AbsolutePRP™ GOLD (PURE GOLD SERIES)
GenesisCS Component Concentrating System
Instruction for Use
Platelet Concentrating System
Date: September 2023

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

1. The AbsolutePRP™ Gold 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.

MATERIALS

2. 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

3. 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 deem necessary by the clinical use requirements.
4. The safety and effectiveness of this device for in vivo indications for use, such as bone healing and hemostasis, have not been established.
5. The PRP prepared by this device has not been evaluated for any clinical indications.
6. The PRP prepared by this device is NOT indicated for delivery to the patient's circulatory system.

USER POPULATION

7. 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.

DEVICE USE ENVIRONMENT

8. The device is intended to be used in in a health care setting such as a surgery room, clinic or outpatient care center.

WARNING AND PRECAUTIONS

9. Use proper safety precautions to guard against needle sticks.
10. Follow manufacturer instructions when using centrifuge. Use only EmCyte provided general purpose centrifuge. Outcomes using centrifuges from other manufacturers are unknown.
11. Do not use sterile components of this system if package is opened or damaged.
12. Single use device. Do not reuse. Do not attempt to clean or re-sterilize this product.
13. Do not use after expiration date.
14. Use prepared PRP within 4 hours after drawing blood according to current AABB guidelines.

POSSIBLE RISKS

15. 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.
16. Reuse may be a potential biohazard

POSSIBLE ADVERSE EFFECTS

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

STERILITY

21. The AbsolutePRP™ Gold 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 20mL SYSTEM

PREPARATION PROTOCOL:

22. NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.
23. WHOLE BLOOD DRAW: Attach the sterile filter needle onto the sterile 20mL syringe. Draw 2mL of Anticoagulant Citrate Dextrose Solution A into the 20mL syringe. Remove the filter needle from the syringe. Attach the butterfly needle onto 20mL syringe and prime the needle with the anticoagulant. Slowly draw 18mL of whole blood from the patient filling the syringe to 20mL. Gently, but thoroughly mix the blood and anticoagulant upon collection to prevent coagulation.

CONCENTRATING PROTOCOL:

24. 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
25. 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.
26. SPIN:
    a. Sapphire Series Centrifuge: AbsolutePRP Gold
    b. Platinum Series Centrifuge: AbsolutePRP Gold
    c. Executive Series Centrifuge: 1.5 minutes 4000 RPM
27. Press the start button. Once the centrifuge stops, remove the Concentrating Device.
28. PRP EXTRACTION: Attach the sterile 12mL syringe to the needle-less port. Slowly aspirate platelet enriched plasma leaving the RBC layer behind.

INSTRUCTIONS FOR USE FOR 40mL SYSTEM

PREPARATION PROTOCOL:

29. NOTE: Use standard sterile aseptic technique throughout the following procedure. Always swab needle-less ports with alcohol before and after accessing.
30. WHOLE BLOOD DRAW: Attach the sterile filter needle on to two sterile 20mL syringes. Draw 2mL of Anticoagulant Citrate Dextrose Solution A into each 20mL syringe. Remove the filter needle from each syringe. Attach the butterfly needle onto the first 20mL syringe and prime the needle with the anticoagulant. Slowly draw 18mL of whole blood into each syringe from the patient filling each syringe to 20mL. Collect a total of 40mL. Gently, but thoroughly mix the blood and anticoagulant upon collection to prevent coagulation.

CONCENTRATING PROTOCOL:

31. 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 into each Concentrating Device
32. BALANCE: Make sure each Concentrating Device have same amount of volume. Then place them directly opposite to each other in the centrifuge rotor buckets.
33. SPIN:
    a. Sapphire Series Centrifuge: AbsolutePRP Gold
    b. Platinum Series Centrifuge: AbsolutePRP Gold
    c. Executive Series Centrifuge: 1.5 minutes 4000 RPM
34. Press the start button. Once the centrifuge stops, remove the Concentrating Device.
35. PRP EXTRACTION: Attach the sterile 12mL syringe to the needle-less port of each device. Slowly aspirate platelet enriched plasma leaving the RBC layer behind.

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

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

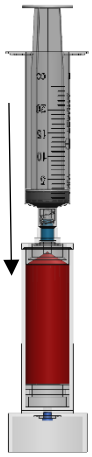
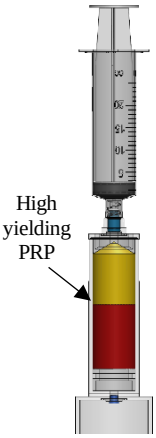
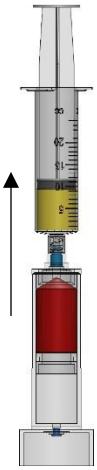
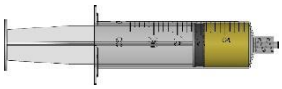
GS301-EU: IFU ILLUSTRATION

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

PREPARING PROTOCOL

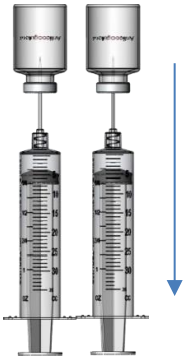
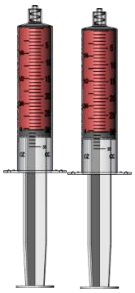
Step 1:	Step 2:
	
Attach the sterile filter needle onto the sterile 20mL syringe. Draw 2mL of Anticoagulant Citrate Dextrose Solution A into the 20mL syringe. Remove the filter needle from the syringe.	Attach the butterfly needle onto 20mL syringe and prime the needle with the anticoagulant. Slowly draw 18mL of whole blood from the patient filling the syringe to 20mL. Gently, but thoroughly mix the blood and anticoagulant upon collection to prevent coagulation.

CONCENTRATING PROTOCOL

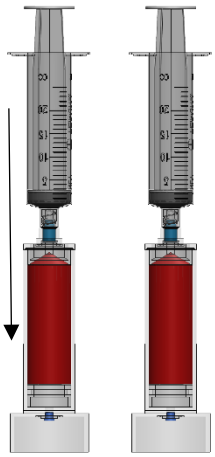
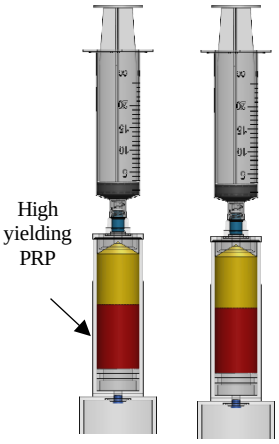
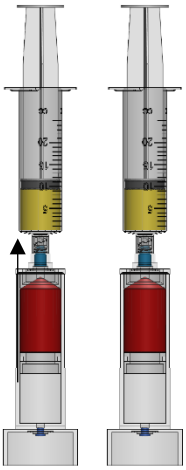
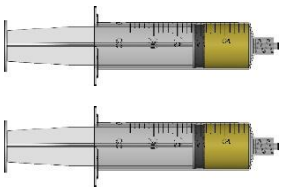
Step 1:	Step 2:	Step 3:	Step 4:
	Counterbalance at opposite ends and process at Sapphire Series Centrifuge AbsolutePRP Gold Platinum Series Centrifuge AbsolutePRP Gold Executive Series Centrifuge 1.5 minutes 4000 RPM		
Remove and discard the red vented cap from the needle-less port of the Concentrating Device. Slowly add 20mL of anticoagulated whole blood into the Concentrating Device.		After centrifugation, the high yielding platelet rich plasma will be separated above the RBC layer.	Using the 12mL syringe, aspirate the high yielding PRP, leaving the RBCs behind.  High yielding PRP

GS302-EU: IFU ILLUSTRATION
NOTICES: ALWAYS SWAB SELF-SEALING PORT WITH STERILE ALCOHOL PRIOR TO ACCESSING WITH A STERILE SYRINGE

PREPARATION PROTOCOL

STEP 1:	**STEP 2:**
 Attach the sterile filter needle onto two sterile 20mL syringes. Draw 2mL of Anticoagulant Citrate Dextrose Solution A into each 20mL syringe. Remove the filter needle from each syringe.	 Attach the butterfly needle onto the first 20mL syringe and prime the needle with the anticoagulant. Slowly draw 18mL of whole blood into each syringe from the patient filling each syringe to 20mL. Collect a total of 40mL. Gently, but thoroughly mix the blood and anticoagulant upon collection to prevent coagulation.

CONCENTRATING PROTOCOL

STEP 1:	**STEP 2:**	**STEP 3:**	**STEP 4:**
 Remove and discard the red vented cap from the needle-less port of the Concentrating Device. Slowly add 20mL of anticoagulated whole blood into each Concentrating Device.	Counterbalance at opposite ends and process at Sapphire Series Centrifuge AbsolutePRP Gold Platinum Series Centrifuge AbsolutePRP Gold Executive Series Centrifuge 1.5 minutes 4000 RPM	 After centrifugation, the high yielding platelet rich plasma will be separated above the RBC layer in each device.	 Using 12mL syringes, aspirate the high yielding PRP from each device, leaving the RBCs behind.  High yielding PRP

EmCyte Corporation
4331 Veronica S. Shoemaker Blvd., Suite 4 Fort Myers, FL 33916, USA www.emcyte.com
PL-42-86, Rev. 5