XCELL Protein Concentration System Family

Single Use Only Device
IFU PN 70-099 Rev 1.3

These instructions support the following products:

SKU	Description	IFU PN
XC-PC-60	XCELL Protein Concentration System 60mL	70-099
XC-PC-120	XCELL Protein Concentration System 120mL	70-099
AB-FVR-02	XCELL PC 'Fluid Volume Reducer 120mL	70-099

▲***CAUTION:*** **Federal Law restricts the device to sale by or on the order of a physician.**

▲***CAUTION:*** **The XCELL Protein Concentration System is provided sterile. DO NOT use any component of the system if the packaging is opened or damaged. DO NOT clean and/or re-sterilize. Single-use only.**

COMPANY INFO: APEX Biologix is a medical device and biologics company that markets products in the fields of interventional pain management, sports medicine, and orthopedics. An industry leader, APEX Biologix provides comprehensive tools to help practitioners become successful in these disciplines.

Filtration Supplement Summary: The XCELL Protein Concentration System 120mL is provided with the HPH Junior Hemoconcentrator. The instructions that follow address the use of only the filtration portion of the process. For PRP processing, please see the relevant XC-PRP-60 and XC-PRP-60 Supplemental IFU's, which have also been provided.

PRP INDICATIONS FOR USE: The XCELL PRP™ System is intended to be used for the safe and rapid preparation of autologous platelet-rich plasma (PRP) from a small sample of peripheral blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to the application to a bony defect for improving handling characteristics.

HPH Junior Intended Use: The HPS Junior Hemoconcentrator is intended for use as an ultrafiltration system to remove excess fluid during and/or following cardiopulmonary bypass procedures where acute hemodilution is employed. The device is intended, as is the predicate, for all patients (including all pediatric subgroups) where a small priming volume is desired. In pediatric patients this device must be used only as a part of the cardiopulmonary bypass or circulatory support circuit, with the circuit being connected to the patient.

CONTRAINDICATIONS: The XCELL Protein Concentration System 120mL may be contraindicated when used in a non-sterile environment, patients taking aspirin within 72 hours, drugs that affect platelet function, patients with any serious medical conditions that would make the subject unable to safely tolerate the extracorporeal blood components and/or volume required for the procedure. The blood products from this device are not to be used for transfusion.

▲*WARNING AND PRECAUTIONS:*

1. Appropriate precautions should be taken to protect against needle sticks.
2. Do not use the components in the XC-PC kit if the packaging is open or damaged.
3. Do not use after expiration date.
4. Use only the Instruction for Use of the XC-PC system.
5. The physician and all staff who will be utilizing the XC-PC system should be well versed in the use of the system, ancillary equipment, maintaining a sterile environment, trained phlebotomists, disposal of biohazards, etc.
6. The PRP/PPP/PC sample should be used within 4 hours of blood draw.
7. The PRP/PPP/PC is not intended to be returned to the patient's circulatory system.
8. The XC-PC-60, XC-PC-120, AB-FVR-02 systems are single use. DO NOT clean or re-sterilize any part of this system. Dispose of all components immediately after procedure is complete, with special attention to placing needles in sharps containers immediately after use.
9. Venipuncture, collection and platelet harvest process of the patient's blood should occur under aseptic conditions. The disposable XCELL Protein Concentration System 120mL, syringes and accessories, must be properly discarded following standard biohazard guidelines after each use. Sealed sterile packages containing the XCELL systems and accessories must be inspected before opening. If seal is broken, contents may not be sterile.
10. The patient should be informed of the risks associated with whole blood aspiration which include, but are not limited to, hemorrhage, thrombosis formation, infection, and/or persistent pain at the site of aspiration.

▲*Patient Warning of Side Effects:*

1. As previously noted, hemorrhage (ruptured blood vessel), thrombosis formation (clotting), infection and/or persistent pain at the aspiration (blood draw) site may result.
2. Temporary or permanent nerve damage that may result in pain or numbness associated with the aspiration (blood draw) site may result.
3. Early or late postoperative infection is associated with any surgical procedure.

▲***CAUTION:*** Centrifugation: The Eppendorf 5702 (non-refrigerated) benchtop centrifuge with Eppendorf PN A-4-38 rotor/bucket is an approved centrifuge for use with XCELL systems. The Drucker Boost 4+ Flex centrifuge is also approved for use with the XCELL systems.

Benchtop Processing Station (BPS) Basic Instructions

- The Benchtop Processing Station (BPS) is provided for extracting blood components from the Concentrating Device. The gloved and masked user should remove the P60A Cap and green Silicone Cap then, with the center shaft in the down position, install the post-centrifuged Concentrating Device with the 20, 10, 6mL markings facing the user. Turning the handle counter-clockwise will engage the shaft with the green Piston at the base of the Concentrating Device. Attach a 60mL Syringe. Additional counter-clockwise twisting of the Dial will move the Piston upwards aspirating blood components into the attached syringe. Please see pictorial instructions

below or the Benchtop Processing Station Quick Start Guide.

Note on Anticoagulant: Single-use Anticoagulant Citrate Dextrose Solution A (ACD-A) is provided with the XCELL PRP Platelet Concentrating System. Additional ACD-A (PN 70-039) may be ordered through Apex Biologix by calling 844-897-4910, email at orders@apexbiologix.com or by contacting your local Apex sales representative. When ordering, please have the part number and your Medical License number ready. Only ACD-A with the following chemical makeup should only be used with the XCELL PRP Platelet Concentrating System.

If sourcing ACD-A, the chemical composition should match this specification:
Citric Acid, anhydrous, USP .....0.073 g
Sodium Citrate, dihydrate, USP .....0.220 g
Dextrose, monohydrate, USP..... 0.223- 0.245 g
Water for Injection, USP .....q.s.
pH: 4.5 – 5.5

See the IFU of the product you are using for proper ACD-A dosage.

DEVICE DESCRIPTION:

The XCELL Protein Concentrate System is made up of multiple, single-use, sterile kits consisting of blood draw components, syringes, and a concentrating device. It concentrates blood components and aids in separation of the blood components by density through the use of its components, specifically the concentrating device and the centrifuge which is to be used with the XCELL PRP Platelet Concentrating System. The system prepares platelet rich plasma (PRP) from a small volume of blood that is drawn at the time of treatment. The materials of the system's components consist of medical grade polymers, elastomers, and stainless steels suitable for use in medical devices.

BUNDLE CONTENTS:

(1) XC-PRP-60 Platelet Concentrating System 60mL kit
(1) XC-PRP-60 Supplement Platelet Concentrating System 60mL kit (for 120mL applications only)
(1) 60mL Vac-Lok Syringe
(1) Fluid Volume Reducer filter w/connectors
(2) Fluid Dispensing Connectors

***Non-Pyrogenic:** All blood-contacting components (identified by asterisk) are non-pyrogenic.

BEST PRACTICES: Follow processing guides and protocols described below. Apply initial training and always adhere to clinical safety procedures.

XC-PC-60, XC-PC-120, AB-FVR-02 Quick Start Reference. The detailed instructions should be read first. The following instructions may be utilized for either 60mL or 120mL processing.

XCELL PC
by APEX BIOLOGIX

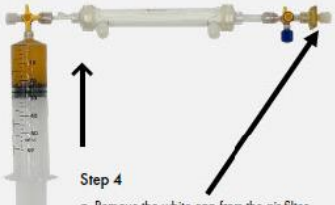
Quick Start Guide: For Processing Plasma from **60mL Whole Blood**

PLEASE REFER TO THE IFU FOR A 60mL PRP PROCESSING AND OBTAIN ~30mL PPP.

Step 1
Set the air filter assembly yellow stopcock to this orientation.

Step 2
Remove the red caps and attach the air filter assembly.

Step 3
Remove the blue cap, opposite the air filter assembly and attach the PPP syringe.



Step 4
a. Remove the white cap from the air filter.
b. Purge air from assembly by advancing the PPP syringe until it stops.
c. Re-cap the air filter.

Step 5
Flip the assembly and reset stopcock orientation as shown.

Step 6
Remove blue cap and connect primed 60mL syringe.

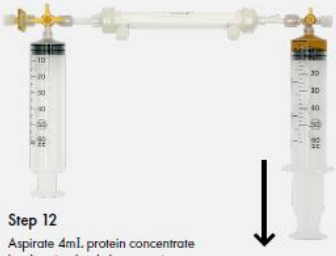
Step 7
Remove one of the white caps on the bottom of the filter, connect Vaclok syringe, and draw back to 60mL.

Step 8
Hold both 60mL syringe and tangentially process using a table or bench.

Step 9
Transfer plasma back and forth between syringes @5mL/1sec rate until plasma is gone. Observe abundant water in the Vaclok.

Step 10
Remove the Vaclok syringe and re-cap the port.

Step 11
a. Compress the air filter-side syringe, close the stopcock.
b. Remove the air filter cap.



Step 12
Aspirate 4mL protein concentrate by drawing back the opposite syringe. Turn the stopcock to seal the port, remove and cap the syringe.

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XCELL PC
by APEX BIOLOGIX

APEX Biologix

Quick Start Guide: For Processing Plasma from **120mL Whole Blood**

PLEASE REFER TO THE IFU FOR A 120mL PRP PROCESSING AND OBTAIN ~60mL PPP.

Step 1

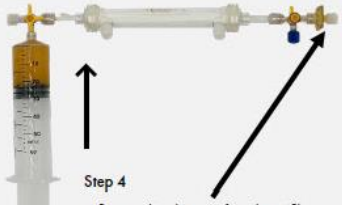
Set the air filter assembly yellow stopcock to this orientation.

Step 2

Remove the red caps and attach the air filter assembly.

Step 3

Remove the blue cap, opposite the air filter assembly and attach the PPP syringe.



Step 4

a. Remove the white cap from the air filter.

b. Purge air from assembly by advancing the PPP syringe until it stops.

c. Re-cap the air filter.

Step 5

Flip the assembly and reset stopcock orientation as shown.

Step 6

Remove blue cap and connect primed 60mL syringe.

Step 7

Remove one of the white caps on the bottom of the filter, connect Vaclok syringe, and draw back to 60mL.

Step 8

Hold both 60mL syringe and tangentially process using a table or bench.

Step 9

Transfer plasma back and forth between syringes @5mL/1sec rate until about 4mL remains. Observe abundant water in the Vaclok.

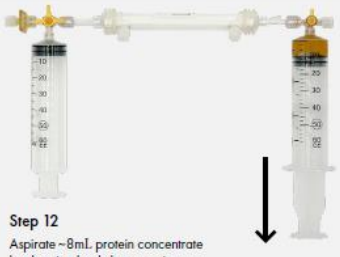
Step 10

Remove the Vaclok syringe and re-cap the port.

Step 11

a. Compress the air filter-side syringe, close the stopcock.

b. Remove the air filter cap.



Step 12

Aspirate ~8mL protein concentrate by drawing back the opposite syringe. Turn the stopcock to seal the port, remove and cap the syringe.

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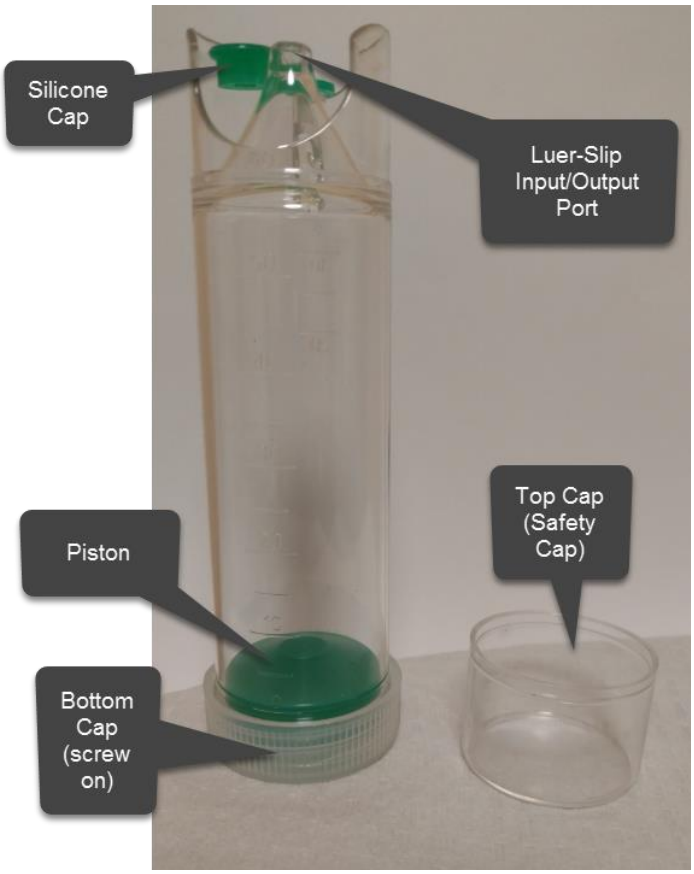
Definitions for the XCELL PRP Concentrating Device

1. Silicone Cap: Use to seal the Input/Output port. Flexible silicone, with retaining pin, for ease of use.
2. Luer-Slip Input/Output Port: Add whole blood and aspirate PPP and PRP here.
3. Top Cap: Placed over the Silicone Cap for additional safety and retention.
4. Piston: Moves up the Concentrating Device to aspirate PPP and PRP. Used in conjunction with the BPS.
5. Bottom Cap: Retains the Piston.



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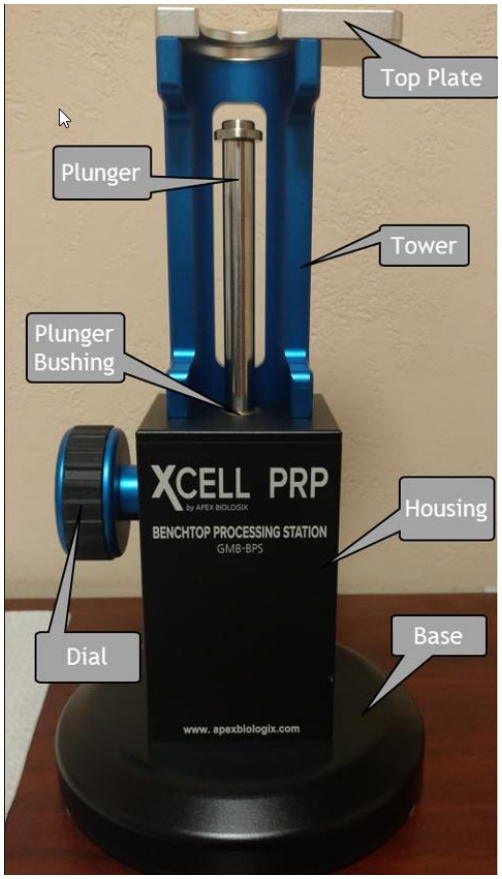
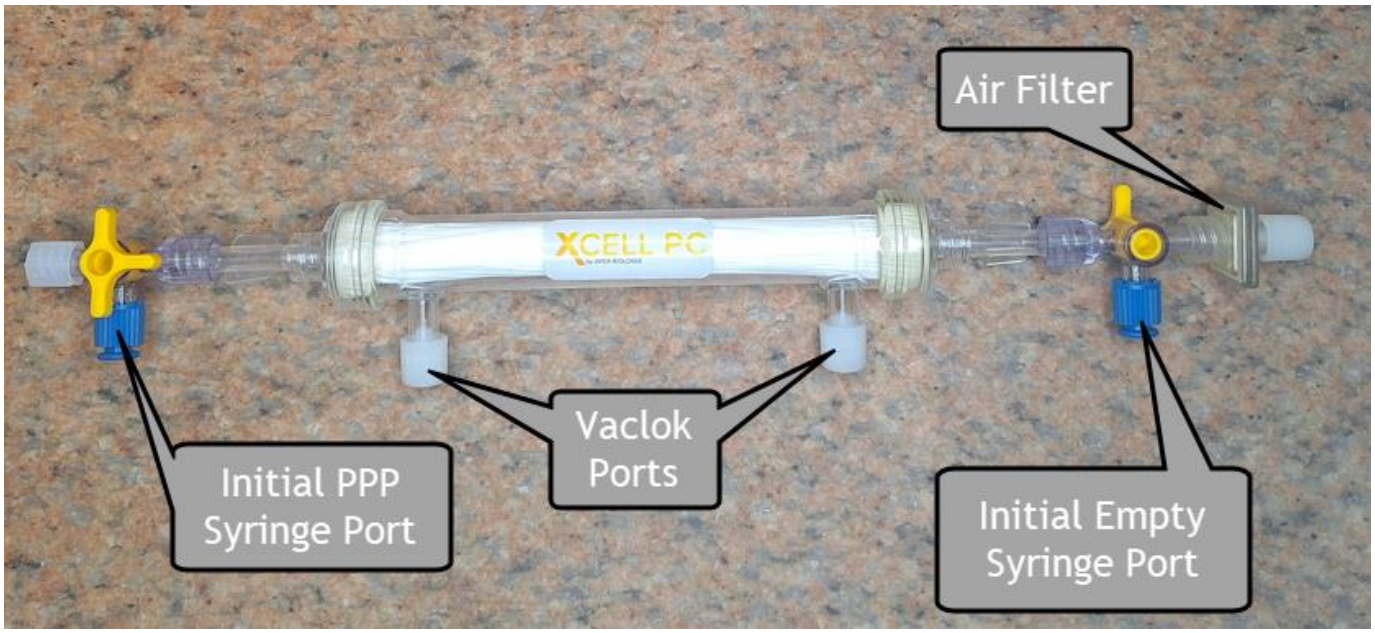
Definitions for the BPS

- Top Plate: the retainer for the Concentrating Device when loading into the BPS.
- Tower: Supports the Top Plate.
- Plunger: Driven by the Dial and moves the piston of the Concentrating Device upwards.
- Housing: Supports and encloses the internal mechanism.
- Dial: Causes the Plunger to be raised or lowered.
- Base: Provides a sturdy foundation for the BPS.
- Base Cover: Finishing for the Base.

Note: You may have a lighted BPS that can provide backlighting for better visibility in processing. The switch may be located on the right side or back of the BPS.



Definitions for the FVR Filter



Instructions for Use:

Note: ***Please create a sterile workstation before beginning. Use defined aseptic technique with the following procedure.***

Note: Refer to the appropriate XCELL Platelet Concentrating System IFU for instruction on blood draw and PRP/PPP preparation.

60mL Whole Blood Processing

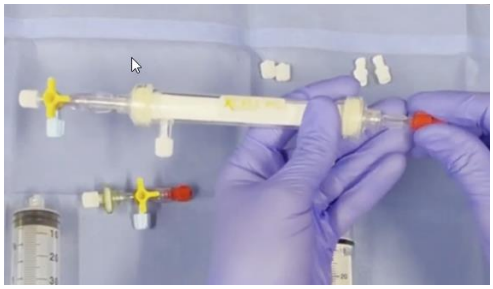
60mL of whole blood will yield a PRP dose of 3-7mL and 27-31mL Platelet Poor Plasma (PPP). This PPP quantity is considered the starting volume for Protein Concentrate processing.

1. Obtain the ~30mL of platelet-poor-plasma (PPP), in a single syringe, harvested from the 60mL PRP processing. PPP obtained from a non-Apex PRP system may be used.

   Note: ***The physician should be masked and gloved before proceeding. Prime all new syringes before beginning.***

2. Layout all kit components in the prepared sterile area.

3. Remove the red cap from the FVR filter assembly.



4. On the stopcock/air filter assembly, orientate the stopcock as shown, and remove the red cap.

5. Remove the two red caps and attach the air filter assembly to the main FVR filter

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6. Remove the blue cap on the opposite side of the air filter assembly and attach the PPP syringe.

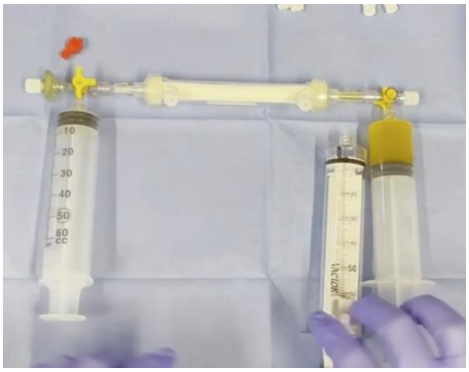
Note: Do not overtighten syringes or caps. Luer fittings will not withstand over-torquing and will break.

7. Remove the white cap from the air filter. Purge air from the system by advancing the PPP syringe plunger until it stops. Air will be pushed through the FVR filter and out the air filter. PPP will not pass through the air filter, causing the syringe to stop advancing.

8. Re-cap the air filter.

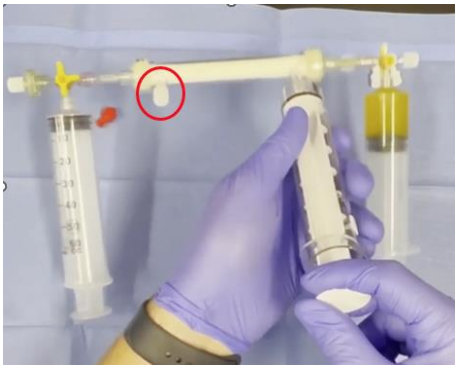
9. Flip the filter/syringe assembly over and re-orientate the stopcock as shown.

10. Remove the second blue cap and attach the primed, empty, 60mL syringe.

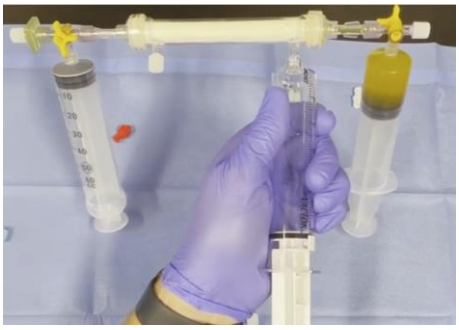


11. Remove one of the white caps (either is acceptable) and attach the Vaclok syringe. Do not over-tighten the Lure fitting.

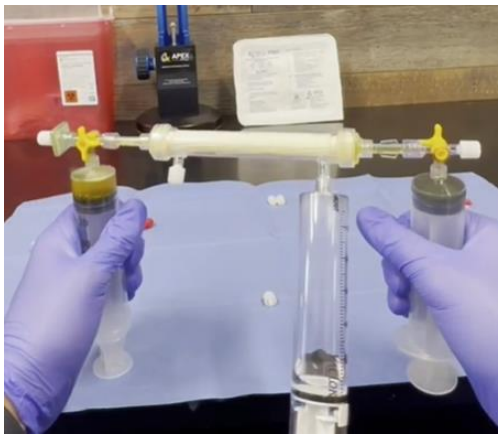
Note: Be sure the remaining port on the FVR is capped (see red circle in image).

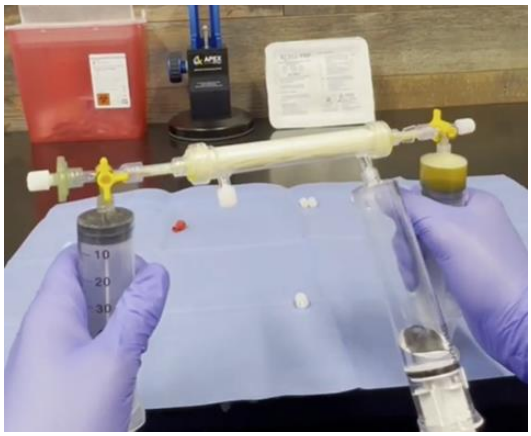


12. Draw the Vaclok back to the 60mL mark, and lock in place. The system is now pressurized.

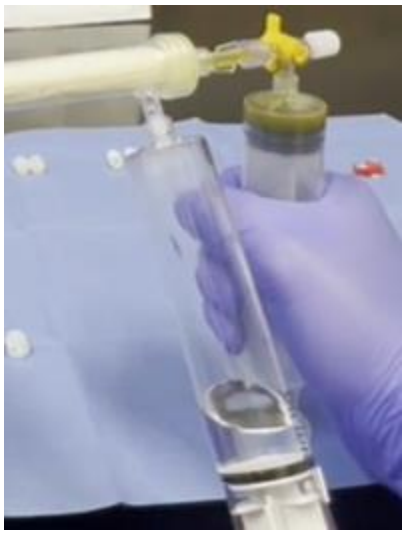


13. The system is now ready to begin processing. Holding each 60mL syringe, place the full syringe handle on the table/bench and press PPP slowly through the FVR and into the empty syringe at a rate of about 5mL/second. Now alternate to the other syringe and repeat.





14. Water will begin to fill the Vaclok syringe.



Note: While processing, if water does not immediately begin to flow into the Vaclok syringe or if the syringes are difficult to cycle, please check the orientation of your stopcocks and that you have pressurized the system by drawing back the Vaclok, locking into the 60mL position.

15. For maximum concentration, continue tangentially processing until the syringes can no longer move. Note that very little volume will remain in the two 60mL syringes. Tangential processing is complete and normally takes 2-3 minutes.

16. Push down on the 60mL syringes nearest the air filter and close off the stopcock to retain pressurization and prevent spillage.

17. Remove the Vaclok syringe and cap the port.

Note: Air may be heard escaping the system when the Vaclok is removed. This is normal as the system de-pressurizes. A small amount of water may drip from the port.

18. Remove the white cap from the air filter.

19. Aspirate by pulling down on the opposite 60mL syringe to recover the concentrated protein plasma from the FVR filter.

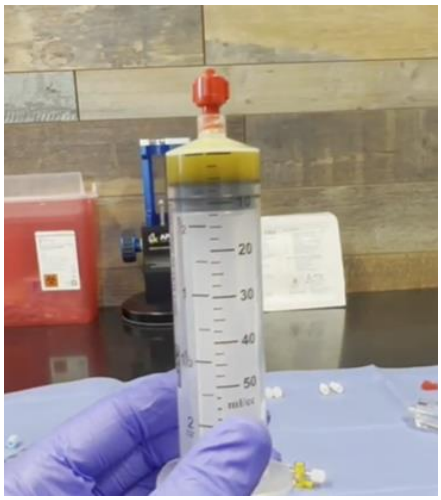
Note: A small amount of foaming may occur, which is normal.

20. When no additional concentrate or foam is aspirated, close the stopcock.

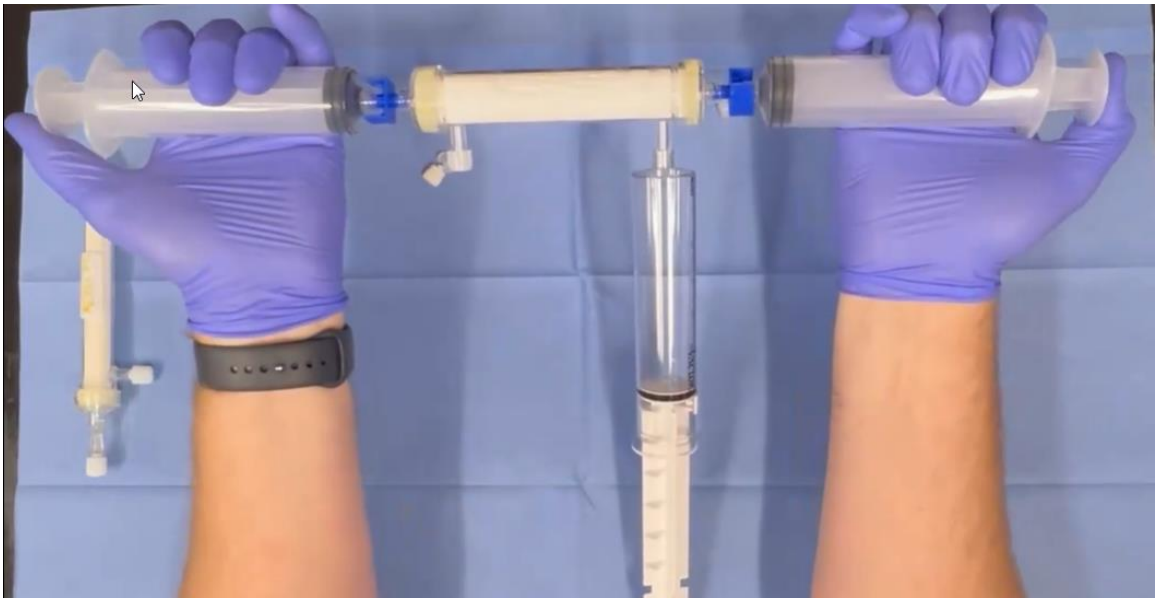
Note: It may be helpful to pull back on the 60mL syringe, while indexing the stopcock, to prevent PC from reversing into the FVR filter due to back-pressure.

21. Remove and cap the 60mL syringe which will contain ~4mL protein concentrate. PC processing is complete.

Note: Dispose of all single-use components in biohazard containers.



Note: Traditional in-line processing is also supported by this system. Follow the above instructions, replacing the stopcocks with the provided connectors or using the attached female-to-female connectors. Some spillage will occur with this method. Process over an absorbent pad. If the users hands/wrists become sore with this method, it is recommend to utilize the method described above.



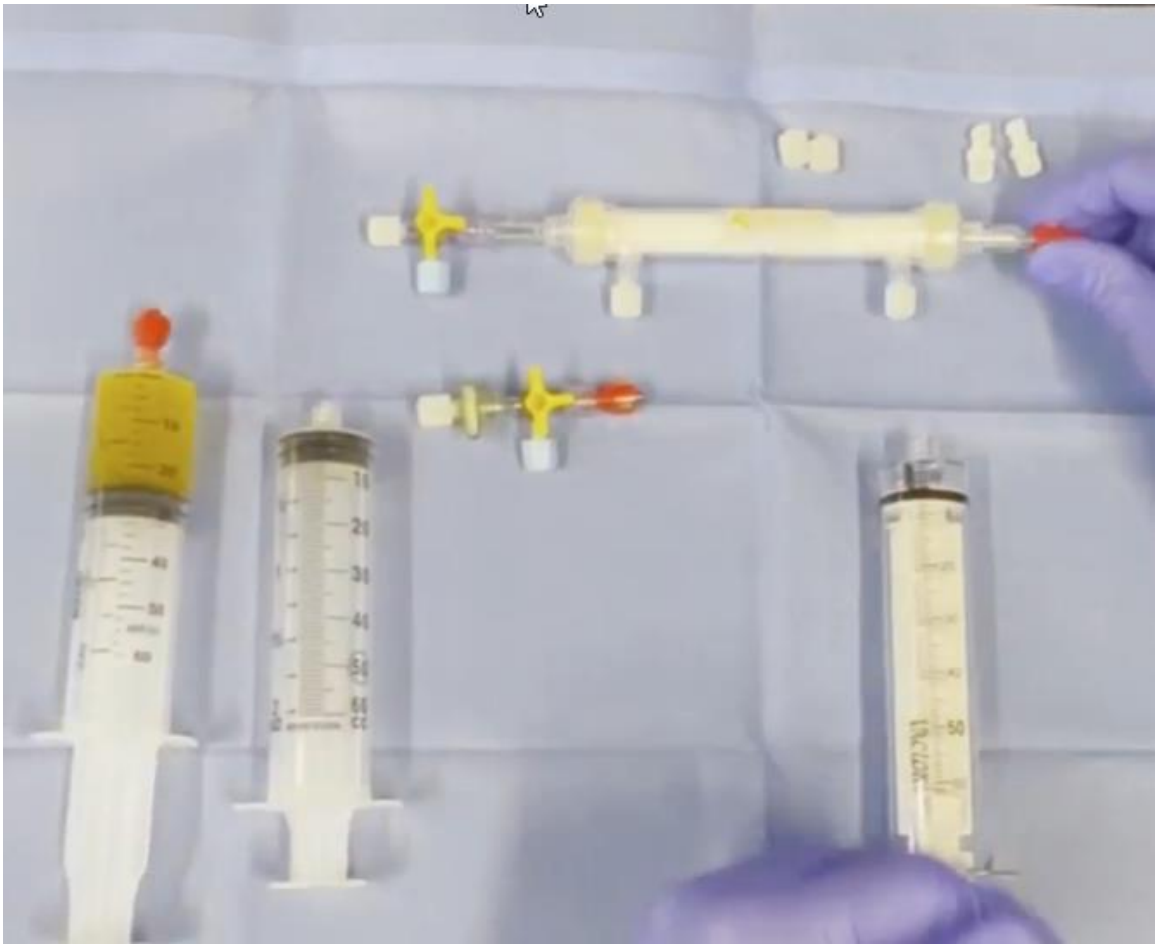
120mL Whole Blood Processing

120mL of whole blood will yield a PRP dose of 6-14mL and 54-62mL Platelet Poor Plasma (PPP). This PPP quantity is considered the starting volume for Protein Concentrate processing.

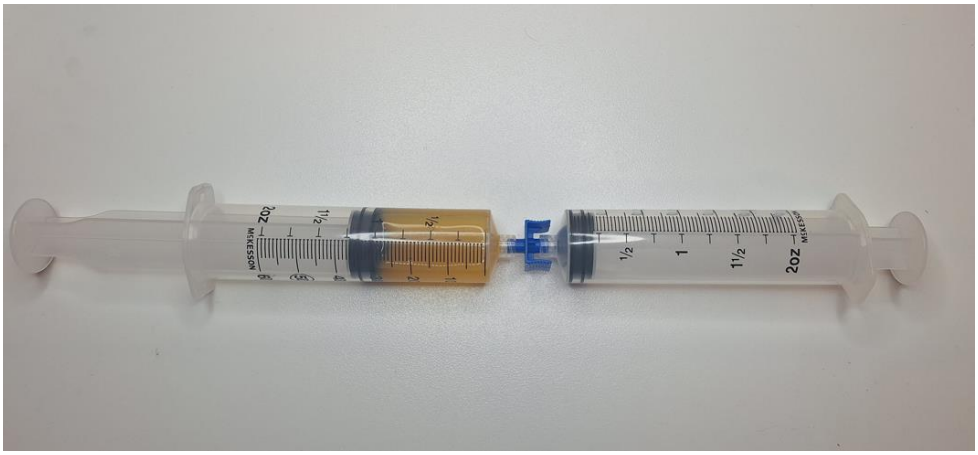
1. Obtain the ~60mL of platelet-poor-plasma (PPP), in a single syringe, harvested from the 60mL PRP processing. PPP obtained from non-Apex PRP systems may be used.

   ***Note:** The physician should be masked and gloved before proceeding. Prime all new syringes before beginning.*

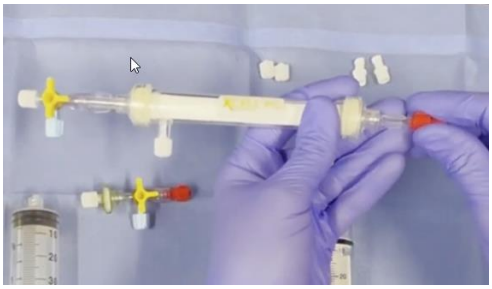
2. Layout all kit components in the prepared sterile area.



0. After the PRP 120 processing is complete, connect the two 60mL PPP syringes together with a female-to-female connector or the fluid dispending connectors (provided) and transfer all PPP into one syringe.



3. Remove the red cap from the FVR filter assembly.

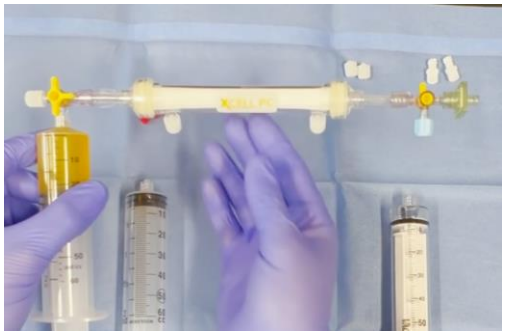


4. On the stopcock/air filter assembly, orientate the stopcock as shown, and remove the red cap.

5. Remove the two red caps and attach the air filter assembly to the main FVR filter

6. Remove the blue cap on the opposite side of the air filter assembly and attach the PPP syringe.

Note: Do not overtighten syringes or caps. Luer fittings will not withstand over-torquing and will break.

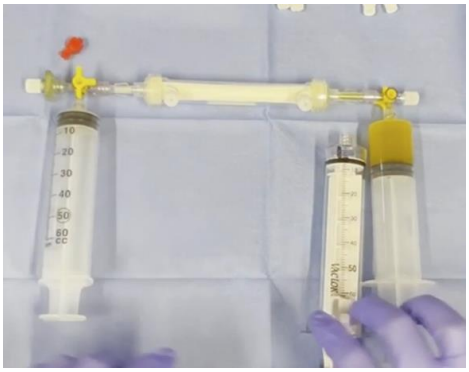


7. Remove the white cap from the air filter. Purge air from the system by advancing the PPP syringe plunger until it stops. Air will be pushed through the FVR filter and out the air filter. PPP will not pass through the air filter, causing the syringe to stop advancing.

8. Re-Cap the air filter.

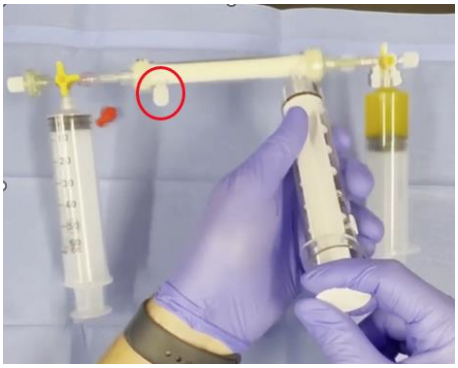
9. Flip the filter/syringe assembly over and re-orientate the stopcock as shown.

10. Remove the second blue cap and attach the primed, empty, 60mL syringe.

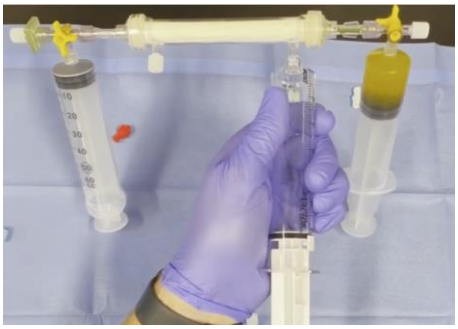


11. Remove one of the white caps (either is acceptable) and attach the Vaclok syringe. Do not over-tighten the Luer fitting.

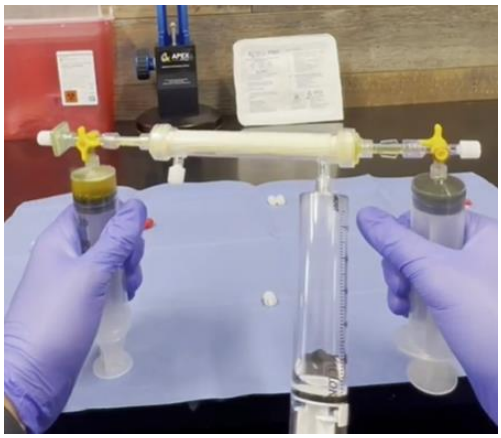
Note: Be sure the remaining port on the FVR is capped (see the red circle in the image).

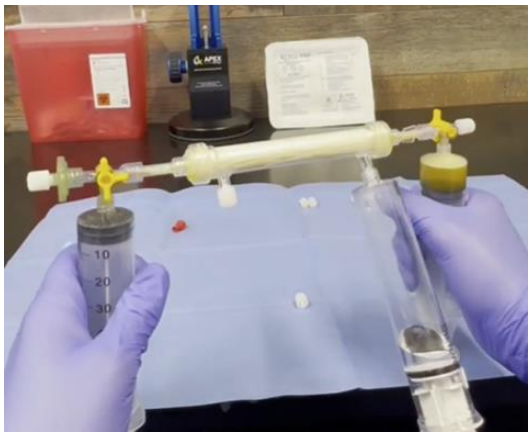


12. Draw the Vaclok back to the 60mL mark, and lock in place. The system is now pressurized.

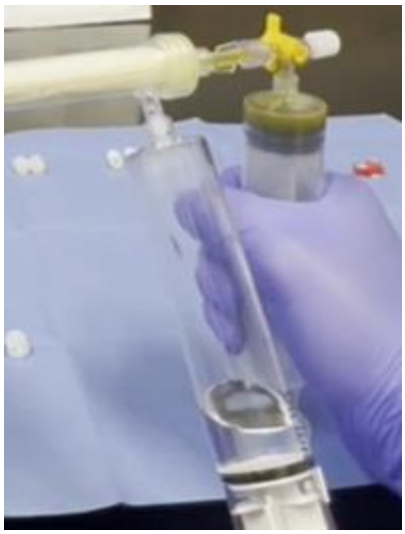


13. The system is now ready to begin processing. Holding each 60mL syringe, place the full syringe handle on the table/bench and press PPP slowly through the FVR and into the empty syringe at a rate of about 5mL/second. Now alternate to the other syringe and repeat.





14. Water will begin to fill the Vaclok syringe.



Note: While processing, if water does not immediately begin to flow into the Vaclok syringe or if the syringe are difficult to cycle, please check the orientation of your stopcocks and that you have pressurized the system by drawing back the Vaclok and locking into the 60mL position.

15. For maximum concentration, continue tangentially processing until one syringe has 0mL and the has other 4mL. Tangential processing is complete and normally takes 4-5 minutes.

16. Push down on the 60mL syringes nearest the air filter (0mL PPP) and close off the stopcock to retain pressurization and prevent spillage.

17. Remove the Vaclok syringe and cap the port.

Note: Air may be heard escaping the system when the Vaclok is removed. This is normal as the system de-pressurizes. A small amount of water may drip from the port.

18. Remove the white cap from the air filter.

Note: Noticeable pressure may be needed to draw back the syringe.

19. Aspirate by pulling down on the opposite 60mL syringe to recover the concentrated protein plasma from the FVR filter.

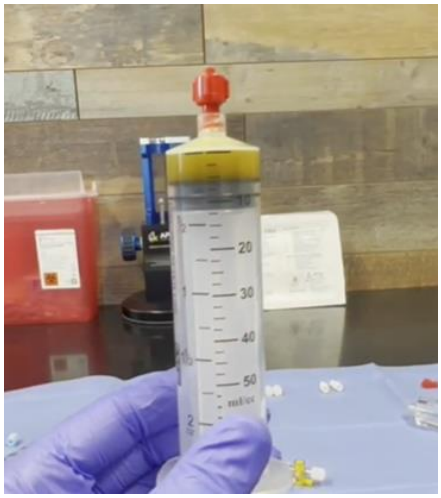
Note: A small amount of foaming may occur, which is normal.

20. When no additional concentrate or foam can be aspirated, close the stopcock.

Note: It may be helpful to pull back on the 60mL syringe, while indexing the stopcock, to prevent PC from reversing into the FVR filter due to back-pressure.

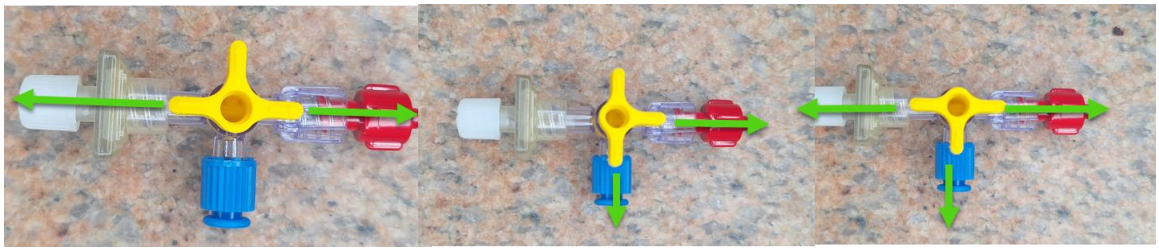
21. Remove and cap the 60mL syringe which will contain 8mL protein concentrate. PC processing is complete.

Note: Dispose of all single-use components in biohazard containers.

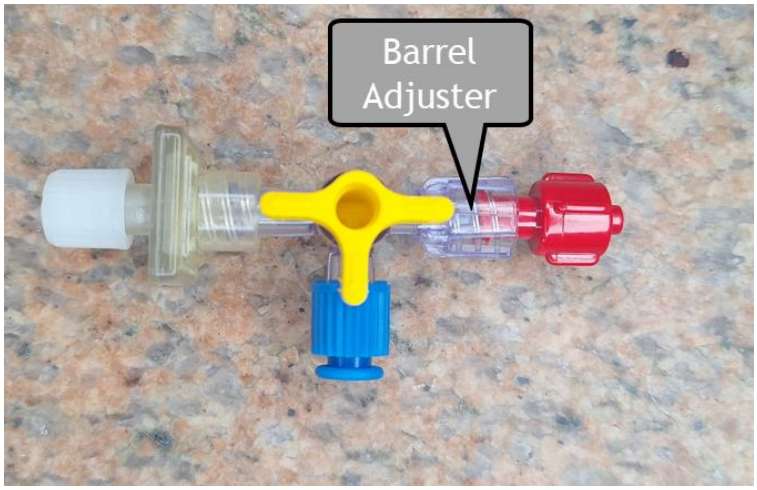


Protein Concentration Troubleshooting

1. After assembling the system, the syringes will not move tangentially.
    a. Check the stopcock orientation. Stopcock spokes point to the direction of flow.



2. I cannot get the syringes aligned in the orientation shown in the instructions or in a comfortable position.
    a. The stopcocks have a universal adjuster. Loosen the adjuster, orientate the syringes to your preference, then tighten the adjuster.



3. Water is not appearing in the Vaclok syringe
    a. Be certain the Vaclok is charged to the 60mL indicator.

4. The PC volume is greater than 4mL for 60mL or 8mL for 120mL.
    a. Continue cycling the PPP back and forth through the FVR filter until the desired volume is achieved.

5. The XC-PC-120 PC volume is low, less than 8mL.
    a. Processing past 4mL has occurred. Use the sample as-is or add more PPP. (This may mean opening a new XC-PC-120 kit).

When PC Should be Discarded?

1. If the sterility of any aspect of the protocol is in question, the sample, along with all components, should be discarded and a new XC-PC-60 or XC-PC-120 kit obtained.

2. If the timepoint from blood draw to usage exceeds 4 hours, the sample along with all components, should be discarded and a newXC-PC-60 or XC-PC-120 kit obtained. During the 4-hour timepoint samples may be refrigerated at 4c (39F).

3. If after the PRP is prepared, the physician discovered either the XC-PC-60 or XC-PC-120 kit or ACD-A is beyond its expiration, the sample, along with all components, should be discarded and a new kit obtained.

4. If the patient, at any point before PRP use, reveals previously undisclosed information about medications or other health conditions the physician determines would compromise the PRP's intended use.

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IMPORTANT: Please reference XCELL PRP™ Platelet Concentrating System Lot Control number and REF number in all communications. Call or email Apex Biologix Customer Service for product questions, concerns, returns, or adverse events at 844-897-4910 or orders@apexbiologix.com