GenesisCS Component Concentrating System
Platelet Concentrating System
PUREPRP® TWO
Plasma Ultrafiltration System 60mL
FC60-PURE
Date: May 2024

Instruction for use

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® TWO 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 deem 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 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

CORE™ ULTRAFILTRATION

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

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. Close the lid.
26. FIRST SPIN:
    a. **Sapphire Series Centrifuge: PUREPRP 60 SPIN 1.**
    b. **Platinum Series Centrifuge: PUREPRP SP SPIN 1.**
    c. **Executive Series Centrifuge: 2.0 minutes and 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 1mL 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: PUREPRP 60 SPIN 2.**
    b. **Platinum Series Centrifuge: PUREPRP SP SPIN 2.**
    c. **Executive Series Centrifuge: 4.0 minutes and 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.
32. **PROTEIN RICH PRP: Follow Illustration Steps 24-47.**
33. **Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

INSTRUCTION FOR USE
Macro-Micro Filtration

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

34. The CORE™ Ultrafiltration System is manufactured by EmCyte Corporation. The kit concentrates platelet poor plasma proteins from a small sample of platelet poor plasma at the point of care. The system contains syringes and the concentrating device accessories.

MATERIALS

35. The materials consist of medical grade polymers, elastomers 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

36. The safety and effectiveness of this device for in vivo indications for use have not been established.
37. The plasma concentrate prepared by this device has not been evaluated for any clinical indications.
38. The plasma concentrate prepared by this device is not indicated for delivery to the patient's circulatory system.
39. For investigational use.

USER POPULATION

40. 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 practitioner is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.

DEVICE USE ENVIRONMENT

41. 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

42. Use proper safety precautions to guard against needle sticks.
43. Do not use sterile components of this system if package is opened or damaged.
44. Single use device. Do not reuse. Do not attempt to clean or re-sterilize this product.
45. Do not use after expiration date.

POSSIBLE RISKS

46. 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.
47. Reuse may be a potential biohazard

POSSIBLE ADVERSE EFFECTS

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

STERILITY

52. The CORE™ Ultrafiltration System is 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.

Do not use if package is damaged	Attention, read instruction for use	Store in a dry place	Store in a cool place
STERILE EO	Do not re-sterilize	Consult instruction for use	Rx Only Prescription Use
Single use only	Non-pyrogenic	MD Medical Device	EmCyte Corporation 4331 Veronica S. Shoemaker Blvd. Fort Myers, FL 33916 Phone: 239-481-7725

PUREPRP® TWO PRP ILLUSTRATION

PREPARATION PROTOCOL

STEP 1:

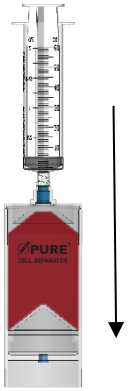
Using the filtered needle, draw up 6mL of Sodium Citrate Anticoagulant into the 60mL syringe.

STEP 2:

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

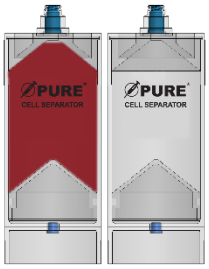
CONCENTRATING PROTOCOL

STEP 3:



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

STEP 4:



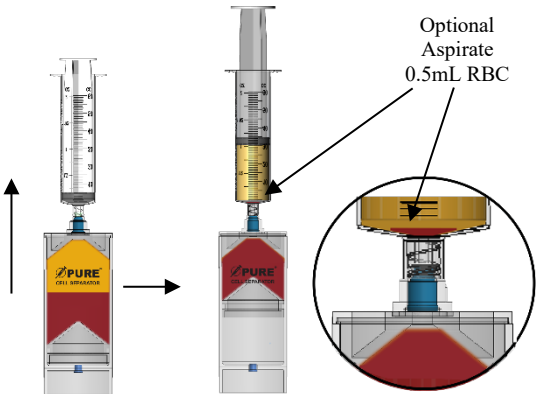
Counterbalance with equal volume and place at opposite ends in the centrifuge rotor.

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 RPM**

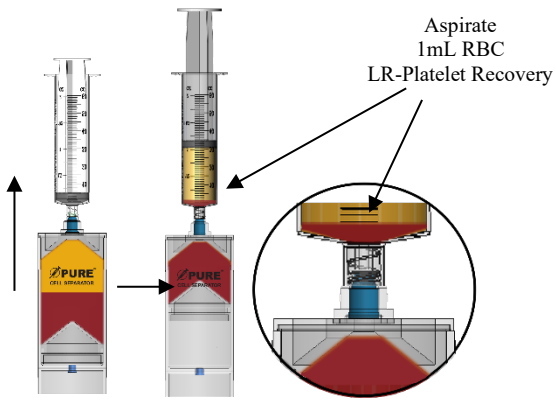
STEP 5: LP-PROTOCOL A



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.

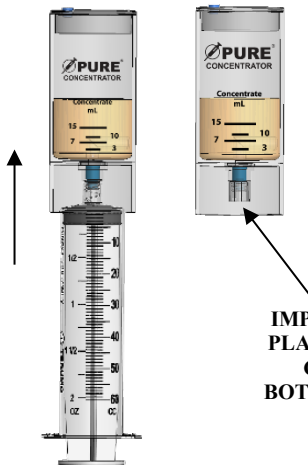
OR

LR-PROTOCOL B



LR-PROTOCOL B: Connect the 60mL syringe to the top port and aspirate the platelet plasma suspension (PPS). Aspirate additional 1mL of RBC for LR-platelet recovery.

STEP 6:

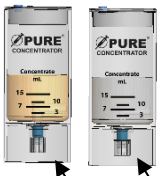


IMPORTANT!!
PLACE CLEAR
CAP ON
BOTTOM PORT

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

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

STEP 7:



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 RPM**

STEP 8:

Platelet Concentrate Buffycoat

After centrifugation

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

STEP 9:

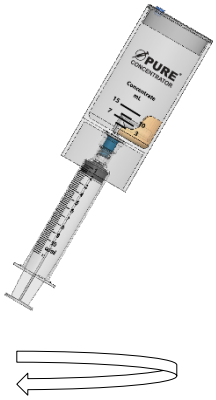
Aspirate Platelet Poor Plasma

Leave approximately 7mL or the desired amount

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

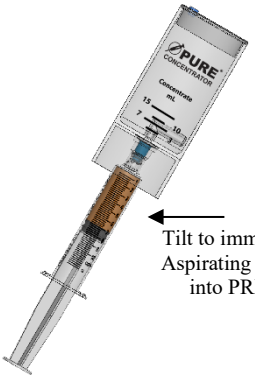
Leave 7mL or the desired amount.

STEP 10:



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

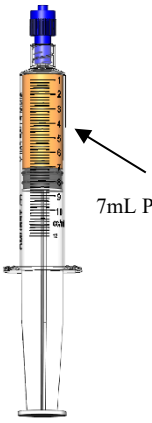
STEP 11:



Tilt to immerse Aspirating Pipe into PRP

Tilt to immerse the Aspirating Pipe into the PRP

STEP 12:

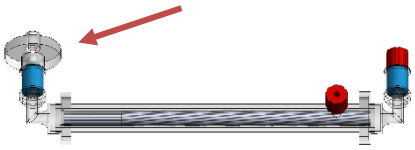


7mL PRP

Extract the PRP into the 12mL syringe.

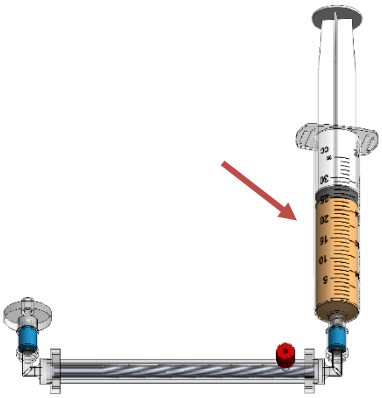
CORE™ PLASMA ULTRAFILTRATION ILLUSTRATION

STEP 13:



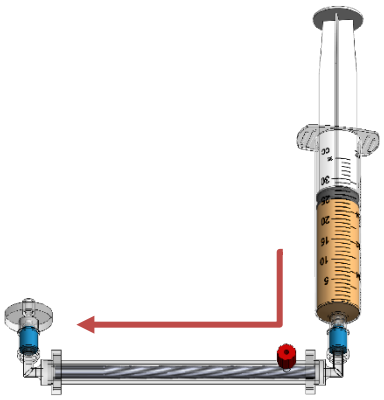
Remove the red vented cap on the far side of the effluent port and attach the hydrophobic filter.

STEP 14:



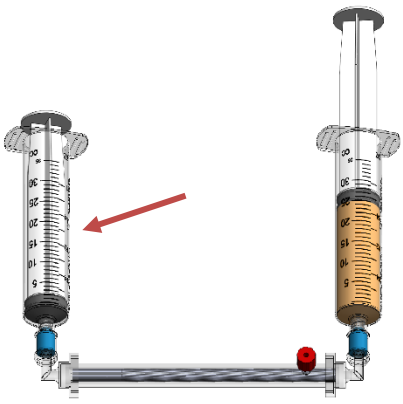
Remove the red cap on the near side of the effluent port and attach the 30mL plasma syringe.

STEP 15:



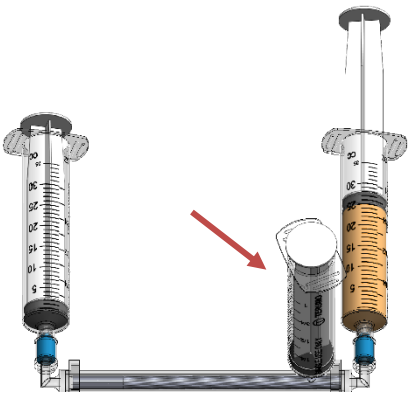
Inject plasma through the device until it reaches the filter.

STEP 16:



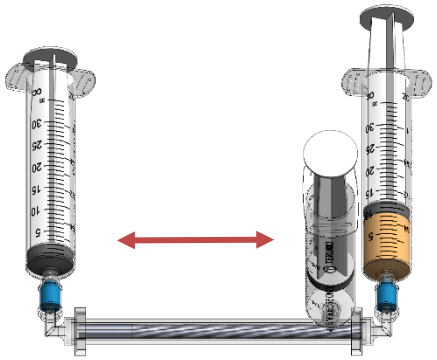
Remove the filter and attach the 30mL transfer syringe.

STEP 17:



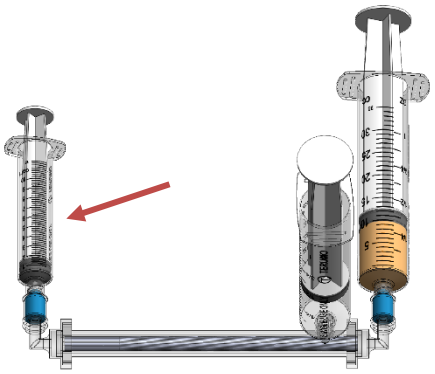
Break the seal of the effluent syringe, remove the red cap and attach the syringe to the effluent port.

STEP 18:



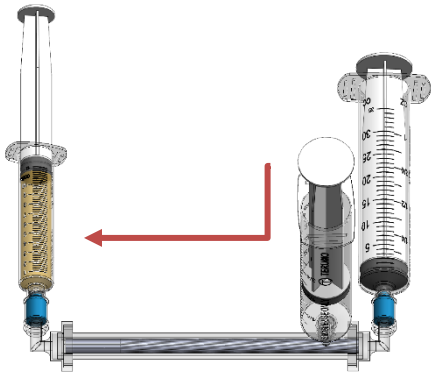
Begin the **Macro-Filtration** process by injecting the plasma back and forth through the 30mL syringes until the plasma retentate reaches approximately 10mL.

STEP 19:



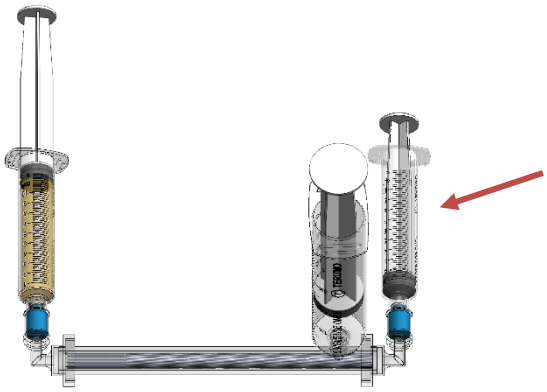
Replace the empty 30mL syringe with a 12mL syringe.

STEP 20:



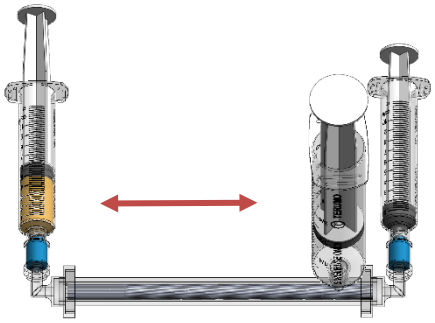
Inject the 10mL plasma retentate into the 12mL syringe

STEP 21:



Replace the second 30mL syringe with a 12mL syringe.

STEP 22:



Begin the **Micro-Filtration** process by injecting the plasma back and forth through the 12mL syringes until the plasma retentate reaches 5mL.

STEP 23:

Final protein concentrate.

PUREPRP® TWO PROTEIN RICH PRP ILLUSTRATION

PREPARATION PROTOCOL:

STEP 24:

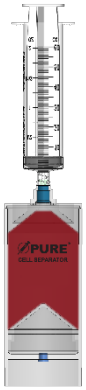
Using the filtered needle, draw up 6mL of Sodium Citrate Anticoagulant into the 60mL syringe.

STEP 25:

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

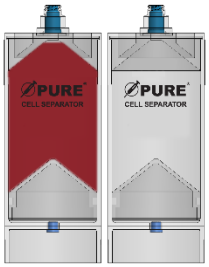
CONCENTRATING PROTOCOL

STEP 26:



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

STEP 27:



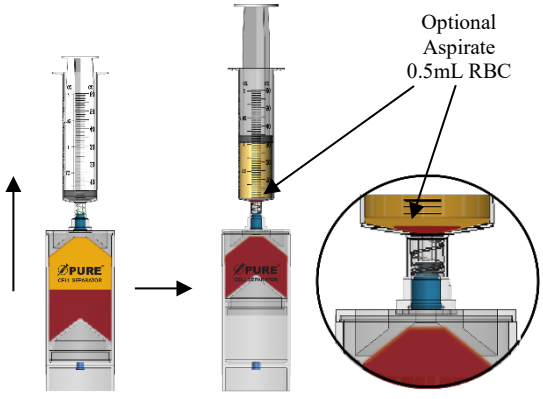
Counterbalance with equal volume and place at opposite ends in the centrifuge rotor.

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 RPM**

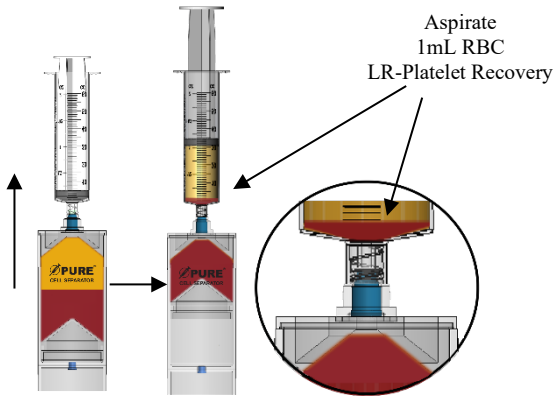
STEP 28: LP-PROTOCOL A



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.

OR

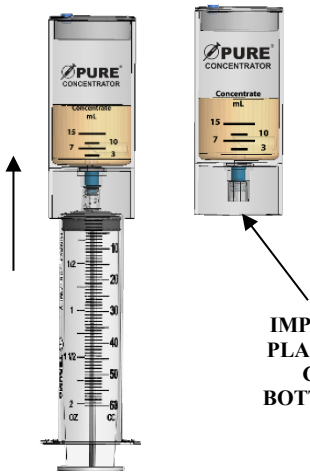
LR-PROTOCOL B



LR-PROTOCOL B: Connect the 60mL syringe to the top port and aspirate the platelet plasma suspension (PPS). Aspirate additional 1mL of RBC for
LR-platelet recovery.

EmCyte Corporation
4331 Veronica S. Shoemaker Blvd., Suite 4, Fort Myers, Florida 33916, USA. www.emcyte.com

STEP 29:

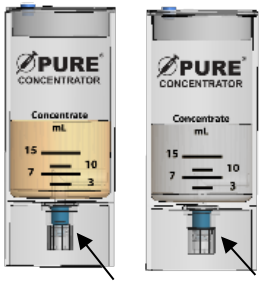


IMPORTANT!!
PLACE CLEAR
CAP ON
BOTTOM PORT

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

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

STEP 30:



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

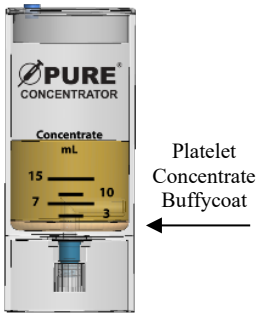
Counterbalance with equal volume then place directly opposite to each other in the centrifuge rotor buckets.

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 RPM**

STEP 31:

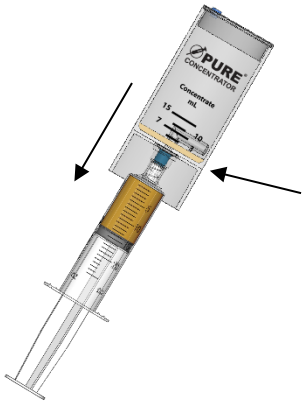


Platelet
Concentrate
Buffycoat

After centrifugation

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

STEP 32:



Aspirate **ALL** of the
Platelet Poor Plasma

Leaving only the platelet
buffycoat

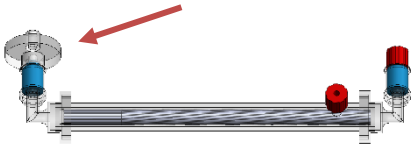
Attach 60mL syringe to bottom port. Aspirate ALL of the platelet poor plasma from the **Concentrator Device.**

Leaving ONLY the platelet buffycoat at the bottom of the device

CONCENTRATE THE PLASMA PROTEINS IN THE CORE™ ULTRAFILTRATION DEVICE.

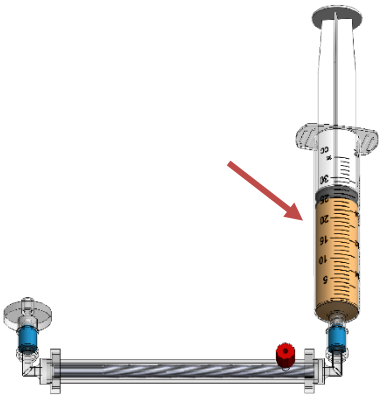
CORE™ PLASMA ULTRAFILTRATION ILLUSTRATION

STEP 33:



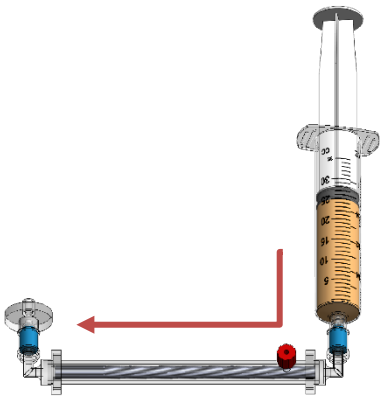
Remove the red vented cap on the far side of the effluent port and attach the hydrophobic filter.

STEP 34:



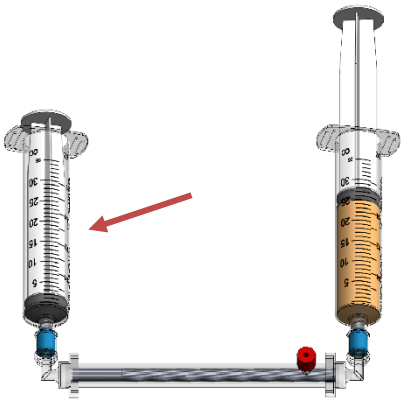
Remove the red cap on the near side of the effluent port and attach the plasma syringe.

STEP 35:



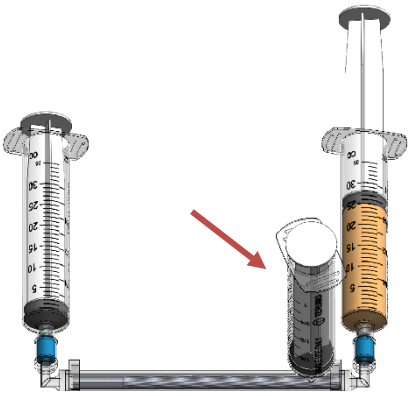
Inject plasma through the device until it reaches the filter.

STEP 36:



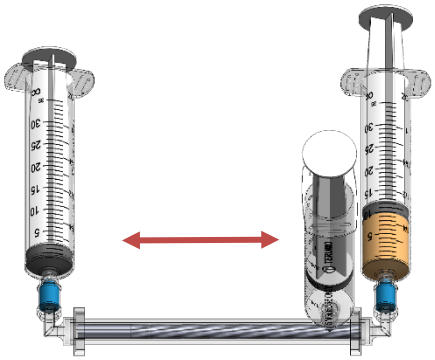
Remove the filter and attach the transfer syringe.

STEP 37:



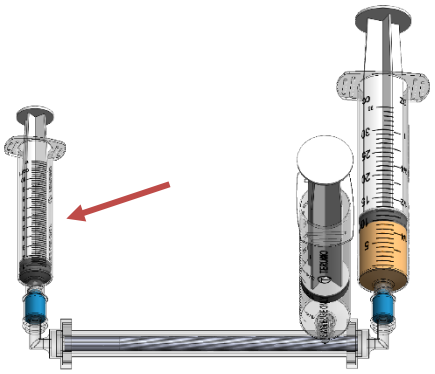
Break the seal of the effluent syringe, remove the red cap and attach the syringe to the effluent port.

STEP 38:



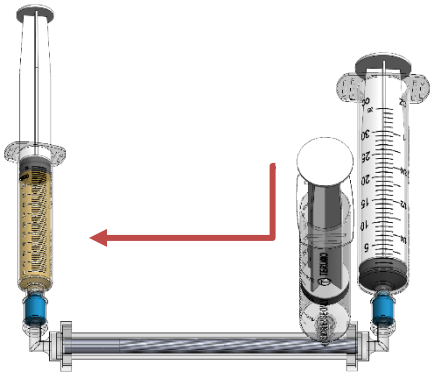
Begin the **Macro-Filtration** process by injecting the plasma back and forth through the syringes until the plasma retentate reaches approximately 10mL.

STEP 39:



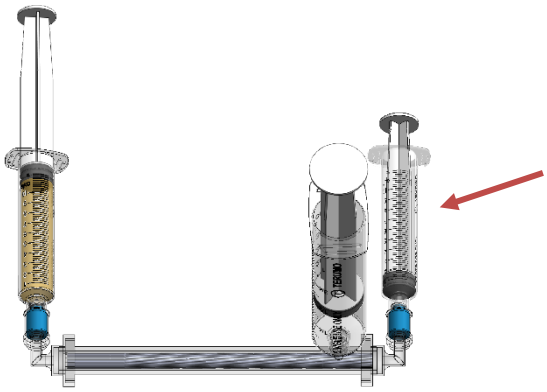
Replace the empty syringe with a 12mL syringe.

STEP 40:



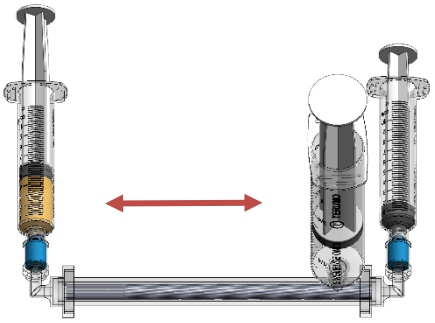
Inject the 10mL plasma retentate into the 12mL syringe

STEP 41:



Replace the second syringe with a 12mL syringe.

STEP 42:

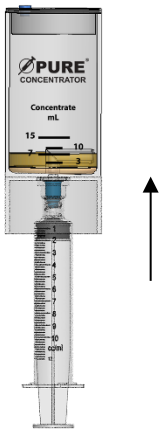


Begin the **Micro-Filtration** process by injecting the plasma back and forth through the 12mL syringes until the plasma retentate reaches 7mL or the desired amount.

STEP 43:

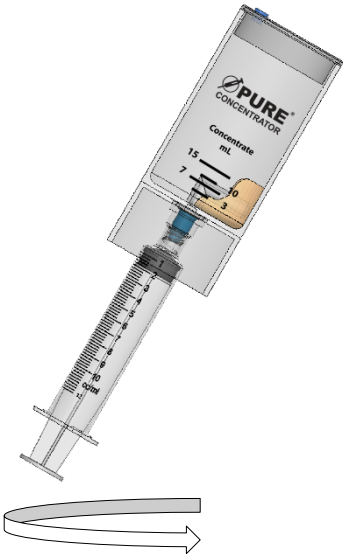
Final protein rich plasma.

STEP 44:



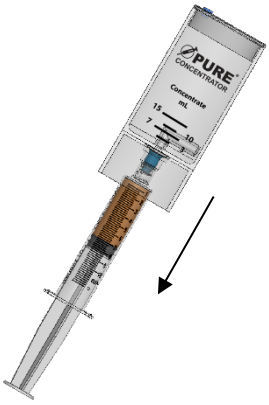
Inject the Protein Rich Plasma into the Concentrator with platelet buffycoat. .

STEP 45:



Resuspend the platelet buffycoat into the Protein Rich Plasma

STEP 46:



Tilt to aspirate the Protein Rich PRP

STEP 47:

Protein Rich PRP

Platelet Concentrate
A2M Concentrate
Fibrinogen Concentrate