

**1000021380**  
**(REV. A)****HARVEST® CLEAR PRP KIT**

4/2023

**HARVEST® CLEAR PRP KIT**  
51410 (LP-10)  
INSTRUCTIONS FOR USE  
GLOBUS MEDICAL 1000021380  
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® CLEAR PRP KIT**  
**INSTRUCTIONS FOR USE****DESCRIPTION**

The Clear PRP (Red Cell Reduction) Procedure Kit is used to reduce the level of hematocrit in a Harvest® PRP (platelet-rich plasma) product to less than 1% hematocrit. For use with the 60 mL PRP procedure packs; 51401 (PC-60-01) and 51406 (APC-60).

**INDICATIONS**

The Harvest® PRP Separation System is designed to be used for the safe and rapid preparation of autologous platelet-rich plasma from a small sample of 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 SmartPrep® System 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 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 of blood samples and blood products.
7. Separated blood 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 remix 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. To ensure proper device operation, allow the procedure pack or kit to come to room temperature before use.
15. 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.

**PROCEDURE KIT COMPONENTS**

**Caution:** Follow sterile technique whenever you are passing components into the sterile field.

Quantity	Component
1	10 mL Syringe
1	10 mL Syringe (separate package)
1	Female-Female Luer Lock Connector
1	Blunt 17 G Cannula with Protective Sheath
2	Alcohol Pad
1	Tip Cap
2	Patient Label Sheet (6 labels)

**Figure 1: Clear PRP Procedure Kit****PREPARATION FOR PROCESSING**

Prepare a 10 mL Harvest® PRP product from 60 mL of anticoagulated blood using the SmartPrep® Centrifuge System. After you have withdrawn 10 mL of PRP into the platelet concentrate syringe with blunt needle (included in Harvest® PRP Procedure Packs) from the 60 mL process disposable, complete the following steps:

1. Place the sterile 10 mL syringe and the sterile female-female luer lock connector into the sterile field.
2. Place the Clear PRP process disposable into the tube stand, as shown in Figure 2.

**Figure 2: Clear PRP process disposable in the tube stand**

3. Insert the platelet concentrate syringe into the red port on the Clear PRP process disposable and dispense the contents of the syringe, as shown in Figure 3. Do not overfill the Clear PRP 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 PRP.

**Figure 3: Dispensing the PRP into the Clear PRP process disposable**

## PROCESSING THE PRP IN THE SMARTPREP® CENTRIFUGE SYSTEM

Refer to the SmartPrep® Centrifuge System operator's manual for additional information concerning SmartPrep® Centrifuge System operation and maintenance, contraindication, warnings, and cautions. The Clear PRP hardware kit that contains the two purple Clear PRP adapters is required to operate the SmartPrep® Centrifuge System with the Clear PRP process disposable.



**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.

1. Install the two adapters into the rotor buckets.
2. Ensure that each adapter is seated properly, as shown in Figure 4.



**Figure 4: Clear PRP adapters properly installed**

3. Complete one of the following steps to load the system properly and avoid an imbalance:

- Load a Clear PRP process disposable into one of the adapters, as shown in Figure 5, and load the purple balance weight into the other adapter.
- Load Clear PRP process disposables of equal volume into each adapter.



**Figure 5: Loading a Clear PRP process disposable into a Clear PRP adapter**

4. Close the lid and verify that the LID OPEN indicator is not illuminated.
5. Complete the following steps if you are using the SmartPrep® 2 Centrifuge System:
  - a. Press the PRP button. Watch for the SmartPrep® 2 Centrifuge System to complete the first spin cycle, which occurs approximately 3 minutes after pressing the PRP button.
  - b. When the rotor has come to a complete stop, press the STOP button to end the processing cycle. The rotor may momentarily rotate in reverse.
  - c. Press the LID button to open the lid, and remove the Clear PRP process disposable.
6. Complete the following steps if you are using the SmartPrep® 3 Centrifuge System:
  - a. Press the Clear-PRP button.
  - b. When the processing cycle is complete and the rotor has stopped, press the LID button to open the lid, and remove the Clear PRP process disposable, as shown in Figure 6.



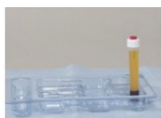
**Caution:** After processing on the SmartPrep® Centrifuge System, make sure the process disposable is properly supported in an upright position. Tilting or tipping it could cause fluids to remix and affect processing results.



**Figure 6: Removing the Clear PRP process disposable**

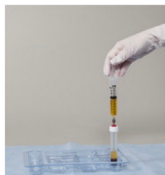
## TRANSFERRING THE CLEAR PRP PRODUCT

1. Keep the Clear PRP process disposable in an upright position and place it in the tube stand, as shown in Figure 7.



**Figure 7: Clear PRP process disposable in the tube stand**

2. Attach the 17 G blunt cannula to the remaining 10 mL syringe, and remove the protective sheath from the cannula.
3. Insert the blunt cannula into the red port on the Clear PRP process disposable.
4. Withdraw the Clear PRP product and leave behind the red blood cells, as shown in Figure 8.



**Figure 8: Withdrawing the Clear PRP product**

5. Remove the blunt cannula from the 10 mL syringe, and if necessary, place the tip cap on the syringe.
6. Complete the following steps to transfer the Clear PRP product out of the sterile field:
  - a. Attach the female-female luer lock connector to the 10 mL syringe (remove the tip cap from the syringe if necessary).
  - b. Connect the 10 mL syringe to the syringe that will be used for treatment.
  - c. Transfer the Clear PRP product from the 10 mL syringe to the treatment syringe via the luer lock connector, as shown in Figure 9.



**Figure 9: Transferring the Clear PRP product out of the sterile field**

## STORAGE CONDITIONS

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

Permitted Excursions: -29°C to 0°C (-20°F to 32°F) for up to 72 hours  
25°C to 50°C (77°F to 122°F) for up to 6 weeks

## 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			
<b>REF</b>	CATALOGUE NUMBER	<b>STERILE R E O A</b>	COMPONENTS STERILIZED USING MULTIPLE METHODS
<b>LOT</b>	LOT NUMBER		CONSULT INSTRUCTIONS FOR USE
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
	DO NOT RESTERILIZE		TEMPERATURE RANGE
	PRODUCT QUANTITY		DO NOT USE IF PACKAGE IS DAMAGED
<b>Rx ONLY</b>	PRESCRIPTION ONLY		