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(REV. A)

HARVEST® PLATELET-RICH PLASMA (PRP) PROCEDURE PACK

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HARVEST® PLATELET-RICH PLASMA (PRP) PROCEDURE PACK
51414 (APC-30N), 51415 (APC-60N), 51436 (APC-120N)
INSTRUCTIONS FOR USE
HEALTHCARE OR CLINIC USE ONLY
GLOBUS MEDICAL 1000031831
RX ONLY

GLOBUS MEDICAL, INC.
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
USA
Customer Service:
Phone 1-866-GLOBUS1 (OR)
1-866-456-2871
Fax 1-866-GLOBUS3 (OR)
1-866-456-2873

WITHIN THE UNITED STATES ONLY

ENGLISH

HARVEST® PLATELET-RICH PLASMA (PRP) PROCEDURE PACK INSTRUCTIONS FOR USE

INDICATIONS
The Platelet-Rich Plasma (PRP) Procedure Pack is indicated for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of peripheral blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

CONTRAINDICATIONS
The use of the Platelet-Rich Plasma (PRP) Procedure Pack may be contraindicated if any of the following conditions occur:

- There is clinical or laboratory evidence of septicemia.
- The patient has taken aspirin or other medications that alter platelet function within 3 days prior to surgery.
- The patient has a disorder associated with platelet dysfunction.

WARNINGS
1. Federal law (U.S.) restricts this device to sale by or on the order of a physician. The physician is solely responsible for the use of this device.
2. Plasma, platelets, and cell concentrate prepared with this system are not intended for transfusion.
3. This device is only intended for use on a single patient during a single procedure, and it should not be used for multiple patients.
4. **Do Not Reuse/Not for Reuse:** Globus Medical products bearing the "Single Use Only" symbol are intended for single use only and are not intended to be reused or re-sterilized in any manner. Globus Medical cannot ensure the functionality or sterility of the product if it is reused or re-sterilized.

   Reuse of a single-use product could result in:

   - Product performance issues due to a loss of product integrity, including but not limited to the following:
     - Fluid leaks
     - Parts that are warped or deformed
     - Plastics that are brittle and discolored
     - Filters that have reduced filtration capabilities
   - Exposure to excessive ethylene oxide (EO) residuals
   - Viral infections such as hepatitis or human immunodeficiency virus (HIV)
   - Bacterial infections
   - Cross-contamination

   Any of these risks could result in serious injury or death. These risks are shared by product users, donors, patients, and recipients of end products of the device.

CAUTIONS
1. Do not use if the packaging is open or damaged.
2. Use aseptic technique throughout all procedures to ensure patient safety or product quality.
3. Always follow aseptic technique when entering a sterile container; wipe all ACD-A access sites and process disposable chamber access sites (white and red ports) with an alcohol pad prior to entry, to maintain sterility and to avoid contamination.
4. Follow sterile technique whenever you are passing components into the sterile field.
5. All blood and blood components should be handled as infectious. To minimize the potential for exposure to blood-borne pathogens, observe universal precautions when handling blood and blood components.
6. Disposables that have come in contact with adipose tissue should be considered biohazardous waste and should be handled and disposed of in accordance with applicable regulations and your institution's standard operating procedures (SOPs). Incineration and decontamination by autoclaving are the currently recommended methods for disposing of adipose tissue samples and adipose tissue products.
7. Separated adipose tissue products should be used within four (4) hours of collection.
8. After processing on the SmartPrep® Centrifuge System, make sure the process disposable is properly supported in an upright position. Tilting or tipping it could cause fluids to spill from one chamber into another and affect processing results.
9. Health professionals responsible for blood collection must be trained in the practice of venipuncture and be aware of the inherent risks. Aseptic technique, proper skin preparation, and continued protection of the venipuncture site are essential.
10. Using excessive force could activate platelets and hemolyze red blood cells.
11. Inadequate mixing may cause the blood to clot in the syringe and could result in suboptimal process results.
12. To ensure that the system is balanced when you load a process disposable, always load either another process disposable of equal volume or a corresponding balance weight in the opposite rotor bucket.
13. If the system is not loaded properly, an imbalance will occur, and the system will stop the processing cycle.
14. Do not force a process disposable into a rotor bucket. A process disposable should fit snugly but should not require excessive force to install. If there is resistance, check for obstructions in the rotor and/or debris on the process disposable, and ensure that the process disposable is properly oriented in the rotor bucket
15. To ensure proper device operation, allow the procedure pack or kit to come to room temperature before use.
16. Refer to the package label to ensure the kit is within the expiration date.
17. Clean and disinfect the SmartPrep® Centrifuge System after each use and between uses. Please refer to the SmartPrep® Centrifuge System Operator's Manual for cleaning and disinfecting.
18. The PRP Procedure Packs should only be used with the SmartPrep® Centrifuge System.

PROCEDURE PACK COMPONENTS
Caution: Follow sterile technique whenever you are passing components into the sterile field.

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Caution: Ensure all required components from the table below are present in the applicable procedure pack before you begin the procedure.

Note: ACD-A and alcohol pads are required for the procedure, but are not included in the procedure pack, so the user must supply the ACD-A and the alcohol pads.

Note: Please follow your healthcare facility's processes and procedures for acquiring components not included in your kit configuration.

Process Kit Components

51414 (APC-30n)	51415 (APC-60n)	51436 (APC-120n)	Components
1	–	–	30 mL Process Disposable
–	1	2	60 mL Process Disposable
–	–	1	120 mL Blood Draw Kit
–	–	1	10 mL Syringe with (1) Blunt Fill Needle (red)
1	–	–	10 mL Platelet Concentrate Syringe with Blunt Cannula
–	1	2	20 mL Platelet Concentrate Syringe with Blunt Cannula
1	–	–	20 mL Plasma Syringe with Blunt Cannula and Spacers
–	1	2	30 mL Plasma Syringe with Blunt Cannula and Spacers
1	1	1	Sterile Plastic Cups (3)

Blood Draw Kit Components

51436 (APC-120n)	Components
2	Blunt Plastic Cannula
3	Blunt Fill Needle
1	5 mL Anticoagulant Syringe
2	60 mL Blood Draw Syringe

Convenience Kit Components

51414 (APC-30n)	51415 (APC-60n)	51436 (APC-120n)	Components
1	1	1	19 G Safety Winged Infusion Set
1	1	1	Red Clamp
1	1	–	3 mL Syringe (spare)
1	1	–	10 mL Syringe (spare)
1	1	–	Blunt Plastic Cannula
3	3	–	Blunt Fill Needle
1	–	–	35 mL Blood Draw Syringe
–	1	–	60 mL Blood Draw Syringe
1	1	1	Patient Label Sheet (6 labels)

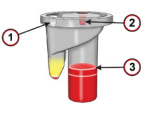

Figure 1: Process disposable included in the process kit

1. **White port:** Allows for platelet-poor and platelet-rich plasma to be removed and for ACD-A to be added
2. **Red port:** Allows for whole blood to be added
3. **Floating shelf:** Isolates RBCs from other blood components during separation

PREPARATION FOR PROCESSING
Refer to the SmartPrep® Centrifuge System operator's manual for additional information concerning SmartPrep® Centrifuge System operation and maintenance, warnings, and cautions.

1. Remove the process disposable from the packaging and place it on an appropriate work space.
2. Ensure that the shelf in the process disposable slides up and down freely. If the shelf does not move freely, do not dispense blood or cellular material into the process disposable. Either tap the bottom of the process disposable to dislodge the shelf or use a sterile syringe to push the shelf to the bottom of the process disposable.
3. For a 30 mL process disposable, complete the following steps:
   a. Draw 4 mL of ACD-A (Anticoagulant Citrate Dextrose Solution A) into a blood draw syringe.
   b. Insert the blood draw syringe into the white port on the process disposable to transfer 1 mL of the ACD-A into the plasma chamber, using the method shown in the figure below. 3 mL of ACD-A remain in the blood draw syringe for use during the blood collection.
4. For a 60 mL process disposable, complete the following steps:
   a. Draw 8 mL of ACD-A into a blood draw syringe.
   b. Insert the blood draw syringe into the white port on the process disposable to transfer 2 mL of the ACD-A into the plasma chamber, using the method shown in the figure below. 6 mL of ACD-A remain in the blood draw syringe for use during the blood collection.

Figure 2: Transferring ACD-A into the plasma chamber

PREPARATION OF THE VENIPUNCTURE SITE
The following steps provide general guidelines for preparing the venipuncture site for blood collection.

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Caution: Health professionals responsible for blood collection must be trained in the practice of venipuncture and be aware of the inherent risks. Aseptic technique, proper skin preparation, and continued protection of the venipuncture site are essential.

Note: Select a large peripheral vein that is free of lesions, such as the antecubital (cephalic) vein. A central venous line can also be used.

1. Apply a tourniquet or a blood pressure cuff to the patient's arm, and identify the venipuncture site.
2. Complete the following steps to disinfect the intended venipuncture site:
   - Apply either an aqueous solution of iodophor compound or an alcohol preparation pad moving outward in a circular motion from the intended venipuncture site to an area of at least 4 cm (1.5 in).
   - Let the skin dry for approximately 30 seconds. Do not touch the skin once it has been prepared, and do not re-palpate the vein at the intended venipuncture site.
3. Perform the venipuncture.
4. Once intravenous access is confirmed, clamp the intravenous tubing using the red clamp provided, and secure the needle and tubing to the skin.

DRAWING PATIENT BLOOD
Draw the patient's blood prior to starting the procedure and before administering any fluids, particularly systemic anticoagulant.

1. Connect the blood draw syringe to the safety winged infusion set (or other appropriate venous access).
2. Release the red clamp on the intravenous tubing.

3. Draw blood from the patient, as shown in the figure below, at a continuous rate that minimizes excessive vacuum pressures, typically no faster than 1 mL per second. For the 30 mL process disposable, fill the blood draw syringe with 27 mL of blood. For the 60 mL process disposable, fill the blood draw syringe with 54 mL of blood.

Figure 3: Drawing blood from the patient

4. Close the red clamp on the intravenous tubing, and disconnect the blood draw syringe.
5. Release the tourniquet or blood pressure cuff.

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Caution: Using excessive force could activate platelets and hemolyze red blood cells.

6. Invert the blood draw syringe several times to ensure adequate mixing of the blood and anticoagulant, and ensure that there is a bubble in the syringe.

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Caution: Inadequate mixing may cause the blood to clot in the syringe and could result in suboptimal process results.

7. Attach a blunt plastic cannula to the blood draw syringe.
8. Insert the blood draw syringe into the red port on the process disposable, as shown in the figure below, and dispense the contents into the blood chamber at approximately 1 mL per second. Do not overfill the process disposable. To avoid dislodging the red port:
   - Make sure the needle is centered in and perpendicular to the port.
   - Do not push down on the port or use excessive force when either inserting the needle or dispensing the blood.

Figure 4: Inserting the blood draw syringe into the red port

PROCESSING THE BLOOD IN THE SMARTPREP® CENTRIFUGE SYSTEM

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Caution: To ensure that the system is balanced when you load a process disposable, always load either another process disposable of equal volume or a corresponding balance weight in the opposite rotor bucket.
Caution: If the system is not loaded properly, an imbalance will occur, and the system will stop the processing cycle.
Caution: Do not force a process disposable into a rotor bucket. A process disposable should fit snugly but should not require excessive force to install. If there is resistance, check for obstructions in the rotor and/or debris on the process disposable, and ensure that the process disposable is properly oriented in the rotor bucket.

1. Press the LID button to open the lid.
2. Load the process disposable(s) into the rotor buckets.
3. If needed, load the appropriate balance weight into the opposing rotor bucket.
4. Rotate the process disposable so the white dot is facing the center of the rotor, as shown in the figure below.

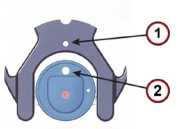

Figure 5: Process disposable in the centrifuge (top view)

1. **White dot:** Aids in alignment of process disposable when placed in the centrifuge
2. **White port:** Align with white dot on centrifuge rotor

5. Ensure that the process disposable is properly seated and aligned.
6. Close the lid, and make sure the LID OPEN indicator is not illuminated.
7. Press the PRP button to start the processing cycle. The total processing time is approximately 14 minutes.
8. When the processing cycle is complete, press the LID button to open the lid.

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Caution: After processing on the SmartPrep® Centrifuge System, make sure the process disposable is properly supported in an upright position. Tilting or tipping it could cause fluids to spill from one chamber into another and affect processing results.

9. Carefully remove the process disposable and keep it in an upright position when handling, as shown in the figure below.

Figure 6: Process disposable in an upright position to maintain separation

ADJUSTING THE FINAL VOLUME OF PRP IN THE PROCESS DISPOSABLE

You can adjust the final volume of PRP (platelet-rich plasma) in the process disposable by removing a syringe/cannula spacer from the plasma syringe. The spacers determine the volume of platelet-poor plasma that is withdrawn from the plasma chamber. Repeat the 60 mL process disposable spacer removal twice when using the 120 mL process disposable. Before you begin withdrawing platelet poor plasma from the plasma chamber, use the information in the following table to determine how many spacers to remove to achieve a final volume of PRP in the appropriate process disposable.

	Number of spacers to remove	Final volume of PRP in the process disposable
30 mL Process Disposable	None	4 mL
	1 (remove the front yellow spacer)	3 mL
60 mL Process Disposable	None	10 mL
	1 (remove the front yellow spacer)	7 mL

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Caution: Always follow aseptic technique when entering a sterile container; wipe all ACD-A access sites and process disposable chamber access sites (white and red ports) with an alcohol pad prior to entry, to maintain sterility and to avoid contamination.

Complete the following steps to withdraw the platelet-poor plasma:

1. If necessary, remove a spacer from the plasma syringe, as shown in the figures below, without touching the cannula.
2. Insert the plasma syringe into the white port on the process disposable.
3. Withdraw platelet-poor plasma from the plasma chamber until air enters the plasma syringe.
4. Remove the plasma syringe from the white port on the process disposable.
5. Discard the recovered platelet-poor plasma or transfer it to the sterile field, if needed.

Figure 7: Plasma syringe (60 mL kit) with the spacer intact

Figure 8: Removing the spacer from the plasma syringe

Note: Always place the blood components in the appropriate sterile plastic specimen cup.

RESUSPENDING THE PLATELETS

Complete the following steps to prepare platelet-rich plasma (PRP):

1. Withdraw the remaining platelet-poor plasma into the platelet concentrate syringe with a blunt cannula and no spacer.
2. Gently inject the fluid into and withdraw the fluid out of the plasma chamber, as shown in the figure below. Repeat this 2 to 3 times until the cells are visibly suspended in the plasma..

Figure 9: Gently injecting and withdrawing the fluid

3. Once the cells are suspended, draw the total volume into the platelet concentrate syringe.
4. Observe the base and walls of the plasma chamber to confirm that all cells have been drawn into the platelet concentrate syringe.
5. Transfer the PRP to a plastic cup located in the sterile field..

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Caution: Disposables that have come in contact with blood should be considered biohazardous waste and should be handled and disposed of in accordance with applicable regulations and your institution's standard operating procedures (SOPs). Incineration and decontamination by autoclaving are the currently recommended methods for disposing blood samples and blood products.

HYDRATING THE GRAFT MATERIAL

1. Create a mixture of 1000 IU Thrombin in 10% Calcium Chloride.
2. Aspirate the required amount of PRP in a syringe.
3. In a separate syringe, aspirate the required amount of 1000 IU Thrombin/10% Calcium Chloride to achieve a 10:1 ratio of PRP to 1000 IU Thrombin/10% Calcium Chloride.
4. With the two syringes, saturate the graft material using a graft mixing/hydration kit. The graft is ready for application.

STORAGE CONDITIONS

Long-term Storage Range: 0°C to 25°C (32°F to 77°F)

LATEX AND PYROGEN STATEMENTS

This product is not made with natural rubber latex. The fluid pathways are non-pyrogenic.

RETURN OF USED PRODUCT

If for any reason this product must be returned to Globus Medical, a returned authorization (an RA number) is required from Globus Medical prior to shipping.

IT IS THE RESPONSIBILITY OF THE HEALTH CARE INSTITUTION TO ADEQUATELY PREPARE AND IDENTIFY THE PRODUCT FOR RETURN SHIPMENT.

Please contact your local representative for information regarding returned goods and product complaints.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R EO A	COMPONENTS STERILIZED USING MULTIPLE METHODS
LOT	LOT NUMBER		CONSULT INSTRUCTIONS FOR USE
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
2 STERILE	DO NOT RESTERILIZE		TEMPERATURE RANGE
1	PRODUCT QUANTITY		DO NOT USE IF PACKAGE IS DAMAGED
Rx ONLY	PRESCRIPTION ONLY		