


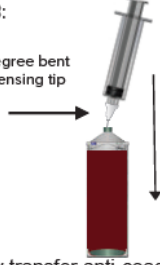
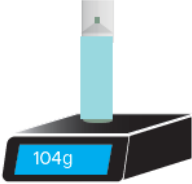


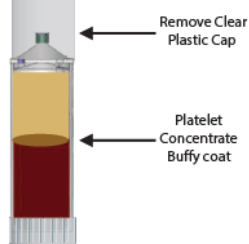

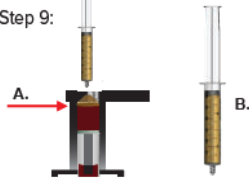
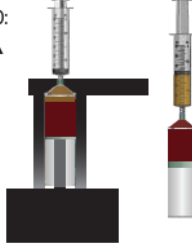



Apex Biologix Benchtop Processing Station™ Quick Start Guide

Benchtop Processing Station (BPS) IFU

- The Benchtop Processing Station (BPS) is for use with the XCELL PRP P60A Concentrating Device. When used according to instructions, the BPS provides a safe and effective method for extraction of blood components from the Concentrating Device.

For a brief overview of use of the BPS, please review the following guide for the XCELL PRP Platelet Concentrating System 60ml. The detailed instructions should be thoroughly understood before using the quick start.

 <p>**PLEASE CREATE A STERILE WORK STATION AND BE MASKED & GLOVED BEFORE PROCEEDING**</p> <p>Wipe sealing port with sterile alcohol prior to accessing with a sterile syringe</p> <p>For questions please contact: 844-897-4910</p>	<p>Step 1:</p>  <p>Draw 9mL of *ACD-A into 60mL Syringe</p>	<p>Step 2:</p>  <p>Draw whole blood from the patient, filling the syringe to maximum 60mL. Once blood is drawn, detach the tube, cap syringe and invert a minimum of 15 times to ensure ACD-A mixing.</p>	<p>Step 3:</p>  <p>45 Degree bent dispensing tip</p> <p>Slowly transfer anti-coagulated whole blood using the 45 degree bent dispensing tip into the XCELL Concentrating Device</p>
<p>Step 4:</p>  <p>**Secure the green silicone cap and the clear safety cap to the Concentrating Device. Match 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 at 3800rpm/2300rcf 10 Minute</p>	<p>Step 6:</p>  <p>Prime the 60mL 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 60mL syringe to prevent splatter</p>	<p>Step 7:</p>  <p>Remove Clear Plastic Cap</p> <p>Platelet Concentrate Buffy coat</p> <p>After spin, carefully remove XCELL Concentrating Device from the centrifuge. Remove the caps from Step 4 and attach the 60ml syringe.</p>
<p>Step 8:</p>  <p>Keeping syringe/Concentrating Device vertical, insert the assembly into BPS.</p>	<p>Step 9:</p>  <p>A. Using the BPS push PPP into 60mL syringe until the buffy coat reaches 6mL (outlined on Concentrating Device.) (See red arrow)</p> <p>B. Retract the BPS plunger and remove the Concentrating Device/60ml syringe assembly.</p> <p>C. Keeping the assembly vertical, remove and cap and 60ml syringe.</p>	<p>Step 10:</p>  <p>Aspire PRP</p> <p>Attach the 12ml Syringe to the Concentrating Device and place assembly into the BPS. Push the remaining PRP until the buffy coat is captured (6.5ml)</p>	<p>Step 11:</p>  <p>Retract the BPS plunger and remove the Concentrating Device/12ml syringe assembly. Cap the 12ml syringe and gently remix the suspension and process is complete.</p>

*Anticoagulant Sodium Citrate Dextrose Solution A (ACD-A) is not provided with the XCELL PRP kit. If you require a source please contact APEX Biologix Customer Service at 844-897-4910 or info@apexbiologix.com

**If attaching the green silicone cap is undesirable, use the optional Low-Profile Cap provided

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.



Using the BPS

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

1. Always place the BPS on a sturdy table or bench.
2. Verify the Plunger is in the full down position by rotating the Knob clockwise until the Plunger stops.



3. Prime the 60cc and 12cc Syringe's, leaving 5cc air in each.

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

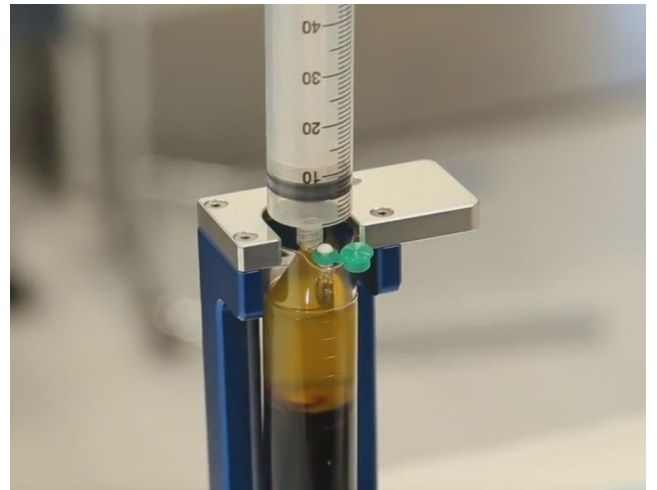
4. Obtain the P60A Concentrating Device, post-centrifugation, and remove P60A Cap and green Silicone Cap. Attach the 60cc Syringe and, keeping the assembly vertical, place into the BPS in the orientation seen here.



5. Gently turn the Knob counter-clockwise until the Concentrating Device touches the Top Plate.

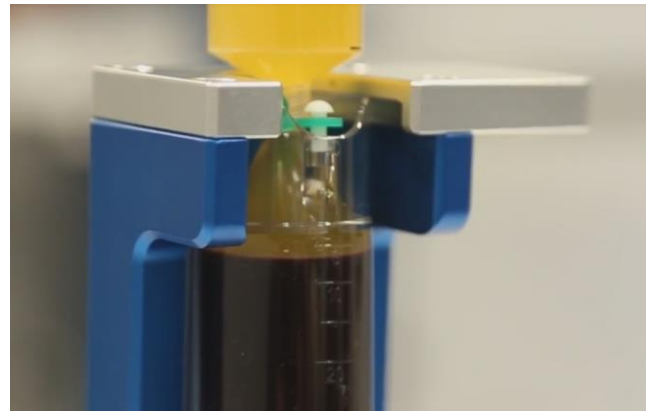
Note: *Be sure the Concentrating Device is parallel with the Tower and Plunger.*

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



6. Slowly rotate the Knob counter-clockwise to push the plasma into the 60cc Syringe until the buffy coat reaches the 6cc mark on the Concentrating Device.
7. Retract the Plunger to full-down (see step 2) by rotating the Knob clockwise. Carefully remove the assembly.

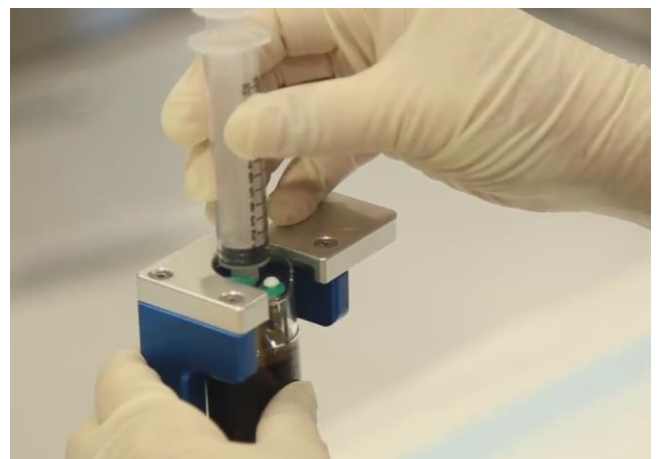
Caution: It is important to slowly rotate the Knob to minimize the possibility of contaminating the working surfaces of the BPS with blood/plasma.



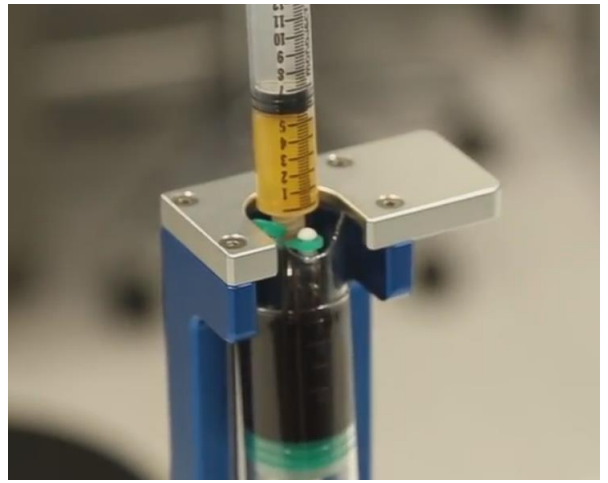
8. Detach the 60cc Syringe and cap using the provided Luer Lock Universal Cap and set aside.



9. Attach the 12cc Syringe to the Concentrating Device and place the assembly in the BPS, as was performed with the 60cc Syringe/Concentrating Device assembly (see step 4).



10. Rotate the Knob counter-clockwise and push the desired amount of concentrate into the 12cc Syringe (see XCELL PRP Instructions for Use, provided).
11. Now retract the Plunger to full-down and remove the assembly.



12. Carefully detach the 12cc Syringe and cap using the provided Luer Lock Universal Cap.
13. Gently invert the 12cc Syringe at least 15 times to re-mix the suspension.



14. Re-attach the green Silicone Cap and P60A Cap to the Concentrating Device 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.





Troubleshooting

Note: For PRP-related troubleshooting, please see XCELL PRP Instructions for Use.

The BPS is a very straightforward and reliable device to use, however in case of malfunction:

Note: The BPS is not intended to be field-serviced or disassembled in any way. Please contact Apex Biologix for servicing at orders@apexbiologix.com.

1. Knob will not turn
 - a. Rotate the opposite direction.
 - b. Check for obstructions to the Plunger travel.
 - c. Observe if the Knob or Plunger are damaged. If so, please contact Apex Biologix (see contact below).
 - d. If the BPS has been dropped or shipped inappropriately, damage may occur to the internal components. Please contact Apex Biologix (see contact below).
2. The plunger will not travel far enough to extract PRP.
 - a. Verify that you started with 60cc whole blood. A lesser amount may not allow the Plunger to travel far enough to extract PRP and is not supported by the XC-PRP-60 IFU.
 - b. Observe if the Knob or Plunger are damaged. If so, please contact Apex Biologix (see contact below).
 - c. If the BPS has been dropped or shipped inappropriately, damage may occur to the internal components. Please contact Apex Biologix (see contact below).
3. The Concentrating Device is not parallel with Tower and/or Plunger.
 - a. Back off the pressure on the Knob, by rotating clockwise, and realign the Concentrating Device. Continue processing.
 - b. Observe that all fasteners are tight. If not, remove the PRP sample, have an assistant tighten the fasteners, then perform the steps outlined in the "Benchtop Processing Station Maintenance Instructions" and attempt again. Please note that PRP should be used within 4 hours of draw or discarded.
4. If other issues are observed, please contact Apex Biologix at the number/email listed below.

Maintenance

The BPS is a maintenance-free device. Should the device stop performing its basic functions or become obviously damaged, please return the device to Apex Biologix for evaluation. Include your contact information along with a description of issues. You may also send this information to orders@apexbiologix.com.



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Electrical Safety

The BPS is not electrically powered and therefore does not require electrical safety compliance.

Cleaning

Please see “Benchtop Processing Station Maintenance Instructions” provided.

▲CAUTION: 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 and should be discarded.

▲CAUTION: The platelet rich plasma should be used within 4 hours of collection.

▲CAUTION: Centrifuge: The Eppendorf 5702 (non-refrigerated) benchtop centrifuge with Eppendorf PN A-4-38 rotor/bucket is an approved centrifuge for use with the XC-PRP-60 system. The Drucker Boost 4+ Flex centrifuge is also approved for use with the XC-PRP-60 system.

Manufactured by:

APEX Biologix
5650 S. Green Street, Ste. B, Murray, UT 84123
Phone: 844-897-4910 (Att. Customer Service)
Email: info@apexbiologix.com
www.apexbiologix.com

For Warranty or Service Please Contact:

APEX Biologix
5650 S. Green Street, Ste. B, Murray, UT 84123
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www.apexbiologix.com

IMPORTANT: Please reference Benchtop Processing Station Lot Control number (found on the back of the BPC) 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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