium Citrate Anticoagulant to clear the residual line blood.
14. 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.
15. FIRST SPIN:
 - a. Platinum Series Centrifuge: Close the lid and set to PUREPRP SP SPIN 1.
 - b. Executive Series Centrifuge: Close the lid and set to 1.5 minutes and 3.8 x 1000 RPM (3800 RPM).Press the start button. Once the centrifuge stops, remove the Concentrating Device.
16. FIRST EXTRACTION & TRANSFER: Attach the sterile 60mL syringe to the needle-less port. 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 through the needle-less port into the Concentrating Accessory.
17. SECOND SPIN: Counterbalance the Concentrating Accessory with equal volume and place them directly opposite to each other in the centrifuge rotor buckets.
 - a. Platinum Series Centrifuge: Close the lid and set to PUREPRP SP SPIN 2.
 - b. Executive Series Centrifuge: Close the lid and set to 5 minutes and 3.8 x 1000 RPM (3800 RPM).
 - c. Press the start button. Once the centrifuge stops, remove the Concentrating Accessory.
18. SECOND EXTRACTION: Using the 60mL syringe, aspirate plasma from the needle-less port leaving 7mL in the Concentrating Accessory.
19. RESUSPEND THE PRP: Gently swirl the Concentrating Accessory to re-suspend the platelet concentrate into the plasma.
20. EXTRACT PRP: Attach a sterile 12mL 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.

INSTRUCTIONS FOR USE FOR 30mL SYSTEM

PREPARATION PROTOCOL:

21. NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.
22. WHOLE BLOOD DRAW: Attach the sterile filter needle onto the sterile 30mL syringe. Draw 3mL of Sodium Citrate Anticoagulant into the 30mL syringe. Remove the filter needle from the syringe. Attach the butterfly needle onto 30mL syringe and prime the needle with the anticoagulant. Slowly draw 27mL of whole blood from the patient filling the syringe to 30mL. Gently, but thoroughly mix the blood and anticoagulant upon collection to prevent coagulation.

CONCENTRATING PROTOCOL:

23. LOAD: Remove and discard the red vented cap from the needle-less port of the Concentrating Device. Slowly add the anticoagulated whole blood through the needle-less port of the Concentrating Device. OPTIONAL STEP: Using the 3mL syringe, purge the tubing with 1mL of Sodium Citrate Anticoagulant to clear the residual line blood.
24. 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.
25. FIRST SPIN:
 - a. Platinum Series Centrifuge: Close the lid and set to PUREPRP SP SPIN 1.
 - b. Executive Series Centrifuge: Close the lid and set to 1.5 minutes and 3.8 x 1000 RPM (3800 RPM).Press the start button. Once the centrifuge stops, remove the Concentrating Device.
26. FIRST EXTRACTION & TRANSFER: Attach the sterile 30mL syringe to the needle-less port. Slowly aspirate the platelet plasma suspension into the 30mL 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 through the needle-less port into the Concentrating Accessory.
27. SECOND SPIN: Counterbalance the Concentrating Accessory with equal volume and place them directly opposite to each other in the centrifuge rotor buckets.
 - a. Platinum Series Centrifuge: Close the lid and set to PUREPRP SP SPIN 2.
 - b. Executive Series Centrifuge: Close the lid and set to 5 minutes and 3.8 x 1000 RPM (3800 RPM).
 - c. Press the start button. Once the centrifuge stops, remove the Concentrating Accessory.
28. SECOND EXTRACTION: Using the 30mL syringe, aspirate plasma from the needle-less port leaving 4mL in the Concentrating Accessory.
29. RESUSPEND THE PRP: Gently swirl the Concentrating Accessory to re-suspend the platelet concentrate into the plasma.
30. EXTRACT PRP: Attach a sterile 12mL 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.

INSTRUCTIONS FOR USE FOR 120mL SYSTEM



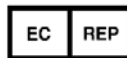








PREPARATION PROTOCOL:

31. NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.
32. 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:

33. LOAD: 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 1mL of Sodium Citrate Anticoagulant to clear the residual line blood.
34. BALANCE: Make sure each device contains the same amount of volume. Then place them directly opposite to each other in the centrifuge rotor buckets.
35. FIRST SPIN:
 - a. Platinum Series Centrifuge: Close the lid and set to PUREPRP SP SPIN 1.
 - b. Executive Series Centrifuge: Close the lid and set to 1.5 minutes and 3.8 x 1000 RPM (3800 RPM).
 Press the start button. Once the centrifuge stops, remove the Concentrating Device.
36. 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.
37. SECOND SPIN: Counterbalance the Concentrating Accessory with equal volume and place them directly opposite to each other in the centrifuge rotor buckets.
 - a. Platinum Series Centrifuge: Close the lid and set to PUREPRP SP SPIN 2.
 - b. Executive Series Centrifuge: Close the lid and set to 5 minutes and 3.8 x 1000 RPM (3800 RPM).
 - c. Press the start button. Once the centrifuge stops, remove the Concentrating Accessory.
38. SECOND EXTRACTION: Using the 60mL syringe, aspirate plasma from the needle-less port leaving 14mL in the Concentrating Accessory.
39. RESUSPEND THE PRP: Gently swirl the Concentrating Accessory to re-suspend the platelet concentrate into the plasma.
40. 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.

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