

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 Concentrating Systems. When used according to instructions, the BPS provides a safe and effective method for precisely utilizing the Concentrating Device for the collection of blood components.

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.



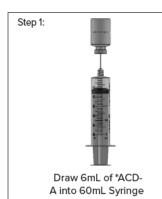
*PLEASE CREATE A STERILE WORK STATION AND BE MASKED & GLOVED **BEFORE PROCEEDING***

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

For questions please contact:

844-897-4910

Step 4:



Step 5: Place XCELL counterbalance and concentrating device on opposite ends inside

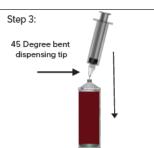
centrifuge and spin:

Drucker: 3500 RPM/2300 RCF 10 minutes

Eppendorf: 3800 RPM/2300 RCF 10 minutes



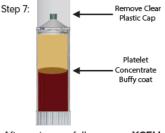
Draw whole blood from the patient, filling the syringe to maximum 60mL. Once blood is drawn, detach the tube and ensure the anti-coagulant spreads throughout the blood sample



Slowly transfer anti-coagulated whole blood using the 45 degree bent dispensing tip into the XCELL concentrating device



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



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



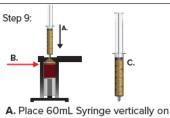
**Secure the green silicone cap and the

clear saftey cap to the concentrating

device. Match

counterbalance to +/- 1.0g of

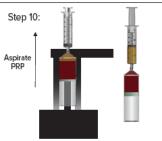
Insert XCELL Concentrating Device into Bench Top Processing Station then twist DIAL to move plasma to the bottom of the Luer-slip fitting.



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

C. Remove and cap 60mL syringe



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



Cap the 12mL syringe and gently remix the suspension and process is complete

^{*}Anticoagulant Sodium Citrate Dextrose Solution A (ACD-A)

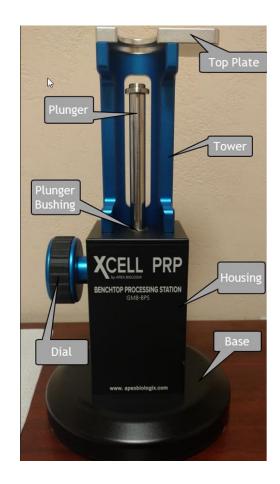
^{**}If attaching the green silicone cap is undesirable, use the optional Low-Profile Cap provided



Definitions for the BPS

- Top Plate: the retainer for the 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.



Using the BPS

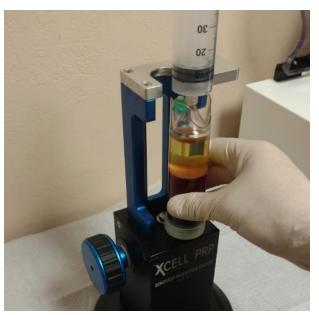


Critical: The BPS should be cleaned before each use following the procedure found in the Benchtop Processing Station Maintenance Instructions, provided.

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



- 3. Prime the PPP syringe and dose syringe's, leaving 5mL 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 Concentrating Device, postcentrifugation, and remove Top Cap (where applicable) and green Silicone Cap. Attach the PPP syringe and, keeping the assembly vertical, place into the BPS in the orientation seen here.

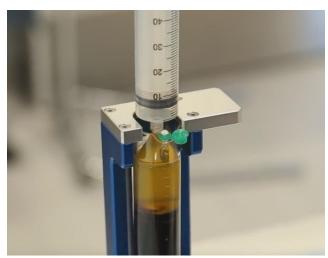




5. Gently turn the Dial counterclockwise until the Concentrating Device engages the Top Plate.

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 Dial counterclockwise to push the plasma into the PPP Syringe until the buffy coat reaches the appropriate mark on the Concentrating Device (see specific product IFU)
- 7. Retract the Plunger to full-down (see step 2) 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.

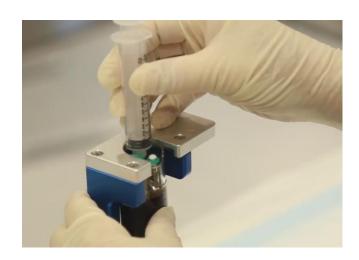


8. Detach the PPP Syringe and cap using the provided Luer Lock Universal Cap and set aside.





 Attach the dose syringe to the Concentrating Device and place the assembly in the BPS, as was performed with the PPP Syringe/Concentrating Device assembly (see step 4).



- 10. Rotate the Dial counterclockwise and push the desired amount of concentrate into the Dose Syringe (see the specific product IFU).
- 11. Now retract the Plunger to full-down and remove the assembly.



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





14. Re-attach the green Silicone Cap and Top Cap (if applicable) 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 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. Dial will not turn
 - a. Rotate the opposite direction.
 - b. Check for obstructions to the Plunger travel.
 - c. Observe if the Dial 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 the appropriate volume of whole blood. A lesser amount may not allow the Plunger to travel far enough to extract PRP.
 - Observe if the Dial 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 Dial, by rotating clockwise, and realign the Concentrating Device. Continue processing.
 - b. Observer 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.

Electrical Safety

The BPS is not electrically powered and therefore does not required 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 Phone: 844-897-4910 (Att. Customer Service)

Email: info@apexbiologix.com
www.apexbiologix.com

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