



XCELL Platelet Concentrating System 30mL™ (SKU: XC-PRP-30 /

PN: 90-011)

IFU PN 70-109 Rev 1.0

Single Use Only Device

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

▲ CAUTION: The XCELL PRP Platelet Concentrating System 60mL (REF: XC-PRP-30) 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.

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.

CONTRAINDICATIONS: The XCELL PRP™ Platelet Concentrating System 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-PRP-30 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-PRP-30 system.
5. The physician and all staff who will be utilizing the XC-PRP-30 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 sample should be used within 4 hours of blood draw.
7. The PRP is not intended to be returned to the patient's circulatory system.
8. The XC-PRP-30 system is 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 PRP™ Platelet Concentrating System, syringes, and accessories, must be properly discarded following standard biohazard guidelines after each use. Sealed sterile packages containing the XCELL PRP™ Concentrating Device 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:** Centrifuge: The Eppendorf 5702 (with A-4-38 rotor/bucket) and Drucker Boost4+ Flex centrifuges are the only approved centrifugation equipment for use with the XC-PRP-30 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 P30A's green Silicone Cap then, with the center shaft in the down position, install the post-centrifuged Concentrating Device with the concentration volume markings facing the user. Turning the handle counterclockwise will engage the shaft with the green Piston at the base of the Concentrating Device. Attach a 30mL Syringe. Additional counterclockwise 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 Platelet Concentrating System 30mL. 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, 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 3mL ACD-A per 27mL whole blood for a total volume of 30mL to be processed, or 10% ACD-A to whole blood.



DEVICE DESCRIPTION:

The XCELL PRP Platelet Concentrating System is a single-use, sterile kit 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 Eppendorf Model 5702 or Drucker Boost 4+ 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.

KIT CONTAINS:

- (1) *APEX P30A Concentrating Device
- (2) *30mL Syringe (Luer lock)
- (1) *12mL Syringe (Luer lock)
- (1) *Needle 18g
- (2) *Luer Lock Universal Cap
- (1) Prep Towel
- (2) Alcohol Prep Pad
- (1) *45 Degree Bent Dispensing Tip
- (4) Traceability Labels
- (1) Blood Draw Kit

BLOOD DRAW KIT CONTAINS:

- (1) *19g Winged Infusion Needle
- (2) Alcohol Prep Pad
- (5) Gauze Sponge 4x4 8-Ply
- (2) Adhesive Bandage
- (1) Tourniquet
- (1) *Luer Lock Universal Cap

***Non-Pyrogenic:** All blood-contacting components (those with an asterisk) 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.

XC-PRP-30 Quick Start Reference. The detailed instructions should be read first. After a clear understanding is achieved, the following quick start guide for the XCELL PRP Platelet Concentrating System 30mL may be used.

XCELL PRP

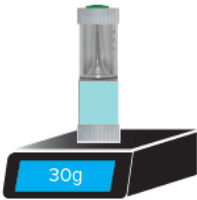


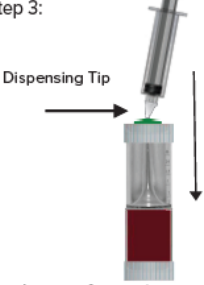
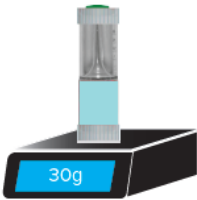



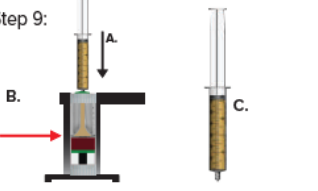
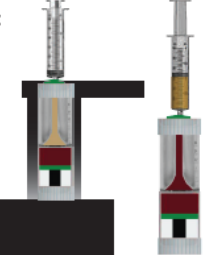

by APEX BIOLOGIX

PLEASE CREATE A STERILE WORK STATION AND BE MASKED & GLOVED BEFORE PROCEEDING

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

For questions please contact:

844-897-4910

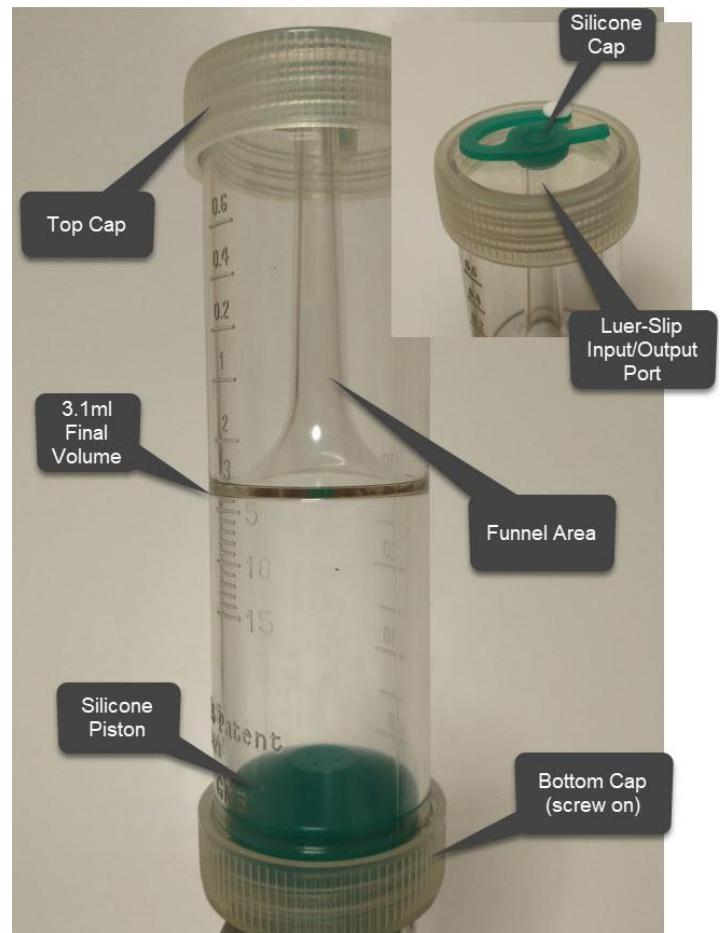
<p>Step 4:</p>  <p>Secure the green silicone cap to the concentrating device. Match the counterbalance to +/- 1.0g of concentrating device.</p>	<p>Step 1:</p>  <p>Draw 3mL of *ACD-A into 30mL Syringe.</p>	<p>Step 2:</p>  <p>Draw whole blood from the patient, filling the syringe to 30mL. Once blood is drawn, detach the tube and ensure the anti-coagulant spreads throughout the blood sample.</p>	<p>Step 3:</p>  <p>Slowly transfer anti-coagulated whole blood, using the dispensing tip, into the XCELL concentrating device.</p>
<p>Step 4:</p>  <p>Secure the green silicone cap to the concentrating device. Match the counterbalance to +/- 1.0g of concentrating device.</p>	<p>Step 5:</p> <p>Place XCELL counterbalance and concentrating device on opposite ends inside centrifuge and spin:</p> <p>Drucker: 3500 RPM/2300 RCF 4 minutes</p> <p>Eppendorf: 3800 RPM/2300 RCF 4 minutes</p>	<p>Step 6:</p>  <p>Prime the 30mL and 12mL 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 the 30mL syringe to prevent splatter.</p>	<p>Step 7:</p>  <p>After spin, carefully remove XCELL concentrating device from the centrifuge. Remove the cap from Step 4.</p>
<p>Step 8:</p>  <p>Insert XCELL Concentrating Device into Bench Top Processing Station then twist DIAL to move plasma to the bottom of the Luer-slip fitting.</p>	<p>Step 9:</p>  <p>A. Place 30mL Syringe vertically on XCELL concentrating device B. Using the Bench Top Processing Station push PPP into 30mL syringe until the buffy coat reaches 3mL (outlined on concentrating device.) (See red arrow) C. Remove and cap 30mL syringe</p>	<p>Step 10:</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 and process is complete</p>

*Anticoagulant Sodium Citrate Dextrose Solution A (ACD-A)

See Next Page

Definitions for the XCELL PRP Concentrating Device

- **Silicone Cap:** Use to seal the Input/Output port. Flexible silicone, with retaining pin, for ease of use.
- **Luer-Slip Input/Output Port:** Add whole blood and/or aspirate PPP and PRP here.
- **Top Cap:** Retains the Silicone Cap.
- **Piston:** When used with BPS, functions to move blood components to the Output Port.
- **Funnel Area:** Condenses blood components to the Output Port.
- **Bottom Cap:** Retains the Piston.

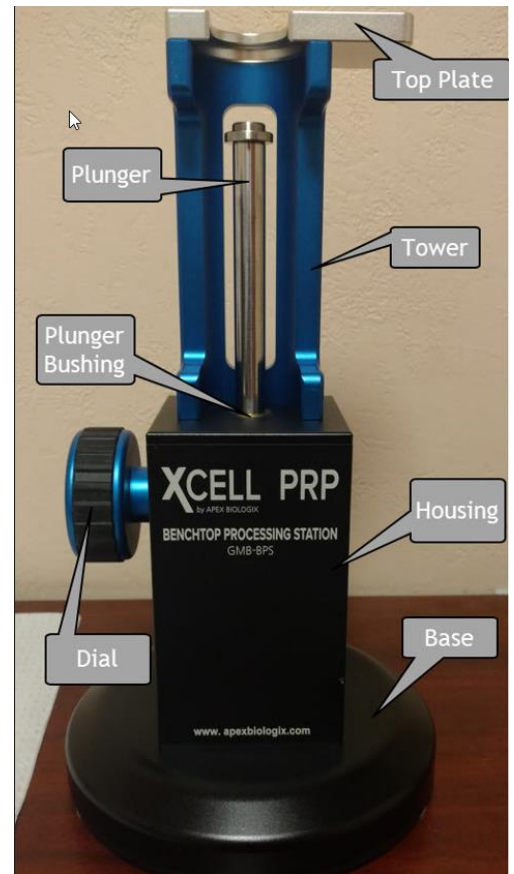




Definitions for the BPS

- 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.



Instructions for Use:

Note: Please create a sterile work environment 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.

Note: Retrieve the supply of ACD-A.



1. Have an assistant open and present the components to the technician.
2. The technician should be masked and gloved before proceeding.
3. Layout all kit components on a sterile surface (a sterile Prep Towel is provided if needed).
Note: The technician may choose to provide the Traceability Labels to the assistant for documentation.
4. Attached the 18g Needle to one of the 30mL Syringes.
5. Using a provided Alcohol Prep Pad, swab the injection site of the ACD-A vial.
6. Prime the 30mL Syringe, then draw 3mL ACD-A. Remove the 18g Needle and discard in a sharp's container. Cap with the provided Luer Lock Universal Cap.



7. With an assistant, prep the patient for blood draw:
 - a. Gloved technician opens the Blood Draw Kit, lays out items on the sterile surface and hands the provided Tourniquet to the assistant who will apply it to the patient.
 - b. If the technician needs additional assistance, that assistant should also be masked and gloved.



- c. Clean the venipuncture site with provided Alcohol Swab.
 - d. Connect the 19g Winged Infusion Needle to the ACD-A dosed 30mL Syringe. (Place cap on sterile surface)

Note: Additional Alcohol Prep Pads are provided and to be used at the technician's discretion





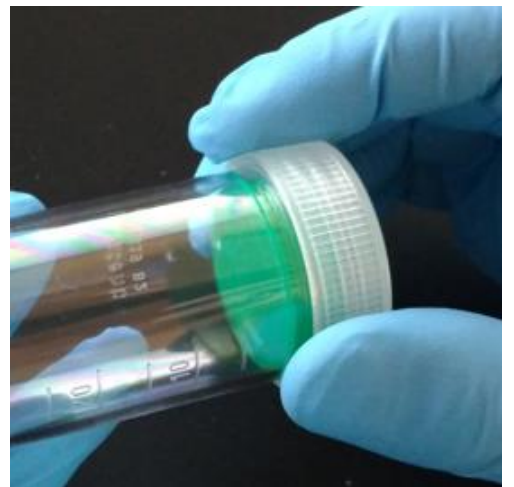
- e. Prime the IV line expelling air with ACD-A.
- f. The technician inserts the 19g needle and begins the blood draw.
- g. Slowly draw back the syringe to 30mL.
- h. Detach the infusion needle tube and cap using the Luer Lock Universal Cap. Utilize provided Gauze Sponge as needed and apply provided Adhesive Bandage.



Note: It is critical to mix the ACD-A with the whole blood immediately after draw is complete. Invert the capped syringe for a minimum of 15 times.



Note: before transferring to the Concentrating Device, verify the Bottom Cap is tightened securely, by rotating until the cap “clicks” into place. Overtightening may cause binding in centrifuge carriers.



8. Attach the Dispensing Tip to the 30mL Syringe containing the patient's whole blood then slowly transfer blood into the P30A Concentrating Device through the Input/Output Port. Fill to the 30mL marker.



9. Place the P30A Concentrating Device's built-in Silicone Cap over the Input/Output Port and snap into place.



10. Using a lab scale, weigh the Concentrating Device and match the counterbalance to within $\pm 1.0g$.
11. Place the Concentrating Device and counterbalance into opposite buckets of the centrifuge and close the lid.
 - a. See respective centrifuge quick-start for details.

Note: Do not mix centrifuge buckets or inserts from different machine brands.





12. Set the centrifuge to 4 minutes and 2300rcf and start the cycle.
 - a. Eppendorf 3800rpm
 - b. Drucker 3500rpm (or PRP 30 cycle)



13. Prime the 12mL Syringe and second 30mL Syringe leaving 5mL's of air.

Note: Leaving the 5mL air gap aids in normalizing pressure between the Concentrating Device and syringe allowing for cleaner separation of the two devices.



14. When centrifugation is complete, carefully remove the Concentrating Device and observe the cell layering. You should see a clear separation between red blood cells (RBC), the buffy coat and plasma.





Note: Always place the BPS on a sturdy table or bench.

Critical: The BPS should be cleaned before each use utilizing the procedure found in the Benchtop Processing Station Maintenance Instructions, provided.

15. Verify the Plunger is in the full down position by rotating the Dial clockwise until the Plunger stops.



16. Remove the P30A green Silicone Cap and place into the BPS in the orientation seen here, with the dose mL markings facing the technician.



17. Attach a 30mL syringe to the output port of the concentrating device, then gently turn the Dial counterclockwise until the Concentrating Device touches the Top Plate

Note: *Be sure the Concentrating Device is parallel with the Tower and Plunger.*

Caution: *Following these instructions carefully, minimizes the possibility of contaminating the working surfaces of the BPS with blood/plasma.*

18. Slowly rotate the Dial counterclockwise to push the plasma into the 30mL Syringe until the buffy coat reaches the 3mL mark on the Concentrating Device.

Caution: *It is important to slowly rotate the Dial to minimize the possibility of contaminating the working surfaces of the BPS with blood/plasma.*

19. Detach the 30mL Syringe and cap using the provided Luer Lock Universal Cap and set aside.

20. Attach the 12mL Syringe to the Concentrating Device's Luer Output Port.





21. Continue to rotate the Dial counterclockwise and push concentrate, including buffy coat, into the 12mL Syringe (3mL total).

Note: The XCELL system allows for flexible dose volume. Observe the mL markings on the dose-side of the Concentrating Device and adjust the stop point of the buffy coat to correlate with the desired final volume.



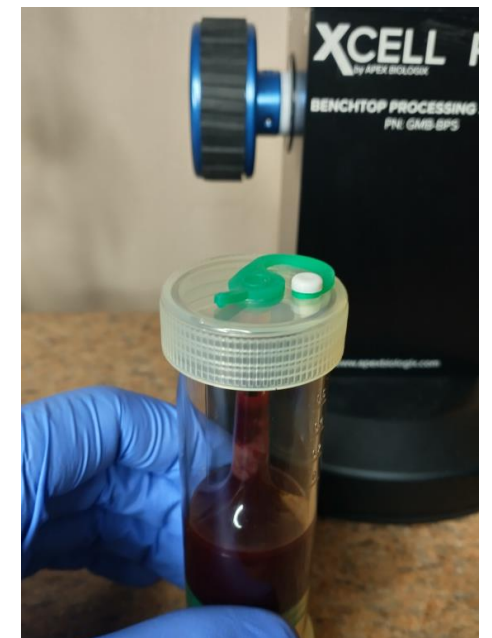
22. Retract the Plunger to full-down and remove the assembly.
23. Carefully detach the 12mL Syringe and cap using the provided Luer Lock Universal Cap.
24. Gently invert the 12mL Syringe at least 15 times to re-mix the suspension.



25. Re-attach the green Silicone Cap and P30A cap and set aside.
26. PRP processing is complete

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

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





XC-PRP-30 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 XC-PRP-30 kit and review IFU.
2. Overfilled P30A Concentrating Device
 - a. Using the still-sterile 45 Dispensing Tip, attached to the 30mL draw syringe, and carefully extract whole blood to the 30mL-mark on the P30A 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-tint 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 P30A Concentrating Device. See instructions.
 - iii. Verify centrifuge is not shaking. Move to stable surface.
 - iv. Check P30A 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 RBC. If the RBC volume is undesirable, discard, open a new XC-PRP-30 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.

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 XC-PRP-30 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 new XC-PRP-30 kit obtained. During the 4-hour timepoint samples may be refrigerated at 4°C (39°F).
3. If after the PRP is prepared, the physician discovered either the XC-PRP-30 kit or ACD-A is beyond its expiration, the sample, along with all components, should be discarded and a new XC-PRP-30



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, the procedure should be halted and PRP discarded

Manufactured by:

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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

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