XCELL PRP®

Instructions for Use

bioventus®

Innovations For Active Healing

XCELL PRP Label Symbol Descriptions and Equipment Classification

	Consult instructions for use
REF	Catalog Number
	Manufacturer
SN	Serial number (first four digits of the serial number indicate the month and year of manufacture)
Rx ONLY	Federal Law (U.S.A.) restricts this device to sale, distribution, or use by or on the order of a physician or properly licensed practitioner. This device is only intended for use by the individual for whom it is prescribed.
	Caution symbol: Indicates the need for the user to consult the instructions for use for important cautionary information.
	Do not use if package is damaged and consult instructions for use Do not use if tamper-device is damaged or missing
	Non-pyrogenic
	Sampling site
STERILE A	Sterilized using aseptic processing techniques
STERILE EO	Sterilized using ethylene oxide
	Does not contain or is not in the presence of natural rubber latex
	Use-by date
	Date of manufacture
STERILE	Sterile
	Distributor

MD	Indicates the item is a medical device.
	Indicates a medical device that has not be subjected to sterilization.
	Indicated a medical device that needs to be protected from moisture.
	Indicates the temperature limits to which the medical device can be safely exposed.
	Indicates a medical device that is intended for one single use only.
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified.
UDI	Indicates a carrier that contains Unique Device Identifier information.
	Product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling

Caution

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

The XCELL PRP Platelet Concentrating System 60mL 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.

XCELL Platelet Concentrating System 60mL™ (SKU XC-PRP-BV-60 / PN 90-001)

IFU PN 70-094 Rev 2.8
Single Use Only Device

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-BV-60 kit or ACD-A if the sterile barrier is open or damaged.

3. Do not use after expiration date.

4. Use only the Instruction for Use of the XC-PRP-BV-60 system.

5. The physician and all staff who will be utilizing the XC-PRP-BV-60 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-BV-60 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.

11. ACD-A is a clear odorless liquid and should be representative of that when used.

12. ACD-A expiration date is valid only when stored according to USP Controlled Room Temperature

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

Only approved centrifuges may be utilized with the XCELL Concentrating Systems and after setup is performed by a qualified technician. The following centrifuges are approved for use:

- Eppendorf model 5702 w/PN A-4-38 rotor/PN 79 bucket
- Drucker model Boost 4+Flex w/PN 03-1-0001-0138 rotor/ PN 03-1-0007-123 bucket/PN 03-1-0007-0107 Insert

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 counterclockwise will engage the shaft with the green Piston at the base of the Concentrating Device. Attach a 60mL 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 PRP Platelet Concentrating System. Only ACD-A with the following chemical makeup should be used with the XCELL PRP Platelet Concentrating System. Additional ACD-A (PN 70-039) may be ordered through Bioventus by calling 800-836-4080, email at customerserviceusa@bioventusglobal.com or by contacting your local Bioventus 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.

Caution

1. Store at room temperature, avoid freezing and excessive heat

2. ACD-A is a clear, colorless solution. If the product is discolored or cloudy in appearance, discard.

3. The vial closure system provides a biological barrier and should be intact. Discard product if this system is visually compromised.

4. Aseptic technique must be maintained at all times.

5. ACD-A is not for intravenous use.

If sourcing liquid 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 or anhydrous, USP.....0.223- 0.245 g
Water for Injection, USP .....q.s.
pH …….....4.5 – 5.5

Dosage is 6mL ACD-A per 54mL whole blood for a total volume of 60mL 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 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 P60A Concentrating Device
(1) *APEX P60A Cap
(2) *60mL 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) Adhesive Patient Labels
(1) *Luer Lock Low-Profile Cap
(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 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-60 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 60mL may be used.

XCELL PRP®

STEP 1

Draw 6 mL of ACD-A into 60 mL syringe.*

STEP 2

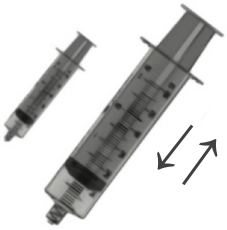
Draw whole blood from the patient, filling the syringe to maximum 60 mL. Once blood is drawn, detach the tube and ensure the anticoagulant spreads throughout the blood sample.

STEP 5

Place **XCELL** counterbalance and concentrating device opposite of each other in buckets inside the centrrifuge and spin.

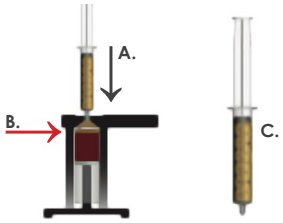
Drucker:
3500 RPM
10 minutes

STEP 6



Prime the 60 mL and 12 mL 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 5 mL of air in the 60 mL syringe to prevent splatter.

STEP 9

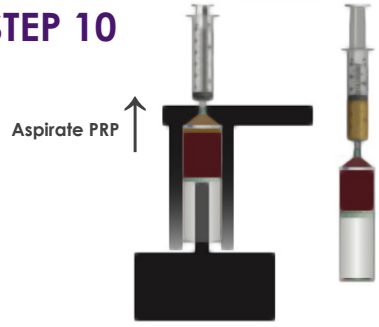


A. Place 60 mL syringe vertically on **XCELL** concentrating device.

B. Using the Benchtop Processing Station, turn dial to push PPP into 60 mL syringe until the buffy coat reaches 6 mL (outlined on concentrating device; see red arrow).

C. Remove and cap 60 mL syringe.

STEP 10



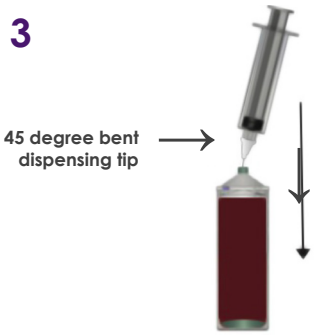
Keeping the assembly vertical, add the primed 12 mL syringe and push the remaining PRP until the syringe captures the buffy coat.

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

Summary of 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.

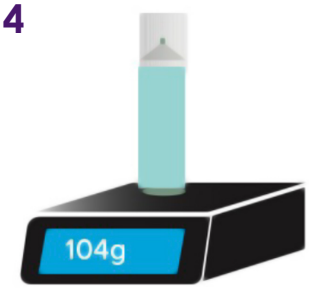
Please create a sterile work station; be masked and gloved before proceeding.
Wipe sealing port with sterile alcohol prior to accessing with a sterile syringe.

STEP 3



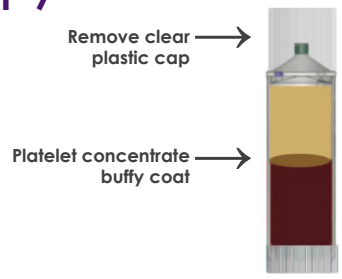
Slowly transfer anticoagulated whole blood using the 45 degree bent dispensing tip into the **XCELL** concentrating device.

STEP 4



Secure the green silicone cap and the clear safety cap to the concentrating device.† Match counterbalance to +/- 1.0 g of concentrating device.

STEP 7



After spin, carefully remove **XCELL** concentrating device from the centrifuge. Remove the caps from Step 4.

STEP 8

Insert **XCELL** Concentrating Device into Benchtop Processing Station, then twist dial to move plasma to the tip of the cone of **XCELL** concentrating device.

STEP 11

With approximately 6mL volume in capped syringe, gently remix the suspension. Process is complete.

Questions?
Please contact Bioventus Customer Service:
800-836-4080

To report a complaint or adverse event, please email **complaints@bioventus.com**.

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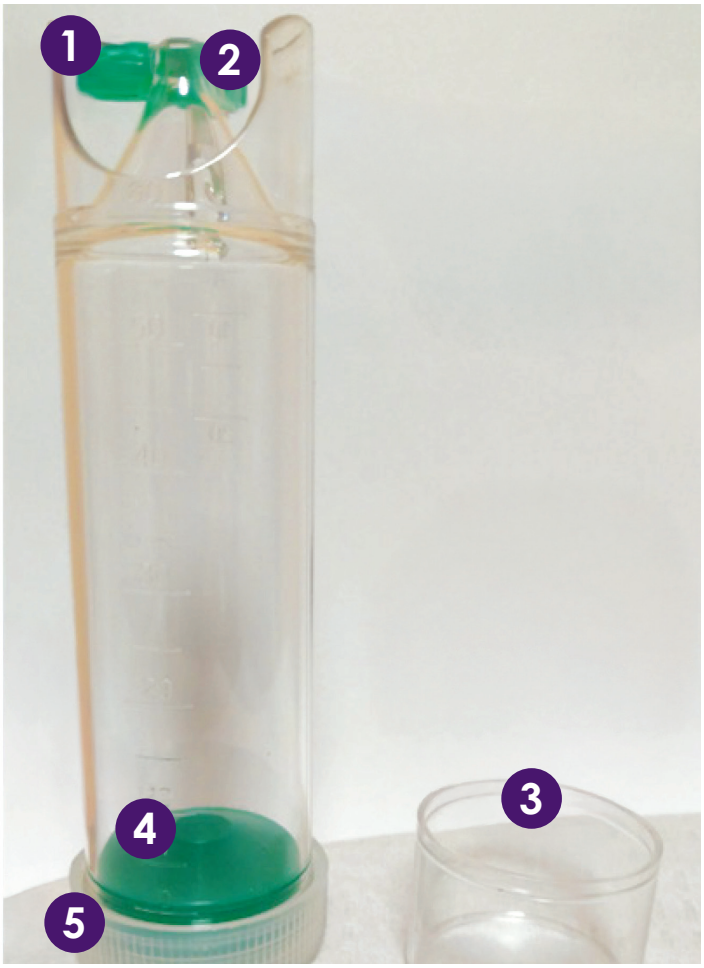
Definitions for the XCELL PRP Concentrating Device

1. **Silicone Cap:** Use to seal the Input/Output port. Flexible silicone, with retaining pin, for easy 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 to aspartate PPP and PRP. Used in conjunction with the BPS.
5. **Bottom Cap:** Retains the Piston.
6. Numbers on the outside of the concentrating device are for filling volume to 60mL. Smaller numbers on the opposite side are for dose volume up to 6mL.



Definitions for the BPS

1. **Top Plate:** the retainer for the Concentrating Device when loading into the BPS.
2. **Tower:** Supports the Top Plate.
3. **Plunger:** Driven by the Dial and moves the piston of the Concentrating Device upwards.
4. **Housing:** Supports and encloses the internal mechanism.
5. **Dial:** Causes the Plunger to be raised or lowered.
6. **Base:** Provides a sturdy foundation for the BPS.
7. **Base Cover:** Finishing for the Base.
8. On/Off switch on the right side

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.

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 and to identify the assistant for documentation.

4. Attach the 18g Needle to one of the 60mL Syringes.

5. Using a provided Alcohol Prep Pad, swab the port of ACD-A vial.

6. Prime the 60mL Syringe, then draw 6mL 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 60mL Syringe. (Place cap on sterile surface)

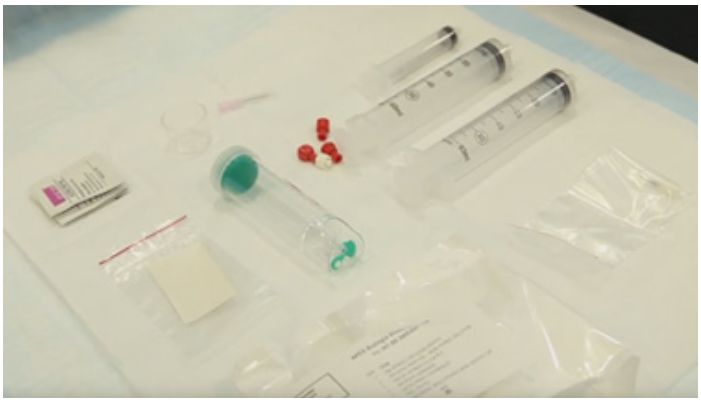
Note: Additional Alcohol Prep Pads are provided and to be used at the technician's discretion

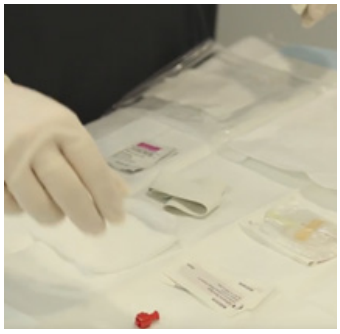
   - **e.** Prime the IV line expelling air with ACD-A.
   - **f.** The technician inserts the 19g needle and begins the blood draw.
   - **g.** Slowly draw back the syringe to 60mL.
   - **h.** Detach the infusion needle tube and cap using the Luer Lock Universal Cap. Utilize provided Gauze Sponge as needed and apply provided Adhesive Bandage.

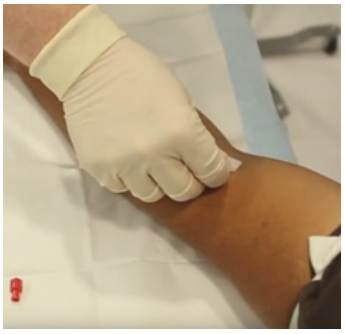
Note: It is critical to mix the ACD-A with the whole blood immediately after draw is complete. Invert the capped syringe for a minimum of 15 times.

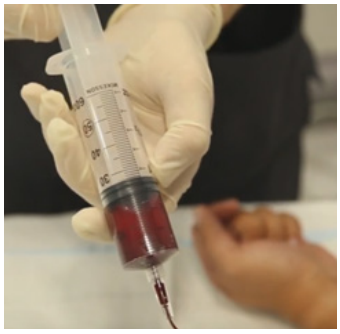
Note: before transferring to the Concentrating Device, verify the Bottom Cap is tightened securely, by rotating until the cap "clicks" into place. Overtightening may cause binding in centrifuge carriers.

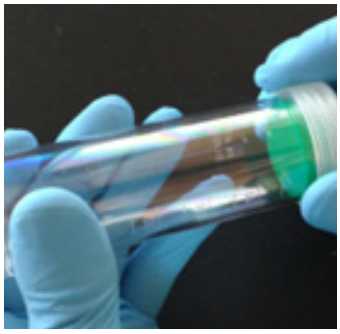
Note: To minimize cell adhesion in the Concentrating Device, it is permissible to utilize an additional 1mL ACD-A, adding through the port, swirl to coat the inside, and discard remainder.

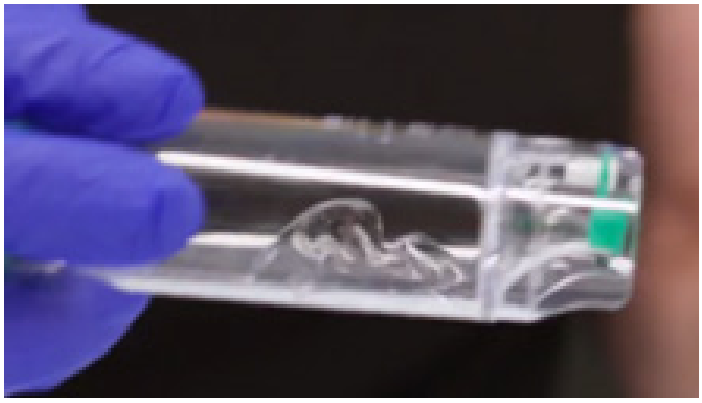












8. Attach the 45 Degree Bent Dispensing Tip to the 60mL Syringe containing the patient's whole blood then slowly transfer blood into the P60A Concentrating Device through the Input/Output Port. Fill to the 60mL marker.

9. Place the P60A Concentrating Device's built-in Silicone Cap over the Input/Output Port.

10. If the physician finds it difficult to manipulate the Silicone Cap, a slightly larger Luer Lock Low-Profile Cap is provided.

11. Secure the P60A's Top Cap to the Concentrating Device. The cap will "click" into place.

12. Using a lab scale, weigh the Concentrating Device and match the counterbalance to within +/-1.0g.

13. Place the Concentrating Device and counterbalance into opposite buckets of the centrifuge and close the lid.
    a. See respective centrifuge quick-start for details.

14. Set the centrifuge to 10 minutes and 2300rcf and start the cycle.
    a. Drucker 3500rpm (or PRP 60 cycle)

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

15. Prime the 12mL Syringe and second 60mL 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.

16. 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.

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

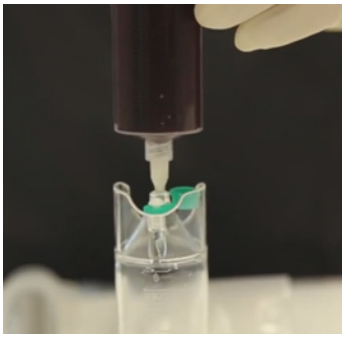
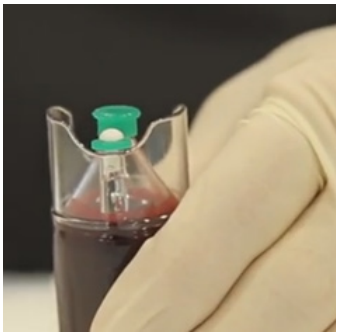
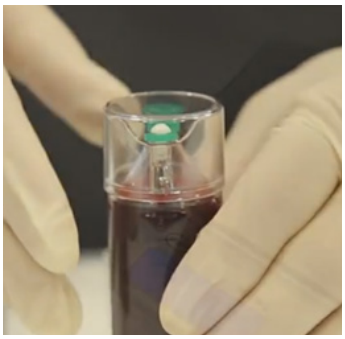
18. Obtain the P60A Concentrating Device, post-centrifugation, and remove the P60A Cap and green Silicone Cap. Attach the 60mL Syringe and, keeping the assembly vertical, place into the BPS in the orientation seen here. Rotate the concentrating device so white pin and dose mL markings are facing the technician.

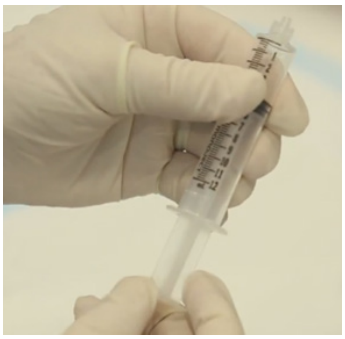
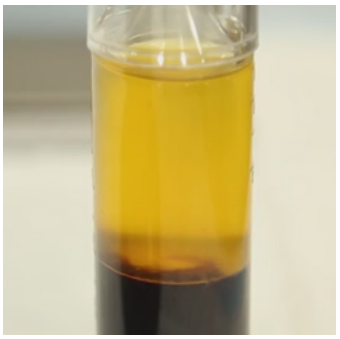
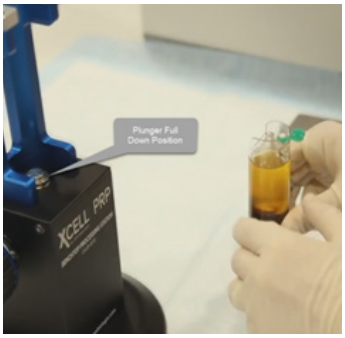
Note: Optionally, the syringe may be attached after placing the device in the BPS.

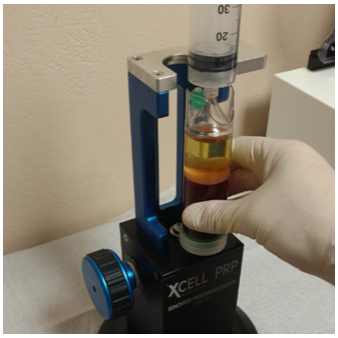
19. Gently turn the Dial counterclockwise until the Concentrating Device touches the Top Plate.

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.



20. Slowly rotate the Dial counterclockwise to push the plasma into the 60mL Syringe until the buffy coat reaches the 6mL mark on the Concentrating Device.

21. Retract the Plunger to full-down (see step 17) by rotating the Dial clockwise. Carefully remove the assembly.

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

22. Detach the 60mL Syringe and cap using the provided Luer Lock Universal Cap and set aside.

23. Attach the 12mL Syringe to the Concentrating Device and place the assembly in the BPS, as was performed with the 60mL Syringe/Concentrating Device assembly (see step 19)

24. Rotate the Dial counterclockwise and push concentrate, including buffy coat, into the 12mL Syringe (6.5mL total).

25. Now retract the Plunger to full-down and remove the assembly.

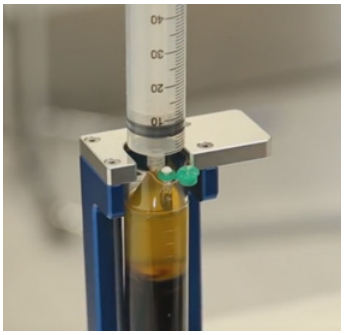
26. Carefully detach the 12mL Syringe and cap using the provided Luer Lock Universal Cap.

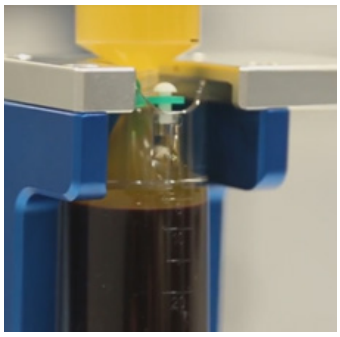
27. Gently invert the 12mL Syringe at least 15 times to re-mix the suspension.

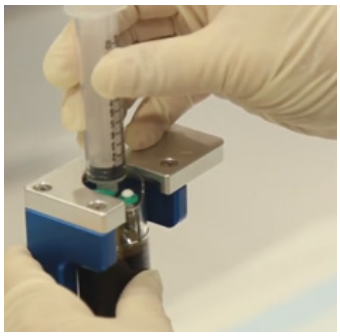
28. Re-attach the green Silicone Cap and P60A cap and set aside. PRP processing is complete

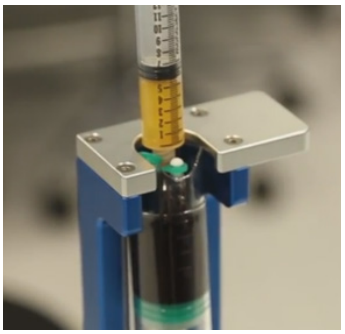
Note: Dispose of all single-use components in biohazard containers.

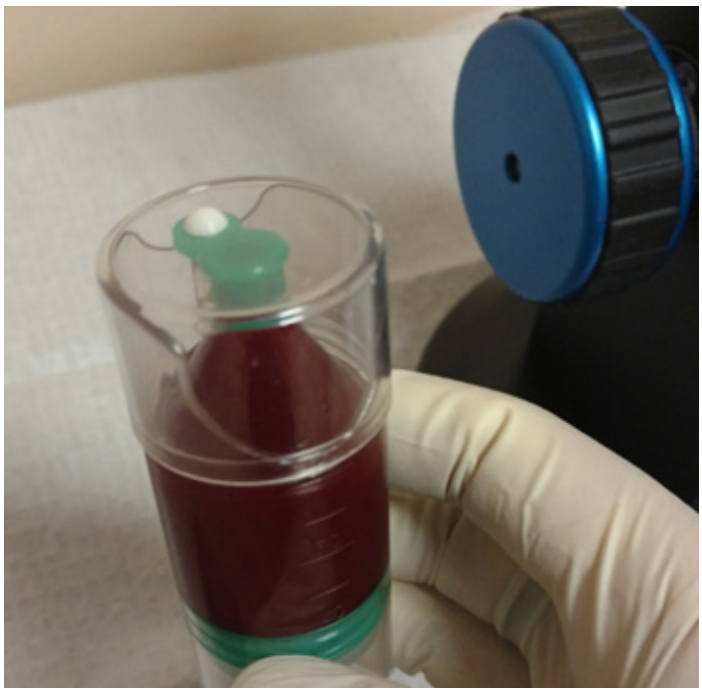
Note: Clean the BPS according to the “Benchtop Processing Station Maintenance Instructions” provided.











XC-PRP-BV-60 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-BV-60 kit and review IFU.

2. Overfilled P60A Concentrating Device

- **a.** Using the still-sterile 45 Dispensing Tip, attached to the 60 mL draw syringe, and carefully extract whole blood to the 60 mL-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-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 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 RBC. If the RBC volume is undesirable, discard, open a new XC-PRP-BV-60 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. If the patients buffy coat frequently adheres to the inside of the Concentrating Device, consider adding 1mL ACD-A through the port on the device before adding the patient’s whole blood. Then, swirl it to coat the inside of the device, and shake it out to discard the remainder. This is not a required action.

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-BV-60 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-BV-60 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-PRP-BV-60 kit or ACD-A is beyond its expiration, the sample, along with all components, should be discarded and a new XC-PRP-BV-60 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

XCELL PRP®

Instructions for Use

Manufactured by:
APEX Biologix
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www.apexbiologix.com

Assembled in the USA by:
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ACD-A Manufactured by:
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IMPORTANT: Please reference XCELL PRP™ Platelet Concentrating System Lot Control number and REF number in all communications. To report a complaint or adverse event, please email customerserviceusa@bioventusglobal.com.

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Innovations For Active Healing