

AbsolutePRP™ GenesisCS Component Concentrating System
Instruction for Use
Platelet Concentrating System
Date: September 2023

ATTENTION OPERATING SURGEON

1. **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.
2. **DESCRIPTION**
The AbsolutePRP™ GenesisCS Component Concentrating System is manufactured by EmCyte Corporation. The kit prepares platelet rich plasma from a small sample of blood at the point of care. The system contains syringes, needles and the concentrating device accessories.
3. **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.
4. **INDICATIONS FOR USE STATEMENTS**
 - a. The GenesisCS Component 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.
 - b. The safety and effectiveness of this device for in vivo indications for use, such as bone healing and hemostasis, have not been established.
 - c. The PRP prepared by this device has not been evaluated for any clinical indications.
 - d. The PRP prepared by this device is **NOT** indicated for delivery to the patient's circulatory system.
5. **USER POPULATION**
The intended user population is medical professionals who are licensed or certified in clinical practice. The operational context of the device requires users to be trained on aseptic technique and understand blood components. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
6. **DEVICE USE ENVIRONMENT**
The device is intended to be used in a health care setting such as a surgery room, clinic or outpatient care center.
7. **WARNING AND PRECAUTIONS**
 - a. Use proper safety precautions to guard against needle sticks.
 - b. Follow manufacturer instructions when using centrifuge. Use only EmCyte provided general purpose centrifuge. Outcomes using centrifuges from other manufacturers are unknown.
 - c. Do not use sterile components of this system if package is opened or damaged.
 - d. Single use device. Do not reuse. Do not attempt to clean or re-sterilize this product.
 - e. Do not use after expiration date.
 - f. Use prepared PRP within 4 hours after drawing blood according to current AABB guidelines.
8. **POSSIBLE RISKS**
 - a. 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.
 - b. Reuse may be a potential biohazard
9. **POSSIBLE ADVERSE EFFECTS**
 - a. Damage to blood vessels, hematoma, delayed wound healing and/or infection is associated with blood draw, and/or surgical procedure.
 - b. Temporary or permanent nerve damage that may result in pain or numbness is associated with blood draw, and/or surgical procedure.
 - c. Early or late postoperative infection is associated with surgical procedure.
 - d. Pain associated with site of whole blood harvest.
10. **STERILITY**
The AbsolutePRP™ GenesisCS Component Concentrating System kits are sterilized by ETO exposure. Do not use any component from an opened or damaged package. Do not resterilize. Discard if kit packaging is damaged or open.

INSTRUCTIONS FOR USE FOR 60mL SYSTEM

PREPARATION PROTOCOL:

11. NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.
12. WHOLE BLOOD DRAW: Attach the sterile filter needle onto the sterile 60mL syringe. Draw 6mL of Sodium Citrate Anticoagulant into the 60mL syringe. Remove the filter needle from the syringe. Attach the butterfly needle onto 60mL syringe and prime the needle with the anticoagulant. Slowly draw 54mL of whole blood from the patient filling the syringe to 60mL. Gently, but thoroughly mix the blood and anticoagulant upon collection to prevent coagulation.

CONCENTRATING PROTOCOL:

13. LOAD: Remove and discard the red vented cap from the needle-less port of the Concentrating Device. Slowly add the anticoagulated whole blood through the needle-less port of the Concentrating Device
14. BALANCE: Make sure the counterbalance device contains the same amount of volume as the Concentrating Device. Then place them directly opposite to each other in the centrifuge rotor buckets.
15. SPIN:
 - a. Sapphire Series Centrifuge: AbsolutePRP/BMC
 - b. Platinum Series Centrifuge: AbsolutePRP/BMC
 - c. Executive Series Centrifuge: 7 minutes 4400 RPMPress the start button. Once the centrifuge stops, remove the Concentrating Device.
16. PRP EXTRACTION: Attach the sterile 60mL syringe to the needle-less port and aspirate the plasma until the RBC interface reaches the 7mL volume marker, then stop aspirating. Then attach the 12mL syringe and aspirate 7mL of PRP. Remove sterile syringe and apply a sterile cap.

INSTRUCTIONS FOR USE FOR 30mL SYSTEM

PREPARATION PROTOCOL:

17. NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.
18. WHOLE BLOOD DRAW: Attach the sterile filter needle onto the sterile 30mL syringe. Draw 3mL of Sodium Citrate Anticoagulant into the 30mL syringe. Remove the filter needle from the syringe. Attach the butterfly needle onto 30mL syringe and prime the needle with the anticoagulant. Slowly draw 27mL of whole blood from the patient filling the syringe to 30mL. Gently, but thoroughly mix the blood and anticoagulant upon collection to prevent coagulation.

CONCENTRATING PROTOCOL:

19. LOAD: Remove and discard the red vented cap from the needle-less port of the Concentrating Device. Slowly add the anticoagulated whole blood through the needle-less port of the Concentrating Device
20. BALANCE: Make sure the counterbalance device contains the same amount of volume as the Concentrating Device. Then place them directly opposite to each other in the centrifuge rotor buckets.
21. SPIN:
 - a. Sapphire Series Centrifuge: AbsolutePRP/BMC
 - b. Platinum Series Centrifuge: AbsolutePRP/BMC.
 - c. Executive Series Centrifuge: 5 minutes 4400 RPMPress the start button. Once the centrifuge stops, remove the Concentrating Device.
22. PRP EXTRACTION: Attach the sterile 30mL syringe to the needle-less port and aspirate the plasma until the RBC interface reaches the 3mL volume marker, then stop aspirating. Then attach the 12mL syringe and aspirate 3-4mL of PRP. Remove sterile syringe and apply a sterile cap.

INSTRUCTIONS FOR USE FOR 120mL SYSTEM

PREPARATION PROTOCOL:

23. **NOTE:** Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.
24. **WHOLE BLOOD DRAW:** Attach the sterile filter needle onto two sterile 60mL syringes. Draw 6mL of Sodium Citrate Anticoagulant into each 60mL syringe. Remove the filter needle from the syringe. Attach the butterfly needle onto the first 60mL syringe and prime with the anticoagulant. Slowly draw 54mL of whole blood into each syringe from the patient filling each syringe to 60mL. Gently, but thoroughly mix the blood and anticoagulant upon collection to prevent coagulation. Collect a total of 120mL













CONCENTRATING PROTOCOL:

25. **LOAD:** Remove and discard the red vented cap from the needle-less port of each Concentrating Device. Slowly add the 60mL of anticoagulated whole blood through the needle-less port into each Concentrating Device.
26. **BALANCE:** Make sure each device contains the same amount of volume. Then place them directly opposite to each other in the centrifuge rotor buckets.
27. **SPIN:**
 - a. Sapphire Series Centrifuge: AbsolutePRP/BMC
 - b. Platinum Series Centrifuge: AbsolutePRP/BMC.
 - c. Executive Series Centrifuge: 7 minutes 4400 RPM

Press the start button. Once the centrifuge stops, remove the Concentrating Device.




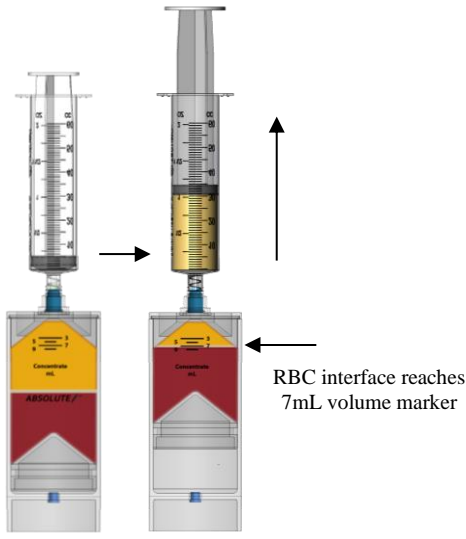
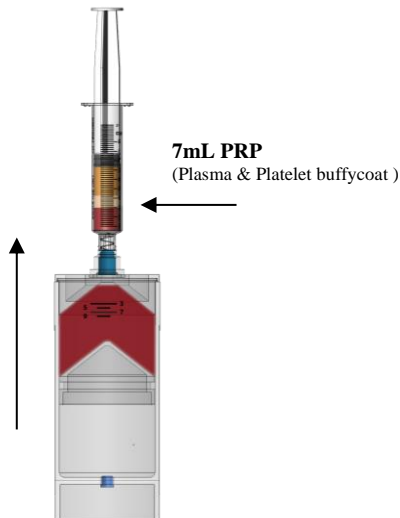
28. **PRP EXTRACTION:** Attach a sterile 60mL syringe to the needle-less port of each device and aspirate the plasma until the RBC interface reaches the 7mL volume marker, then stop aspirating. Then aspirate 7mL of PRP from each device. Remove sterile syringes and apply a sterile cap to each syringe.

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

 Do not use if package is damaged	 Attention, read instruction for use	 Single use only	 Store in a cool place	 Rx Only Prescription Use
 STERILE EO	 Do not re-sterilize	 Consult instruction for use	 Store in a dry place	 Non-pyrogenic
 MD Medical Device	 EmCye Corporation 4331 Veronica S. Shoemaker Blvd. Fort Myers, FL 33916 Phone: 239-481-7725			



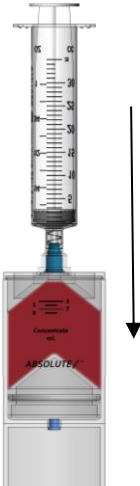
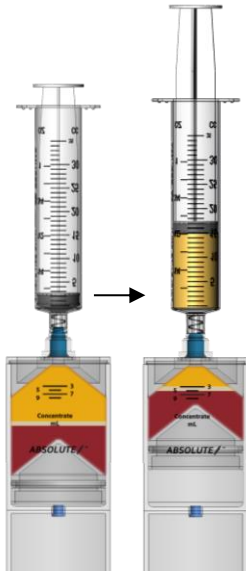
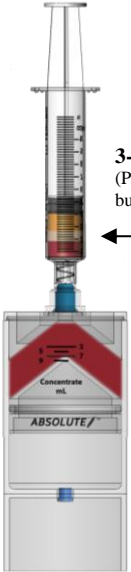
GS60: IFU ILLUSTRATION

NOTICES: ALWAYS SWAB SELF-SEALING PORT WITH STERILE ALCOHOL PRIOR TO ACCESSING WITH A STERILE SYRINGE

<p>Step 1:</p>  <p>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>Load anticoagulated whole blood into the Concentrating Device</p>	<p>Step 4:</p> <p>Counterbalance at opposite ends and process the Concentrating Device at</p> <p>Sapphire Series Centrifuge Set to: AbsolutePRP/BMC</p> <p>Platinum Series Centrifuge Set to: AbsolutePRP/BMC</p> <p>Executive Series Centrifuge Set to: 7 minutes / 4400 RPM</p>
<p>Step 5:</p>  <p>RBC interface reaches 7mL volume marker</p> <p>Attach the 60mL syringe and aspirate the plasma until the RBC interface reaches the 7mL volume marker, then stop aspirating</p>		<p>Step 6:</p>  <p>7mL PRP (Plasma & Platelet buffycoat)</p> <p>Attach the 12mL syringe and aspirate 7mL PRP (Gently rock the syringe to re-suspend the platelet buffycoat into the plasma)</p>	

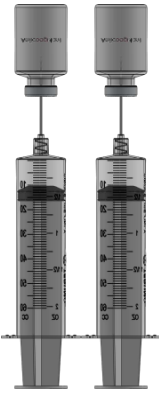
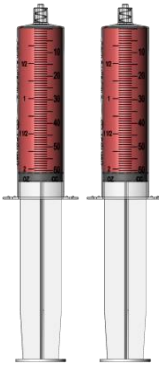

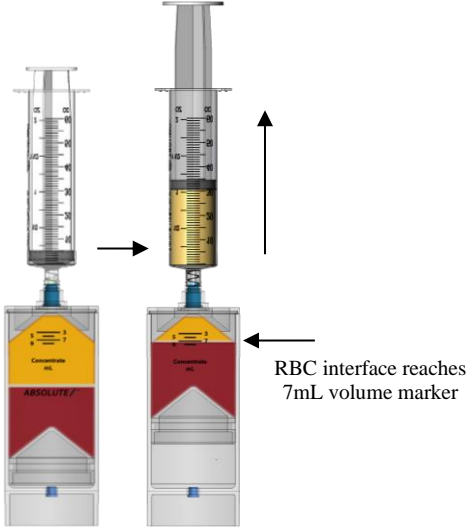
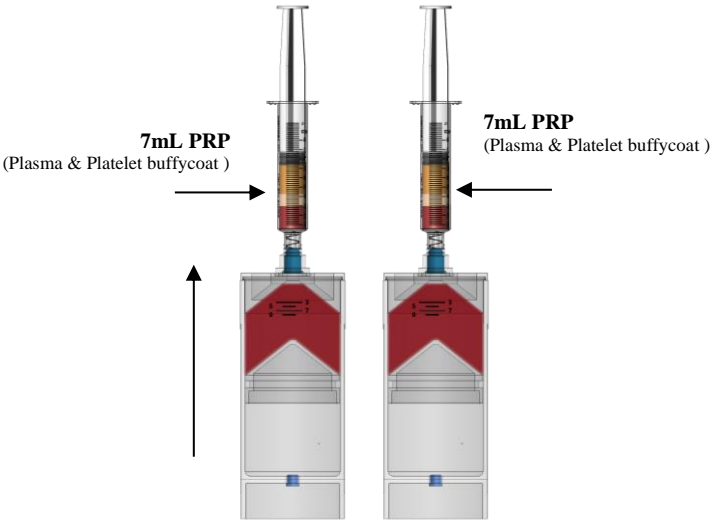
GS30: IFU ILLUSTRATION

NOTICES: ALWAYS SWAB SELF-SEALING PORT WITH STERILE ALCOHOL PRIOR TO ACCESSING WITH A STERILE SYRINGE

<p>Step 1:</p>  <p>Draw 3mL of Sodium Citrate Anticoagulant into 30mL Syringe</p>	<p>Step 2:</p>  <p>Draw 27mL whole blood from the patient, filling the syringe to 30mL</p>	<p>Step 3:</p>  <p>Load anticoagulated whole blood into the Concentrating Device</p>	<p>Step 4:</p> <p>Counterbalance at opposite ends and process the Concentrating Device at</p> <p>Sapphire Series Centrifuge Set to: AbsolutePRP/BMC</p> <p>Platinum Series Centrifuge Set to: AbsolutePRP/BMC</p> <p>Executive Series Centrifuge Set to: 5 minutes / 4400 RPM</p>
<p>Step 5:</p>  <p>RBC interface reaches 3mL volume marker</p> <p>For each concentrating device attach the 30mL syringe and aspirate the plasma until the RBC interface reaches the 3mL volume marker, then stop aspirating</p>		<p>Step 6:</p>  <p>3-4mL PRP (Plasma & Platelet buffycoat)</p> <p>Attach the 12mL syringe and aspirate 3-4mL PRP (Rotate the syringe to re-suspend the platelet buffycoat into the plasma)</p>	

GS120: IFU ILLUSTRATION

NOTICES: ALWAYS SWAB SELF-SEALING PORT WITH STERILE ALCOHOL PRIOR TO ACCESSING WITH A STERILE SYRINGE

<p>Step 1:</p>  <p>Draw 6mL of Sodium Citrate Anticoagulant into two 60mL Syringes</p>	<p>Step 2:</p>  <p>Draw 54mL whole blood from the patient, filling each syringe to 60mL</p>	<p>Step 3:</p>  <p>Load anticoagulated whole blood into each Concentrating Device (make sure they contain the same volume)</p>	<p>Step 4:</p> <p>Counterbalance at opposite ends and process the Concentrating Device at</p> <p>Sapphire Series Centrifuge Set to: AbsolutePRP/BMC</p> <p>Platinum Series Centrifuge Set to: AbsolutePRP/BMC</p> <p>Executive Series Centrifuge Set to: 7 minutes / 4400 RPM</p>
<p>Step 5: Repeat for each Device</p>  <p>RBC interface reaches 7mL volume marker</p> <p>For each concentrating device attach the 60mL syringe and aspirate the plasma until the RBC interface reaches the 7mL volume marker, then stop aspirating</p>	<p>Step 6:</p>  <p>7mL PRP (Plasma & Platelet buffycoat)</p> <p>7mL PRP (Plasma & Platelet buffycoat)</p> <p>Attach a 12mL syringe to each device and aspirate 7mL PRP from each device. (Rotate the syringes to re-suspend the platelet buffycoat into the plasma)</p>		