

PUREPRP® TWO

GenesisCS Component Concentrating System

Instruction for Use

Platelet Concentrating System

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 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.

INSTRUCTIONS FOR USE FOR 60mL SYSTEM

PREPARATION PROTOCOL

22. NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.
23. **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

24. **LOAD:** Remove and discard the red vented cap from the needle-less port of the **Separator Device**. Slowly add the anticoagulated whole blood through the needle-less port of the Concentrating Device.
25. **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.
26. **FIRST SPIN:**
 - a. **Sapphire Series Centrifuge:** Close the lid and set to PUREPRP 60 SPIN 1.
 - b. **Platinum Series Centrifuge:** Close the lid and set to PUREPRP SP SPIN 1.
 - c. **Executive Series Centrifuge:** Close the lid and set to 2.0 minutes and 4.4 x 1000 RPM (4400 RPM).
 - d. Press the start button. Once the centrifuge stops, remove the **Separator Device**.
27. **FIRST EXTRACTION & TRANSFER:**
 - a. **LP-Protocol A** - Aspirate the platelet plasma suspension (PPS) into the 60mL syringe. (Optionally, aspirate additional 0.5mL of RBC for optimal platelet recovery.)
 - b. **LR-Protocol B** - Aspirate the platelet plasma suspension (PPS) and approximately 2mL of RBC into the 60mL syringe.
 - c. Inject the platelet plasma suspension through bottom port of **Concentrator Device**. Then **PLACE THE CLEAR CAP ON THE BOTTOM PORT!**
28. **SECOND SPIN:** Counterbalance the **Concentrator Device** with equal volume and place them directly opposite to each other in the centrifuge rotor buckets.
 - a. **Sapphire Series Centrifuge:** Close the lid and set to PUREPRP 60 SPIN 2.
 - b. **Platinum Series Centrifuge:** Close the lid and set to PUREPRP SP SPIN 2.
 - c. **Executive Series Centrifuge:** Close the lid and set to 4.0 minutes and 4.4 x 1000 RPM (4400 RPM).
 - d. Press the start button. Once the centrifuge stops, remove the **Concentrator Device**.
29. **SECOND EXTRACTION:** Using the 60mL syringe, aspirate plasma from the needle-less port leaving 7mL or the desired amount in the **Concentrator Device**.
30. **RESUSPEND THE PRP:** Gently swirl the **Concentrator Device** to re-suspend the platelet concentrate into the plasma.
31. **EXTRACT PRP:** Attach a sterile 12mL syringe to the needle-less port and tilt the **Concentrator Device** 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

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 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

33. **LOAD:** Remove and discard the red vented cap from the needle-less port of the **Separator Device**. Slowly add the anticoagulated whole blood through the needle-less port of the Concentrating Device.
 34. **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.
 35. **FIRST SPIN:**
 - a. **Sapphire Series Centrifuge:** Close the lid and set to PUREPRP 30 SPIN 1.
 - b. **Platinum Series Centrifuge:** Close the lid and set to PUREPRP SP SPIN 1.
 - c. **Executive Series Centrifuge:** Close the lid and set to 1.0 minute and 4.4 x 1000 RPM (4400 RPM).
 - d. Press the start button. Once the centrifuge stops, remove the **Separator Device**.
 36. **FIRST EXTRACTION & TRANSFER:**
 - a. **LP-Protocol A** - Aspirate the platelet plasma suspension (PPS) into the 30mL syringe. (Optionally, aspirate additional 0.5mL of RBC for optimal platelet recovery.)
 - b. **LR-Protocol B** - Aspirate the platelet plasma suspension (PPS) and approximately 1mL of RBC into the 30mL syringe.
 - c. Inject the platelet plasma suspension through bottom port of **Concentrator Device**. **Then PLACE THE CLEAR CAP ON THE BOTTOM PORT!**
 37. **SECOND SPIN:** Counterbalance the **Concentrator Device** with equal volume and place them directly opposite to each other in the centrifuge rotor buckets.
 - a. **Sapphire Series Centrifuge:** Close the lid and set to PUREPRP 30 SPIN 2.
 - b. **Platinum Series Centrifuge:** Close the lid and set to PUREPRP SP SPIN 2.
 - c. **Executive Series Centrifuge:** Close the lid and set to 3.0 minutes and 4.4 x 1000 RPM (4400 RPM).
 - d. Press the start button. Once the centrifuge stops, remove the **Concentrator Device**.
 38. **SECOND EXTRACTION:** Using the 60mL syringe, aspirate plasma from the needle-less port leaving 3-4mL or the desired amount in the **Concentrator Device**.
 39. **RESUSPEND THE PRP:** Gently swirl the **Concentrating Device** to re-suspend the platelet concentrate into the plasma.
- EXTRACT PRP:** Attach a sterile 12mL syringe to the needle-less port and tilt the **Concentrator Device** 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












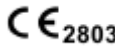

NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.

40. **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

41. **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 anticoagulated whole blood through the needle-less port into the Concentrating Device.
42. **BALANCE:** Make sure each device contains the same amount of volume. Then place them directly opposite to each other in the centrifuge rotor buckets.
43. **FIRST SPIN:**
 - a. **Sapphire Series Centrifuge:** Close the lid and set to PUREPRP 60 SPIN 1.
 - b. **Platinum Series Centrifuge:** Close the lid and set to PUREPRP SP SPIN 1.
 - c. **Executive Series Centrifuge:** Close the lid and set to 2.0 minutes and 4.4 x 1000 RPM (4400 RPM).
 - d. Press the start button. Once the centrifuge stops, remove the **Separator Devices**.
44. **FIRST EXTRACTION & TRANSFER:**
 - a. **LP-Protocol A** - Aspirate the platelet plasma suspension (PPS) into each 60mL syringe. (Optionally, aspirate additional 0.5mL of RBC for optimal platelet recovery.)
 - b. **LR-Protocol B** - Aspirate the platelet plasma suspension (PPS) and approximately 2mL of RBC into each 60mL syringe.
 - c. Inject all of the platelet plasma suspension into the single **Concentrator Device**. **Then PLACE THE CLEAR CAP ON THE BOTTOM PORT!**
45. **SECOND SPIN:** Counterbalance the **Concentrator Devices** with equal volume and place them directly opposite to each other in the centrifuge rotor buckets.
 - a. **Sapphire Series Centrifuge:** Close the lid and set to PUREPRP 60 SPIN 2.
 - b. **Platinum Series Centrifuge:** Close the lid and set to PUREPRP SP SPIN 2.
 - c. **Executive Series Centrifuge:** Close the lid and set to 5.0 minutes and 4.4 x 1000 RPM (4400 RPM).
 - d. Press the start button. Once the centrifuge stops, remove the **Concentrator Devices**.
46. **SECOND EXTRACTION:** Using the 60mL syringe, aspirate plasma from the needle-less port leaving 14mL or the desired amount in the **Concentrator Device**.
47. **RESUSPEND THE PRP:** Gently swirl the **Concentrator Device** to re-suspend the platelet concentrate into the plasma.
48. **EXTRACT PRP:** Attach a sterile 20mL syringe to the needle-less port and tilt the **Concentrator Device** 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	 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	<table border="1" data-bbox="690 556 876 630"> <tr> <td data-bbox="690 556 779 630">EC</td> <td data-bbox="784 556 876 630">REP</td> </tr> </table> Authorized Representative Emergo Europe, Westervoortsedijk 60 6827 AT Arnhem The Netherlands	EC	REP
EC	REP			
 Non-pyrogenic	 CE 2803	 MD Medical Device		

GS60-PURE II: IFU ILLUSTRATION

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

PREPARATION PROTOCOL

Step 1: Using the filtered needle, draw up 6mL of Sodium Citrate Anticoagulant into the 60mL syringe.

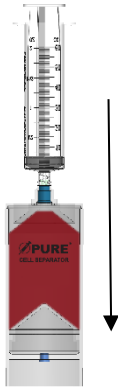


Step 2: Using the butterfly needle draw 54mL whole blood from the patient, filling the syringe to 60 mL



CONCENTRATING PROTOCOL

Step 1:



Load anticoagulated whole blood into the **Separator Device**

Step 2:

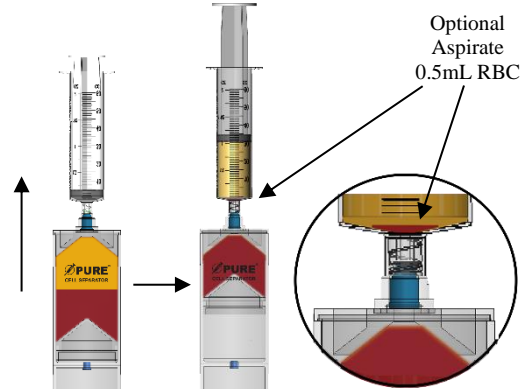
Counterbalance with equal volume and place at opposite ends in the centrifuge rotor.

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

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

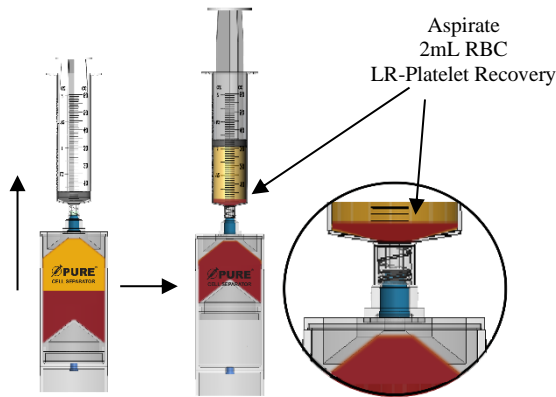
Executive Series Centrifuge
Set to **2 minutes and 4400**

Step 3: **LP-PROTOCOL A**



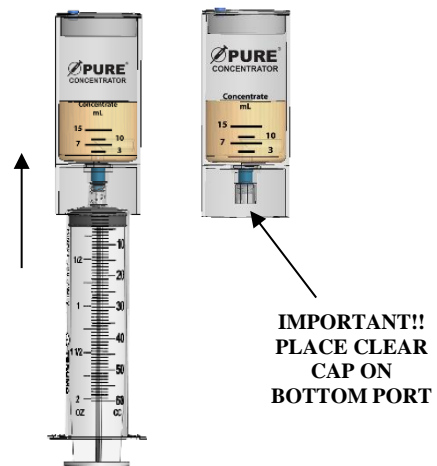
LP-PROTOCOL A: Connect the 60mL syringe to the top port and aspirate the platelet plasma suspension (PPS). Optionally aspirate additional 0.5mL of RBC for optimal platelet recovery.

Step 5: **LR-PROTOCOL B**



LR-PROTOCOL B: Connect the 60mL syringe to the top port and aspirate the platelet plasma suspension (PPS). Aspirate additional 2mL of RBC for LR-platelet recovery.

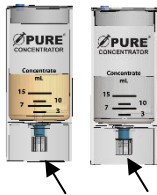
Step 4:



Transfer the platelet plasma suspension (PPS) into the **Concentrator Device**

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 **PUREPRP 60 SPIN 2**

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

Executive Series Centrifuge
Set to **4 minutes and 4400**

Step 6:



Platelet
Concentrate
Buffycoat

After centrifugation

Platelet concentrate buffycoat separates out at the bottom of the **Concentrator Device**

Step 7:



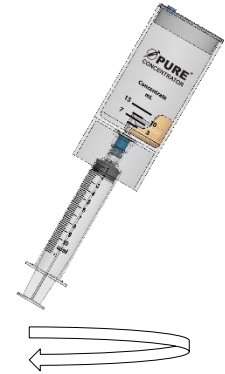
Aspirate Platelet
Poor Plasma

Leave
approximately 7mL
or the desired
amount

Attach 60mL syringe to bottom port. Aspirate platelet poor plasma from the **Concentrator Device**.

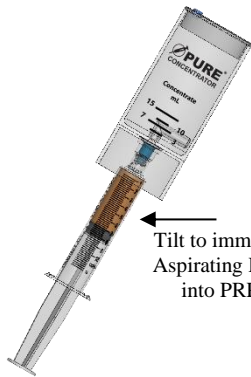
Leave 7mL or the desired amount.

Step 8:



Attach the 12mL syringe to bottom port and gently swirl to resuspend the platelet buffycoat into the plasma.

Step 9:



Tilt to immerse
Aspirating Pipe
into PRP

Tilt to immerse the Aspirating Pipe into the PRP

Step 10:



7mL PRP

Extract the PRP into the 12mL syringe.

GS30-PURE II: IFU ILLUSTRATION

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

PREPARATION PROTOCOL

Step 1: Using the filtered needle, draw 3mL of Citrate Anticoagulant into 30mL Syringe



Step 2: Using the butterfly needle, draw 27mL whole blood from the patient, filling the syringe to 30mL



CONCENTRATING PROTOCOL

Step 1:



Load anticoagulated whole blood into the **Separator Device**

Step 2:

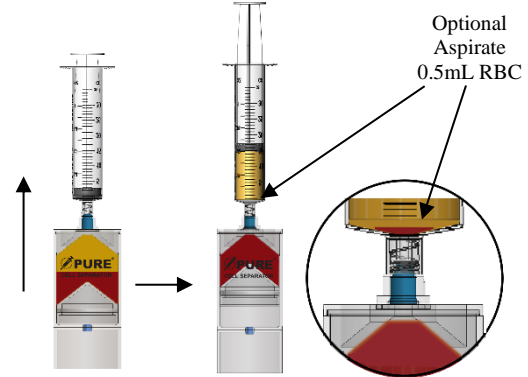
Counterbalance with equal volume and place at opposite ends in the centrifuge rotor.

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

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

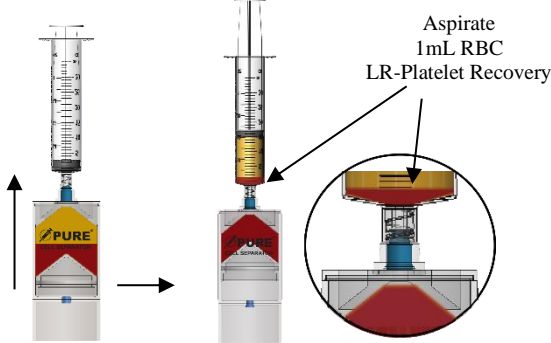
Executive Series Centrifuge
Set to **1 minutes and 4400**

Step 3: **LP-PROTOCOL A**



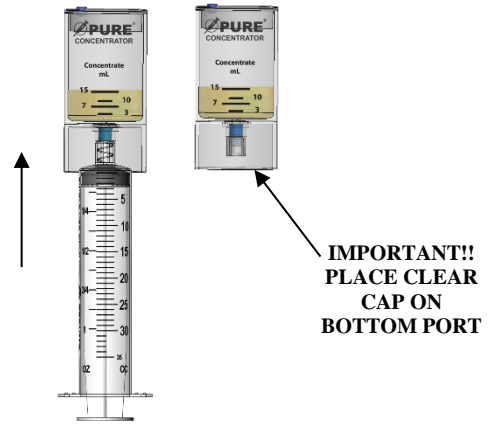
LP-PROTOCOL A: Connect the 30mL syringe to the top port and aspirate the platelet plasma suspension (PPS). Optionally aspirate additional 0.5mL of RBC for optimal platelet recovery.

Step 5: **LR-PROTOCOL B**



LR-PROTOCOL B: Connect the 30mL syringe to the top port and aspirate the platelet plasma suspension (PPS). Aspirate additional 1mL of RBC for LR-platelet recovery.

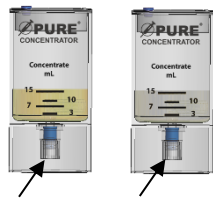
Step 4:



Transfer the platelet plasma suspension (PPS) into the **Concentrator Device**

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

Step 5:



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

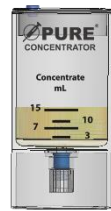
Counterbalance with equal volume then place directly opposite to each other in the centrifuge rotor buckets.

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

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

Executive Series Centrifuge
Set to **3 minutes and 4400**

Step 6:



Platelet Concentrate Buffycoat

After centrifugation

Platelet concentrate buffycoat separates out at the bottom of the **Concentrator Device**

Step 7:



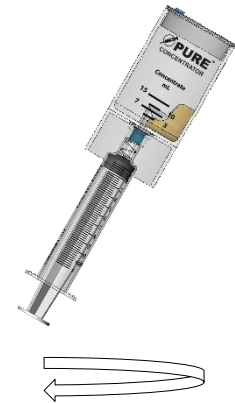
Aspirate platelet poor plasma

Leave approximately 3-4mL or the desired amount

Attach 30mL syringe to bottom port. Aspirate platelet poor plasma from the **Concentrator Device**.

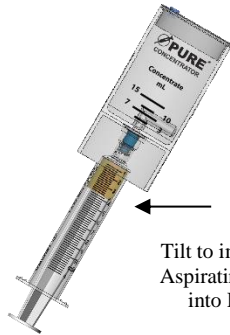
Leave 3-4mL or the desired amount.

Step 8:



Attach the 12mL syringe to bottom port and gently swirl to resuspend the platelet buffycoat into the plasma.

Step 9:



Tilt to immerse Aspirating Pipe into PRP

Tilt to immerse the aspirating pipe into the PRP and extract the PRP into the 12mL syringe.

Step 10:



3-4mL PRP

GS120-PURE II: IFU ILLUSTRATION

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

PREPARATION PROTOCOL

Step 1: Using the filtered needle, draw up 6mL of Sodium Citrate Anticoagulant into each 60mL syringes.

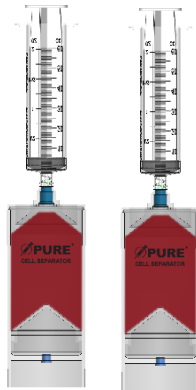


Step 2: Using the butterfly needle draw 54mL whole blood in each syringe from the patient, filling each syringe to 60 mL. Collect 120mL of solution.



CONCENTRATING PROTOCOL

Step 1:



Load anticoagulated whole blood into each Separator Device

Step 2:

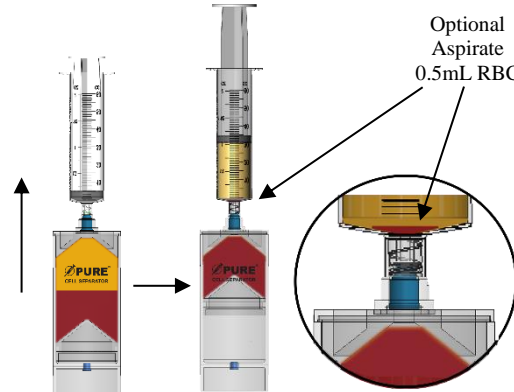
Make sure each device has equal volume and place at opposite ends in the centrifuge rotor.

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

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

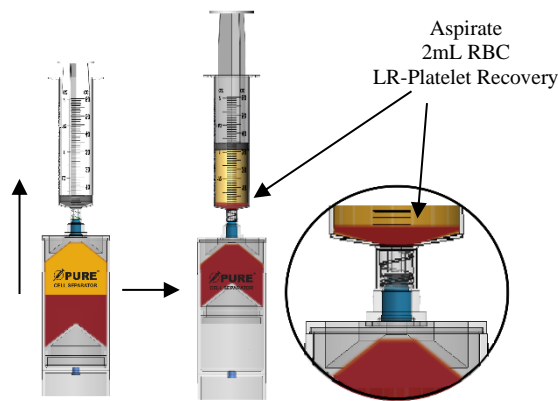
Executive Series Centrifuge
Set to **2 minutes and 4400**

Step 3: **LP-PROTOCOL A: For each Device do the following.**



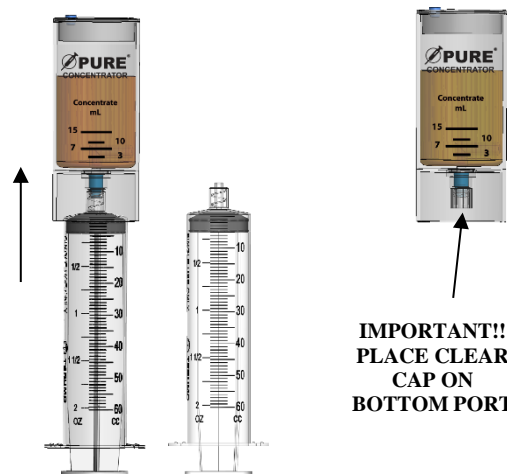
LP-PROTOCOL A: Connect the 60mL syringe to the top port and aspirate the platelet plasma suspension (PPS). Optionally aspirate additional 0.5mL of RBC for optimal platelet recovery.

Step 5: **LR-PROTOCOL B: For each device do the following.**



LR-PROTOCOL B: Connect the 60mL syringe to the top port and aspirate the platelet plasma suspension (PPS). Aspirate additional 2mL of RBC for LR-platelet recovery.

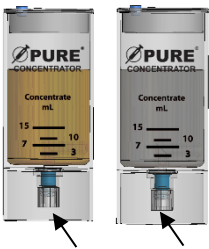
Step 4:



Transfer all of the platelet plasma suspension (PPS) collected from both Separator Devices into the single Concentrator Device

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

Step 5:



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

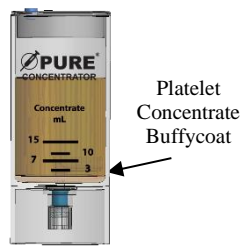
Counterbalance with equal volume then place directly opposite to each other in the centrifuge rotor buckets.

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

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

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

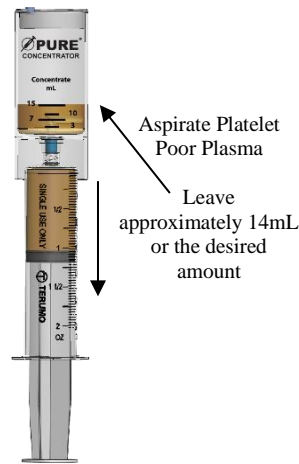
Step 6:



After centrifugation

Platelet concentrate buffycoat separates out at the bottom of the **Concentrator Device**

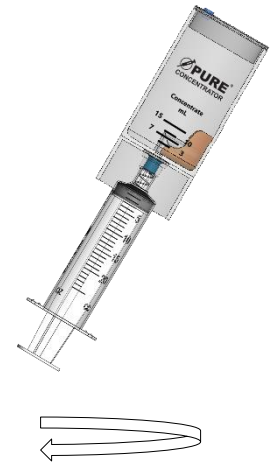
Step 7:



Attach 60mL syringe to bottom port. Aspirate platelet poor plasma from the **Concentrator Device**.

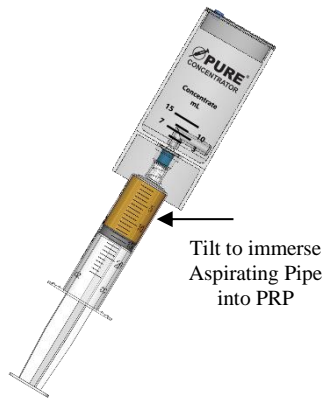
Leave 14mL or the desired amount.

Step 8:



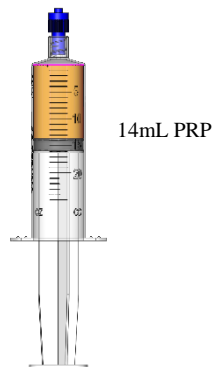
Attach the 12mL syringe to bottom port and gently swirl to resuspend the platelet buffycoat into the plasma.

Step 9:



Tilt to immerse the aspirating pipe into the PRP and extract the PRP from device.

Step 10:



14mL PRP