

PUREPRP® TWO
PROTEIN RICH PRP System 120mL
FC120-PURE
GenesisCS Component Concentrating System
May 2024

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 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

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: For each concentrating device** do the following steps. 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 each device contains the same amount of volume. 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: FOR EACH DEVICE**
 - 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:** Make sure each device has 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: FOR EACH DEVICE.** Using the 60mL syringe, aspirate plasma from the needle-less port leaving 7mL or the desired amount in each **Concentrator Device**.
30. **RESUSPEND THE PRP:** Gently swirl each **Concentrator Device** to resuspend the platelet concentrate into the plasma.
31. **EXTRACT PRP:** Attach a sterile 12mL syringe to the needle-less port of each device 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 20-39.**
33. **Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

**CORE™ ULTRAFILTRATION
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

- 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	 Single use only	 Store in a cool place	 Rx Only Prescription Use
 STERILE EO	 Do not re-sterilize	 Consult instruction for use	 Store in a dry place	 MD Medical Device
 Non-pyrogenic				

 EmCyte Corporation
4331 Veronica S. Shoemaker Blvd.
Fort Myers, FL 33916
Phone: 239-481-7725

PUREPRP® TWO PRP ILLUSTRATION

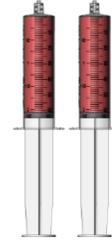
PREPARATION PROTOCOL

STEP 1:



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

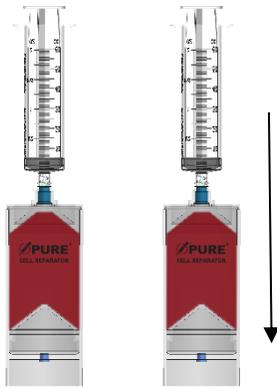
STEP 2:



Using the butterfly needle draw 54mL whole blood from the patient, filling two syringes with 60 mL each.

CONCENTRATING PROTOCOL

STEP 3:



Load anticoagulated whole blood into each Separator Device

STEP 4:



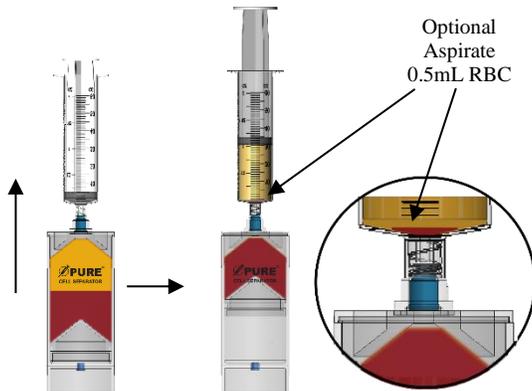
Make sure each device has equal volume and place at opposite ends in the centrifuge rotor.

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

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

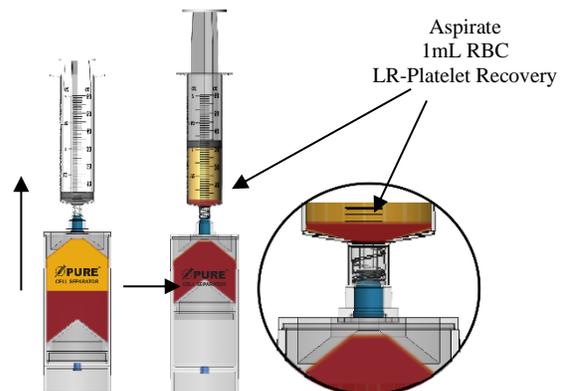
Executive Series Centrifuge
Set to **2 minutes and 4400 RPM**

STEP 5: FOR EACH DEVICE: 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.

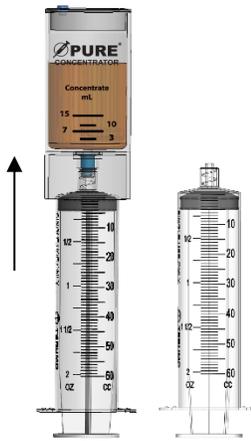
LR-PROTOCOL B



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.

OR

STEP 6:



**IMPORTANT!!
PLACE CLEAR
CAP ON
BOTTOM PORT**

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 7:



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

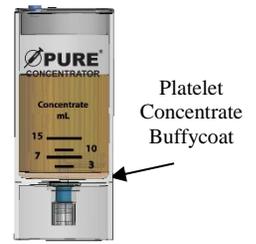
Counterbalance with equal volume then place directly opposite to each other in the centrifuge rotor buckets.

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

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

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

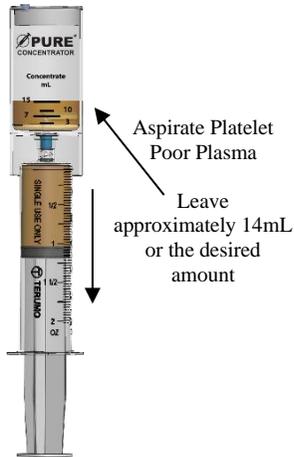
STEP 8:



After centrifugation

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

STEP 9:

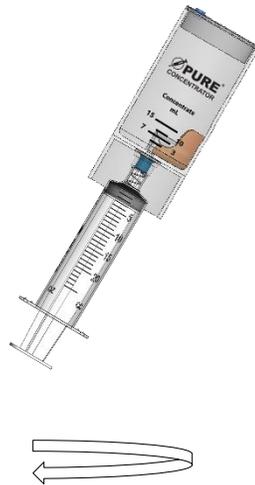


Aspirate Platelet Poor Plasma
Leave approximately 14mL or the desired amount

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

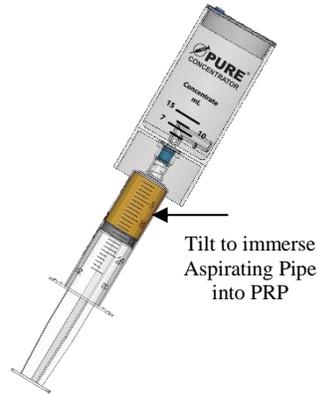
Leave 14mL or the desired amount.

STEP 10:



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

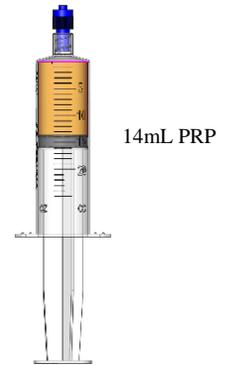
STEP 11:



Tilt to immerse Aspirating Pipe into PRP

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

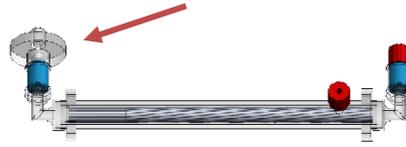
STEP 12:



14mL PRP

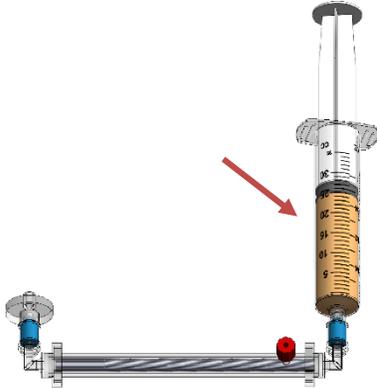
CORE™ PLASMA ULTRAFILTRATION ILLUSTRATION

STEP 13:



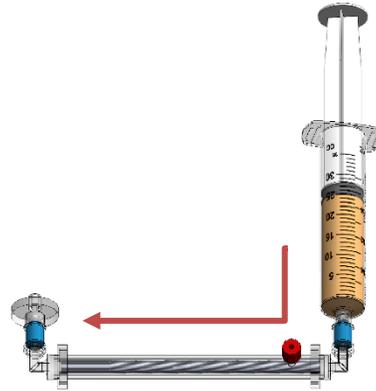
Remove the red vented cap on the far side of the effluent port and attach the hydrophobic filter.

STEP 14:



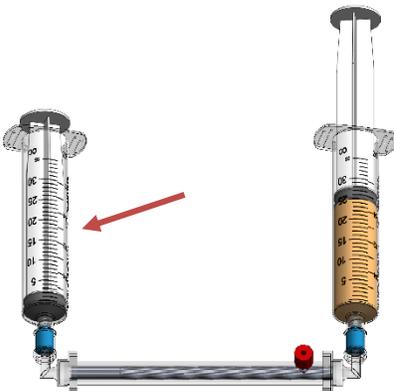
Remove the red cap on the near side of the effluent port and attach the plasma syringe.

STEP 15:



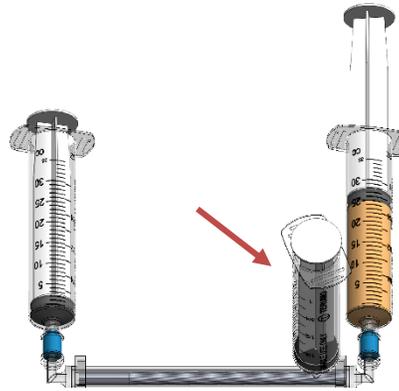
Inject plasma through the device until it reaches the filter.

STEP 16:



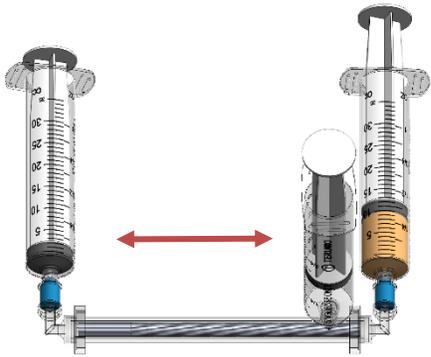
Remove the filter and attach the transfer syringe.

STEP 17:



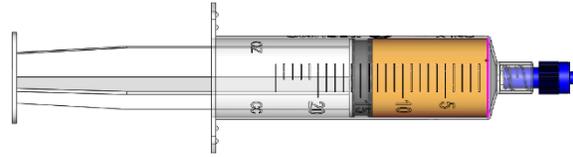
Break the seal of the effluent syringe, remove the red cap and attach the syringe to the effluent port.

STEP 18:



Begin the **ultrafiltration** process by injecting the plasma back and forth through the syringes until the plasma retentate reaches approximately 14mL or the desired amount.

STEP 19:



14mL Protein Concentrate.

FINAL PRODUCT

**Platelet Rich
Plasma
14mL**



**Protein
Concentrate
14mL**



PUREPRP® TWO PROTEIN RICH PRP ILLUSTRATION

PREPARATION PROTOCOL:

STEP 20:



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

STEP 21:



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

CONCENTRATING PROTOCOL

STEP 22:



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

STEP 23:



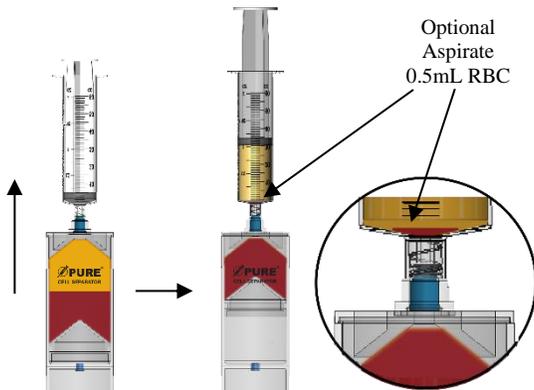
Counterbalance with equal volume and place at opposite ends in the centrifuge rotor.

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

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

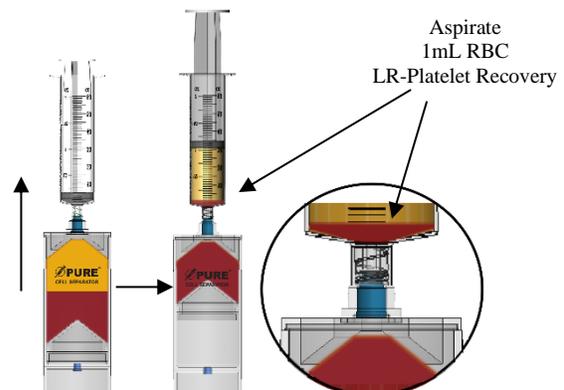
Executive Series Centrifuge
Set to **2 minutes and 4400 RPM**

STEP 24: 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.

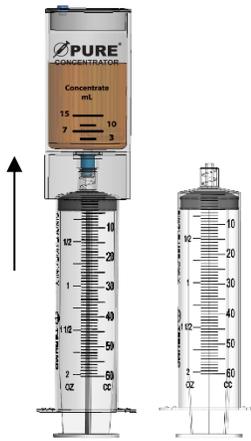
LR-PROTOCOL B



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.

OR

STEP 25:



**IMPORTANT!!
PLACE CLEAR
CAP ON
BOTTOM PORT**

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 26:



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

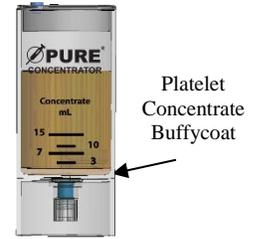
Counterbalance with equal volume then place directly opposite to each other in the centrifuge rotor buckets.

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**

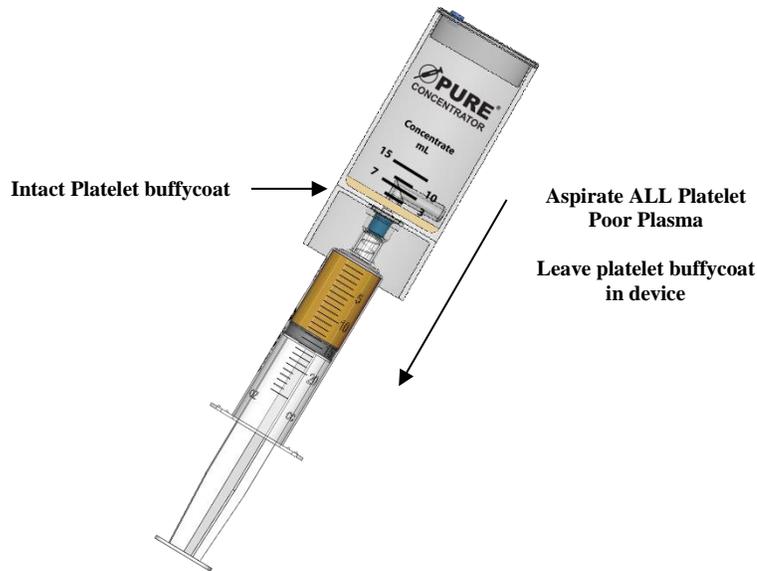
STEP 27:



After centrifugation

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

STEP 28:

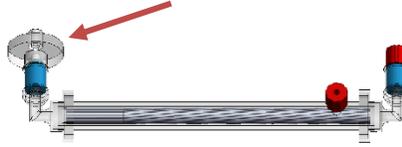


Attach 60mL syringe to bottom port. Aspirate ALL of the platelet poor plasma from the **Concentrator Device**.

Leave the platelet buffycoat intact at the bottom of the device.

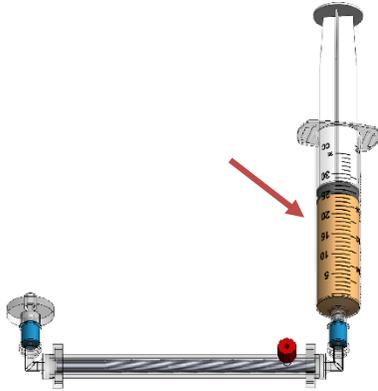
CORE™ PLASMA ULTRAFILTRATION ILLUSTRATION

STEP 29:



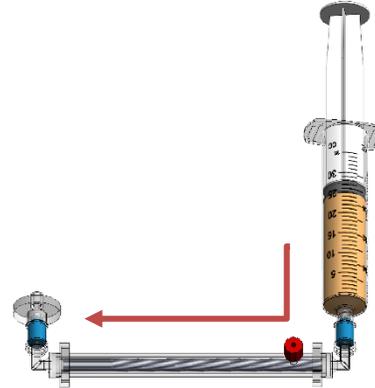
Remove the red vented cap on the far side of the effluent port and attach the hydrophobic filter.

STEP 30:



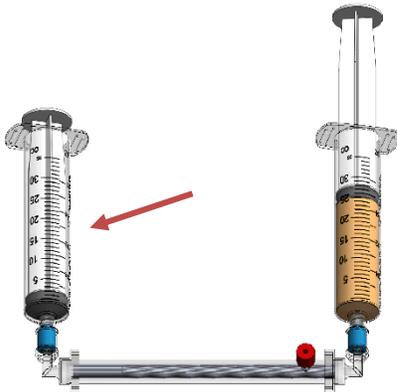
Remove the red cap on the near side of the effluent port and attach the collected plasma syringe.

STEP 31:



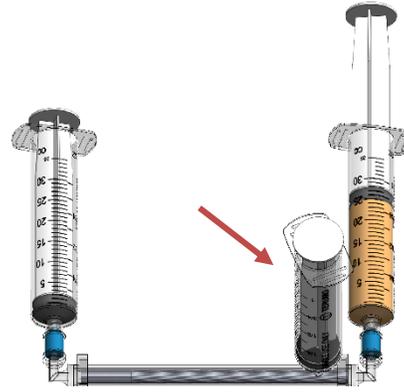
Inject plasma through the device until it reaches the filter.

STEP 32:



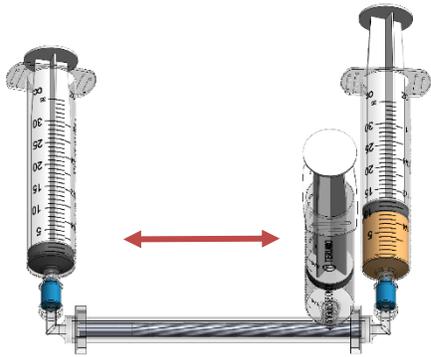
Remove the filter and attach the transfer syringe.

STEP 33:



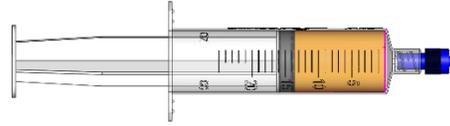
Break the seal of the effluent syringe, remove the red cap and attach the syringe to the effluent port.

STEP 34:



Begin the **ultrafiltration** process by injecting the plasma back and forth through the syringes until the plasma retentate reaches approximately 14mL or the desired amount.

STEP 35:



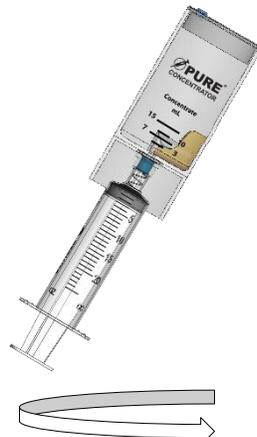
Protein Rich Plasma
14mL or desired amount.

STEP 36:



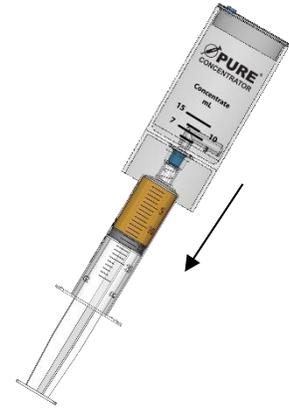
Inject the Protein Rich Plasma into the Concentrator with platelet buffycoat.

STEP 37:



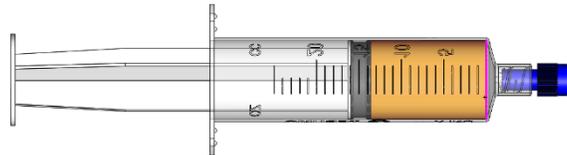
Resuspend the platelet buffycoat into the Protein Rich Plasma

STEP 38:



Tilt to aspirate the Protein Rich PRP

FINAL PRODUCT



Protein Rich PRP
14mL

Platelet Concentrate
A2M Concentrate
Fibrinogen Concentrate