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PL-42-75
REV 1

**PurePRP® Supraphysiologic
Concentrating System
Instruction for Use**

ATTENTION OPERATING
SURGEON

- NOTE: DEVICE IS FOR SINGLE USE ONLY. Discard the entire disposable system after one use, using an acceptable disposal method for products potentially contaminated with blood.
- DESCRIPTION
The PurePRP® Supraphysiologic Concentrating System is manufactured by EmCyte Corporation. The kit prepares platelet poor plasma and platelet concentrate (platelet rich plasma) from a small sample of blood at the point of care. The system contains syringes, needles and the concentrating device accessories.
- MATERIALS
The materials used are syringes, needles, tubing, connectors, and concentrating devices. The materials consist of medical grade polymers, elastomers and stainless steel that are suitable for use in medical devices. All components in this system are packaged, labeled and sterilized as indicated by the manufacturer's labeling. All components in this system are latex-free.

INDICATIONS FOR USE STATEMENTS

- 510(k) clearance statement
The PurePRP® Supraphysiologic Concentrating System is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP can be mixed with autograft and allograft bone prior to application to an orthopedic surgical site as deemed necessary by the clinical use requirements.

WARNING AND PRECAUTIONS

- Use proper safety precautions to guard against needle sticks.
- Follow manufacturer instructions when using centrifuge. Use only EmCyte provided general purpose centrifuge. Outcomes using centrifuges from other manufacturers are unknown.
- Do not use sterile components of this system if package is opened or damaged.
- Single use device. Do not reuse.
- Do not use after expiration date.
- The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
- Use prepared PPP or PRP within 4 hours after drawing blood according to current AABB guidelines.
- The patient is to be made aware of the general risks associated with whole blood aspiration. These risks include, but are not limited to: hemorrhage, seroma formation, infection, and/or persistent pain at the site of aspiration.
- The safety and effectiveness of this device for in vivo indications for use, such as bone healing and hemostasis, have not been established.
- The PRP prepared by this device has not been evaluated for any clinical indications.
- The PRP prepared by this device is NOT indicated for delivery to the patient's circulatory system.
- Device is single use only. Do not attempt to clean or re-sterilize this product. After use, this product may be a potential biohazard.

POSSIBLE ADVERSE EFFECTS

- Damage to blood vessels, hematoma, delayed wound healing and/or infection is associated with blood draw, and/or surgical procedure.
- Temporary or permanent nerve damage that may result in pain or numbness is associated with blood draw, and/or surgical procedure.
- Early or late postoperative infection is associated with surgical procedure.
- Pain associated with site of whole blood harvest.

STERILITY

- The PurePRP® Supraphysiologic Concentrating System kits are sterilized by ETO exposure. Do not use any component from an opened or damaged package. Do not resterilize. Single Use Only. Do not use past the expiration date.

INSTRUCTIONS FOR USE

(See REFERENCES for 30mL, 60mL and 120mL SYSTEMS)

- NOTE: Use standard aseptic technique throughout the following procedure.
- WHOLE BLOOD DRAW: Attach the sterile filter needle onto the [A] syringe. Draw [B] amount of Citrate Anticoagulant into [C] syringe. Remove the filter needle from the syringe. Slowly draw [D] of whole blood from the patient filling [E] syringe/s to [F] of volume. Gently, but thoroughly mix the blood and anticoagulant upon collection to prevent coagulation.
- LOAD: Slowly add the anticoagulated whole blood into the TOP port of the Concentrating Device (60mL per device if processing more than one device). Once added, attach the non-vented clear cap to the BOTTOM port of the device/s. Load into the Executive Series Centrifuge II machine.
- BALANCE: Counterbalance the Concentrating Device. Place the counterbalance (or second Concentrating Device if processing two device) and the Concentrating Device directly opposite to each other in the centrifuge rotor and make sure they contain the same amount of volume.
- FIRST SPIN: Close centrifuge lid. Set RPM to 3800 (2.3 RCF) and the time to 1.5 minutes. Press the start button. Once the centrifuge stops, remove the Concentrating Device/s.
- FIRST EXTRACTION & TRANSFER: Attach the [A] syringe to the TOP port of the Concentrating Device/s. Slowly aspirate the Platelet Plasma Suspension (PPS) into the [A] syringe. Aspirate until the pipe completely fills with RBC. Then remove the clear cap from the BOTTOM port and transfer the PPS back into the Concentrating Device. Recap the bottom port with the sterile clear cap.
- SECOND SPIN: Counterbalance and place back into the centrifuge. Close centrifuge lid. Set RPM to 3800 (2.3 RCF) and the time to 5 minutes. Press the start button. Once the centrifuge stops, remove the Concentrating Device/s.
- SECOND EXTRACTION: Using the [A] syringe, aspirate the plasma leaving [G] of volume in the device.
- RESUSPEND THE PRP: Gently swirl the Concentrating Device to re-suspend the platelet concentrate into the plasma.
- EXTRACT PRP: Attach the sterile [H] syringe to the BOTTOM port and aspirate the PRP. Remove sterile syringe and apply sterile cap.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

REFERENCES

For 30mL SYSTEM		For 60mL SYSTEM		For 120mL SYSTEM	
[A] 30mL	[E] One	[A] 60mL	[E] One	[A] 60mL	[E] Two
[B] 3mL	[F] 30mL	[B] 6mL	[F] 60mL	[B] 6mL	[F] 60mL
[C] 30mL	[G] 3mL	[C] 60mL	[G] 7mL	[C] Two 60mL	[G] 7mL
[D] 27mL	[H] 12mL	[D] 54mL	[H] 12mL	[D] 54mL	[H] 20mL



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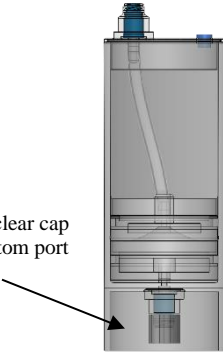
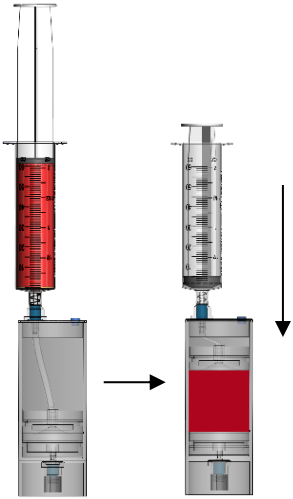
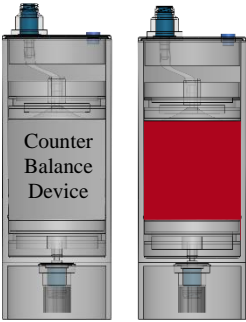


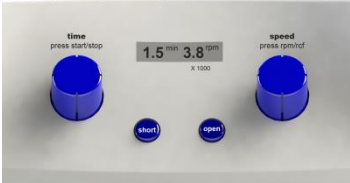
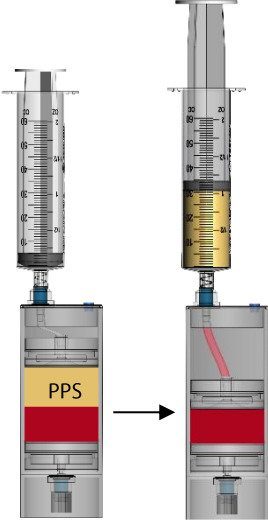
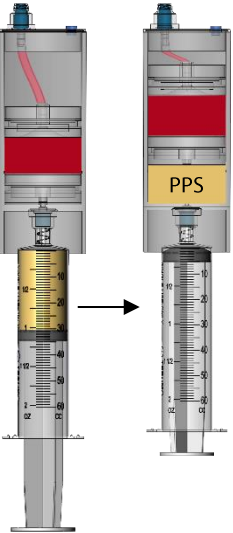
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IMPORTANT NOTICES!

Always swab needle-less port with sterile alcohol before accessing with a sterile syringe or cap

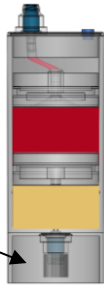
Discard RED vented cap from concentrating device before use

ILLUSTRATION OF PREPARATION STEPS 60mL

<p>Step 1:</p>  <p>Using the filtered needle, draw 6mL of Sodium Citrate Anticoagulant into 60mL Syringe</p>	<p>Step 2:</p>  <p>Draw 54mL whole blood from the patient, filling the syringe to 60mL</p>	<p>Step 3:</p>  <p>Place clear cap on bottom port</p> <p>IMPORTANT!! Place clear cap on the bottom needle-less port to seal during centrifugation</p>	<p>Step 4:</p>  <p>Inject anticoagulated whole blood through the top needle-less port (To clear the residual blood, purge the line with 1.5mL of anticoagulant)</p>
<p>Step 5:</p>  <p>Using the counterbalance device, counterbalance with equal volume</p>  <p>Place in the centrifuge rotor at opposite ends</p>	<p>Step 6:</p> <p>Process at:</p> <p>PLATINUM SERIES CENTRIFUGE</p> <p>PurePRP® SP SPIN 1</p>  <p>EXECUTIVE SERIES CENTRIFUGE</p> <p>1.5 minutes, 3800 RPM</p> 	<p>Step 7:</p>  <p>After centrifugation, connect the 60mL syringe to the top needle-less port and slowly aspirate the Platelet Plasma Suspension (PPS). Aspirate until aspirating pipe fills with RBCs</p>	<p>Step 8:</p>  <p>Remove clear cap from the bottom needle-less port and inject the Platelet Plasma Suspension (PPS)</p>

Step 9:

Place clear cap on bottom port



IMPORTANT!!
Place new sterile clear cap onto bottom needle-less port



Place back into the centrifuge rotor at opposite ends

Step 10:

Process at:

**PLATINUM SERIES
CENTRIFUGE**

PurePRP® SP SPIN 2



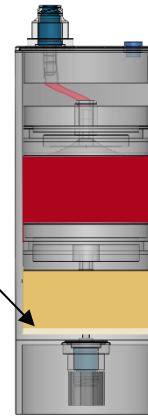
**EXECUTIVE SERIES
CENTRIFUGE**

5 minutes, 3800 RPM



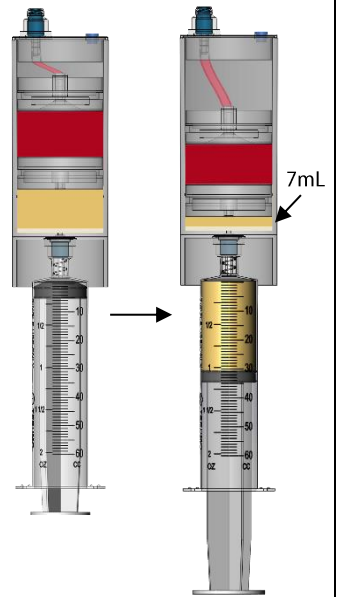
Step 11:

Platelet buffycoat at the bottom of the device



After centrifugation the platelet buffycoat will be separated at the bottom of the device

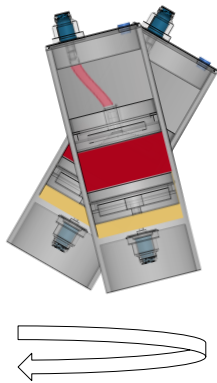
Step 12:



Connect the syringe to the bottom needle-less port and aspirate plasma leaving 7mL in the device

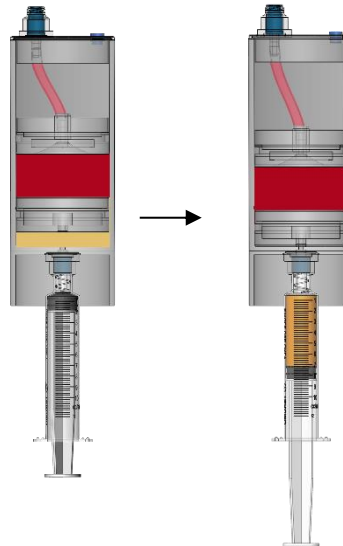
(stop at the 7mL marker)

Step 13:



Gently agitate to resuspend the platelet buffycoat into the plasma

Step 14:



Connect the 12mL syringe and aspirate the remaining 7mL of supraphysiologic pure platelet rich plasma

Step 15:



7mL PurePRP® SupraPhysiologic

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