PUREPRP® SUPRAPHYSIOLOGIC
PROTEIN RICH PRP System 60mL
FC60-SP
GenesisCS Component Concentrating System
Date: 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® Supraphysiologic 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 PurePRP® Supraphysiologic 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 is mixed with autograft and allograft bone prior to application to an orthopedic site to improve bone graft handling characteristics.
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 according to current AABB guidelines.

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® SupraPhysiologic 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 8mL of 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 52mL 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: **IMPORTANT: Attach sterile non-vented clear cap to the bottom port of the device. The clear cap MUST be always attached to the bottom port before centrifugation.**
25. **WITH VENT LID OPEN,** slowly add the anticoagulated whole blood through the top port of the Concentrating Device. **THEN CLOSE VENT LID.**
26. 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. Close the lid.
27. FIRST SPIN:
    a. **Sapphire Series Centrifuge: PUREPRP 60 SPIN 1**
    b. **Platinum Series Centrifuge: PUREPRP SP SPIN 1**
    c. **Executive Series Centrifuge: 2 minutes and 4400 RPM**
    d. Press the start button. Once the centrifuge stops, remove the Concentrating Device.
28. FIRST EXTRACTION & TRANSFER: Attach the sterile 60mL syringe to the top port.
    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. Remove the clear cap from the bottom port and inject the PPS solution through it. **Recap the bottom port with sterile non-vented clear cap.**
29. SECOND SPIN: Place Concentrating Device back into the centrifuge rotor bucket directly opposite the counterbalance device. Close the lid.
    a. **Sapphire Series Centrifuge: PUREPRP 60 SPIN 2**
    a. **Platinum Series Centrifuge: PUREPRP SP SPIN 2**
    b. **Executive Series Centrifuge: 4 minutes and 4400 RPM**
    c. Press the start button. Once the centrifuge stops, remove the Concentrating Device.
30. SECOND EXTRACTION: Remove the clear cap from the bottom port. Using the 30mL syringe, aspirate plasma from the bottom port leaving 7mL in the device.
31. RESUSPEND THE PRP: Gently swirl the Concentrating Device to re-suspend the platelet concentrate into the plasma.
32. EXTRACT PRP: Attach a sterile 12mL syringe to the bottom port and tilt to aspirate the platelet rich plasma through the open port of the aspirating pipe. Remove sterile syringe and apply a sterile cap.
33. **PROTEIN RICH PRP: Follow Illustration Steps 25-49.**

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

CORE™ ULTRAFILTRATION

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

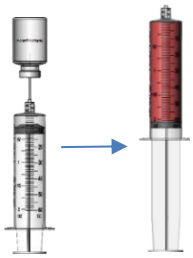
52. The CORE™ Ultrafiltration System is sterilized by ETO exposure. Do not use any component from an opened or damaged package. Do not re-sterilize. Discard if kit packaging is damaged or open.

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

PUREPRP® SUPRAPHYSIOLOGIC PRP ILLUSTRATION

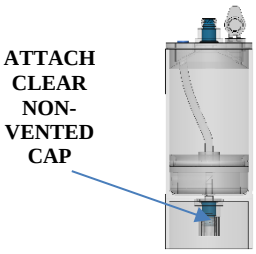
PREPARATION PROTOCOL

STEP 1:



Using the filtered needle, draw 8mL of Sodium Citrate Anticoagulant into 60mL Syringe. Then collect 52mL whole blood filling syringe to 60mL.

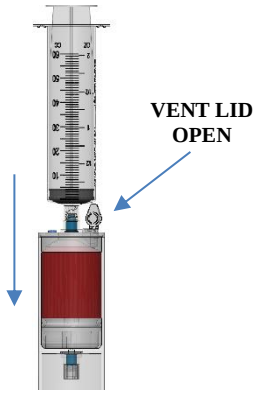
STEP 2:



Attach clear non vented cap to the bottom port.

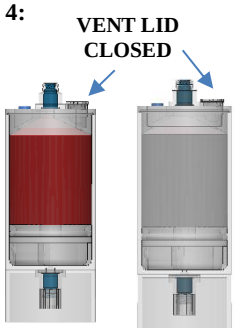
CONCENTRATING PROTOCOL

STEP 3:



With **VENT LID OPEN**
Inject anticoagulated whole blood through the top needle-less port.

STEP 4:



Close VENT LID and counterbalance device with equal volume

Place in the centrifuge rotor at opposite ends.

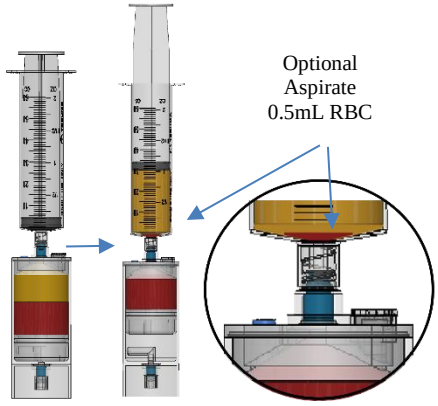
STEP 5:

Sapphire Series Centrifuge:
PUREPRP 60 SPIN 1

Platinum Series Centrifuge:
PUREPRP SP SPIN 1

Executive Series Centrifuge
Set to 2 minutes and 4400

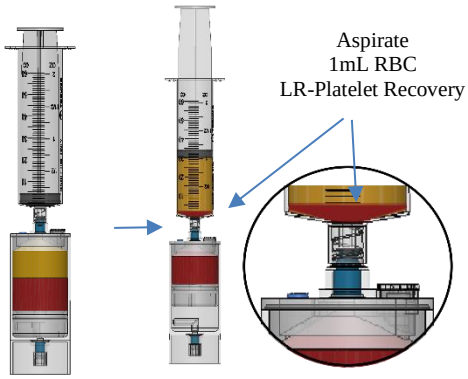
STEP 6: LP-PROTOCOL A



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

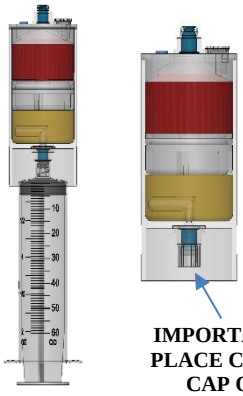
LR-PROTOCOL B

OR



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

STEP 7:



IMPORTANT!! PLACE CLEAR CAP ON BOTTOM PORT

Inject PPS solution into the device through the bottom port.

THEN RECAP WITH STERILE CLEAR CAP ON BOTTOM PORT

STEP 8:

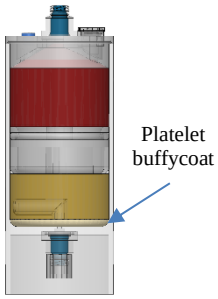
Place back in centrifuge rotor.
Process at:

Sapphire Series Centrifuge: PUREPRP 60 SPIN 2

Platinum Series Centrifuge: PUREPRP SP SPIN 2

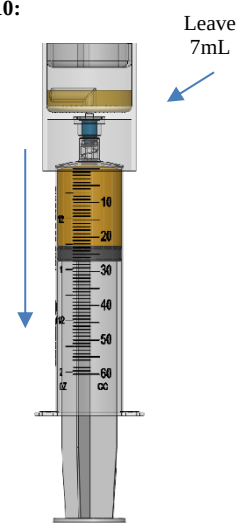
Executive Series Centrifuge 4 minutes and 4400

STEP 9:



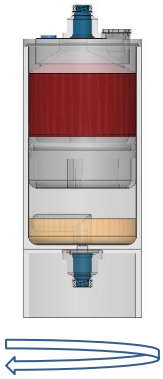
After centrifugation, the platelet buffycoat will be separated at the bottom of the device.

STEP 10:



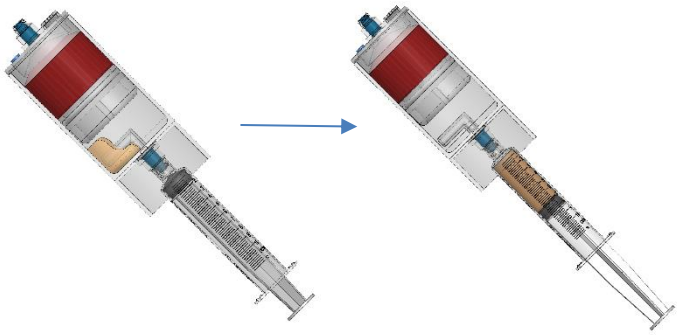
Connect the syringe to the bottom needle-less port and aspirate plasma, leaving 7mL in the device.

STEP 11:



Gently swirl to resuspend the platelet buffycoat into the plasma.

STEP 12:



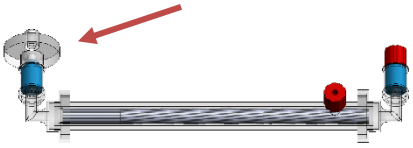
Connect the 12mL syringe to the bottom needle-less port and tilt to aspirate the PRP through the open port of the Aspirating Pipe.

STEP 13:

7mL Clinical PRP

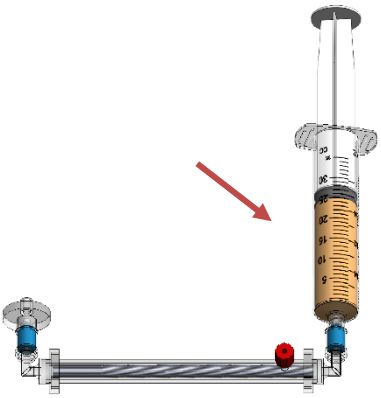
CORE™ PLASMA ULTRAFILTRATION ILLUSTRATION

STEP 14:



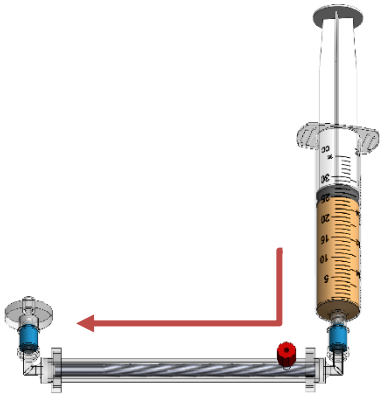
Remove the red vented cap on the far side of the effluent port and attach the hydrophobic filter.

STEP 15:



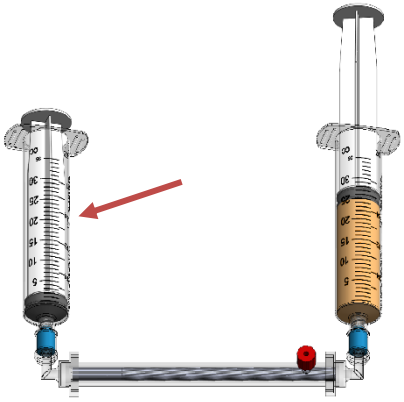
Remove the red cap on the near side of the effluent port and attach the 30mL plasma syringe.

STEP 16:



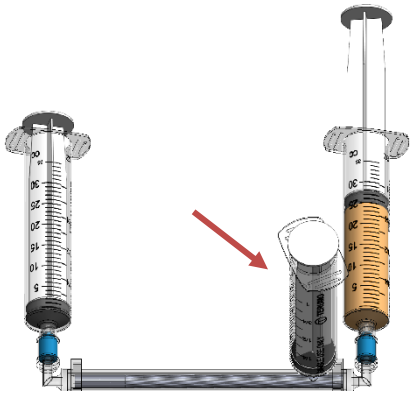
Inject plasma through the device until it reaches the filter.

STEP 17:



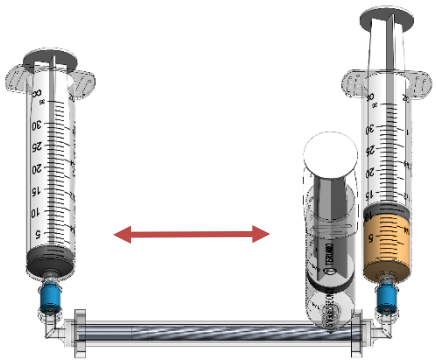
Remove the filter and attach the 30mL transfer syringe.

STEP 18:



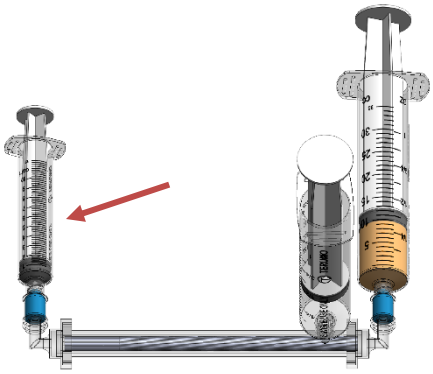
Break the seal of the effluent syringe, remove the red cap and attach the syringe to the effluent port.

STEP 19:



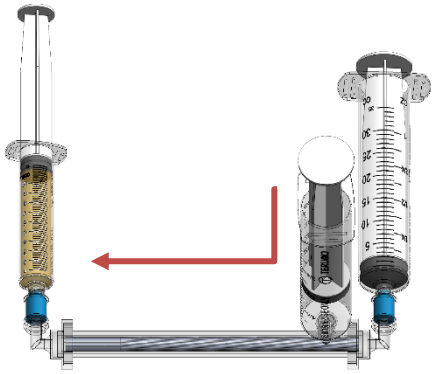
Begin the **Macro-Filtration** process by injecting the plasma back and forth through the 30mL syringes until the plasma retentate reaches approximately 10mL.

STEP 20:



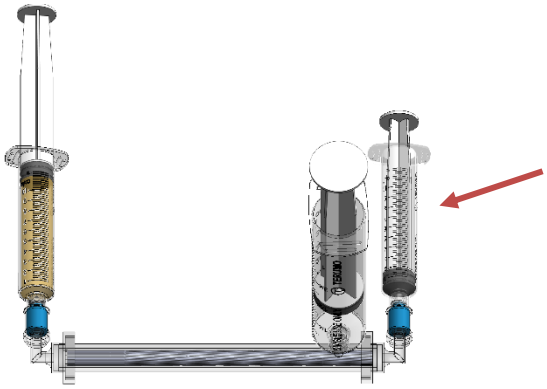
Replace the empty 30mL syringe with a 12mL syringe.

STEP 21:



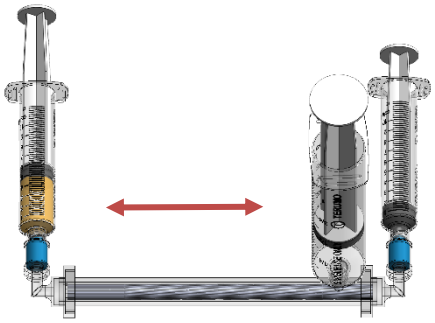
Inject the 10mL plasma retentate into the 12mL syringe

STEP 22:



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

STEP 23:



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

STEP 24:

Final protein concentrate.

FINAL PRODUCT

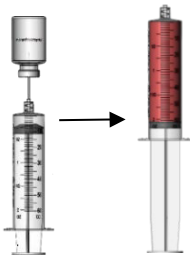
7mL Platelet Rich Plasma

7mL Protein Concentrate

PUREPRP® SUPRAPHYSIOLOGIC PROTEIN RICH PRP ILLUSTRATION

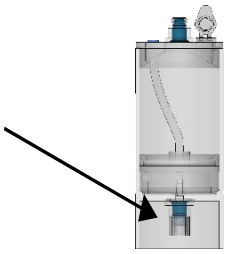
PREPARATION PROTOCOL

STEP 25:



Using the filtered needle, draw 8mL of Sodium Citrate Anticoagulant into 60mL Syringe. Then collect 52mL whole blood filling syringe to 60mL.

STEP 26:



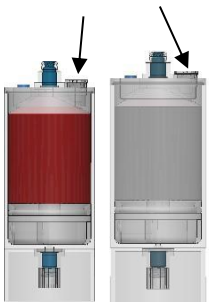
Attach clear non vented cap to the bottom port.

CONCENTRATING PROTOCOL

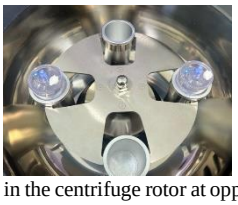
STEP 27:

With **VENT LID OPEN**
Inject anticoagulated whole blood through the top needle-less port.

STEP 28:



Close VENT LID and counterbalance device with equal volume.



Place in the centrifuge rotor at opposite ends.

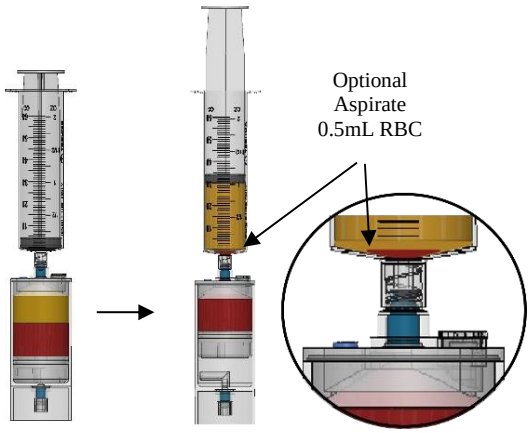
STEP 29:

Sapphire Series Centrifuge:
PUREPRP 60 SPIN 1

Platinum Series Centrifuge:
PUREPRP SP SPIN 1

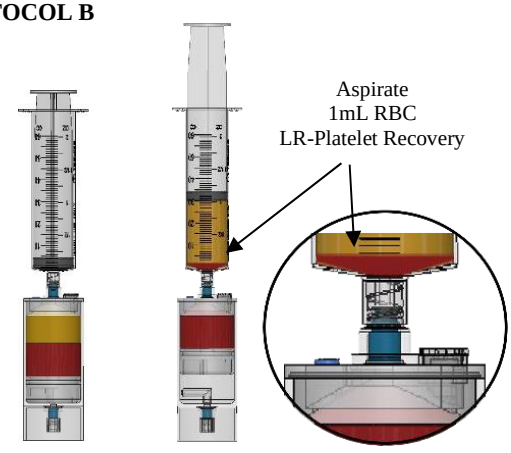
Executive Series Centrifuge:
Set to 2 minutes and 4400

STEP 30: LP-PROTOCOL A



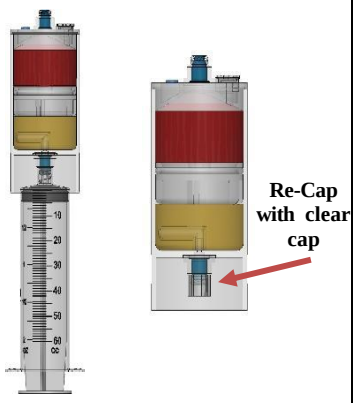
LP-PROTOCOL A: Connect the 60mL syringe to the top port and aspirate the platelet plasma suspension (PPS) into the 60mL syringe. (Optionally, aspirate additional 0.5mL of RBC for optimal platelet recovery).

LR-PROTOCOL B



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

STEP 31:



Inject PPS solution into the device through the bottom port. Then recap with sterile clear cap.

STEP 32:

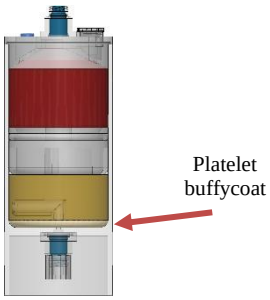
Place back in centrifuge rotor.
Process at:

Sapphire Series Centrifuge:
PUREPRP 60 SPIN 2

Platinum Series Centrifuge:
PUREPRP SP SPIN 2

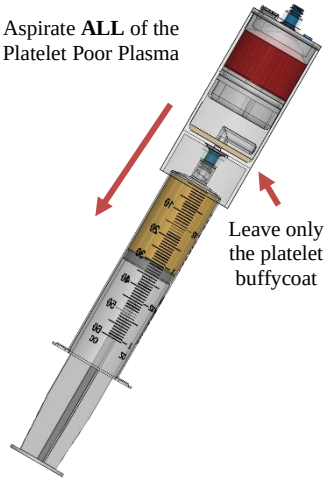
Executive Series Centrifuge
4 minutes and 4400

STEP 33:



After centrifugation, the platelet buffycoat will be separated at the bottom of the device.

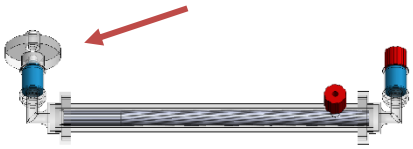
STEP 34:



Connect the syringe to the bottom needle-less port and TILT to aspirate all of the platelet poor plasma leaving the buffycoat at the bottom of the device

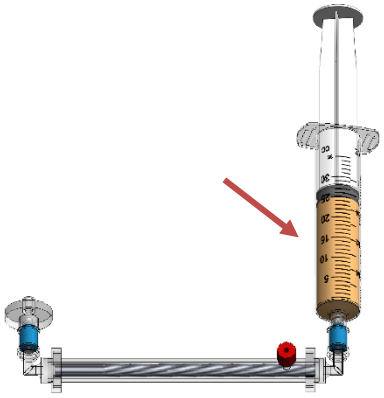
CORE™ PLASMA ULTRAFILTRATION ILLUSTRATION

STEP 35:



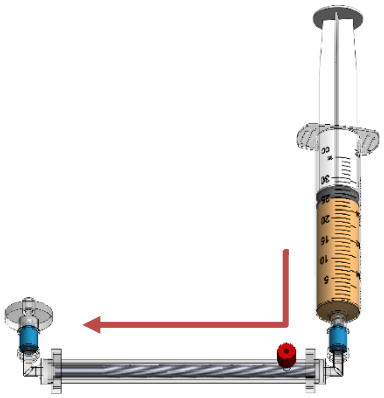
Remove the red vented cap on the far side of the effluent port and attach the hydrophobic filter.

STEP 36:



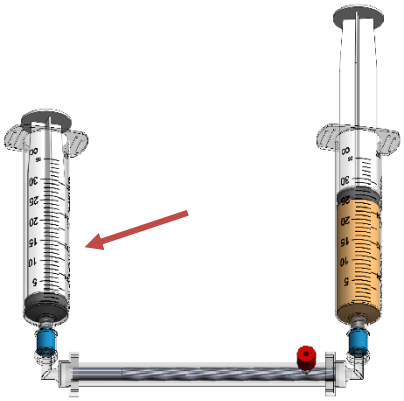
Remove the red cap on the near side of the effluent port and attach the plasma syringe.

STEP 37:



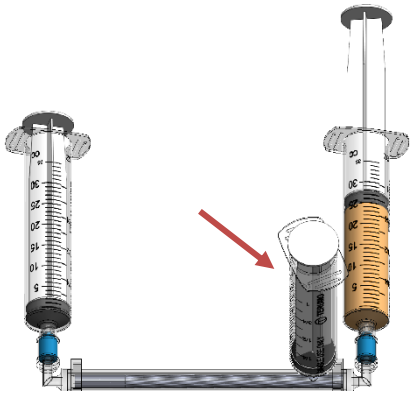
Inject plasma through the device until it reaches the filter.

STEP 38:



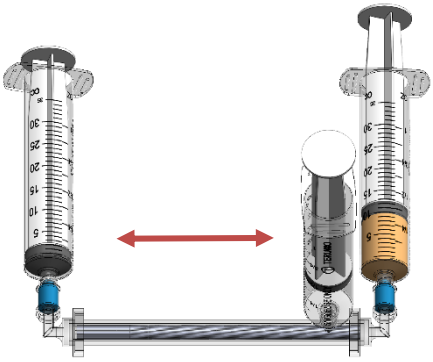
Remove the filter and attach the transfer syringe.

STEP 39:



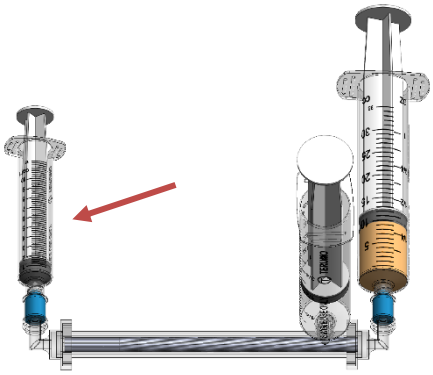
Break the seal of the effluent syringe, remove the red cap and attach the syringe to the effluent port.

STEP 40:



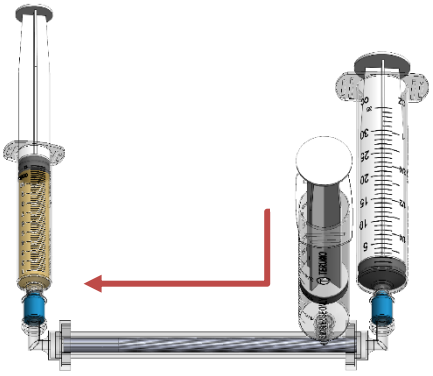
Begin the **Macro-Filtration** process by injecting the plasma back and forth through the syringes until the plasma retentate reaches approximately 10mL.

STEP 41:



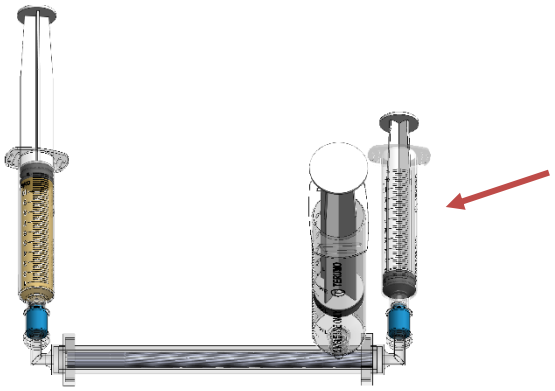
Replace the empty syringe with a 12mL syringe.

STEP 42:



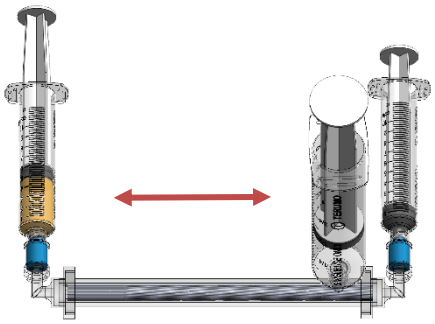
Inject the 10mL plasma retentate into the 12mL syringe

STEP 43:



Replace the second syringe with a 12mL syringe.

STEP 44:

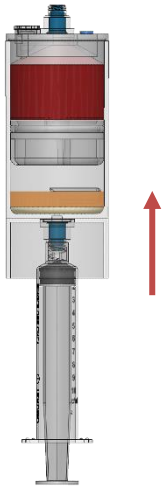


Begin the **Micro-Filtration** process by injecting the plasma back and forth through the 12mL syringes until the plasma retentate reaches 7mL or the desired amount.

STEP 45:

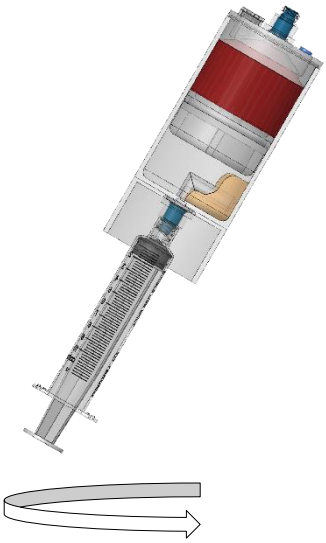
Final protein rich plasma.

STEP 46:



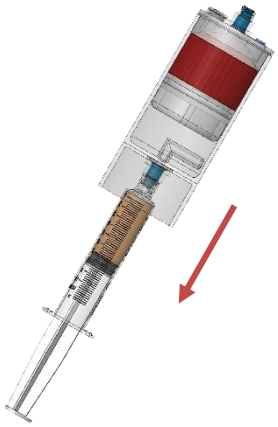
Inject the Protein Rich Plasma into the Concentrator with platelet buffycoat

STEP 47:



Resuspend the platelet buffycoat into the Protein Rich Plasma

STEP 48:

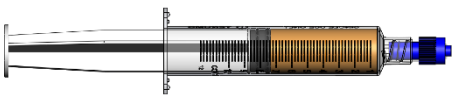


Tilt to aspirate the Protein Rich PRP

STEP 49:

FINAL PRODUCT

7mL Protein Rich PRP



Protein Rich PRP

Platelet Concentrate
A2M Concentrate
Fibrinogen Concentrate