



XCELL Bone Marrow System 60ml™ (SKU: XC-BMSC-60 / PN: 90-010)

Single Use Only Device

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

▲ **CAUTION:** The XCELL Bone Marrow System 60ml (XC-BMSC-60), which includes the XCELL Bone Marrow Aspiration System 60ml (XC-BMA-SC-60) and XCELL Bone Marrow Aspirate Concentrating System 60ml (XC-BMC-SC-60) 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 Bone Marrow System 60ml (XC-BMSC-60), which includes the XCELL Bone Marrow Aspiration System 60ml (XC-BMA-SC-60) and XCELL Bone Marrow Aspirate Concentrating System 60ml (XC-BMC-SC-60) is classified as a Convenience Kit under the General Hospital and Personal Use Devices segment of FDA's Convenience Kits Interim Regulatory Guidance (FDA-2020-D-0957). The kit is not specifically indicated.

CONTRAINDICATIONS: The XCELL Bone Marrow System 60ml (XC-BMSC-60), which includes the XCELL Bone Marrow Aspiration System 60ml (XC-BMA-SC-60) and XCELL Bone Marrow Aspirate Concentrating System 60ml (XC-BMC-SC-60) 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/marrow 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 kit if the packaging is open or damaged.
3. Do not use after expiration date.
4. Use only the QSG (Quick Start Guide) and Instruction for Use of the XC-BMSC-60 system.
5. The physician and all staff who will be utilizing the XC-BMSC-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 BMA/BMC sample should be used within 4 hours of blood draw.
7. The BMA/BMC is not intended to be returned to the patient's circulatory system.
8. The XC-BMSC-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, bone marrow aspiration, and cell harvest process of the patient's blood should occur under aseptic conditions. The disposable XC-BMSC-60 system, syringes and accessories, must be properly discarded following standard biohazard guidelines after each use. Sealed sterile



packages containing the XCELL XC-BMSC-60 system 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 and bone marrow 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 (non-refrigerated) benchtop centrifuge with Eppendorf PN A-4-38 rotor/bucket is an approved centrifuge for use with the XC-BMSC-60 system. The Drucker Boost 4+ Flex centrifuge is also approved for use with the XC-BMSC-60 system.

Benchtop Processing Station (BPS) Basic Instructions

- The Benchtop Processing Station (BPS) is provided for extracting blood/marrow 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, 6cc 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 60cc 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 not provided with the XCELL Bone Marrow System 60ml. ACD-A can be ordered through Apex Biologix by calling 844-897-4910, email 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. This ACD-A 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.



Heparin is provided with the XCELL Bone Marrow System 60ml in a concentration of 30,000usp units in a 30ml file (1,000usp units per ml). As an anticoagulant, Heparin should be used at a ratio of 5-10% to blood/marrow volume, with 5% being used for straight Heparin. This dosage allows the physician to dilute at a 1-to-1 ratio with saline, if desired. If a dilution is used, a 10% dilution-to-blood/marrow is recommended.

DEVICE DESCRIPTION:

The XCELL Bone Marrow System is a single-use, sterile kit consisting of bone marrow aspiration and bone marrow concentration components. The system is a convenience kit designed to provide the physician with all components needed to support various aspiration techniques and to then concentrate the aspirated bone marrow using provided hardware. The Eppendorf 5702 or Drucker Boost 4+ centrifuges are provided to support centrifugation needs. The system prepares bone marrow concentrate (BMC) from a small volume of blood/marrow that is aspirated 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 CONTENTS for XC-BMC-SC-60 Bone Marrow Aspirate Concentrating System 60ml (sub-kit):

- (1) *APEX P60A Concentrating Device
- (1) *APEX P60A Cap
- (2) *60cc Syringe (Luer lock)
- (2) *10cc Syringe (Luer lock)
- (1) *45 Degree Bent Dispensing Tip
- (2) Alcohol Prep Pad
- (1) *150um IN-line Filter, Capped
- (2) *Universal Non-Vented Cap
- (1) *Female-to-Female Luer Connector
- (2) *Male Vented Luer Cap
- (1) Drape/Towel
- (5) White Patient Labels
- (1) Glassine Bag

KIT CONTENTS for XC-BMA-SC-60 Bone Marrow Aspiration System 60ml (sub-kit):

- (9) *Syringe 10ml (Luer lock), Capped
- (1) 30cc Syringe (Luer lock)
- (1) *Female-to-Female Luer Connector
- (2) *Male Vented Luer Cap
- (1) 18g x 1.5" Needle
- (2) *Universal Non-Vented Cap
- (2) Alcohol Prep Pad
- (1) *120ml Specimen Cup
- (1) *11g Bone Marrow Needle



***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-BMSC-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 Bone Marrow System 60ml may be used.



INSTRUCTIONS FROM USER



PROCESSING VIDEO

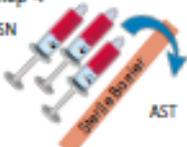
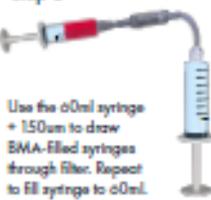
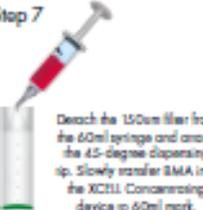
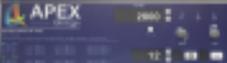
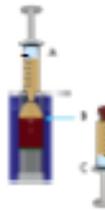
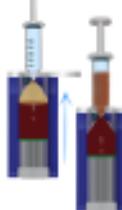


EDUCATIONAL MATERIALS

XCELL BMC

by APEX BIOLOGIX

- *This guide does not include general patient preparation for a BMC procedure.
- *The Centrifuge should be prepared for the procedure.
- *Create a sterile work environment and be masked/ gloved before proceeding.
- *Wipe injection site of Heparin vial with provided sterile alcohol pad prior to aspirating.
- *The AST (Assistant or Circulating Nurse) should open the BMC kit, remove the sterile Inner Tray and/or components, and lay them out as desired on the sterile field.

<p>Step 1</p>  <p>AST prepares the Heparin vial for aspiration and presents to SN.</p>	<p>Step 2</p>  <p>AST re-gloves for optimal sterility. AST receives 30ml syringe from SN after heparinizing BMA components.</p>	<p>Step 3</p>  <p>Use 30ml Heparin syringe & female-female connector to heparinize: 60ml syringe, 60ml syringe + 150um filter, two 10ml syringes, 45 degree tip, XCELL Concentrating Device.</p>
<p>Step 4</p>  <p>AST receives filled BMA syringes from the SN.</p>	<p>Step 5</p>  <p>AST removes all BMA syringes, inverting 15-20 times.</p>	<p>Step 6</p>  <p>Use the 60ml syringe + 150um to draw BMA-filled syringes through filter. Repeat to fill syringes to 60ml.</p>
<p>Step 7</p>  <p>Detach the 150um filter from the 60ml syringe and attach the 45-degree dispensing tip. Slowly transfer BMA into the XCELL Concentrating device to 60ml mark.</p>	<p>Step 8</p>  <p>Secure the green silicone stopper and the clear safety cap to the XCELL Concentrating Device. Weigh sample and match counterbalance to +/- 1.0g.</p>	<p>Step 9</p>  <p>Place XCELL and Counterbalance in opposite buckets of centrifuge. Spin at 2000cf for 12 minutes or select the BMC 60 cycle.</p>
<p>Step 10</p>  <p>Prime the heparinized 10ml and 60ml syringes by cycling the plunger back and forth 2 or 3 times. Leave 5ml of air in the 60ml syringes to prevent splatter.</p>	<p>Step 11</p>  <p>Remove clear and green caps. After spin, carefully remove the XCELL concentrating device from the centrifuge. Remove the caps from Step 10.</p>	<p>Step 12</p>  <p>Place the XCELL concentrating device into the BPS and slowly turn the knob until the plasma reaches the bottom of the low slip fitting.</p>
<p>Step 13</p>  <p>Connect the primed 60ml syringe into the XCELL Concentrating Device. Using the BPS, hold the handle and push PFF into the syringe until the top of the bulb just reaches the 60ml marker (see blue arrow). Remove and cap the 60ml syringe.</p>	<p>Step 14</p>  <p>Add the heparinized and primed 10ml syringe and push the remaining BAC capturing all of the buffy coat and ~20ml of BAC. Cap the 10ml syringe and gently mix. BAC process is complete.</p>	<p>Step 15</p>  <p>AST attaches the female-female connector to the 10ml BAC above syringe. SN performs a resulting 10ml syringe. Syringes are attached across the sterile field and the BAC is transferred.</p>

***This process provides 0-6.5ml BMC concentrate. For higher TNC counts, continue pushing RBC into the 10ml syringe to the 8-9ml mark. If lower volume, higher concentration is desired, push the buffy coat above the 6ml mark on the concentrating device in step 14, then add the 10ml syringe and push to the needed volume.



INSTRUCTIONS FOR USE



PROCESSING VIDEO

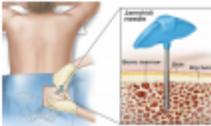


EDUCATIONAL MATERIALS

XCELL BMA

by APEX BIOLOGIX

- *This guide does not include general patient preparation for a BMA procedure.
- *Create a sterile work environment and be masked/ gloved before proceeding.
- *Wipe injection site of Heparin vial with provided sterile alcohol pad prior to aspirating.
- *The AST (Assistant or Circulating Nurse) should open the BMA kit and present components or Inner Tray to SN (Scrub Tech or Nurse) who will lay them out on the sterile field.

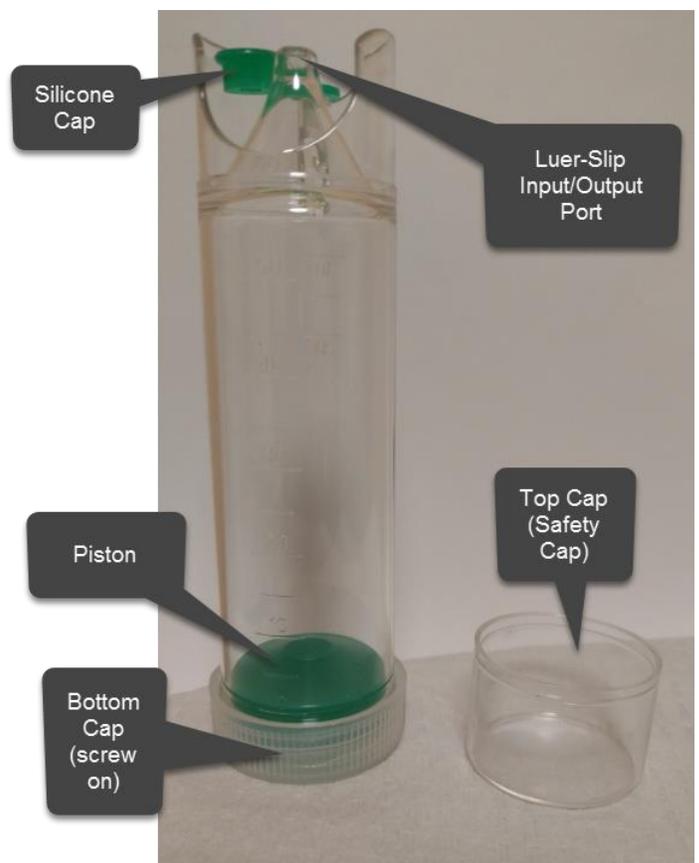
<p>Step 1</p>  <p>Remove non-sterile Heparin vial and place on the non-sterile area.</p>	<p>Step 2</p>  <p>AST prepares Heparin. SN prepares 30ml syringe.</p>	<p>Step 3</p>  <p>AST presents Heparin to SN. SN draws heparin.</p>
<p>Step 4</p>  <p>SN places desired Heparin amount in specimen cup.</p>		<p>Step 5</p>  <p>SN Heparinizes all BMA contacting components.</p>
<p>Step 6</p>  <p>Add .5ml Heparin to all 10ml syringes.</p>	<p>Step 7</p>  <p>SN passes unused Heparin, in the 30ml syringe to the AST.</p>	<p>Step 8</p>  <p>**Insert the biopsy needle into the patients iliac crest (guided).</p>
<p>Step 9</p>  <p>Draw 5-10ml BMA into the 10ml syringes. Thoroughly mix by inverting 15-20 times.</p>		<p>Step 10</p>  <p>Repeat step 9 until 60ml of BMA is collected in syringes. Pass syringes to AST.</p>

** See the biopsy needle IFU for precise aspiration instructions. The physician is responsible for selecting the technique utilized.

See Next Page

Definitions for the XCELL 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.



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.

Note: The Scrub Tech or Scrub Nurse is abbreviated with SN. The Circulatory Nurse or Assistant is abbreviated as AST.



XC-BMA-SC-60 Bone Marrow Aspiration System 60ml:

1. The semi-sterile Apex nurse or rep (ANR) opens the BMA kit and presents to the scrub nurse (SN) who:
 - a. Places the entire tray on the patient sterile field or
 - b. Dumps the components on the sterile field and arranges the components as-needed for the procedure. The tray is discarded.
 - c. In either case, the SN will also need to open the BMA needle tray, place the needle and discard the tray.
2. The ANR presents the Heparin vial to the SN, across the field, who utilizes the 30ml syringe + 18g x 1.5 sub-assembly to aspirate all 30ml from the vial.
3. The SN will expel about 15ml, into the syringe or specimen cup, or both, to heparinize the following BMA components:
 - a. 8x 10ml syringes, leaving .5ml heparin in each.
 - b. Female-to-female connector
 - c. BMA needle
4. The SN will pass the unused portion over to the ANR for heparinizing the BMC components.
5. BMA component preparation is complete.

XC-BMC-SC-60 Bone Marrow Aspirate Concentrating System 60ml:

1. The ANR cleans and prepares the centrifuge (Drucker only) counterbalance and BPS.
2. The ANR opens the BMC kit and presents to the SN who:
 - a. Opens the 24" x 14" towel (on top of components) and lays out on the bench.
 - b. Places the entire tray on the back-bench sterile field or
 - c. Dumps the components on the field. The tray is discarded.
3. The ANR provides the Heparin to the SN when ready.
4. The ANR washes and re-gloves.
5. While the SN is heparinizing the BMA components, the ANR will lay out the BMC components.
6. When the SN is done heparinizing, he/she will pass the remaining ~15ml Heparin, in the 30ml syringe + 18g x 1.5 sub-assembly across the field to the ANR.
7. The ANR will heparinize and prep the remaining BMC components which include:
 - a. P60A Concentrating Device (close silicone cap afterwards)
 - b. #1 60ml syringe + 150um filter sub-assembly.
 - c. #2 60ml PPP syringe
 - d. 45 Degree Dispensing Tip
 - e. #1 10ml dose syringe
 - f. #2 10ml backup syringe
 - g. Female-to-Female connector
8. BMC component preparation is complete.
 - a.



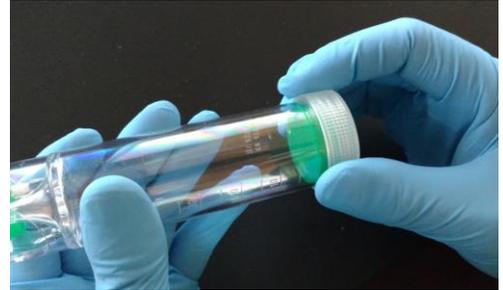
Bone Marrow Aspiration and Concentration Process:

1. After prepping the patient, the physician starts the procedure by inserting the BM needle (guided) into the upper iliac crest (right or left). After accessing the marrow, the following steps occur:
2. #1 10ml syringe (w/.5ml Heparin) is attached to the BMA needle. Using a specific method, about 7-10ml of marrow is aspirated.
3. The physician hands the filled syringe to the SN, who hands it across the field to the ANR.
4. The ANR, ensures the aspirate and Heparin are well mixed, then using the #1 60ml Syringe + 150um filter sub-assembly, pulls the aspirate through the filter and into the 60ml syringe.
5. Process 2-4 repeats until the physician has 60-62ml aspirate. The ANR communicates with the SN and physician.
6. The ANR carefully mix
7. The ANR removes the 150um filter and attaches the 45 Degree Dispensing Tip to #1 60ml aspirate syringe.
 - a. Note: The SN may choose to run the filtering process on the BMA side. If so, he/she may request the #1 60ml Syringe + 150um Filter sub-assembly from the ANR before or after heparinizing.
8. The ANR transfers the aspirate into the P60A Concentrating Device filling to the 60ml mark.
9. The ANR verifies the counterbalance, loads the centrifuge with aspirate and counterbalance, and executes the cycle at 2800rcf for 12 minutes.
10. When centrifugation is complete, the ANR transfers the P60A Concentrating Device to the Benchtop Processing Unit.
11. The #2 60ml syringe is attached to the top of the P60A Concentrating Device and ~30ml of platelet-poor-plasma is pushed off. The syringe is removed, capped with #1 Universal Cap, and placed on the back-bench sterile field for optional use by the physician.
12. The #1 10ml syringe is attached to the P60A Concentrating Device and ~6ml of BMC is pushed off. The syringe is removed and capped with #2 Universal Cap.
13. The ANR notifies the SN and physician that the BMC is ready.
14. The ANR un-caps the #1 10ml BMA syringe, attaches the Female-to-Female connector and approaches the field.
15. The SN removes the cap from #9 10ml syringe, on the BMA side, and approaches the field.
16. The ANR and SN mate the two syringes with the SN drawing the BMC into that syringe.
17. The ANR grasps the Female-to-Female connector and the SN removes the 10ml syringe and caps. The BMC is ready for the physician's use.
18. The BMAC process is complete. All components are disposed of. The ANR removes the centrifuge, counterbalance and BPS as directed.

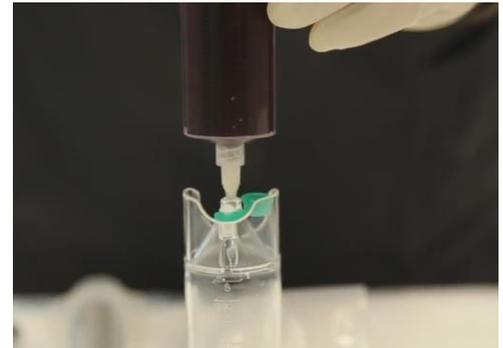
Note: It is critical to mix the Heparin with the blood/marrow immediately after aspiration is complete. Invert the capped syringe for a minimum of 15 times.

Concentrating Device and BPS Usage:

Note: before transferring to the Concentrating Device, verify the Bottom Cap is tightened securely, using the handholds in the adjacent image and rotating the cap clockwise until snug.



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

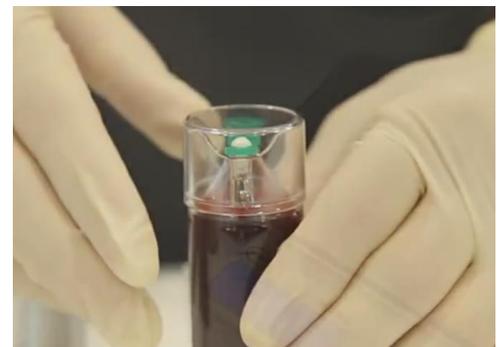


10. Place the P60 Concentrating Devices built-in Silicone Cap over the Input/Output Port.



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

12. Secure the P60A's Top Cap to the Concentrating Device



13. Using a lab scale, weigh the Concentrating Device and match the counterbalance to within +/-1.0g.
14. 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.

15. Set the centrifuge to 12 minutes and 2800rcf and start the cycle.
 - a. Eppendorf 4200rpm
 - b. Drucker 3900rpm

16. Prime the 10cc Syringe and second 60cc Syringe leaving 5cc's of air.

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

17. 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.

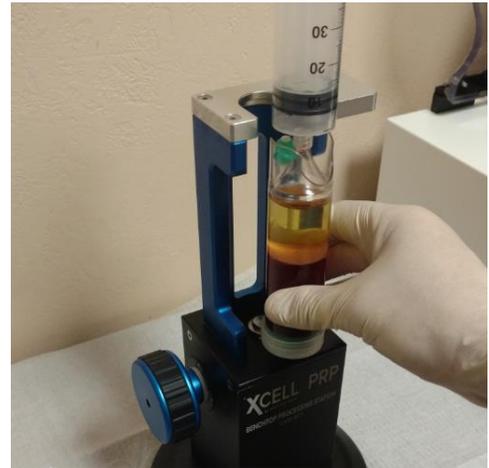
18. Verify the Plunger is in the full down position by rotating the Knob clockwise until the Plunger stops.



19. Prime the 60cc and 10cc 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.

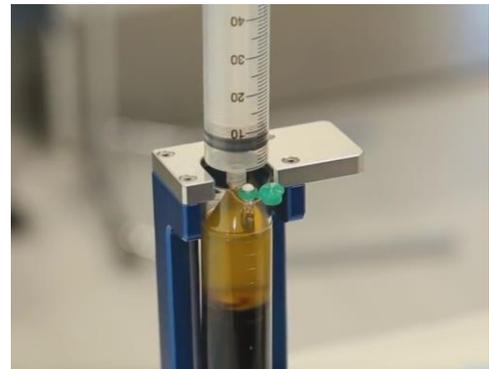
19. Obtain the P60A Concentrating Device, post-centrifugation, and remove P60A Cap and green Silicone Cap. Attach the 60cc Syringe and, keeping the assembly vertical, place into the BPS in the orientation seen here.



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

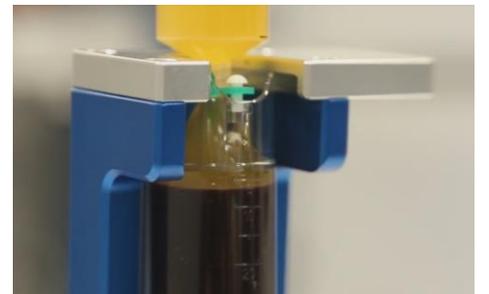
Note: Be sure the Concentrating Device is parallel with the Tower and Plunger.

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



21. 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.

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

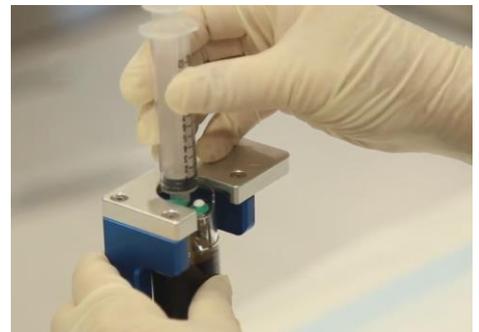


Caution: It is important to slowly rotate the Knob to minimize the possibility of contaminating the working surfaces of the BPS with blood/plasma.

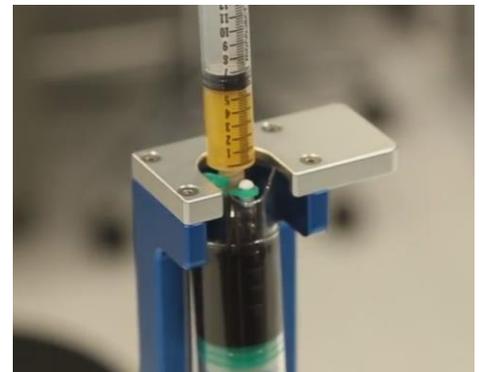
23. Detach the 60cc Syringe and cap using the provided Luer Lock Universal Cap and set aside.



24. Attach the 10cc Syringe to the Concentrating Device and place the assembly in the BPS, as was performed with the 60cc Syringe/Concentrating Device assembly (see step 19)



25. Rotate the Knob counter-clockwise and push concentrate, including buffy coat, into the 10cc Syringe (6.5cc total).
26. Now retract the Plunger to full-down and remove the assembly.



27. Carefully detach the 10cc Syringe and cap using the provided Luer Lock Universal Cap.
28. Gently invert the 10cc Syringe at least 15 times to re-mix the suspension.



29. Re-attach the green Silicone Cap and P60A cap and set aside. BMC 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-BMSC-60 Troubleshooting

1. Whole Blood/marrow sample appears to have “clumps”
 - a. This is an indication the Heparin was not mixed after drawing. Discard, open a new XC-BMSC-60 kit and review IFU.
2. Overfilled P60A Concentrating Device
 - a. Using the still-sterile 45 Dispensing Tip, attached to the 60cc draw syringe, and carefully extract blood/marrow to the 60cc-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. Some remixing has occurred, however BMC will always be more red than PRP.
 - 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 BMC sample is too red.
 - a. The user has taken excessive RBC. If the RBC volume is undesirable, discard, open a new XC-BMSC-60 kit and review IFU.

When BMA or BMC 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-BMSC-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-BMSC-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-BMSC-60 kit or ACD-A is beyond its expiration, the sample, along with all components, should be discarded and a new XC-BMSC-60 kit obtained.
4. If the patient, at any point before BMC 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
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Phone: 844-897-4910 (Att. Customer Service)
Email: info@apexbiologix.com
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Assembled in the USA 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 info@apexbiologix.com

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				Revision History	
Rev.	PN	Initial	Description of Change	Effective Date	
A	70-092	BB	Original IFU	5/12/22	