



XCELL Protein Concentration System with XC-PSPC-120 Fluid Volume Reducer 120ml

Single Use Only Device

Note: The following product configurations include the XC-PSPC-120 Fluid Volume Reducer which these instructions-for-use may be applied to:

1. AB-FVR-01 (Includes XC-PSPC-120)
2. AB-FVR-02 (Includes XC-PSPC-120+ VacLok 60ml)
3. XC-PC-60 (Includes XC-PRP-60+ XC-PSPC-120+ VacLok 60ml)
4. XC-PC-120 (Includes XC-PRP-60+ XC-PRP-60 Supplemental + XC-PSPC-120+ VacLok 60ml)

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

▲ **CAUTION:** The XCELL Protein Concentration System 120ml (XC-PC-120) and accessory XC-PSPC-120 Fluid Volume Reducer 120ml are 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 XCELL Fluid Volume Reducer accessory. The instructions that follow only address the use of the volume reduction /filtration components of the Protein Concentration System. For PRP processing, please see the relevant XCELL PRR IFU's, which are also provided with those products' specific documentation.

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.

XC-PSPC-120 Fluid Volume Reducer Use: The XCELL Fluid Volume Reducer is for laboratory use and intended as an ultrafiltration device to reduce the starting volume by approximately 75% through the removal of water.

CONTRAINDICATIONS: The XCELL Protein Concentration System 120ml and XCELL Fluid Volume Reducer may be contraindicated when used in a non-sterile environment, patients taking aspirin within 72 hours, drugs that affect platelet function, in patients with any serious medical conditions that would make the subject unable to safely tolerate the aspiration of 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-120 Protein Concentration System or XC-PSPC-120 Fluid Volume Reducer if the packaging is open or damaged.
3. Do not use after expiration date.
4. Use only the Instruction for Use of the Protein Concentration System or XC-PSPC-120 Fluid Volume Reducer.
5. The physician and staff who will be utilizing the Protein Concentration System and XC-PSPC-120 Fluid Volume Reducer 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/PC sample should be used within 4 hours of blood draw.
7. The PRP/PC is not intended to be returned to the patient's circulatory system.
8. The Protein Concentration System and XC-PSPC-60 Fluid Volume Reducer 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, XC-PSPC-120 Fluid Volume Reducer, syringes and accessories, must be properly discarded following standard biohazard guidelines after each use. Sealed sterile packages containing the XCELL Protein Concentration System, XC-PSPC-60 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 the Protein Concentration System and XC-PSPC-120 Fluid Volume Reducer. The Drucker Boost 4+ Flex centrifuge is also approved for use with the Protein Concentration System and XC-PSPC-120 Fluid Volume Reducer system.

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 Knob 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: Anticoagulant Citrate Dextrose Solution A (ACD-A) is provided with the XCELL PRP Platelet Concentrating System (part of the Protein Concentration System). Additional ACD-A (PN 70-039) may be ordered through APEX Biologix by calling 844-897-4910, emailing at info@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, USP0.073 g
Sodium Citrate, dihydrate, USP0.220 g
Dextrose, monohydrate, USP..... 0.223-0.245 g
Water for Injection, USPq.s.
pH: 4.5 – 5.5

Dosage is 9ml ACD-A per 51ml whole blood for a total volume of 60ml to be processed.

DEVICE DESCRIPTION:

The XCELL Protein Concentrate System 120ml, which includes XCELL Platelet Concentrating and XCELL Fluid Volume Reducer 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, centrifugation and filtering. The system prepares platelet rich plasma (PRP) and protein concentrate (PC) 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.

Typical Contents:

- (1) XC-PRP-60 Platelet Concentrating System 60ml kit
- (1) XC-PRP-60 Supplement Platelet Concentrating System 60ml kit
- (1) XC-PSPC-120 Fluid Volume Reducer
- (1) 60ml VacLok Syringe
- (1) PVDF Air Filter
- (2) Adapter Tips (Luer-to-Luer)
- (2) Syringe Caps

***Non-Pyrogenic:** All blood-contacting components (those with asterisk on kit or product labeling) are non-pyrogenic as required by FDA.

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



XCELL Protein Concentration System Quick Start Guide. The detailed instructions should be read first. After a clear understanding is attained, the following quick start guide for the XCELL Protein Concentration System 120ml may be used. Note, the 120ml system is capable of processing starting PPP volumes of up-to 120ml.

See Next Page

XCELL PRP



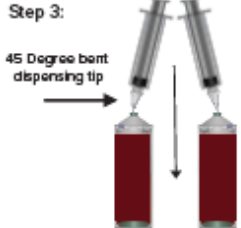
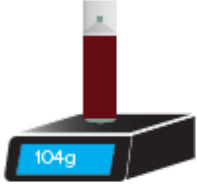



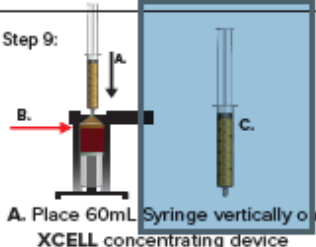
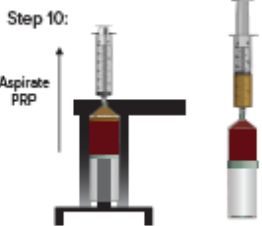

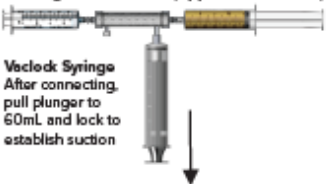
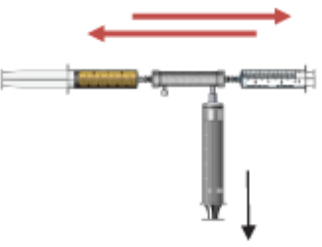
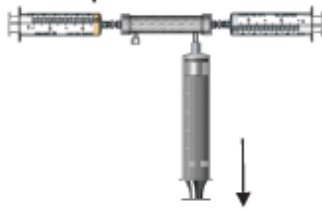
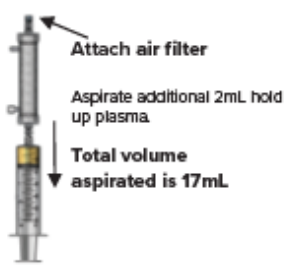
by APEX BIOLOGIX

Protein Concentration Kit (120 ML Kit)

**** PLEASE CREATE A STERILE WORKING STATION BEFORE OPENING KIT ****

Wipe sealing port with sterile alcohol prior to accessing with a sterile syringe

For questions please contact:
844-897-4910

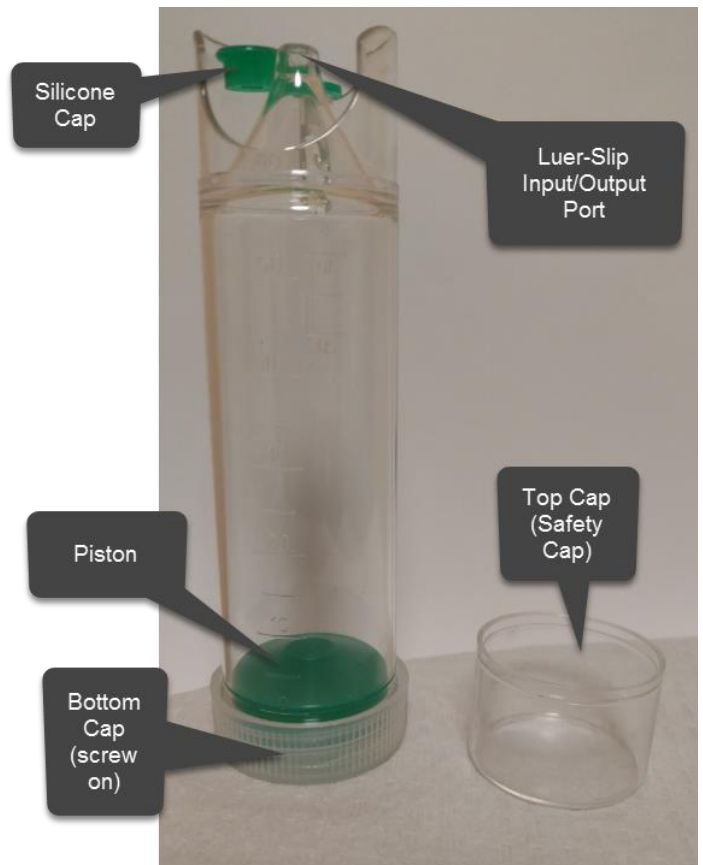
<p>Step 1:</p>  <p>Draw 9mL of *ACD-A into two separate 60mL Syringes</p>	<p>Step 2:</p>  <p>Draw whole blood from the patient, filling each syringe to maximum 60mL. Once blood is drawn, detach the tube and ensure the anti-coagulant mixes throughout the blood sample.</p>	<p>Step 3:</p>  <p>Slowly transfer anti-coagulated whole blood from each 60mL syringe using the 45 degree bent dispensing tips into two separate XCELL concentrating devices.</p>	
<p>Step 4:</p>  <p>**Secure the green silicone cap and the clear safety cap to each of the concentrating devices. Match the concentrating devices to +/- 1.0g of each other.</p>	<p>Step 5: Place XCELL counterbalance and concentrating device on opposite ends inside centrifuge and spin:</p> <p>Drucker: 3500 RPM/2300 RCF 10 minutes</p> <p>Eppendorf: 3800 RPM/2300 RCF 10 minutes</p>	<p>Step 6:</p>  <p>Remove Clear Plastic Cap</p> <p>Platelet Concentrate Buffy coat</p> <p>After spin, carefully remove XCELL concentrating devices from the centrifuge. Remove the caps from Step 4</p>	<p>Step 7:</p>  <p>Insert XCELL Concentrating Device into Bench Top Processing Station then twist knob to move plasma to the bottom of the Luer-slip fitting.</p>
<p>Step 8:</p>  <p>Prime the other syringes to ensure that the barrel moves freely. This is done by simply pulling back and forth on the plunger two to three times. Leave 5mL of air in syringe to prevent splatter</p>	<p>Step 9:</p>  <p>A. Place 60mL Syringe vertically on XCELL concentrating device B. Using the Bench Top Processing Station push PPP into 60mL syringe until the buffy coat reaches 6mL (outlined on concentrating device.) (See red arrow) C. Remove and cap 60mL syringe</p>	<p>Step 10:</p>  <p>Aspirate PRP</p> <p>Keeping the assembly vertical, add the primed 12mL syringe and push the remaining PRP until the syringe captures the buffy coat</p>	<p>Step 11:</p>  <p>Cap the 12mL syringe and gently remix the suspension</p> <p>Step 12:</p> <p>Repeat steps 7 through 11 with the second XCELL concentrating device using the same 60mL syringe of PPP</p>
<p>Step 13:</p> <p>**Connect the PPP syringe to the fluid volume reducer at either end. Connect an empty 60mL syringe to the port at opposite end of the reducer. Connect VakLok syringe to an open evacuation port and apply 60mL of vacuum</p> <p>Starting PPP volume (approx. 55-60mL)</p>  <p>Vaclock Syringe After connecting, pull plunger to 60mL and lock to establish suction</p>	<p>Step 14:</p> <p>Transfer the plasma into the empty syringe then transfer the plasma back into the first syringe</p> 	<p>Step 15:</p> <p>**Continue to transfer the plasma back and forth until 15mL is left in the starting syringe</p> <p>Leave 15mL in the syringe</p> 	<p>Step 16:</p> <p>**Remove empty syringe and attach air filter. Hold assembly vertical and aspirate 2mL plasma. Total volume is 17mL.</p>  <p>Attach air filter</p> <p>Aspirate additional 2mL hold up plasma</p> <p>Total volume aspirated is 17mL</p>

*Anticoagulant Sodium Citrate Dextrose Solution A (ACD-A)
**If attaching the green silicone cap is undesirable, use the optional Low-Profile Cap provided

**Step 15: Processed volume will be ~25% of starting volume.
**Step 16: Total volume is processed volume plus 2mL recovered volume.

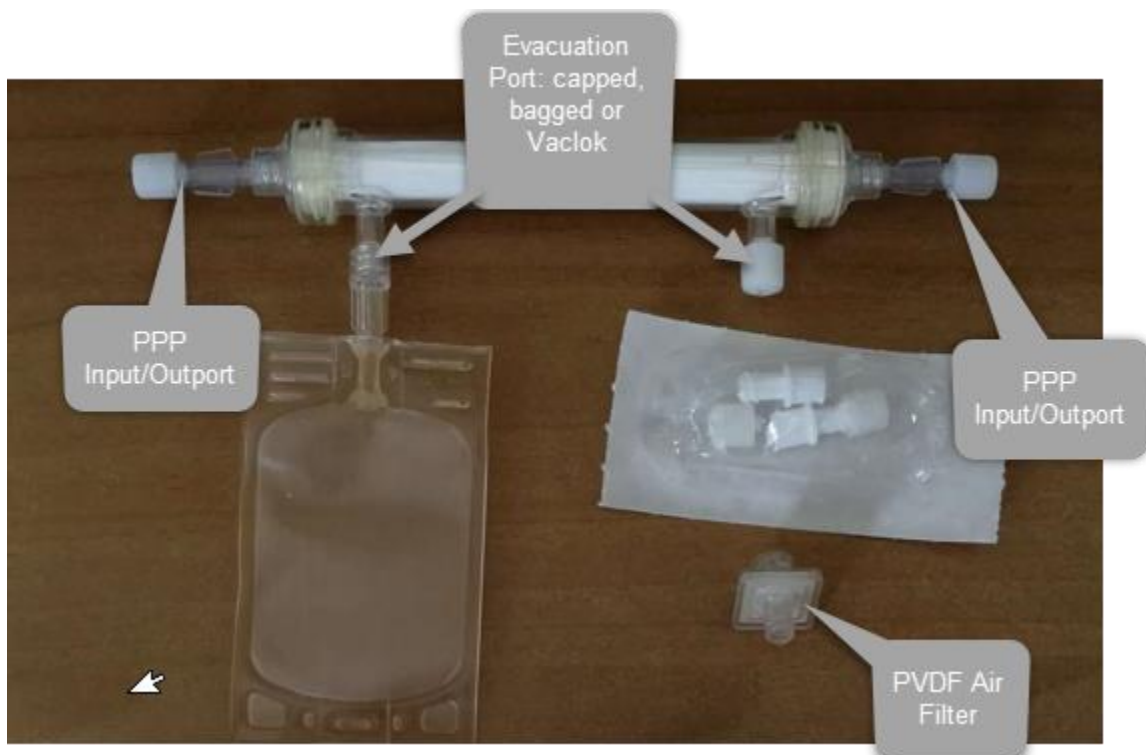
Definitions for the XCELL PRP Concentrating Device

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.



Definitions for the XCELL Fluid Volume Reducer:

1. Filter Assembly: The filter assembly consists of the filter pre-assembled with lure connectors at either end, a 40ml blood bag, and caps.
2. A PPP Input/output port is at either end of the filter. Flow is non-directional.
3. The Evacuation Ports may have caps, a 40ml blood bag or VacLok syringe attached.



Definitions for the BPS

- Top Plate: the retainer for the P60A Concentrating Device when loading into the BPS.
- Tower: Supports the Top Plate.
- Plunger: Driven by the Knob and moves the piston of the P60A upwards.
- Housing: Supports and encloses the internal mechanism.
- Knob: Causes the Plunger to be raised or lowered.
- Base: Provides a sturdy foundation for the BPS.
- Base Cover: Finishing for the Base.



Instructions for Use:

Note: Please create a sterile work station before beginning. Use standard aseptic technique with the following procedure.

Note: Please ensure the Benchtop Processing Station has been cleaned prior to use. Refer to Benchtop Processing Station Maintenance Instructions.

1. Obtain the ~60ml of platelet-poor-plasma (PPP) processed from the XC-PRP-60 or XC-PRP-60 Supplemental systems.
2. The physician should be masked and gloved before proceeding.



3. Layout all kit components on a sterile surface (a sterile Prep Towel is provided if needed).



4. Connect both PPP syringes to either end of the Fluid Volume Reducer.



5. Connect the 60ml VacLok syringe to one of the ports of the Fluid Volume Reducer, and charge the VacLok by drawing back the syringe, rotating the plunger slightly, and locking in place.

Note: With vacuum being pulled, you may notice both PPP syringes compress slightly, which is normal.

Note: Be sure the remaining evacuation port of the Fluid Volume Reducer is capped.



6. Push the PPP back and forth between the two 60ml PPP syringes.



Note: Water will begin to transfer into the VacLok syringe.



7. Continue pushing PPP back and forth until the desired volume is achieved, which is typically 25% of starting volume. E.g., 60ml starting PPP volume will reduce to 15ml concentrated plasma, with 2ml remaining in the filter for a total of 17ml finished volume.



8. When the concentration process is complete, disconnect the empty 60ml PPP syringe, and the VacLok syringe. Cap the VacLok syringe and the port on the filter.

9. Connect the PVDF Air Filter to open port to the open end of the Fluid Volume Reducer and aspirate the remaining recoverable PPP from the Reducer. This will be about 2ml for a total of about 17ml PC concentrate.



10. The protein concentration process is complete. Cap the syringe and set aside for use.





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

Note: Clean the BPS according to the “Benchtop Processing Station Maintenance Instructions” provided.

Protein Concentration System Troubleshooting

1. Whole blood sample appears to have “clumps”
 - a. This is an indication the ACD-A was not mixed after drawing. Discard, open a new processing kit and review IFU.
2. Overfilled P60A Concentrating Device
 - a. Using the still-sterile 45 Dispensing Tip, attached to the 60ml draw syringe, and carefully extract whole blood to the 60ml-mark on the P60A Concentrating Device.
3. Centrifuge Shaking or Out of Balance Error
 - a. Table/bench is unstable. Move centrifuge to stable surface
 - b. Sample and counterbalance not +/-1.0g. Adjust and restart cycle.
 - c. Rotor/bucket incorrectly installed. Refer to operator’s manual provided.
4. Spun Sample appears red throughout, or has red-ish PPP.
 - a. Remixing has occurred.
 - i. Check the braking setting on the centrifuge using the brand-specific user guide.
 - ii. Verify you have used the correct caps on the P60A Concentrating Device. See instructions.
 - iii. Verify centrifuge is not shaking. Move to stable surface.
 - iv. Check P60A Cap for correct installation.
5. For Benchtop Processing Station concerns, see “Benchtop Processing Station Quick Start Guide”.
6. The PRP sample is too red.
 - a. The user has taken excessive RBCs. If the RBC volume is undesirable, discard, open a new processing kit and review IFU.
7. The Concentrating Device requires pressure to insert into centrifuge buckets/carriers and/or becomes stuck in the bucket/carrier.
 - a. The Bottom Cap is overtightened. Remove the entire bucket/carrier assembly from the centrifuge, pull and twist to remove the concentrating device. Refer to step #7 of the IFU. Note that the blood sample may become remixed and unusable. Fully remix the sample, centrifuge again, and continue the procedure.
8. The protein concentrate volume is greater than ~15ml after processing.
 - a. Continue cycling the PPP back and forth through the filter until a volume reduction of about 75% is achieved.
9. The protein concentrate volume is low, less than 10ml.
 - a. The starting volume of PPP was less than 60ml. Use the sample as-is or add more PPP. (This may mean opening a new processing kit).



- b. Excessive ACD-A was added. Discard the sample, open a new concentration system, and start over after reviewing the IFU.
- c. The user may have cycled the PPP through the filter too many times. A low volume PC should not be discarded, but used more sparingly.

When PRP 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 protein concentration system obtained with new blood draw performed.
2. If the timepoint from blood draw to usage exceeds 4 hours, the sample along with all components, should be discarded and a new protein concentration system obtained and new blood draw performed. During the 4-hour timepoint samples may be refrigerated at 4c (39F +/- 5f).
3. If after the PRP is prepared, the physician discovered either the processing system components or ACD-A is beyond its expiration, the sample, along with all components, should be discarded and a new protein concentration system 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.

Manufactured by:

APEX Biologix
2561 S 1560 W, Suite B, Woods Cross, UT 84087
Phone: 844-897-4910 (Att. Customer Service)
Email: info@apexbiologix.com
www.apexbiologix.com

Assembled in the USA by:

Zien Medical Technologies Inc.
2490 S 300 W, South Salt Lake, UT 84115
Phone: 385-444-2666
www.zienmedical.com

For Warranty or Service Please Contact:

APEX Biologix
2561 S 1560 W, Suite B, Woods Cross, UT 84087
Phone: 844-897-4910 (Att. Customer Service)
Email: info@apexbiologix.com
www.apexbiologix.com



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 info@apexbiologix.com

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